

DEA Compliance Manual



Cardinal Health

PLAINTIFFS TRIAL
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COMPLIANCE MANUAL

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PREFACE

The Drug Enforcement Administration (DEA) is the primary federal law enforcement agency charged with combating drug abuse in this country. Established in 1973, it is a combination of the agencies formerly known as the Bureau of Narcotics and Dangerous Drugs, the Office for Drug Abuse Law Enforcement, the Office of National Narcotic Intelligence, and certain drug related elements of both the Bureau of Customs and the Office of Science and Technology. The intent of the amalgamation of agencies is to eliminate the piecemeal approach to the control of narcotics and dangerous drugs and, by coordinating the effort, to control more effectively narcotic and dangerous drug activity and abuse.

Prior to this amalgamation of agencies, the laws on the control of drugs were collected and conformed into one piece of legislation, the Comprehensive Drug Abuse Prevention Control Act of 1970 (the "Controlled Substances Act"). This act consolidated over 50 pieces of legislation that had been enacted in piecemeal fashion since 1914. The thrust of this Controlled Substances Act is the improvement of the administration and regulation of manufacturing, distribution, and dispensing of controlled substances by establishing a "closed" system for legitimate drug handlers so that controlled drugs can be traced from their origin to their eventual user.

The act contains nine major control mechanisms that apply to the manufacture, purchase and distribution of substances subject to the act. They are:

- registration of handlers;
- recordkeeping requirements;
- manufacturing quotas;
- distribution restriction;
- dispensing restrictions;
- limitations on imports and exports;
- conditions of storage of drugs;
- reports of transactions to the government; and
- criminal, civil and administrative penalties for violations.

Each of these mechanisms has a considerable impact upon the industry, especially the penalties and loss of registration provisions. Each violation of the act (which may be as little as misplacing one bottle of controlled substances) is punishable by up to 15 years imprisonment and \$10,000 in fines. In addition, a relatively speedy administrative hearing can result in a finding of inadequate security. Such a finding could lead to loss of registration, effectively putting a company out of the controlled drugs distribution business. It has, therefore, become a cost justified good business practice to establish effective control measures in the first instance. DEA, like most other federal agencies, prefers voluntary rather than forced compliance.

This manual is intended as a resource to the Controlled Substances Act and Regulations. It is intended as a guide so that you can better understand DEA's function. Further, it is intended to help you learn to deal with the agency that has a tremendous impact on our business.

In addition to this manual, you should also have the following DEA publications available for ready reference:

**Code of Federal Regulations 21. Food and Drugs
Part 1300 to End -- available from:**

Superintendent of Documents
U.S. Government Printing Office
Washington, D.C. 20402
(202) 783-3238

ARCOS Reporting Manual -- available from:

United States Department of Justice
Drug Enforcement Administration
ARCOS Unit, P.O. Box 27273
Central Station
Washington, D.C. 20038-7273
(202) 307-8600

Note: The Automation of Reports and Consolidated Orders System (ARCOS) is the automated system developed by DEA to monitor selected controlled substances. ARCOS software enables the government to maintain a current and historical record of controlled substance inventories and transactions from the point of manufacture to the point of sale, distribution, or other disposition, and finally, to the dispensing (consumption) level.

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INTRODUCTION

The Controlled Substances Act and implementing regulations (21 CFR 1300 to the end) impose a substantial number of requirements upon wholesalers and other handlers and prescribers of controlled drugs. This training manual deals with the records of controlled drug transactions that must be kept by wholesalers and the reports that wholesalers must submit. The theory behind the records requirements for Schedule III through V controlled drugs is that a registrant's regular, normal business records are acceptable provided that they contain all necessary elements of information and that these elements are readily retrievable from the records (more later on retrievability). Special, separate records are required from Schedule II controlled drugs (see Biennial Inventory and Order Forms). The importance of accuracy in taking required inventories and in recording controlled substances transactions should be stressed to wholesaler employees charged with these responsibilities.

11/27/95

Records and Reports - Introduction

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INVENTORY

There are specific regulations with regards to inventory. DEA requires a biennial inventory, and a year-end ARCOS inventory. As company policy, periodic inventories are recommended. Unless otherwise specified, the general requirements pertain to each type of inventory.

Biennial

(21 CFR 1304.11 (c))

Frequency. Every two years, the wholesaler is required to take a physical inventory of all controlled drug stocks on hand in live, morgue and brokerage.

When. The regular biennial inventory date is every two years from the date the wholesaler initially became registered to distribute controlled substances. Thus, for all firms who were provisionally registered on May 1, 1971, the biennial inventory date is May 1st every odd year. For any firm registered after May 1, 1971, or which has been issued a new registration since May 1, 1971, the regular inventory date is two years from the initial date of registration, e.g., Firm A which first became registered on August 21, 1974, has a regular biennial inventory date of August 21 every even year. The wholesaler may take the inventory within four days of the inventory date if he/she notifies the DEA special agent in charge in advance.

Changing Inventory Date. To coincide with a fiscal year, year-end ARCOS inventory, general inventory time, or any other reason, the wholesaler may change the controlled drug inventory date to another fixed date provided that the new is within two years of the previous biennial date. DEA does not have to be notified.

Cardinal Health had received prior authorization from DEA for all Cardinal Health locations to conduct biennial inventories on December 31 of even numbered years and will continue to do so. Refer to DEA correspondence 11/21/96.

Year-End ARCOS

(21 CFR 1304.33 (b))

Frequency. Every year, the wholesaler is required to take a physical inventory of all reportable controlled substances on hand in live, morgue and brokerage.

When. The inventory should report the stock on hand as of the close of business on December 31st.

Reporting. A report of the inventory shall be filed with the ARCOS Unit of the DEA by January 15th of the following year.

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Inventory

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Periodic

(21 CFR 1304.11, 21 CFR 1301.74)

Frequency. A daily count of controlled substances and narcotics having movement (sales, purchases, and returns) on the previous day should be conducted, and a monthly count of all controlled substances in the facility.

When. Counts should be conducted as close to the end of day processing so as not to interfere with the current day's business. The monthly count should be conducted as close to the same time each month as possible.

General Requirements

Newly Controlled Drugs. An initial inventory must be taken of all stocks on hand of a newly controlled drug on the effective date of control. Subsequently, the newly controlled drug will be reinventoried on the same date as all other controlled drugs. (21 CFR 1304.11 (d))

Note: Many wholesalers have been cited for missing the initial inventory date on newly controlled drugs. For example, anabolic steroids were controlled (Schedule III) effective February 27, 1991, and an initial inventory should have been taken on that date.

Drugs to Be Included. All controlled substances on hand as of the inventory date must be included. Returns, damaged goods, and any other drugs awaiting disposal must be inventoried.

Note: Wholesalers often overlook returns and drugs awaiting disposal in taking inventory.

Required Inventory Records. The inventory must be maintained in written, typewritten, or printed form. It should be signed by those taking the count and both the date of the inventory and whether it was taken as of the opening of business or close of business must be recorded. Inventories of all Schedule I (research drugs) and Schedule II substances must be separated from inventories for all other substances. Schedule III through V substances may be maintained separately from all other substances or in a readily retrievable manner. Readily retrievable means that the records (whether ADP, electronic, or mechanical) are kept in such a manner that they can be separated out in a reasonable time and/or the items are identifiable visually from other items appearing on the records (asterisk, redlined, etc.).

For each controlled substance in finished form, the required inventories must contain:

- Name of the substance;
- Each finished form (e.g., 10-mg. tablet or 10-mg. concentration per fluid ounce or milliliter);
- Number of units or volume of each finished form in each commercial container (e.g., 100-tablet bottle or 3-milliliter vial); and
- Number of commercial containers of each such finished form (e.g., four 100-tablet bottles or six 3-milliliter vials).

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Inventory

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For controlled substance returns, damaged goods, or substances awaiting disposal, the inventory must contain:

- Name of the substance;
- Total quantity of the substance to the nearest metric unit of weight or the total number of units of finished form; and
- Reason for the substance being maintained by the registrant.

(21 CFR 1304.22 (b), 21 CFR 1304.11(2))

Count Requirements. When taking an inventory, the following steps should be taken,

- Do not allow any product into or out of the area during the count or recount.
- Counts should be conducted from count sheet with the on hand quantities suppressed.
- Compare the inventory results with the current on-hand balance of each item.
- Recount any out-of -balance item.
- Run audit report for any out-of-balance item.
- Research the error, checking for orders picked but not invoiced, mispicks, etc.
- Make appropriate adjustments as errors causing variances are detected.
- The Distribution Center Manager should sign off on the count sheet that he has reviewed all exceptions and that variances have been explained.
- File DEA Form 106, on a timely basis, for any item that cannot be resolved.
- Create ARCOS transactions for any reportable items on DEA Form 106.

Retention of Inventory Records. The records must be retained for two years from the date the inventory was taken and must be available for DEA inspection at the registered location where the inventory was made. (21 CFR 1304.04)

Note: State record keeping requirements may be more than two years and should be maintained accordingly.

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DEA REGISTRATION

Detecting Fraudulent Registration Numbers

A DEA registration number consists of a two-character prefix and a seven-character suffix which are determined as follows:

Prefix. 1st character is A or B for all practitioners, hospitals, pharmacies and teaching institutions; it is P or R for all other classes of registrants. M is used for mid-level practitioners (MLP). (Refer to **DEA Correspondence 8/25/93**). The 2nd character is the first letter of the registrant's last name if an individual, or the first letter in the first word of the name if a firm (Note, a "9" is inserted in this position if the firm's name begins with a number—e.g., "101 A Street, Inc.").

Suffix. The suffix contains seven numeric characters, the seventh of which is a check digit that is determined as follows:

Add the number of the 1st, 3rd and 5th characters to twice the sum of the 2nd, 4th and 6th characters; if the total is a single-digit number, that number is the check digit; if the total is a two-digit number, the digit in the ones column is the check digit and is inserted in the seventh position.

Checking Expiration Dates

A system to verify the renewal of registration number can be standardized by expiration date because all registrations with the same second character in the prefix expire on the same date. The expiration dates for these characters are:

January 31	M	July 31	B
February 28	S	August 31	C, E
March 31	L, P	September 30	F, G
April 30	Q, R, 9	October 31	H, N
May 31	U, V, W, X, Y, Z	November 30	I, T
June 30	A, D	December 31	J, K, O

Note: Practitioners, hospitals, pharmacies, and teaching institutions re-register every three years. All others register annually.

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DEA Registration

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DEA Registration Verification

(21 CFR 1301.74(a))

The wholesaler is responsible for verifying that customers possess a valid, current DEA Certificate of Registration (Exhibit J). DEA will not verify routinely, and it is left to the wholesaler to develop a system. There are several methods the wholesaler may use.

Cardinal's policy and procedure requires that new accounts provide a photocopy of a current DEA registration prior to being allowed to purchase controlled substances. A copy of the account's state license should be obtained at the same time.

Registration expiration dates for existing accounts are monitored on a monthly basis. Those accounts whose registration is due to expire are contacted either by letter, telephone, or sales representative and are requested to provide an updated copy of their registration (Exhibits K, L). A copy of the state license should also be requested.

In addition, the computer system prohibits the purchase of controlled substances by any customer who does not have a DEA registration number loaded into the computer system or whose registration has expired. The system also limits the purchase of controlled substances to the schedules for which the customer is registered.

Cardinal purchases, on a quarterly basis, a tape from the DEA of all current registrations. This tape is run against each division's customer database. The Quarterly DEA Exception Report (Exhibit N) is a listing of all customers in a division's database whose DEA number or expiration date does not match the DEA database. Review and maintenance of this report must be done to assure sales of controlled substances are only made to current registrants of the DEA.

Questioned Registrations

Whenever there is reason to question a customer's registration (i.e., the number does not pass the check digit, there is a question whether the registration includes the schedule(s) ordered or a pharmacy has changed hands and the new owner is using the old DEA number), further inquiry should be made to ensure that the customer is properly registered. The local DEA office will check this type of situation. Calls to the local DEA office should be documented on a Regulatory Agency Contact Form (Form #1).

Delayed Registration Renewal Certificates

From time to time, computer delays at DEA cause customer renewals to be late, even though renewal applications were submitted in a timely fashion. When the customer tells the wholesaler that this has occurred, the wholesaler should contact the local DEA office to confirm this fact and to authorize continued shipments. If the authorization is made by telephone, the wholesaler should write down the confirmation, including the name of the authorizing DEA official, the date, and the details of the authorization. Document this on a Regulatory Agency Contact Form. Refer to DEA Correspondence 9/7/93.

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DEA Registration

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Modification of DEA Registration

When a registrant moves to a new location, they must have the new location inspected by the DEA and obtain a new DEA registration with a corrected address. Many customers continue to use the old registration and expect that their controlled substance orders will be delivered to the new address. This is a violation of DEA regulations. Controlled substances can only be shipped to properly registered location and only to the address listed on the registration. (21 CFR 1301.51)

Transfer of Ownership

For a change of pharmacy ownership and continuing operation on a previous owner's DEA registration, the primary condition is that both the buyer and seller enter into a **Limited Power Of Attorney (Form #25)** that specifically sets forth the following:

- The seller agrees to allow the controlled substance activities of the pharmacy to be carried out under the seller's DEA registration;
- The seller agrees to allow the buyer to carry out the controlled substance activities of the pharmacy, including the ordering of controlled substances, as an agent of the seller;
- The seller acknowledges that, as the registrant, they will be held accountable for any violations of controlled substance laws which may occur; and
- The buyer agrees that the controlled substance activities of the pharmacy may be carried out under the seller's registration for no more than 45 days after the purchase date, which shall be recorded in the agreement.

Prior to selling product to the new owner, you should obtain a copy of the **Power Of Attorney** and file it with the copy of the previous owner's DEA registration certificate.

In addition, you must monitor the 45-day limit on controlled substance activity imposed as part of this policy. Refer to **DEA Correspondence 8/25/93**.

Termination of DEA Registration

(21 CFR 1301.52)

The closing of a facility requires that a DEA certificate of registration be terminated. At least 14 days prior to close and controlled substance transfer, submit a registered or certified letter, return receipt requested, to local DEA supervisor containing the following information:

- name, address, registration number of distribution center which is transferring the controlled substances and associated records and terminating the registration,
- name, address, registration number of distribution center to whom the controlled substances and associated records will be transferred,
- date of the controlled substance transfer and a description of the proposed transfer procedure,
- date and time of termination.

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DEA Registration

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Contact state licensing agencies and follow their specific procedures for registration termination.

On the date of the transfer, a complete inventory of all controlled substances being transferred must be taken. A copy must be maintained with the records for each distribution center. The transfer must be documented as a purchase and sale. Purchase orders, 222's, invoices and receiving documents must be created.

The Corporate Compliance Department will arrange and supervise the transfer of all controlled substances.

Upon termination of the registration, submit to the regional DEA office by registered or certified mail, return receipt requested, a cover letter and the following:

- DEA Certificate of Registration,
- unused DEA Forms 222.

Chemical Registration

Any person or persons who distribute products covered by the Methamphetamine Control Act (ephedrine, pseudoephedrine, phenylpropanolamine) must have either a controlled substance registration or a chemical registration. They do not have to possess both registrations. Registrations must be renewed annually.

A DEA chemical registration number consists of a six character prefix and a three character suffix which are determined as follows:

Prefix. The prefix contains six numeric characters. There is no check digit as in a controlled substance registration.

Suffix. The suffix contains three alpha characters. The first is the first letter in the registrant's name. The second is a random letter and the third identifies the activity of the registrant as listed below.

- W - Manufacturer
- Y - Distributor
- V - Retail Distributor
- X - Importer
- Z - Exporter

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DEA Registration

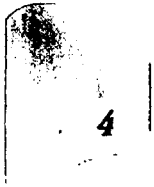
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MAINTENANCE OF RECORDS

The wholesaler is required to maintain on a current basis a complete and accurate record of every controlled substance received, distributed, or otherwise disposed of. Separate records are required for each registered location. Records of Schedule I (research drugs) and II drugs must be maintained separately (see section on Order Forms). All required records must be retained for two years. (21 CFR 1304).

Required Record Information

(21 CFR 1304.22 (b))

The following information is required for each controlled substance:

- Name of the substance.
- Each finished form (e.g., 10-mg. tablet or 10-mg. concentration per fluid ounce or milliliter) and the number of units or volume of finished form in each commercial container (e.g., 100-tablet bottle or 3-milliliter vial).
- Number of commercial containers of each such finished form received from other persons, including the date of and number of containers in each receipt and the name, address, and registration number of the person from whom the containers were received.

Note: Many wholesalers have been cited for failing to record the actual date of receipt on the document of transfer (e.g., invoice or packing slip) as well as the accurate name, address and registration number of the shipper.

- Number of commercial containers of each such finished form distributed to other persons, including the date of and number of containers in each distribution and the name, address and registration number of the person to whom the containers were distributed.

Note: Wholesalers also have been cited for failing to record the actual shipping date as well as the accurate name, address, and registration number of the person to whom it was shipped. Ditto marks on DEA Form 222 are not acceptable for recording dates.

Note: When providing backup service for another division, and shipping directly to the division's customer, your records must show that

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Maintenance of Records

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customer as the recipient of the product. Refer to DEA Correspondence 6/28/95.

- Number of units or volume of finished forms and/or commercial containers distributed or disposed of in any other manner (e.g., by distribution as complimentary samples or by destruction) including the date and manner of distribution or disposal, the name, address and registration number of the person to whom distributed, and the quantity of the substance in finished form distributed or disposed of.

Automated Records Systems

Federal requirements can be met by either automated or manual records systems provided that the specific system contains all the necessary data elements. The wholesaler has the option of maintaining records for Schedule III through V transactions either separately or, if they are readily retrievable, with noncontrolled drug transactions. Ready retrievability requires that the records (whether an automated system, a manual system or a combination) clearly identify controlled drug transactions so that they can be extracted readily (i.e., identified by schedule symbol (C-III) or asterisk, redlined, on separate invoices for controlled drugs only, etc.).

Returns from Customers or to Manufacturers

Care must be taken to ensure that all the data elements are included on records for returns. These records must have the same information as that required on all receiving/shipping records including the name, address, and registration number of the customer/supplier, the name of the substance, each finished form, the number of units or volume and the number of containers; and the actual date the substance was received by the wholesaler or returned to the supplier. Schedule II returns must be made pursuant to a valid order form (see section on Order Forms).

Note: Wholesalers often fail to place the required information on return documents or to maintain Schedule III through V returns records in a readily retrievable manner.

Rules for Central Record Keeping

(21 CFR 1304.04)

Recognizing the trend toward the automation of business records in a central data center covering multiple locations, DEA allows financial and shipping records to be kept at a central location following written notification to the DEA special agent in charge of the field office covering the area where the registrant is located. The central records system may commence 14 days after the special agent in charge receives notification (sent in triplicate by certified or registered mail, return receipt requested). The notification must contain the name, address, and registration number of all locations to be included, the name and address of the exact location where the central records will be kept, a brief description of the records system and the records to be maintained centrally, and a statement agreeing

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Maintenance of Records

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to make the records available at the registered location within two business days. If there is no response from DEA within 14 days after receipt by the special agent in charge, the wholesaler can proceed with the central records system. The wholesaler must, if DEA chooses, allow inspection at the central location in lieu of delivery to the registered location.

Exception: Inventories for all schedules of controlled drugs and Schedule II order forms must be kept at the registered location.

ARCOS participants wishing authorization to report from other than their registered location must obtain a separate central reporting identifier from the ARCOS Unit, P.O. Box 28293, Central Station, Washington, D.C. 20005, (202) 307-8600.

Microfilm/Microfiche Records

DEA does not consider copies of primary records an acceptable substitute for primary documents due to the opportunity for alteration when copying an original document. However, DEA will consider for approval on a case-by-case basis any system that simultaneously generates the copy and the original record. Approval of such a system requires DEA access to readers and printers as well as to the film. If a wholesaler microfilms/microfiches the originals for ease of handling, but retains the originals in backup storage for two years, this would satisfy DEA concerns as the originals could be made available for review as needed.

Drop Shipments of Controlled Substances

Wholesaler records of drop shipments are not required because these controlled substances are shipped directly from the supplier to the customer and never enter the wholesaler's possession. All such purchase orders and invoices must be clearly marked as drop shipments and should not be stored with records that document the actual receipt or distribution of controlled substances. Further, Schedule III narcotic substances which are drop-shipped are ARCOS reportable by the supplier on DEA Form 333.

Storage of Records

Care should be exercised to ensure that, for at least the two years they must be retained, all the wholesaler's controlled substances records are maintained in a secure and yet accessible manner. The controlled substance records are as follows:

- Receiving documentation
- Invoices and credit memos
- Narcotic Sales Report
- Narcotic Order Forms (DEA Form 222), brown and blue copies, and related records
- Monthly ARCOS Report
- ARCOS Edit Error Report and submission

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Maintenance of Records

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- Count Sheets from Periodic Inventories
- Suspicious Order Analysis, or Excessive Purchase Report
- DEA Form 106
- DEA Form 41
- Return Receipt Requested forms for any mailings
- Debit Memos for Returns to Vendors
- Year-End ARCOS Inventory
- Biennial Inventory

DEA requires that records be maintained for two years. Record retention requirements for individual states may vary. Additional records may be maintained as required by division policy.

Shipping Errors

Shipping errors must be documented as any normal transfer of controlled substances would be and as mandated by DEA record keeping and reporting requirements. In other words, any transfer of controlled substances, regardless if shipped in error, must be appropriately documented with 222s, invoices, credit memos, and ARCOS reporting as applicable. The swapping of the right product for the wrong product is inappropriate. Each distribution and return must be documented as a separate independent transaction. These requirements apply to intra-company as well as customer shipments. Several examples of shipping error scenarios and the corresponding corrective actions are included as Exhibit Q.

Brokerage Operations

Some Cardinal Distribution facilities have brokerage business operating within their distribution center. The brokerage business operates on the division's DEA registration number, therefore the division is ultimately responsible for compliance with DEA regulatory requirements as they apply to brokerage operations. Key compliance issues related to the division/brokerage operating relationship are as follows:

- Brokerage personnel must coordinate with division personnel to ensure they are following all division procedures related to the receipt, distribution, storage, inventory, etc. of controlled substances.
- All transaction records and reports for brokerage purchases, sales and other dispositions of controlled substances must be included in the division's records. On the distract system this is accomplished through a month end records transfer from the brokerage system to the division system. HP divisions maintain hard copy records and adds ARCOS records through a manual process.
- Records for controlled substance transactions between brokerage and the division are not required records since brokerage operates on the division's DEA registration. These records must be deleted from the brokerage and division record keeping systems.

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Maintenance of Records

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- Brokerage controlled substance inventory must be stored in the cage and vault, but is maintained separately from the division's inventory and is identified as brokerage inventory.
- Although brokerage inventory is maintained separately, it must be included in all inventories conducted by the division.
- The division must be licensed, as required, in those states into which they distribute to brokerage customers.
- The division must verify and maintain a copy of all brokerage customer DEA registrations and state licenses.

A more detailed description of brokerage operations is contained in the **Brokerage Warehouse Operations Procedures Manual** which should be available to you from brokerage personnel located in your division.

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Maintenance of Records

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ORDER FORMS

(21 CFR 1305)

All transactions of Schedule I and II substances must be made on federal order forms - **DEA Form 222 (Exhibit O)**. Any exceptions to this requirement must be approved by DEA on a case-by-case basis. Purchases from vendors and returns from customers are executed on order forms issued by Cardinal Health. Sales to customers are executed on order forms issued by the customer.

Obtaining and Executing Order Forms

Only persons registered to handle Schedule I and/or II substances may obtain order forms. Order forms may be executed only on behalf of the registrant named on the order form provided that the registrant **currently** is registered to handle the scheduled substances ordered.

When blanks are received from the DEA, the order form numbers should be logged on the **DEA Narcotic Blank Log (Form #4)**, and kept in the vault for safekeeping, pending use.

Separate Records Requirement

DEA has taken the position that order forms are the primary record of Schedule II transactions and, therefore, that the maintenance of order forms in a separate file satisfies the requirement that records of Schedule II transactions be maintained separately. Secondary records (e.g., invoices accompanying order forms) are not required to be maintained separately.

Purchases and Returns of Schedule I and II substances

Procedure for Executing Order Forms

(21 CFR 1305.06)

- The purchaser simultaneously prepares and executes order forms in triplicate by means of interleaved carbon sheets which are part of the DEA Form 222. Order forms are prepared by use of a typewriter, pen or indelible pencil. A wholesaler may consider rejecting any Form 222 completed in pencil, indelible or not, as the identification of indelible over regular lead is tenuous at best.
- Only one item is entered on each numbered line. There are 10 lines on each order form. Some registrants still are using the old five-line order forms, which are valid.

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Order Forms

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If one order form is insufficient to include all items in an order, additional forms are used. The last line completed is noted on that form in the space provided. This number should correspond to the number of lines used. For example, if two lines are used on an order form to describe one item, the number of lines completed at the bottom is two.

- An item consists of one or more commercial or bulk containers of the same finished or bulk form and quantity of the same substance; a separate item is made for each commercial or bulk container of different finished or bulk form, quantity or substance. For each item, the form should show the name of the product ordered, the finished or bulk form of the product (e.g., 10-mg. tablet, 10-mg. concentration per fluid ounce or milliliter or U.S.P), the number of units or volume in each commercial or bulk container (e.g., 10 kilograms), the number of commercial or bulk containers ordered, and the name and quantity per unit of the controlled substance or substances contained in the product if not in pure form. The catalogue number of the product may be included at the discretion of the purchaser.
- The correct name and address of the supplier from whom the controlled substances are being ordered is entered on the form. Only one supplier may be listed on any one form.
- Each order form is signed and dated by a person authorized to sign a requisition for order forms on behalf of the purchaser pursuant to 21CFR 1305.05(c). The name of the purchaser, if different from the individual signing the order form, is inserted in the signature space. Unexecuted order forms may be kept and may be executed at a location other than the registered location printed on the form provided that all unexecuted forms are delivered promptly to the registered location upon an inspection of such location by any officer authorized to make inspection or to enforce any federal, state or local law regarding controlled substances.

Centralized Purchasing of Schedule II Drugs

When the ordering of schedule II drugs and the processing of the DEA Forms 222 is handled by Corporate Purchasing, the following steps are taken:

- Corporate Purchasing orders DEA Form 222's by contacting the appropriate DEA office or the DEA Registration Unit in Washington, D.C., or by completing a 222 Requisition Form.

Note: All 222 Requisition Forms received by the divisions should be forwarded to Corporate Purchasing.

- Order Form Books are received at the division.
- The division logs the order form numbers onto the **DEA Narcotic Blank Log**.
- Division retains adequate supply of order forms for emergency purchases and customer return buybacks and forwards remainder to Corporate Purchasing, along with a copy of the **DEA Narcotic Blank Log**.

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Order Forms

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- Corporate Purchasing receives and stores order forms in a secure area. Corporate Purchasing contacts division if numbers are out of sequence or an order form is missing.
- Corporate Purchasing creates Schedule II purchase order and completes order form according to DEA regulations (21 CFR 1305.06).
- Copy 1 (brown) and Copy 2 (green) copies of order form are mailed to the vendor; Copy 3 (blue) is mailed to the division. Corporate Purchasing makes copy of the order form for purchasing records.

Note: All three copies of voided order forms must be sent to the division.

- Corporate Purchasing adds order form numbers to purchase orders and transmits purchase order file to the division.
- Division receives Copy 3 (blue) copy of order form and records appropriate information onto **DEA Narcotic Blank Log**. Division contacts Corporate Purchasing if numbers are out of sequence or an order form is missing.

Power of Attorney

(21 CFR 1305.07)

Any purchaser may authorize one or more individuals, whether or not located at the registered location of the purchaser, to obtain and execute order forms on his/her behalf by executing a **Power of Attorney (Form #2)** for each such individual. The **Power Of Attorney** is signed by the same person who signed or was authorized to sign, the most recent application for registration or re-registration and by the individual being authorized to obtain and execute order forms. The power of attorney is filed with the executed order forms of the purchaser, and retained for the same period as any order form bearing the signature of the attorney. The power of attorney should be available for inspection together with other order form records. Any power of attorney may be revoked at any time by executing a **Notice Of Revocation (Form #3)**, signed by the person who signed (or was authorized to sign) the power of attorney or by a successor, or by whomever signed the most recent application for registration or re-registration, and filing it with the power of attorney being revoked.

Sales of Schedule I and II Substances

Procedure for Filling Order Forms

(21 CFR 1305.09)

- The purchaser submits copy 1 (brown) and copy 2 (green) of the order form to the supplier and retains copy 3 (blue) in his/her own files.

Note: Order forms given by customers to contract drivers for eventual delivery to the distribution center must be in a sealed envelope. The driver should have no knowledge of the contents of the order form. Refer to DEA Correspondence 07-18-96.

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Order Forms

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- The supplier fills the order, if possible and if the supplier desires to do so, and records on copies 1 (brown) and 2 (green) the number of commercial and bulk containers furnished on each item and the date on which such containers are shipped to the purchaser. If an order cannot be filled in its entirety, it may be filled in part and the balance supplied by additional shipments within 60 days after its execution by the purchaser, except as noted below.
- The controlled substances are shipped to the purchaser at the location printed by the administration on the order form, except as noted below.
- The supplier retains copy 1 (brown) of the order form for his/her own files and forwards copy 2 (green) to the special agent in charge of the DEA field office in the area in which the supplier is located. Copy 2 (green) is forwarded at the close of the month during which the order is filled; if an order is filled by partial shipments, copy 2 (green) is forwarded at the close of the month during which the final shipment is made or during which the 60-day validity period expires.
- The purchaser records on copy 3 (blue) of the order form the number of commercial or bulk containers furnished on each item and the dates on which such containers are received by the purchaser.

Note: Order forms submitted by registered procurement officers of the Armed Services Medical Procurement Agency for delivery to armed services establishments within the United States may be shipped to locations other than the location printed on the order forms, and in partial shipments at different times not to exceed six months from the date of the order, as designated by the procurement officer when submitting the order.

Note: DEA Policy is that the wholesaler or a "direct proprietary agent" of the wholesaler must have the order form in hand before the product is released. The direct proprietary agent can be a sales representative, a depot supervisor or a driver (not common or contract).

Substitutions

It is acceptable to substitute generic product for generic product, generic product for brand name product, or brand name product for generic product provided that the products are equivalent, the name and the NDC number of the actual product shipped are reflected on the order form, and the purchaser agrees to the substitution. Refer to DEA Correspondence 6/29/92.

Faxing Narcotic Order Forms

DEA, as a matter of policy, has stated that they will allow the faxing of order forms when it involves a direct transmission from the customer to the wholesaler; however, the order may not leave the distribution center until the original order form arrives at the distribution

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Order Forms

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center or is in the possession of a direct proprietary agent of the wholesaler. DEA may grant approval in emergency situations on a case-by-case basis for shipping the order before receiving the order form.

The DEA is also not opposed to having order forms faxed from depots to the wholesaler when the following conditions are met:

- The original order forms, when delivered to the depot, are in the possession of an employee of the wholesaler who is familiar with order form regulations.
- The order forms and a **DEA 222 Transmission Log (Form #5)** are faxed to the division and order form receipt is verified to the log.
- Narcotic orders are **not** released at the depot unless there is a corresponding order form.
- The regulatory requirements for the processing of DEA Form 222 are strictly adhered to.

This procedure **shall not be used unless** the depot operation is supervised by a Cardinal employee, the Cardinal employee faxes the order forms, and the Cardinal employee maintains possession of the original order forms until the order forms are exchanged for the controlled substances.

DEA **will not permit**, under any circumstances, the faxing of order forms from contract carrier crossdock locations by contract carrier employees. **Refer to DEA Correspondence 07-18-96 and 08-28-96.**

The faxing of 222s for customers serviced by contract carriers must be handled as follows:

FROM THE CROSSDOCK:

1. Contract delivery drivers deliver original 222s in sealed envelopes to contract carrier crossdock supervisor.
2. Crossdock supervisor delivers sealed envelopes containing 222s to Cardinal crossdock employee.
3. Cardinal crossdock employee removes 222s from envelopes and **completes DEA222 Transmission Log (Form #5).**
4. Cardinal employee faxes 222s to distribution center. **This should be done using one transmission and the DEA222 Transmission Log should be the last page of the fax.**
5. Fax is received in distribution center by Operations Manager or designee.
6. Operations Manager or designee verifies faxed 222s received with information on the DEA 222 Transmission Log. Faxed copies of 222s are checked for legibility and compliance and are processed according to DEA regulations.
 - a) If any discrepancies exist that would require 222s to be re-faxed, Operations Manager or designee contacts Cardinal crossdock employee.

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Order Forms

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7. Cardinal crossdock employee places original 222s in a sealed envelope for delivery to the distribution center.
8. Operations Manager or designee delivers faxed 222s to the vault.
9. Vault clerk fills orders and files faxed 222s. Orders are held until original 222s arrive at the distribution center and are compared to the orders.

FROM THE CUSTOMER:

1. Customer faxes 222 directly to the distribution center.
2. Operations Manager or designee checks 222 for legibility and compliance and processes according to DEA regulations.
 - a) If any discrepancies exist that would require 222 to be re-faxed, Operations Manager or designee contracts the customer.
3. Customer gives original 222 to contract delivery driver in a sealed envelope for delivery to distribution center.
4. Operations Manager or designee delivers faxed 222 to the vault.
5. Vault clerk fills order and files faxed 222. The order is held until the original 222 arrives at the distribution center and is compared to the order.

Preservation of Order Forms

(21 CFR 1305.13)

- The purchaser retains copy 3 (blue) of each filled order form. The purchaser also retains in his/her files all copies of each unaccepted or defective order form and any statements attached to them.
- The supplier retains copy 1 (brown) of each order form that has been filled.
- Order forms must be maintained separately from all other records of inspection for two years (as are all records of controlled substance transactions). If a purchaser has several registered locations, copy 3 (blue) of the executed order forms and any attached statements or other related documents (not including unexecuted order forms which may be kept elsewhere pursuant to **(21 CFR 1305.06 (d))**) must be kept at the registered location printed on the order form.

Note: State record keeping requirements may be more than two years and records should be maintained accordingly.

Unaccepted and Defective Order Forms

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Order Forms

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(21 CFR 1305.11)

Federal regulations applicable to the handling of such order forms are as follows:

- No Order Form shall be filled if it:
 - (1) Is not complete, legible, or properly prepared, executed, or endorsed; or
 - (2) Shows any alteration, erasure, or change of any description.

- If an Order Form cannot be filled for any reason under this section, the supplier shall return Copies 1 (brown) and 2 (green) to the purchaser with a statement as to the reason (e.g., illegible or altered). A supplier may for any reason refuse to accept the order; a statement that the order is not accepted shall be sufficient for purposes of this paragraph.

- When received by the purchaser, Copies 1 (brown) and 2 (green) of the Order Form and the statement shall be attached to Copy 3 (blue) and retained in the files of the purchaser in accordance with 21 CFR 1305.13. A defective Order Form may not be corrected; it must be replaced by a new Order Form in order for the order to be filled.

- Any information which is pre-printed on the order form may not be altered in any way.

Pursuant to these regulations, order forms should be returned to the customer under the following circumstances:

- The writing is illegible or it is otherwise impossible to identify a customer's registration number, items specified or quantities, or there is improper execution or endorsement.
- There are alterations, erasures, or changes resulting in questions regarding the identity of the customer, customer's registration number, items or quantities.
- Signatures are omitted.
- Sixty days have elapsed from the date of execution by the purchaser.
- The last line completed is greater than the last line specified.
- The number of line items is greater than the total number of items specified.
- Customer voids a line.

Federal order forms which identify the customer's registration number, items and quantities, and which are properly signed but are incomplete or have minor errors may be corrected to the following extent:

- The supplier's name, address, city, state, or zip code may be added when omitted by the customer.
- The supplier's address, city, state or zip code may be corrected.
- The date of the order may be added when omitted. Whenever possible, the postal date on the envelope should be used.

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Order Forms

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- It is permitted to add or change hydrochloride, sulfate, phosphate, ampules, tablets, etc. if the customer's order is correct in all respects except that it is specified in error; for example, specifies capsules and the product requested is properly designated and supplied in tablets.
- A letter or digit in the National Drug Code designation may be corrected if the controlled substance is described correctly, or the strength stated may be corrected if the quantity of controlled substance is not increased in any way.
- Order forms may be accepted when the customer has sent all three copies of the form to the supplier, but the customer's copy must be forwarded to him in advance of the shipping product.
- Order forms received by the supplier without interleaf carbon may be accepted, but the supplier must insert a replacement carbon between the forms before making any entries on the form.
- If a form is received which lists a package amount which is unavailable, a lesser amount may be shipped (e.g. order is for package size 100, if unavailable may ship package size 50), or if a form is received which lists a package amount which is unavailable, different package sizes not to exceed the original amount may be shipped (e.g. ordered 1 x 1000, may ship 10 x 100).
- Lesser number of line items ordered than line items specified, if the supplier crosses out the remaining lines before filling the form.
- Last line completed has been incorrectly noted. The order form should not be rejected when it is clear that this is due to misinterpretation, rather than an attempt to facilitate diversion.

A single item must be canceled for the following reasons, but the balance of the order may be shipped:

- If the number of packages, size of package, or strength has been altered by the person preparing the order form.
- If the item requested is discontinued or not listed, or is a non-controlled substance or is a controlled substance other than a Schedule I or II controlled substance.
- Strength is dittoed on the order form rather than designated.
- Strength is omitted (except trademark items when National Drug Code number is listed).
- Size of package incorrectly stated (quantity may be reduced).
- Size of package omitted.
- When a multiple item order is properly prepared and complete in all other respects but a single item has a non-correctable defect, this item may be canceled in lieu of returning the order form to the customer.

Refer to DEA Correspondences 6/29/92, 12/16/92, 7/28/94, and 9/14/95 for regulatory interpretations.

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Order Forms

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Cancellation and Voiding of Order Forms

(21 CFR 1305.15)

- A purchaser may cancel part or all of an order on an order form by notifying the supplier in writing of such cancellation. The supplier indicates the cancellation on copies 1 (brown) and 2 (green) of the order form by drawing a line through the canceled items and printing "Canceled" in the space provided for number of items shipped.
- A supplier may void part or all of an order form by notifying the purchaser in writing of such voiding on an **Order Form Rejection Notification (Form #6)**. The supplier should keep a copy of the order form and the notification. The supplier indicates the voiding in the manner prescribed for cancellation in paragraph (a) of this section.
- No cancellation or voiding permitted by this section affects in any way contract rights of either the purchaser or the supplier.

Narcotic Order Form Review

The DEA has established specific criteria for the acceptance of Narcotic Order Forms. To assure that the appropriate personnel receive continuous training with respect to these regulatory requirements, the previous day's Narcotic Order Forms must be reviewed for compliance with DEA regulations. Complete a **Narcotic Order Review Form (Form #7)** for any order forms that were processed in violation of DEA regulations. Discuss violations and the appropriate responsive action with personnel involved. File the Narcotic Order Review Form with a copy of the corresponding DEA Form 222.

Procedure for Endorsing Order Forms

(21 CFR 1305.10)

- An order form made out to any supplier who cannot fill all or part of the order within the time limitation set forth in 1305.09 may be endorsed to another supplier for filling. The endorsement is made only by the supplier to whom the order form was first made, states (in the space provided on the reverse sides of copies 1 (brown) and 2 (green) of the order form) the name and address of the second supplier, and is signed by the person authorized to obtain and execute order forms on behalf of the first supplier. The first supplier may not fill any part of an order on an endorsed form. The second supplier fills the order if possible and if the supplier desires to do so, in accordance with **21 CFR 1305.09(b),(c) and (d)** including shipping all substances directly to the purchaser.
- Distribution made on endorsed forms is reported by the second supplier in the same manner as all other distributions except that where the name of the supplier is

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Order Forms

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requested on the reporting form, the second supplier records the name, address and registration number of the first supplier.

Lost or Stolen Order Forms

(21 CFR 1305.12)

- If a purchaser ascertains that an unfilled order form has been lost, the purchaser should execute another in triplicate and a statement containing the serial number and date of the lost form, and stating that the goods ordered in the first order form were not received through loss of that order form. Copy 3 (blue) of the second order form and a copy of the statement are retained with copy 3 (blue) of the order form first executed. A copy of the statement is attached to copies 1 (brown) and 2 (green) of the second order form sent to the supplier. If the first order form subsequently is received by the supplier to whom it was directed, the supplier marks it as "Not accepted" and returns copies 1 (brown) and 2 (green) to the purchaser, who attaches it to copy 3 (blue) and the statement.
- Whenever any used or unused order forms are stolen or lost (besides in the course of transmission) by any purchaser or supplier, immediately upon discovery of the theft or loss, that person reports it to the local office of the Drug Enforcement Administration stating the serial number of each form stolen or lost. If the theft or loss includes any original order forms received from purchasers and the supplier is unable to state the serial numbers of such order forms, the supplier should report the date or approximate date of receipt and the names and addresses of the purchasers. If an entire mailing envelope of order forms is lost or stolen, and the purchaser is unable to state the serial numbers of the order forms it contained, the purchaser should report, in lieu of the numbers of the forms contained in the envelope, the date or approximate date the envelope was issued. If any unused order form reported lost or stolen subsequently is recovered or found, the Registration Unit should be notified immediately.

Return of Unused Order Forms

(21 CFR 1305.14)

If the registration of any purchaser terminates (because the purchaser dies, ceases legal existence, discontinues business or professional practice, or changes the name or address shown on the registration), or is suspended or revoked (pursuant to 21 CFR 1301.45 or 1301.46 of this chapter), the purchaser (or his/her executor) should return all unused order forms for controlled substances listed in Schedules I and II for which the purchaser is registered to the nearest DEA office.

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METHAMPHETAMINE CONTROL ACT RECORDKEEPING AND REPORTING REQUIREMENTS (21 CFR 1310)

Pursuant to the Domestic Chemical Diversion and Control Act, DEA has regulated both RX and OTC single-entity ephedrine products since 1994. The Methamphetamine Control Act of 1996 extends these regulations and DEA control to the distribution of OTC combination ephedrine, pseudoephedrine and phenylpropanolamine products. A list of these products covered by the regulations is included as **Appendix E**.

The requirements which became effective October 3, 1997 are not the same as those for controlled substances. These products will not be scheduled, will not have to be kept in secure storage, and complete inventory accounting and ARCOS reporting requirements do not apply.

The MCA regulatory scheme, described in 21 CFR, Part 1310, has four basic components: registration; keeping records of ephedrine, pseudoephedrine and phenylpropanolamine transactions; reporting any unusual losses or excessive purchases to DEA, and taking steps to be sure the purchaser is legitimate.

Registration

Distributors who handle covered products are required to register as a chemical distributor with DEA, however DEA has exempted anyone with a valid DEA controlled substance registration from having to obtain the additional registration.

Your customers should have either a DEA controlled substance registration or a chemical registration.

Please note that there is a pseudoephedrine and phenylpropanolamine registration exemption for customers who meet the definition of a "retail distributor." Retail distributor is defined as a grocery store, drug store or other entity or person whose activities as a distributor of legal drug products containing listed chemicals are limited almost exclusively to sales for personal use (approximately 1200 dosage units), both in number and volume of sales, either directly to walk-in customers or in face to face transactions by direct sale.

The exemption process should be handled on a case by case basis. Customers not currently registered with DEA who believe they qualify for the exemption should be requested to provide written documentation to this effect. Once the documentation is received, the customer can be set up to purchase these items.

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MCA Recordkeeping Requirements

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Note: A review of Cardinal's customer database has indicated that the vast majority of customers currently possess a valid DEA registration. Additionally, customers who do not possess such a registration are of a class that would not typically purchase these products.

Records

You must maintain readily retrievable records of each ephedrine, pseudoephedrine or phenylpropanolamine product transaction for 2 years. Normal business records shall be considered adequate, as long as they contain:

- the name and address of each party to the transaction
- the date of the transaction
- the name, quantity, and form of packaging of the ephedrine or pseudoephedrine product
- the method of transfer
- the type of identification used by the purchaser.

Reports

You must report to your local DEA office:

- Any unusual ephedrine, pseudoephedrine or phenylpropanolamine transaction -- extraordinary quantity, uncommon method of payment or delivery, or any other suspicious circumstances
- Any unusual or excessive loss of ephedrine, pseudoephedrine or phenylpropanolamine product. Pay particular attention to variances discovered during semi-annual inventories
- Any proposed transaction with a person DEA has requested in writing that you monitor (report before completing the sale).

Note: a transaction may not be completed with a person identified by DEA unless approved by DEA. Steps should be taken to prohibit sales to these persons.

Reports are to be made orally, whenever possible, to the local DEA office at the earliest opportunity and as much in advance of the sale as possible. A written report must then be filed within fifteen days of becoming aware of the above circumstances. Written reports must contain the same information as the required records, plus the telephone number of the other party, if possible, and a description of the circumstances leading you to make the report. Written reports should be made on the **MCA Transaction Report (Form #8)**.

Identifying the Customer

The regulations require the wholesaler to "identify the other party" to the transaction. In general, an ongoing agreement with your customer, an account that you had for some time, and other such business relationships indicating you know your customer, should establish the kind of verification DEA is looking for. Credit applications and Dun and Bradstreet reports should be sufficient.

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MCA Recordkeeping Requirements

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Compliance Guidelines

- Verify that your customers are registered to purchase these products or are exempt from the registration requirement.
- Maintain required records (normal business records are sufficient if they contain the required information).
- Generate and review monthly the MCA dosage limit report (Exhibit R). Submit these reports to DEA.
- Report to DEA any unusual or excessive loss or disappearance of any ephedrine, pseudoephedrine or phenylpropanolamine product. Pay particular attention to variances discovered during semi-annual inventories.
- Maintain a file consisting of any reports submitted to the DEA and the monthly Excessive Purchase Report.

Other Regulated Products

The requirements for ephedrine, pseudoephedrine and phenylpropanolamine also apply to other chemical products which wholesalers do not usually stock or stock and distribute in limited quantities. The recordkeeping and reporting requirements for these items, which are listed below, only apply when threshold limits set by the regulations are exceeded. A past review of sales history for the items that are stocked in certain Cardinal Distribution Centers indicated that typical distribution quantities do not come close to meeting these limits. However, division management should be aware of all regulated products in the event that DEA addresses this issue during an audit.

List I Chemicals:	
Chemical	Threshold by base weight
1 Anthranilic acid and its salts	30 kilograms
2 Benzyl cyanide	1 kilogram
3 Ergonovine and its salts	10 grams
4 Ergotamine and its salts	20 grams
5 N-Acetylanthranilic acid and its salts	40 kilograms
6 Piperidine and its salts	500 grams
7 3, 4-Methylenedioxyphenyl-2-propanone	4 kilograms
8 Methylamine and its salts	1 kilogram
9 Ethylamine and its salts	1 kilogram
10 Propionic anhydride	1 gram
11 Isosafrole	4 kilograms
12 Safrole	4 kilograms
13 Piperonal	4 kilograms
14 Hydriotic acid (57%)	1.7 kilograms (or 1 liter by volume).
15 Benzaldehyde	4 kilograms
16 Nitroethane	2.5 kilograms

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MCA Recordkeeping Requirements

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List II Chemicals:		
Imports and Exports		
Chemical	Threshold by volume	Threshold by weight
(A) Acetic anhydride	250 gallons	1,023 kilograms
(B) Acetone	500 gallons	1,500 kilograms
(C) Benzyl chloride	N/A	4 kilograms
(D) Ethyl ether	500 gallons	1,364 kilograms
(E) Potassium permanganate	N/A	500 kilograms
(F) 2-Butanone (MEK)	500 gallons	1,455 kilograms
(G) Toluene	500 gallons	1,591 kilograms

Domestic Sales		
Chemical	Threshold by volume	Threshold by weight
(A) Acetic anhydride	250 gallons	1,023 kilograms
(B) Acetone	50 gallons	150 kilograms
(C) Benzyl chloride	N/A	1 kilograms
(D) Ethyl ether	50 gallons	135.8 kilograms
(E) Potassium permanganate	N/A	55 kilograms
(F) 2-Butanone (MEK)	50 gallons	145 kilograms
(G) Toluene	50 gallons	159 kilograms

Note: The cumulative threshold is not applicable to domestic sales of Acetone, 2-Butanone (MEK), and Toluene.

Chemical	Threshold by volume	Threshold by weight
(A) Hydrochloric acid	50 gallons
(1) <i>Anhydrous hydrochloric acid</i>	27 kilograms
(B) Sulfuric acid	50 gallons

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MCA Recordkeeping Requirements

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REQUIRED REPORTS TO DEA

Wholesalers are required to report regularly to DEA's ARCOS Unit all receipts and disposals of all Schedule I and II drugs and Schedule III narcotics. In addition, wholesalers are required to submit other reports to DEA under certain circumstances (e.g., drug thefts, drug destructions and suspicious orders).

ARCOS Reports

(21 CFR 1304.33)

Every wholesaler who handles controlled substances in Schedule I and II and/or narcotics in Schedule III must report to the ARCOS Unit, as follows:

When

Annual Inventory	To be taken on December 31
Initial Inventory	To be taken on the effective date that a substance becomes reportable
Transaction Reporting	Quarterly, or, with DEA permission, monthly

All reports are required to be submitted within 15 days after the end of the report period by certified or registered mail, return receipt requested.

- ARCOS reports sent via commercial carrier such as Federal Express (FedEx), United Parcel Service (UPS) should be sent to:

DEA Headquarters
Attn: ARCOS Unit
2401 Jefferson-Davis Highway
Alexandria, VA 22301

- ARCOS reports sent via the U.S. Postal Service must use the following address:

Drug Enforcement Administration
ARCOS Unit
P.O. Box 27273
Washington, D.C. 20038-7273

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Required Reports to DEA

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Refer to The ARCOS Reporting Manual (Appendix A) for additional information.

Optional ARCOS Reporting Modes

Registrants using punched card accounting machines or electronic data processing equipment should submit either card decks or magnetic tapes. Registrants without automated systems must use the Manual ARCOS OCR Form - DEA Form 333 - (Form #9).

Reporting ARCOS Data from Another Location

For authorization to report ARCOS data from other than a registered location, a central reporting identified must be obtained from the ARCOS unit at the above address.

DEA Order Forms

(21 CFR 1305.09 (d))

Copy 2 (green) of the order form shall be sent to the local DEA office at the close of the month during which the order was filled. If the order is filled by partial shipments, Copy 2 (green) shall be forwarded at the close of the month during which the final shipment is made or during which the 60-day validity period expires.

Drug Thefts/Losses

(21 CFR 1301.74(c))

The registrant notifies the DEA field office in that area of any theft or significant loss upon discovery of such theft or loss on **Report of Theft or Loss of Controlled Substances -DEA Form 106- (Form #10)**. Reports must be submitted within seven (7) days of the incident. Reporting in-transit losses is the supplier's responsibility. Reporting responsibility for shipments for which you have a signed receipt lies with the customer.

The reporting of inventory variances on DEA form 106 must be carefully evaluated. The most recent DEA policy addressing this issue reads as follows: "DEA regulations require a registrant to maintain inventory records to track the flow of controlled substances but do not require the maintenance of perpetual inventories. If a firm elects to regularly track inventory balances and notes a theoretical discrepancy, the firm should make every effort to resolve it within a timely manner. If it is determined that an actual discrepancy is the result of a theft or significant loss of controlled drug product, then the nearest DEA field office must be notified immediately upon discovery and the theft or loss must be reported on a DEA Form 106." Variances which are the result of record keeping or order filling errors need not be reported.

Any ARCOS reportable items filed on **DEA Form 106** should also be submitted to ARCOS.

Note: Some state agencies require copies of all DEA Forms 106 filed with DEA.

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Required Reports to DEA

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Drug Destructions

(21 CFR 1307.21)

If a wholesaler wants to destroy certain controlled substances (e.g., damaged goods, returns, etc.), the wholesaler should notify the DEA special agent in charge on **Registrant Inventory of Drugs Surrendered - DEA Form 41 - (Form #11)** in triplicate. The special agent in charge will inform the wholesaler how the drug destruction will be handled. Where the wholesaler regularly disposes of controlled substances, the DEA special agent in charge can, upon request, authorize dispositions without prior approval provided that these dispositions are recorded fully and meet all conditions established by the special agent in charge. Destructions of reportable items must be submitted to ARCOS on **ARCOS OCR Form 333**.

Note: It is DEA's policy that if a state agency having jurisdiction over wholesalers has adopted disposal procedures for controlled substances, the wholesaler may follow these procedures in lieu of DEA requirements.

Cardinal has a contract with Reverse Management Systems to handle our destruction of unsaleable merchandise. The product is sold to Reverse Management Systems who in turn destroys it and files **DEA Form 41**. Refer to **DEA Correspondence 8/12/94** for additional information.

DEA Form 41 should also be used for documenting a liquid controlled substance loss when the container accidentally breaks. Any loss of an ARCOS reportable item must also be reported to ARCOS. The pieces of the broken bottle do not need to be retained as evidence of the accident. Refer to **DEA correspondence 11/17/97**.

Suspicious Orders

(21 CFR 1301.74(b))

Wholesalers are responsible for designing and operating a system that will disclose to the wholesaler suspicious orders. The wholesaler informs the DEA field office in that area of all suspicious orders. Suspicious orders include orders of unusual size, orders deviating from a normal pattern and orders of unusual frequency. DEA has no specific form for this.

Establishing Suspicious Order Criteria

Wholesalers should establish **written** criteria of what constitutes a suspicious order. DEA leaves it to the wholesaler to make this determination. The key for the wholesaler is to establish **reasonable** criteria based upon customer purchasing patterns and then to **adhere** to them in monitoring orders. Either a computerized or a manual system can be utilized depending upon the wholesaler's preference and capability.

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Required Reports to DEA

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Complying with 21 CFR 1301.74 (b) is a two-step process. First, each Cardinal Division submits to DEA on a monthly basis an Ingredient Limit Report (Exhibit M). This report is based on a computer program which monitors customer controlled substance purchases for a month and compares these purchases to predetermined averages or limits and if a customer's purchase quantities exceed the established parameters, the customer's activity is printed on the report.

Second, on a daily basis cage and vault personnel should be policing and identifying individual orders that appear excessive in relation to what other customers are buying and/or the customer's purchase history. In these situations, DEA should be notified, if possible, before the order is shipped and a copy of all such orders should be maintained in the division's suspicious order file along with a Regulatory Agency Contact Form (Form #1) noting any specific instructions from DEA.

In an effort to assist cage and vault personnel in identifying these orders, we have developed Dosage Limit Charts (Exhibit P). The products included on these charts are those commonly audited by DEA during their inspections of our facilities and those which have a high potential for diversion. The dosage limits were set by calculating average sales quantities for Knoxville's retail customers and Boston's hospital customer and multiplying by 3 for ARCOS reportable items and 5 for non-ARCOS items.

These charts should be posted in your cage and vault and the hospital and retail dosage limit quantities for particular items should be posted at the product locations.

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Required Reports to DEA

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INTRODUCTION

Security is defined as the elements necessary to deter burglary or theft of controlled substances at a level of effectiveness that equals or exceeds federal regulations applicable to wholesaling. The elements include:

- Physical structures and barriers such as safes, vaults, cages, barricades, grilles, gates, fencing, locks and lighting;
- Electronic systems including burglary detection sensors and controls, emergency (holdup) signal devices, closed-circuit TV surveillance and recording equipment, access control systems, and communications devices; and
- Practices and procedures applicable to the installation, maintenance, inspection, testing and supervision of interrelated security devices and systems.

This section of the manual is provided to educate employees about DEA security requirements and to assist Division Management in evaluating compliance with these requirements.

In evaluating the overall effectiveness of a wholesaler's security against theft and diversion, DEA may consider, in addition to those security requirements previously discussed, any of the following factors:

- The type of activity conducted (e.g., processing of bulk chemicals, preparing dosage forms, packaging, labeling, cooperative buying, etc.);
- The type and form of controlled substances handled (e.g., bulk liquids or dosage units, usable powders or nonusable powders);
- The quantity of controlled substances handled;
- The location of the premises and the relationship such location bears on security needs;
- The type of building construction comprising the facility and the general characteristics of the building or buildings;
- The type of vault, safe, and secure enclosures or other storage system (e.g., automatic storage and retrieval system) used;
- The type of closures on vaults, safes, and secure enclosures;
- The adequacy of key control systems and/or combination lock control systems;
- The adequacy of electric detection and alarm systems, if any including use of supervised transmittal lines and standby power sources;
- The extent of unsupervised public access to the facility, including the presence and characteristics of perimeter fencing, if any;

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Physical and Procedural Security - Introduction

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- The adequacy of supervision over employees having access to manufacturing and storage areas;
- The procedures for handling business guests, visitors, maintenance personnel, and nonemployee service personnel;
- The availability of local police protection or of the registrant's or applicant's security personnel, and;
- The adequacy of the registrant's or applicant's system for monitoring the receipt, manufacture, distribution, and disposition of controlled substances in its operations.

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Physical and Procedural Security - Introduction

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PHYSICAL SECURITY - GENERAL WAREHOUSE

Management must insure that appropriate physical security measures are taken against the loss of company property and assets. The standards set forth in this section will assist in insuring reasonable protection of the company's assets.

Security of Design and Layout

In all cases of security planning, either for new construction or updating of current facilities, assistance should be requested from the Corporate Compliance Department.

It is suggested that management implement basic physical security designs from a **Security In-Depth Approach**.

In considering the design of a facility, use of all available resources in an efficient manner should be taken into consideration in order to achieve adequate protection for the facility. Emphasis should be placed on the operational requirement of the facility to determine the type and extent of physical security needed.

Protecting a drug warehouse in this day and age is a difficult task. Some of the factors to be taken into consideration when setting up an in-depth security protection system are:

- The exact function to be performed at that location
- The environment - political - economic - legal - terrain
- The vulnerability
- The area (geographic, neighborhood)
- The cost involved
- The possible future changes in the operation

The degree of protection should be predicated on what affect the loss would have on the operation and the relevant importance of the operation to the total business. Additionally, consideration should be given to the degree of susceptibility the operation has to outside threats. These threats are acts or conditions that may result in:

- Disruption of the facility
- Damage, loss or destruction of property
- Personal injury or loss of life
- Compromise of critical information

Threat severity depends on such variables as:

- Type of facility

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- Function performed (distribution of drugs)
- Physical layout and construction
- Geographical location
- Stability of location
- Existing state of law and order
- Protection measures already in affect, if any

Perimeter Barriers

Perimeter barriers may be used to define the physical limits of a facility. They are used generally to restrict, channel or impede access. In addition, they offer two important benefits; create a psychological consideration and have a direct impact on the number of security posts that may be needed. The two major categories of barriers are natural and structural. the one most commonly used is fencing. When practical to do so, all facilities should be fenced. This action will provide a first line of defense against the criminal element.

- Fencing should be of the No. 9 gauge or heavier fabric. The mesh openings should not be larger than two inches. To prevent individuals from going under the fence, a cement apron not less than six inches thick can be installed under the fence. The top of the fence should contain an anti-climb overhang or barbed wire, installed at a 45 degree angle outward, consisting of three strands of barbed wire. In some instances, it may be desirable to employ an additional strand of razor ribbon which is interwoven between the strands of the barbed wire on the top of the fence.
- Gates, entrances and other openings in a perimeter barrier should be limited to the number necessary for efficient and safe operation of the distribution center.
- All fence lines should be cleared areas and be free from obstruction. The area should be cleared of weeds, rubbish, or other material capable of offering cover or assistance to an intruder attempting to climb, cut through, or tunnel under.
- Exterior doors may be an inviting entrance for an intruder because of convenience. The vulnerable points at the door are the frame, hinges, door panels and the lock.
- Doors should be installed so that the hinges are located on the inside. If this is not possible, the hinges should be installed so as to prevent their removal and the exterior pins should not be removable. The hinges that are on the exterior of the doors should be welded, brazed, or otherwise secured.
- Doors should be of metal or solid wood construction.
- Glass exterior doors should be equipped with decorative metal bars or be of the type of glass which resists breakage.
- Rolling overhead doors not controlled or locked by electric power should be protected by slide bolts on the bottom bar on the inside and padlocked when not in use.

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- Doors which lead from the warehouse area of the distribution center to the outside should be equipped with a deadbolt lock with at least a one-inch (1") throw. These deadbolt locks should be protected by a case-hardened steel sleeve. This sleeve should cover the deadbolt throw and any other locking mechanism (e.g. electronic strike) on the door.
- Doors which lead from the warehouse area of the distribution center to the outside should be equipped with a wide-angle peep-hole. This mechanism will give employees a view of anyone requesting entry into the distribution center from the outside. If there is any doubt about the person's identity, then that person should be informed to report to the front door of the distribution center.
- Employees at the distribution center should not be allowed to park within fifty feet (50') of either the shipping door(s) or the receiving dock. When parking is limited at the distribution center, then it should be a standard rule that employees that work in these areas do not park near their respective work areas.
- There should be absolutely no markings on the distribution center identifying it as a drug warehouse. This includes signs over both the shipping and receiving doors or decals associated with drug associations attached to the glass on the distribution center.
- Utility boxes which are located on the exterior of the distribution center should be equipped with a padlock. If the utility company requests it, they should be issued a key to this box.
- For distribution centers which warrant it, closed circuit television should be installed on the exterior of the distribution center. The monitors for these cameras should be placed in strategic locations throughout the distribution center. The Corporate Compliance Department should be contacted prior to application of closed circuit television cameras.
- Shrubbery, trees and bushes should be trimmed down so that they are not above window level at the distribution center. Any exterior design, such as brickwork, latticework, or an exterior ladder should be removed from the exterior of the distribution center. These elements provide direct access to the roof of the building.

Protective Lighting

This safeguard has considerable value as a deterrent to thieves and vandals or any unauthorized entry. It is an essential element of an **In-Depth Security Program**. Requirements for protective lighting at facilities will depend on the situation and the areas to be protected.

Each situation requires careful study in order to provide the best visibility that is practical for such security functions as prevention of illegal entry, detection of intruders, inspection of vehicles, and illumination for distribution center employees exiting at night.

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- Plan protective lighting to assure adequate illumination to discourage or detect attempts to penetrate an area, and reveal the presence of unauthorized persons within the area.
- Light sources should be located to insure that illumination is directed toward probable courses of intruders.
- Shadowed areas caused by structures near or adjacent to vital areas should be illuminated.
- Design should provide for overlapping light distribution.
- Exterior areas which should receive consideration are fenced perimeters, gate access areas, entrances to the distribution center, and any outside storage areas.
- Emergency power should be included for critical lighting; controls and switches should be locked.
- Lighting in unattended areas can be controlled by time clocks or light sensor equipment.
- The lighting at the distribution center should be checked by a member of the management staff at the distribution center on a routine, periodic basis. Lighting which is not operating properly or is out completely should be repaired immediately.

Locks and Key Control

Locks are the most generally utilized security device. The lock is most commonly used in protecting installations and activities, personnel, classified information, and company property. It should be noted that regardless of their quality or cost, locks should be considered delay devices only and not positive bars to entry. Locks, therefore, must be supplemented, where appropriate, with other security and protection devices and combined into the Security In-Depth Approach.

- The distribution center should have a Lock and Key Control System. It should be a standard practice at the distribution center that the exterior door locks, along with the cage day-gate, vault day-gate, and the combination to the vault be changed on an annual basis, or when an employee having access to the keys to these locks and/or the combination to the vault leaves the company's employ or is transferred to a new location.
- The key to the front door of the distribution center should **never** be the same as the key to the warehouse. The cleaning crew, alarm company, and the police department should **not** have a key to the distribution center.
- A **Key Log (Form #12)** should be maintained or a **Key Receipt (Form #13)** should be issued for each key distributed at the distribution center. A copy of the key receipt

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goes to 1) the employee; 2) the distribution center manager; and 3) a copy is placed in the employee's personnel file. If an employee is entrusted with a passcard, then that number should also be placed on the key receipt form. Additional Key Receipt forms may be obtained from the Corporate Compliance Department.

- Spare keys to the distribution center, cage, or the combination to the vault should be kept in a secured location at the distribution center. These keys should be kept on the person of the employee entrusted with their care, or they should be kept on a locked desk drawer or small locked cabinet.
- A spare key to the vault should be secured inside the vault in an inconspicuous location. This key should be utilized in case distribution center employees are placed in the vault during the course of a crime.
- Padlocks which are utilized at the distribution center should always be left in the locked position when not in use. The serial numbers on these padlocks should be removed.

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STRUCTURAL SECURITY

Schedule II Controlled Substances (21 CFR 1301.72)

Schedule II controlled substances are stored in a vault, the physical structure of which meets the following specifications or equivalent:

If grandfathered (a vault constructed before, or under construction on, September 1, 1971): substantial construction with a steel door and a combination or key lock.

A vault constructed after September 1, 1971: walls, floor and ceiling constructed of at least eight inches of reinforced concrete or other substantial masonry, reinforced vertically and horizontally with one half inch steel rods tied six inches on center, or the structural equivalent to such reinforced walls, floors and ceilings.

The door and frame unit of the vault (GSA approved, Class V) conforms to the following specifications, or the equivalent:

- 30 man minutes against surreptitious entry;
- 10 man minutes against forced entry;
- 20 man hours against lock manipulation; and
- 20 man hours against radiological techniques.

Refer to DEA Correspondence 2/14/94 for a change in the specifications for the GSA Class V vault door.

DEA will also approve, on a case by case basis, UL listed Class M modular vaults for the storage of Schedule II controlled substances.

If operations require the vault to remain open for frequent access, then it must be equipped with a 'day gate' that is self-closing and self-locking or the equivalent. If the operation requires only that the vault be opened infrequently, such as to remove material in the morning and return material at night, and is always relocked immediately after use, a 'day gate' is not required.

Schedule III, IV, and V Controlled Substance Storage

DEA regulations (21 CFR 1301.72(b)) provide that Schedule III through V controlled substances must be secured as follows:

- In a cage located within the building on the premises meeting the specifications in 1301.72(b)(4)(ii-iv) and Section 1301.72 (b)(3)(ii)(a)(b), which read as follows:

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Structural Security

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21 CFR 1031.72(b)(4):

- A cage, located within a building on the premises, meeting the following specifications:
- Having walls constructed of not less than No. 10 gauge steel fabric mounted on steel posts, which posts are:
 - (a) At least one inch in diameter;
 - (b) Set in concrete or installed with lag bolts that are pinned or brazed; and
 - (c) Which are placed no more than 10 feet apart with horizontal one and one half inch reinforcements every sixty inches;
- Having a mesh construction with openings of not more than two and one half inches across the square.
- Having a ceiling constructed of the same material, or in the alternative, a cage shall be erected which reaches and is securely attached to the structural ceiling of the building. A lighter gauge mesh may be used for the ceilings of large enclosed areas if walls are at least 14 feet in height.
- Is equipped with a door constructed of No. 10 gauge steel fabric on a metal door frame in a metal door flange, and in all other respects conforms to all the requirements of 21 CFR 1301.72(b) (3)(ii)."

21 CFR 1301.72(b)(3):

- Is equipped with self-closing, self-locking doors constructed of substantial material commensurate with the type of building construction, provided, however, a door which is kept closed and locked at all times when not in use and when in use is kept under direct observation of a responsible employee or agent of the registrant is permitted in lieu of a self-closing, self-locking door. Doors may be sliding or hinged. Regarding hinged doors, where hinges are mounted on the outside, such hinges shall be sealed, welded or otherwise constructed to inhibit removal. Locking devices for such doors shall be either of the multiple-position combination or key lock type and:
 - (a) In the case of key locks, shall require key control which limits access to a limited number of employees, or;
 - (b) In the case of combination locks, the combination shall be limited to a minimum number of employees and can be changed upon termination of employment of an employee having knowledge of the combination
- The controlled substance section also provides:
 - The track holding sliding 10-gauge steel gates in place is adjusted to meet self-closing requirements and the track is "trapped" to prevent the gate from being lifted out of the track surreptitiously.

Alternate: Where swinging cage doors are installed, hinges are properly secured.

Note: Schedule III through V controlled substances may be stored with Schedule II controlled substances under security measures previously described for Schedule II controlled substances.

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Structural Security

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Non-controlled substances and other materials may be stored with Schedule III through V controlled substances in any of the secure storage areas required by 21 CFR 1301.72(b) provided that permission for such storage of noncontrolled items is obtained in advance in writing from the Special Agent in Charge of DEA for the area in which storage area is situated. Any such permission tendered must be upon the Special Agent's written determination that such non-segregated storage does not diminish security effectiveness for Schedule III through V controlled substances. This authorization should be posted, in plain sight, in the secured area. An additional copy of the authorization letter should be retained by division management.

Company Vehicles

Vehicles used for the delivery and pickup of controlled substances are equipped with proper vehicle locks including, when appropriate, padlocks for cargo doors.

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Structural Security

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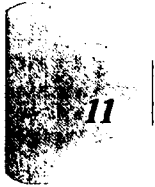
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 Wilson Jones

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ALARM SYSTEMS

The alarm system at the distribution center should be one which provides telephone line security. Of the phone lines leading into the distribution center are compromised or cut, then this action should result in an immediate alarm at the distribution center. The police should then be notified immediately.

Any opening more than ninety-six square inches on the exterior of the distribution center should be added to the alarm system. These openings include air vents, roof hatches, skylights, etc.

The alarm equipment surrounding the cage and vault should be walk-tested at least once a month. Any equipment failures should be corrected immediately. The **Monthly Alarm Walk Test Report (Form #14)** should be completed and filed or distributed accordingly.

Schedule II Controlled Substances

The vault at the distribution center should be on a separate alarm system. This should be a stand-alone system with the following minimum security requirements:

The walls or perimeter of the vault are equipped with an alarm that includes standby power sources. When unauthorized entry is attempted, the alarm transmits a signal over a supervised alarm transmission circuit directly to a central station protection company; a local or state police agency that has a legal duty to respond; a 24-hour control station operated by the registrant; or such other protection as the administrator may approve.

The door of the vault is equipped with contact switches, and the vault has one of the following:

Complete electrical lacing of the walls, floors and ceilings; sensitive ultrasonic, microwave or passive infrared equipment within the vault; a sensitive sound accumulator system; or such other device designed to detect illegal entry as may be approved by the administrator.

Additional motion detectors should be positioned directly outside and along the approach to the vault. These motion detectors should be able to pick up anyone approaching the vault when the alarm is set.

If necessary, due to local conditions or other problems, hold-up buttons shall be placed at strategic points of entry to the perimeter area of the vault.

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Alarm Systems

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Schedule III, IV, and V Controlled Substances

DEA regulations applicable to the security of Schedule III through V controlled substances state that the cage shall be equipped with an alarm system which upon unauthorized entry shall transmit a signal directly to a central station protection agency or a local or state police agency each having a legal duty to respond, or to a 24-hour control station operated by the registrant, or to such other source of protection as the Administration may approve.

A cage is protected by motion sensing devices that are positioned or mounted outside (around) and over the cage to detect an intruder prior to an attempt to enter the cage area.

The cage door(s) is equipped with an alarm contact switch.

Alarm Related Security Procedures

The cage and vault alarm system is tested at least **annually** by the alarm contractors. At that time, the alarm contractor is required to perform a **complete on-site inspection**, test and adjustment of the entire alarm system and to replace any components, sensors or wiring that are defective. The alarm contractor confirms, in writing, the results of this inspection, certifying that the system at the time continues to meet the contractual obligations between the company and the alarm contractor and any applicable UL certification standards.

Division management conducts monthly tests of the vault door alarm contact switch as well as any motion sensing or capacitance devices used in conjunction with vault protection. A log is maintained showing the dates of the tests performed, any defects, the date the alarm company was advised of the defect, and the date the problem was corrected.

Such records are maintained on file for 24 months for review by any DEA agent.

Instructions to the alarm company provide that in response to alarm signals, trouble signals, loss of line security or open telephone circuits, the alarm company will promptly respond to the facility, contact the police, if required, and notify division management as designated on a letter of instruction provided by the wholesaler.

Upon notification by the alarm company of the receipt of a signal condition described above, the designated supervisor identifies the caller, confirms that alarm company guards have been dispatched and the police notified, and then proceeds to the premises.

Note: Return call verification to the alarm company should be made any time Cardinal personnel are requested to appear at the premises.

On arrival, the supervisor verifies the presence of the police and/or the alarm company personnel at the site or if such is not the case, continues in his/her vehicle to a safe telephone location where the supervisor calls the police and/or the alarm company to arrange for their coincidental arrival at the premises. In some instances, it may be necessary for the supervisor to proceed to the police station in the vicinity to request a safe escort to the site.

If only alarm company personnel are present at the supervisor's time of arrival, their identity should be visually confirmed and a request made for the guard to radio his/her office to recall the police. The supervisor and the alarm company should remain outside the premises until the police arrive.

The supervisor should then unlock the entrance door, turn on designated lighting, admit the police and the alarm company personnel, relock the entry door, and then remain in the safest possible area until the police and the alarm company guards have completed their search of the premises.

When entering the premises area, the company supervisor or the alarm company guard should open alarm system protected areas that must be entered in order to search the premises and arrive at the controlled substances vault.

When a search is completed and it has been determined that there is no forced entry or other emergency condition, the company supervisor assists the alarm company guard in resetting the alarms that have been activated and turns off the lights. Both depart the premises through the point of entry in the company of the police and return to their respective stations. An **Incident Report (Form #15)** must be completed and sent to the Corporate Compliance Department.

If it is determined that **an actual burglary attack** has taken place, the police officers radio or telephone for additional officers and other assistance.

Additionally, the interior and exterior areas are searched thoroughly for hidden or fleeing intruders; damage, if any, to the vault is repaired; the alarm system is restored and reset; and appropriate surveillance is established to detect any hidden or returning criminal activity. In the event that the burglary is discovered in the absence of police at the scene, the supervisor immediately contacts them to report the crime and request their prompt assistance. In addition, the local DEA office is promptly notified and DEA Form 106 is prepared and filed in accordance with DEA regulations. An **Incident Report (Form #15)** must be completed and sent to the Corporate Compliance Department.

Note: Many states require that a report be submitted to the board of pharmacy or other agencies with enforcement jurisdictions.

If the controlled substance vault has been physically penetrated or forced open, the supervisor **must remain at the premises** in charge of the scene until the structure or door is restored to normal or the warehouse reopens on the next business day. This is required despite the restoration of the alarm system since a vulnerability to a hit-and-run burglary would exist until the "physical security" has been restored.

If, for any reason, the alarm system cannot be restored to full normal operation, the supervisor must see to it that the following steps are taken:

- The supervisor remains at the scene and requests assistance, if necessary, from other company supervisors;
- The alarm company guard or service personnel responding to the alarm are requested to stay at the premises until the alarm system has been repaired and restored; and
- If the alarm system still cannot be restored, then the supervisor secures the services of alarm company guards, off-duty police officers, contract security guards or other

appropriate security forces to maintain watch on the premises until security against burglary or robbery can be fully restored.

Note: Under such circumstances, there is a vulnerability relating to the safety of the supervisor and others who may remain on duty at the premises. Precautions that should be taken include locking all perimeter doors and windows, requesting that the police return frequently on a patrol basis, and requiring that the supervisor remain in frequent telephone contact with another supervisor located outside the premises at a safe point. In some instances, commercial telephone circuits may be out of order. In such case, the use of portable radio equipment and cellular phones may be required together with procedures for two-way communication between supervisors and/or the alarm company central station and the police.

- When full security has been restored, division management should review the incident to evaluate the cause and any improper or unsafe actions taken by responding personnel, and revise security procedures where appropriate to provide a more effective and safer response to a similar incident. On the day following the restoration of service, the alarm company is required to have a service supervisor thoroughly test the entire system and certify that the alarm system has in fact been restored to its original condition.

Alarm Related Procedures for Police Connect Alarm System Supervision and Response

Alarm systems connected directly to a police station or municipal communications center that is manned on a 24-hour basis require essentially the same response from the supervisors assigned such duties. The variations in response conditions are as follows:

- On receipt of a phone call from the police, the supervisor contacted requests the name and identification number of the police officer calling. The supervisor then recalls the commercially listed number of the police agency and verifies the authenticity of the call prior to departing the safety of his/her residence.
- On arrival at the warehouse, the supervisor verifies the presence of a police officer or proceeds as previously instructed to again call the police to the scene prior to entering the premises.
- When search and entry of the premises are completed, the supervisor restores the alarm circuits and departs with the police officer.
- In the event that the alarm system cannot be restored, the supervisor contacts the 24-hour telephone number of the alarm company (if available) and requests a service man to respond immediately to the premises to repair, adjust or otherwise restore the alarm system. If feasible, the supervisor should request that the police officers remain at the scene until the alarm company service representative arrives.
- An **Incident Report (Form #15)** should be completed and sent to the Corporate Compliance Department.

ACCESS CONTROL

General Warehouse

It is the policy of Cardinal to limit access to the general warehouse to only those employees who have a full-time work assignment that requires their presence in the warehouse. Each division shall maintain a list of employees authorized to have warehouse access. This access shall be controlled by a Card Entry Access Control System.

Specifically excluded from warehouse access without a full-time escort are the following groups of people:

All visitors including:

- Vendor sale representatives
- Cardinal sales representatives
- Management employees except those directly responsible for supervision of employees whose duties require them to be in the warehouse to perform their jobs
- Office employees except those whose duties require their presence in the warehouse.

Signs should be posted on all warehouse entrances regarding limited access (**Exhibit B**).

Outside contractors shall be monitored through a cooperative effort of warehouse supervisory personnel and full-time warehouse employees.

Employees of Cardinal Health who require temporary access to the warehouse may be issued "temporary passes" controlled by the Division Manager or his/her designee.

Controlled Substance Area

DEA regulations related to accessibility to storage areas state:

"The controlled substances storage areas shall be accessible only to an absolute minimum number of specifically authorized employees. When it is necessary for employee maintenance personnel, non-employee maintenance personnel, business guests, or visitors to be present in or pass through controlled substances storage areas, the registrant shall provide for adequate observation of the area by an employee specially authorized in writing." (21 CFR 1301.72(d))

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Access Control

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Division management maintains an **Access and Surveillance List (Form #16)** of those employees whose responsibilities include authorization to access the vault or cage during the open-for-business period. Only those individuals are assigned a key or knowledge of a combination. The authorized access list should be posted along with a **“Restricted Area” (Exhibit C)** sign on the door(s) of the vault and cage.

Temporary employees should never be allowed access to the cage or vault, supervised or unsupervised.

Computer System

The computer system should include security levels to prohibit access to certain files unless an employee's job responsibilities warrant access. Employees should keep passwords to themselves and periodically change them to prevent access by others. Access should be limited for inventory adjustments, customer licensing information and financial records.

Computer room access should be controlled and limited to only those employees who have a full time work assignment that requires access to the computer room.

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Access Control

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PROCEDURAL SECURITY

Receiving

Upon receipt, controlled substance items are physically checked by a receiving clerk. The quantity and description of the materials received are checked against the packing list provided by the vendor and against the controlled substance purchase order. The paperwork is signed and dated by the receiving clerk.

Any variations in quantities or visible damage to cartons are subject to immediate investigation. The matter should be reported to the supervisor prior to the departure of the carrier's representative from the area.

The carrier's representative is required to sign a statement written on the receiving report, describing the shortage, damage, etc. The receiving procedures should be verified by the receiving department supervisor if the actual receiving is handled by a designated employee.

If a discrepancy is noted and cannot be reconciled, the manufacturer(s) is contacted immediately by telephone and confirmation of the shortage or damage is verified in writing on the appropriate form. The loss of controlled substances is to be promptly reported to DEA. **Refer to Drug Thefts/Losses within Required Reports to DEA.** The supplier is responsible for reporting in transit losses of controlled substances by the common or contact carrier selected pursuant to 21 CFR 1301.74 (e) upon discovery of such theft or loss. Thefts must be reported whether or not the controlled substances subsequently are recovered and/or the responsible parties are identified and action taken against them.

Immediately on verification of the order received, the controlled substances and the corresponding paperwork are placed in a rolling locked cage and moved to the vault or to the controlled substance cage. No controlled substances may be left in the receiving area overnight or during periods when the receiving area is not under adequate surveillance.

Stocking

Verify all products and quantities against paperwork. Date and sign each purchase order. Bring discrepancies to the attention of the supervisor immediately. Forward original paperwork to appropriate department for data entry. Retain a copy in the controlled substance area.

For Schedule II items, the product is also verified against Copy 3 (blue) of the DEA order form. The date received and quantity received columns of the order form are completed and the Narcotic Order Blank Log is also updated.

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Procedural Security

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Order Filling

For Schedule III, IV, V controlled substances, the order filler picks the items and quantities as requested on the picking document. As items are picked, each line of the picking document is initialed. The completed order and paperwork is staged pending verification.

For Schedule II controlled substances, the order form - DEA Form 222 - is reviewed for accuracy, then matched to the picking document to make sure all items agree. The items and quantities are picked as requested on the picking document. The picking document is initialed as each item is picked. The completed order and paperwork is staged pending verification. The following fields on the order form must be filled in:

- Packages Shipped
- Date Shipped
- Supplier DEA Registration Number
- National Drug Code

Quality Control

All controlled substance orders should be double checked for accuracy. The quality control clerk matches the items against the picking document and initials the paperwork. The merchandise and copy of the picking document are put in a bag and sealed - preferably a heat-sealed poly bag. The other copy of the pick document is retained at the division per division policy. The outside of the package should be labeled with the name of the customer. There should be no marks identifying the contents as controlled substances. The order is then staged within the controlled substance area until shipped.

Shipping

While most regular orders are manifested on the shipping dock, controlled substance orders are manifested in the cage or vault. Controlled substance packages are not to be left unattended in the shipping department. Product may be placed in locked roll-around cages or left in the controlled substance area until the delivery person is on the premises and ready to sign for them.

Delivery

The driver is required to obtain a customer signature for any packages delivered. The proof of delivery (manifest) is then returned to the carrier or division and retained per division policy.

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Returns from Customers

All returns of controlled substances must be accompanied by a return authorization. The shipments must be distinguished from the other returns without revealing their contents to the delivery drivers. Upon receipt at the distribution center, these returns are to be transferred to the controlled substance area, and processed daily, noting the actual date of receipt.

Returns of Schedule II drugs are discouraged. They must be handled by issuing an order form -DEA Form 222 - to the customer.

Partial returns of controlled substances are prohibited.

Returns to Vendors

Controlled substances returned to the vendor should be accompanied by a return authorization from the vendor and a debit memo from the division. Creating the debit memo should remove the product from inventory. Proof of delivery should be filed at the division with a copy of the debit memo.

Physical Verification of Controlled Substances

When taking an inventory, the following steps should be taken,

- Do not allow any product into or out of the area during the count or recount.
- Counts should be conducted from count sheet with the on hand quantities suppressed.
- Compare the inventory results with the current on-hand balance of each item.
- Recount any out-of-balance item.
- Run audit report for any out-of-balance item. The **Selected Item Audit Report (Exhibit I)** gives all movement - purchases, returns, sales and inventory adjustments - for a requested item during a specified time frame.
- Research the error, checking for orders picked but not invoiced, mispicks, etc.
- Make appropriate adjustments as errors causing variances are detected.
- The Distribution Center Manager should sign off on the count sheet that he has reviewed all exceptions and that variances have been explained.
- File DEA Form 106, on a timely basis, for any item that cannot be resolved.
- Create ARCOS transactions for any reportable items on DEA Form 106.

Inventory Adjustments

Inventory adjustments for controlled substances should only be made after a thorough research. Documentation should be kept on file to support any adjustments.

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Procedural Security

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Breakage

Documentation of breakage occurring in the vault or cage or during delivery is strongly recommended by the DEA. Maintenance of a breakage report is designed to help control any possible intentional breakage for the purpose of removing contents. Concern should arise when the same item is broken repeatedly.

Opening and Closing

The distribution center should be opened by at least two employees. These employees should meet at a safe, well-lighted, off-site location. The employees should then proceed to the distribution center and one employee should enter the distribution center while the other employee waits outside for an "ALL'S CLEAR" signal (the moving of blinds or flickering of lights, etc.). This procedure should be reversed when closing the distribution center. If the utilization of two employees at opening and closing time is totally impractical, one employee opening or closing the facility alone must have security hardware such as a portable panic button.

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Procedural Security

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SHIPPING

Controlled Substance Shipping Area

Schedule II controlled substance orders are retained in the vault until the driver assigned such delivery is ready to depart the premises. At that time, the order is delivered by the vault supervisor to the driver who signs a log, circling the order number of the merchandise on the manifest. The driver then loads the packets or container into the delivery vehicle.

Schedule III through V controlled substance orders in sealed containers are held in the cage or staged in the defined controlled substance staging area under the direct supervision of the shipping department supervisor or a closed-circuit TV surveillance system. The driver assigned to the specific orders signs for the controlled substance items on a log form, circling the order number of the merchandise, and then loads the order on the delivery vehicle.

No controlled substance orders awaiting shipment are left in the shipping dock during the closed period. Such unshipped orders must be returned to the controlled substance cage at the close of business. The shipping department supervisor makes a thorough search of the shipping area prior to his/her departure from that area at the end of the business day.

Shipping Destination

DEA regulations require that controlled substances be distributed only to persons who are properly registered with DEA to possess the controlled substances and that Schedule II controlled substances only be shipped to the purchases at the location printed on the order form (DEA Form 222). Emergency will call orders are an exception to the rule.

Company Delivery Vehicles

Company employees assigned to driving delivery vehicles are screened in accordance with 21 CFR 1301.90 and Cardinal's policy which requires all prospective employees to consent to a drug test and a criminal record check. **Delivery Vehicle Security Rules (Form #17)** are reviewed, and signed by drivers.

The drivers deliver the Schedule II through V controlled substance orders to the customers and obtain a customer signature on one copy of the delivery order, which the driver then attaches to his/her manifest as proof of delivery.

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Shipping

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Common Or Contract Delivery Vehicles

The company selects common or contract carriers that provide adequate security to guard against in-transit losses.

Further, the company takes precautions to assure that shipping containers do not indicate contents are controlled substances so as to guard against storage or in-transit losses.

When distributing controlled substances through agents, the company provides and requires adequate security to guard against theft and diversion while the substances are being stored or handled by the agent or agents.

Delivery Vehicle Security Rules (Form #17) are provided to contract carriers for distribution to drivers. Rules are reviewed and signed by drivers.

Depots/Line Haul Shipments

The use of cross-dockings and line hauls means vehicles with larger quantities of controlled substances and other merchandise and increased vulnerability to theft and/or diversion during the run from the distribution center to the depot. To protect against internal theft that may go undetected until the orders get to the customer level, ensure that vehicle contents are checked and signatures obtained upon pickup and delivery and that line haul vehicles are secured with a numbered seal that must be cut off or broken upon arrival at the depot.

Seal Construction Specifications

Durability A seal must be strong enough to prevent accidental breakage during normal use.

Design The design must be sufficiently complex to make unauthorized manufacture of a replacement seal difficult.

Tamperproof The seal should provide readily visible evidence of tampering and prevent reconstruction after the seal is closed; that is, a seal needs construction to make simulated locking difficult.

Individually Identifiable Identification is best accomplished by embossing serial numbers and owner identification on each seal.

Seal Accountability Procedures

Record of Application Seal numbers are entered or written on transportation documents such as bills of lading and manifests.

Time of Application Trailers must be sealed immediately after the loading is completed. Roll-up-type doors must be sealed at the loading dock. Swing-out doors must be sealed immediately after the unit is far enough away to close the doors.

Verification Seal examination and verification at every stop such as docks and transfer points. Multiple stops require new seals. Persons receiving sealed shipments must examine the seal and record the number on appropriate documentation, such as a log.

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Shipping

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Retain broken seals until it is determined whether there are any discrepancies. If there are none, destroy the seal. If discrepancies are found, retain the seal pending investigation.

U.S. Postal Mailing And Delivery

DEA regulations applicable to the use of the U.S. postal services state: "Controlled substances including Schedule II may be sent in any quantity by registered mail, return receipt requested, from one DEA registrant to another DEA registrant. The packaging must be in plain outer containers and give no indication of the contents."

Will Call Orders

Verification calls are to be made to the person in charge of the licensed premises for whom the order is intended and the name and description of the person picking up the order and the items included in the order are obtained.

When the individual arrives to pick up the order, the shipping supervisor checks the individual's name by asking for the driver's license and comparing the description of that provided by the person in charge of the licensed premises.

The person picking up the orders signs a **Will Call Log (Form #18)** that is dated and initialed by the shipping supervisor. The driver's license number and the person's name are then recorded both on the packing slip and the will call log.

Note: Many wholesalers have discontinued will call orders for controlled substances to avoid this high risk diversion exposure.

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Shipping

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PERSONNEL

Additional information is located in the Employee Handbook.

Pre-Employment Screening

Cardinal Health requires all prospective employees to sign a **Pre-Employment Waiver (Form #19)** consent to a physical examination, which includes a drug test, and to an investigation made of their background and fitness for the position for which they have applied.

Cardinal Health reserves the right to immediately dismiss any employee when the results of the physical examination or drug test show signs of substance abuse and/or the background investigation reveals a history of criminal activity or other information which would deem the employee unfit for the position.

Any information associated with the physical examination or background investigation will be gathered and held in the strictest confidence by Cardinal Health in accordance with all applicable laws.

It is recommended that employment should not commence until the results of the physical examination and drug test are received and reviewed by the appropriate management personnel of Cardinal Health.

Upon commencement of employment, the new employee will complete a **Post-Employment Security Data Information Sheet (Form #20)**. The completed sheet is sent to the Corporate Compliance Department to conduct a criminal record check.

Controlled Substance Requirements

When an employee is promoted or transferred it may be necessary to review his/her background, depending on the nature of the transfer or promotion. Anyone allowed unsupervised access to the cage or vault in order to perform job functions must complete the **Test for Distribution Center Employees Handling Controlled Substances (Appendix B)** as well as the **Post-Employment Security Data Information Sheet**. The test and form must then be submitted to the Corporate Compliance Department. The department will grade the test and each individual must pass with a score no lower than 88%. If an employee does not pass the test, he/she must re-take the test at a later date and must obtain a passing score. The employee should be advised that prior to his or her working inside the controlled substance area an in-depth background investigation will be performed. The results of this background check along with the individuals test score will be shared with division management. The background check should be performed prior to the distribution center manager assigning the employee to the controlled substance area.

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Personnel

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Security Rules

The following list of security rules has been developed to promote a safe and secure working environment for all employees and to assure compliance with United States Drug Enforcement Administration Security Regulations.

- Possessing, dispensing, or using a controlled substance without a medical prescription or reporting to work or working under the influence of alcohol or a controlled substance without a medical prescription is strictly prohibited. If an employee requires medication which may affect their performance, they should notify their supervisor immediately. DEA regulations regarding this should be posted in the facility (**Exhibit D**).
- Defacing Company property or willful negligence resulting in damage due to mishandling of merchandise or destructive abuse of machines or other Company equipment is prohibited.
- Falsifying an employment application, time card, production record, or other documents for yourself, customers, or another employee is prohibited.
- Protection of Company property is a responsibility all employees must share. Any employee discovering theft, loss, or malicious damage has an obligation to report the incident immediately to his supervisor.
- Fighting or instigating a fight with an employee, customer, or supplier while on Company property is strictly prohibited. No permanent personnel action will be taken until there is a complete investigation by Management.
- Tampering with or breaching Company security systems or policies is prohibited.
- Theft or unauthorized removal or use of Company or another employee's property is prohibited.
- Possession of firearms or illegal weapons on Company property is prohibited.
- Employees must use their own card entry access card, and access cards should not be loaned to other employees. Lost access cards should be reported to Management immediately.
- Employees must use authorized employee entrance when entering and exiting the building and must use their own access card when doing so.
- Entrance and exits to the facility are to be closed at all times, unless being used for the purpose they are designed.
- All bags, boxes, lunch boxes, containers, etc., are subject to inspection when exiting the facility. Signs to this affect should be posted throughout the distribution center (**Exhibit E**). Random periodic inspections could serve as a deterrent to internal theft.

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Personnel

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- Locker assignments and locks will be issued by Cardinal Health. Personal locks are not allowed. Locks will be subject to inspection by Management at their discretion.
- Visitor's entering the distribution center should be asked to sign in on a **Visitor's Log (Form #21)**, indicating their name, who they represent, time in, time out, and who they are visiting at the distribution center. Each visitor should wear a badge and must be escorted during their stay.
- Warehouse access is limited to employees who have full-time assignments that require their presence in the warehouse.
- Coats and pocketbooks are not allowed in the warehouse.
- Employees are to adhere to the posted access list for the cage and vault area.
- A **Miscellaneous Security Log (Form #22)** should be used to document any minor security-related incidents that occur but do not need to be explained in detail.

Security rules should be distributed to all employees and a signature obtained to document receipt.

Violence Prevention Procedures

The sign entitled **Violence Prevention Procedures (Exhibit G)** should be posted in conspicuous locations throughout the distribution center. These procedures should be reviewed with distribution center employees on a routine, periodic basis. It is paramount that **all** employees know exactly what to do in case they are confronted with a possible violent situation. Additional copies of these signs may be obtained through the Corporate Compliance Department.

Driver Security Rules

Drivers are required to adhere to the following security rules:

- Test all vehicle locks each day and immediately report defects to a supervisor.
- Keep all merchandise in the rear of the truck. Leave nothing in the cab.
- Secure the truck when making a delivery. Roll up all windows, lock all doors and take the keys with you.
- Do not stop for stranded motorists. This could be a setup for a hijack. If you feel it is necessary to call for assistance, do so at your next stop.

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Personnel

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- Make it a habit to check your rear view mirror to see if you are being followed. If you suspect that you are being followed, obtain a description of the vehicle, the license number and the occupants. Proceed to the local police station; if this is not possible, proceed to your next stop and call the local police or the office.
- If you break down, stay with your truck. Leave only to call for assistance.
- Avoid areas where the threat of theft is high (such as back doors and alleys). If something appears suspicious, do not stop.
- In the event of a robbery:
 - a. Offer no resistance.
 - b. Stay calm.
 - c. Be observant.

Driver security rules should be distributed to all drivers and a signature obtained to document receipt.

12/28/99

Personnel

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INSPECTIONS OVERVIEW

Overview

The Comprehensive Drug Abuse Prevention and Control Act of 1970 (the Controlled Substances Act") authorizes the Drug Enforcement Administration (DEA) to enforce provisions of the act as they apply to registered handlers of controlled substances. The stated DEA goal is *"to significantly reduce the availability of licitly produced drugs used for illicit purposes in the United States."*

The act establishes a comprehensive system to control the manufacture and distribution of controlled substances necessary for legitimate medical needs. Since the controlled substances in question include some of the most potent drugs known to man, the incentive to divert these drugs into the illicit market is great. Drug related deaths and injury statistics indicate that legally produced controlled substances account for a large percentage of drugs associated with drug abuse injuries reported by hospital emergency rooms. In fact, 15 of the top 20 controlled substances reported in hospital emergency room mentions were pharmaceuticals legally available in the United States market.

The DEA Diversion Control Program is responsible for implementing and maintaining controls over the distribution of legally produced controlled substances and for investigating diversion of these substances into the illicit market. The Diversion Control Program prevents, detects, and investigates the diversion of controlled substances from legitimate channels, while at the same time ensuring an adequate and uninterrupted supply of controlled substances required to meet legitimate needs. To achieve this goal, DEA's diversion program uses programs designed to maximize the effect of criminal, civil and regulatory investigations and controls intended to limit the availability of diverted substances.

The diversion control program operates through: periodic investigations to ensure that record keeping, reporting, and security requirements are being met; targeted investigations (for violative registrants); preregistration investigations; an organized system of drug destruction; manufacturing quotas; and drug scheduling (collection of abuse and diversion information). Periodic inspections are conducted as circumstances may require, based in part on the registrant's history of compliance and maintenance of effective controls to guard against the diversion of controlled substances.

These activities are designed to meet DEA's responsibilities under the Controlled Substances Act and to prevent the diversion of controlled substances from legitimate distribution channels. When violations are discovered, appropriate action (administrative, civil or criminal) will be considered.

As we move further into the 1990s, the pharmaceutical industry is facing an increasingly active enforcement and regulatory climate.

DEA registrants must be aware of this climate, and ensure that they are in full compliance with DEA requirements or take immediate corrective action before DEA investigates their facility.

08/17/2000

Inspections Overview

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Notice of Inspection

Cardinal Health recognizes the fact that federal and state regulatory agencies have explicit authority to inspect our premises and records.

Upon notice of a federal or state regulatory inspection, contact the Corporate Compliance Department immediately and advise to the nature of the visit, names of the officials and the agency they represent. The Department can be of assistance in helping to verify an individual's identification if the need arises.

Full cooperation must be given to the inspecting authorities. However, only persons authorized by division management may answer questions posed by the regulatory inspector. Inspections should be monitored closely by qualified Cardinal personnel, and a daily detailed written record in the inspection must be prepared.

Upon arrival of the investigators at the registered location, the manager, his/her designated alternate and the individual who has overall responsibility for controlled substances should meet with the investigators as soon as possible, review their credentials (a picture of the person on an official ID Card) and accept the DEA Notice of Inspection. Inspector(s) should be asked to sign the Visitor's Log and given a Visitor Badge to be worn at all times. A discussion should then be held regarding the purpose and extent of the investigation and the desire of management for a close-out discussion at the completion of the investigation. (21 CFR 1316.05)

If you are not sure that the individual requesting entry is a bona fide city, state, or federal official do not allow them to enter the distribution center. Request information as to whom they report (their immediate supervisor) and how (telephone number) you can verify their identification.

Note: Receptionist should not admit inspector(s) into facility or accept their credentials.

Authority of the DEA Investigator

21 USC 880 and 21 CFR 1316.03 allow DEA investigators to enter a registered location (controlled premises) upon stating their purpose and presenting credentials and a written notice of inspection or, if warranted, an administrative inspection warrant for the purpose of:

- Inspecting and copying records, reports and other documents required to be kept or made;
- Inspecting, within reasonable limits and in a reasonable manner, all pertinent equipment, finished and unfinished controlled substances and other substances or materials, containers, and labeling found at the controlled premises relating to the Controlled Substances Act;
- Conducting a physical inventory of all controlled substances on the premises;
- Collecting samples of controlled substances pursuant to DEA Form 84; and
- Checking records and information regarding the distribution and receipt of controlled substances by the registrant.

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Inspections Overview

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Exclusion From Inspection

Unless consented to in writing by the registrant, no inspection authorized by 21 USC 880 and the implementing regulations should extend to:

- Financial data;
- Sales/receipt data other than shipping and receiving data; or
- Pricing data.

Entry to Premises

DEA officials will conduct the investigation. The officials have the right to enter the registered premises and conduct the investigation at reasonable times in a reasonable manner once they state their purpose, present their credentials and written notice of their inspection authority (DEA Form 82) to their responsible registrant official, and receive informed consent or present an administration inspection warrant.

An administration inspection warrant is not required if informed consent is obtained from the registrant. Whenever possible, the informed consent should consist of a written statement (DEA Form 82 with addendum— language found in Section 1316.08) signed by the registrant.

Investigation

An individual (preferably a responsible officer or employee) who is familiar with the DEA record keeping and reporting requirements and security in place at the facility always should accompany and monitor the investigators.

This individual should be prepared to:

- Immediately notify the personnel responsible for the various areas to be involved in the investigation prior to the investigators visiting the areas;
- Explain the operation/type of security, record keeping and reporting systems/procedures maintained;
- Assist the investigators;
- Verify the accuracy of the information the investigators obtain from inventories, sales and purchases documents and make a list of the records reviewed;
- Obtain copies for and retain copies of any documents the investigators request;
- Assure that information volunteered is clearly beneficial to the wholesaler;
- Assure no misrepresentations are given to the investigators;
- Note any suggestions or criticisms expressed by the investigators. Any violations discovered in this manner should be corrected immediately and documented; and
- Complete a daily detailed written record of inspection that includes the following:
 - any questions raised by the inspector,

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- any questions raised by the monitor,
- any requests made by the inspector,
- what the inspector was shown,
- a list of any records viewed or copied by the inspector,
- items inventoried and verification of the inspector's counts,
- any suggestions of criticisms expressed by the inspectors,
- complete a **DEA Inspection Report (Form #23)** and forward to Corporate Compliance Department.

Note: The registrant using this report and statements made by the investigator should reconstruct the investigation to verify any violations or, as is possible, reveal no violations.

All personnel are instructed not to read, acknowledge in any way, or sign any affidavit presented to any Company employee by an investigator.

Discussion with Management (Close Out)

This phase will be used by DEA to reinforce the findings by acquiring the registrant's acceptance of the cited violations and willingness to correct them, or the registrant's challenge of the findings by non-acceptance of the violations. Explain that Cardinal Health, Inc. employs a Director of Compliance and inquire if the results of the inspection warrants his presence at the exit interview. If yes, contact the Director of Compliance immediately. If the DEA intends to take further action, the registrant may or may not be informed of what courses of action are possible. The registrant will not be informed of the specific action to be recommended.

*Note: DEA is **not required** to conduct a closing discussion at the completion of the investigation. If not initiated by the investigator, the registrant should request a closing discussion at the convenience of the investigator. If this fails, it is suggested that a request be made in writing to the investigator's supervisor, expressing the desire to meet and discuss the findings and any corrective action that may be required.*

If a closing interview is held, the investigator may advise the registrant of any violative conditions. If the registrants cannot obtain a closing discussion, the report prepared by the employee(s) assigned to accompany the investigator during the investigation should be utilized to reconstruct the investigation and findings.

Once aware of any violations, the registrant should take the following initiatives in seeking and implementing corrective actions:

- Reconstruct the investigation and findings, using the same documents, facility review utilized by the investigators and the registrant's internal report.
- Take appropriate action to correct any violations or problems uncovered during the DEA investigation; and
- Convey to DEA the corrective action taken, what steps the registrant has taken to prevent future problems and inquire what further action the registrant should take.

It is suggested that if a registrant's investigation disagrees with the DEA investigation, they should contact DEA immediately and request a meeting to discuss the findings.

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DISTRIBUTOR ACCOUNTABILITY INVESTIGATIONS PROCEDURES

An investigation is divided into four phases: preparation, on-site, follow-up and past history. The information sought by the DEA during each phase is outlined below.

Preparation

Prior to inspecting a facility, the registrant files at the respective DEA location are reviewed; i.e., review of ARCOS reports, review of registration categories and schedules, etc.

On-Site Investigation

Initial Phase

The initial phase involves initial discussion, presentation of investigator credentials and notice of inspection (if a warrant is used, the registrant should consider the need for an attorney). The credentials and notice will be presented to that person who has managerial responsibility for operating the firm. The investigator should state the purpose and indicate the scope of the investigation.

Management at this time should request that the investigators advise them of any violations discovered during the investigation so that corrective action can be taken immediately. Management should state that they desire a closing discussion at the completion of the investigation.

Background Information

The DEA investigators will want to know the:

- Names, addresses, date of birth and social security numbers of corporate officers and/or owners of the registrant and identification of individuals responsible for record keeping and security;
- Number of employees and appropriate registration (federal, state and local); and
- Percentage of business dedicated to controlled substances.

They also will want to review reporting procedures regarding thefts, losses or destruction of controlled substances.

A completed copy of the **DEA On-site Background Information Package (Form #28)** can provide the DEA Inspectors with pertinent company information.

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Distributor Accountability Investigations Procedures

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Closing Inventory

The closing inventory is usually taken before or after business hours, so that no adjustments for transactions outside the accountability period are necessary. An accurate inventory is necessary and advantageous. All shipping, receiving and return areas, as well as other areas where controlled substances might be stored, should be checked.

A responsible employee of the registrant should verify the accuracy of the inventory and make a copy for the registrant's records.

Initial Inventory

An actual inventory taken by the registrant, an inventory from a previous DEA investigation or a computer inventory printout may be utilized if the registrant will attest to its accuracy.

Regardless of the inventory used, the required biennial inventory will be reviewed.

Receiving Records

Order forms will serve as the primary record of documenting the receipt of Schedule II controlled substances. They also will be reviewed for accuracy.

The power of attorney will be reviewed.

ARCOS reports and purchase invoices will be reviewed to verify accuracy of the order form transactions for Schedule II controlled substances and Schedule III narcotic controlled substances.

Receiving records which record supplier's name, address, and DEA number; name of controlled substance; strength; quantity received; and date of receipt for Schedule III through Schedule V will be reviewed. These records must be kept in a readily retrievable manner. The registrant will be required to attest to the accuracy of the records.

Sales Records

Order forms will serve as the primary record documenting the sale of Schedule II controlled substances. They also will be reviewed for accuracy.

Registration of customers will be verified.

A sampling of ARCOS records and customer sales records for Schedule II controlled substances and Schedule III narcotic controlled substances will be reviewed to verify shipments.

The quantity of Schedule III through Schedule V controlled substances distributed may be determined from a number of different types of records. The primary record is the distributor's sales invoice.

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Distributor Accountability Investigations Procedures

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Sales will include all dispositions from inventory, including documented and reported thefts, returns and destructions.

Credits and Returns

A review of credit memoranda will be made to determine that there was physical movement of controlled substances or credit.

Returned controlled substances will be inspected to verify that there is documentation showing returns, disposition by destruction or return to inventory.

Note: If the registrant has another record keeping system, such as the computerized Selected Item Audit Report which contains all required information and attests to its accuracy, these records may and should be used.

ARCOS

Reports will be verified by comparing them to other purchase and sales records.

Accountability

The initial inventory is combined with all receipts (including returns) of controlled substances and compared to the closing inventory plus sales, destructions, returns, reported thefts or losses accounted for by the registrant from its records.

Security

This evaluation will include:

- Review of location, crime classification, building construction, access restrictions and storage areas, including size and type of physical security systems in place;
- Evaluation of alarm systems and test;
- Review of security and procedures employed in shipping and receiving areas, picking areas, and packaging areas;
- Review of procedures for determining proper registration of customers;
- Review of frequency of alarm checks and procedures for key control, after hours entry, badge system and lock changing; and
- A review of the registrant's system for monitoring unusual and excessive orders.

Discussion with Management

This will be used to reinforce the findings by acquiring the registrant's acceptance of the cited violations and willingness to correct them, or the registrant's challenge of the findings by nonacceptance of the violations. If DEA's intention is to take further action,

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Distributor Accountability Investigations Procedures

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the registrant may be informed of courses of action possible, but not the specific action to be recommended.

Note: DEA is not required to conduct a closing discussion at the completion of the investigation. In this case, the registrant should request a closing discussion at the convenience of the investigator. If the request is not successful, it is suggested that the registrant send a written request to the investigator's supervisor, expressing the desire for a meeting to discuss any findings and corrective action which may be required.

Follow-Up Investigation

After the on-site portion of the investigation is completed, a verification of purchases and sales most likely will be performed. The extent of the verification will depend upon the nature of the investigation and discrepancies found. In addition, DEA may conduct file checks on all persons who are interviewed during the investigation.

History of Violations

The registrant's history of violations will be taken into consideration by DEA in determining the type of action to be levied against the registrant.

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Distributor Accountability Investigations Procedures

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VIOLATIONS

The DEA will take action against a registrant in all instances where an investigation reveals violations of the Controlled Substance Act and the implementing regulations. The **Table of Offenses and Penalties (Exhibit H)** summarizes these violations.

Administrative Actions

Revocation of Non-Practitioner Registration or Application Denial

DEA registration or application may be revoked, suspended or denied if at least one of the following conditions is present:

- The application for registration has been materially falsified;
- The registrant (owner, officer, controlling stockholder) has been convicted of a drug related felony;
- The registration is inconsistent with the public interest. Factors to be considered in determining public interest include the following:
 1. Maintenance of effective controls against diversion,
 2. Compliance with applicable state and local law,
 3. Prior conviction record relating to controlled substances,
 4. Registrant's violative history,
 5. Such other factors as may be relevant to and consistent with the public health and safety; or
- The registrant's state license or registration to handle controlled substances has been suspended, revoked or denied.

"No Automatic Renewal" of Registration

To prevent renewal of the registrant's registration, the DEA will place an administrative code on the registration.

This procedure is usually utilized to suspend approval of the renewal application when the investigation shows that the registrant has failed to maintain adequate controls against diversion and grounds for denial exist.

The registrant is authorized to continue operating on a day-to-day basis until final action is taken (voluntary surrender, denial of renewal application or removal of the administrative code).

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Violations

18-1

Letter of Admonition

The letter of admonition advises the registrant of the violations found and documents these violations in written form. This allows for voluntary, corrective actions by the registrant and makes the violations a matter of record should the same violations be encountered at a later date.

Administrative Hearing

A hearing will be held when the severity of the violations and the registrant's attitude toward them render the letter of admonition ineffective. An administrative hearing provides DEA and the registrant with the opportunity to explain their respective views on the violations and to discuss the necessary corrective actions.

Order to Show Cause

An order to show cause may be issued to a registrant for denial, revocation or suspension of a DEA registration for one of the following factors:

- The application for registration has been materially falsified;
- The registrant has been convicted of a drug related felony;
- The registration is inconsistent with the public interest. Factors to be considered in determining public interest include the following:
 1. Maintenance of effective controls against diversion,
 2. Compliance with applicable state and local law,
 3. Prior conviction record relating to controlled substances,
 4. Registrant's violative history,
 5. Such other factors as may be relevant to and consistent with the public health and safety; or
- The registrant's state license or registration to handle controlled substances has been suspended, revoked or denied.

During a show cause hearing, the registrant has the opportunity to explain why the registration should not be suspended or revoked.

Civil or Criminal Prosecution

The use of civil or criminal prosecution will be determined by the severity of the violations found during the investigation and discussions with DEA management and the assistant U.S. attorney.

The determination between civil and criminal prosecution is made based upon the registrant and/or person knowingly or intentionally committing the violation(s).

Civil penalties are assessed at \$10,000 per violation.

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Violations

18-3

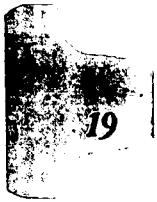
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Guide to Handling ARCOS Transactions

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GUIDE TO HANDLING ARCOS TRANSACTIONS

Introduction

The Automation of Reports and Consolidated Orders System (ARCOS) was developed by the DEA to report inventories of selected controlled substances and increases and decreases to these inventories. The selected controlled substances are Class II and III narcotics.

Transactions can be reported electronically via tape or diskette, or manually using ARCOS Form 333. In most divisions, a majority of the ARCOS records are created automatically during the receiving, invoicing and crediting processes. Other records must be created by manually entering the data into the ARCOS Maintenance Menu.

A report of all ARCOS transactions generated by the system is available for review. Depending on the system, this may be daily or monthly. Prior to submission to ARCOS, erroneous transactions can be changed or corrected using the ARCOS Maintenance Menu.

Distributors are required to take an annual inventory of each reportable controlled substance on December 31st and file it with ARCOS no later than January 15th of the following year. Increases and decreases in the inventory of each reportable controlled substance must be reported on a monthly basis and filed with ARCOS no later than the 15th of the month following the end of the reporting period.

For automated reporters, a tape of these transactions is sent to ARCOS, with a hardcopy report maintained at the division for two years. This report is useful when researching errors identified by ARCOS as it contains additional information, including item number and description, invoice number and customer or vendor number. For manual reporters, hand-written transactions are submitted to ARCOS on Form 333. One copy of the form is maintained at the division for two years.

ARCOS 'reads' the tape and generates a report entitled "ARCOS Daily Transactions Processing Error Report." The report will either acknowledge that no errors were found, or will list the transaction records in error, with the error code, description of the error and a correction number. Corrections must be made and the transactions resubmitted. Error reports should be maintained at the division for two years.

All media submitted to ARCOS should have a barcode label attached. Submissions should be made as described below:

ARCOS reports sent via commercial carrier such as Federal Express (FedEx), United Parcel Service (UPS) should be sent to:

DEA Headquarters
Attn: ARCOS Unit
2401 Jefferson-Davis Highway
Alexandria, VA 22301

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Guide to Handling ARCOS Transactions

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ARCOS reports sent via the U.S. Postal Service must use the following address:

Drug Enforcement Administration
ARCOS Unit
P.O. Box 27273
Washington, D.C. 20038-7273

Inquiries can be made to the ARCOS Unit at (202) 307-8600.

What to do before sending a report to ARCOS

The Distrack system has a daily report of ARCOS transactions, while the HP generates the report at month-end. Each system has the ability to make changes, additions and deletions prior to the submission of the transactions to ARCOS. Instructions can be found in the ARCOS Maintenance Section.

In the review process, look for

- DEA numbers that do not fit the typical format (2 letters followed by 7 numbers),
- blank numbers that do not fit the typical format (9 digit number),
- items that are not ARCOS reportable,
- quantities that appear to be excessive or out of the ordinary, and
- inventory adjustments.

Keep in mind that the only transactions that need to be reported to DEA are those that document an actual transfer of product. Records created by inventory adjustments when the product is moved from the live inventory to the morgue inventory do not represent a transfer of product and should be deleted. Credit and rebills for contract/chargeback purposes and dropship billings are two more examples of financial transactions that do not represent the actual transfer of product.

If changes need to be made to an Associate's DEA registration number, the modification should also be made in the Customer or Vendor Master File so that future transactions do not contain the same error.

ARCOS reportable items that are documented as lost-in-transit or stolen on DEA Form 106 or as destroyed on DEA Form 41, need to be reported as transactions to ARCOS. Since forms to the DEA are submitted manually, ARCOS records are not generated by the system and need to be created.

For an item lost-in-transit,

- use the date of the sale,
- the NDC and quantity of the item,
- the associate DEA number as the original sale record,
- a transaction code of X.

For a theft,

- report the date the theft occurred or was identified,
- the NDC and quantity of the item,
- a transaction code of T.
- The associate DEA number should be left blank.

For a destruction of a controlled substance (destroyed at your registered location),

- use the date the destruction occurred,
- the NDC and quantity of the item,
- a transaction code of Y
- the associate DEA number for the regional DEA office.

Product sent to a third-party for destruction are documented as a sale to the company. ARCOS records should be created through the invoicing process using transaction code S. If these activities occurred during a previous month, they should be reported as late transactions using the I code in the Action Indicator column.

ARCOS reportable items that are returned from an unknown source need to be documented as an addition to the inventory. This record is not generated by the system and needs to be created.

For an unsolicited return,

- use the date the product was received at the facility,
- the NDC and quantity of the item,
- a transaction code of V,
- the associate DEA number of UNKNOWN

The following are some sample lines from a report from the Distrack system., with a summary of what it means.

GR8050

THE MUNSTER COMPANY

ARCOS TRANSACTION EDIT REPORT
CALLED FOR BY SYCS91 - END OF DAY PROCESSING
PERIOD ENDING 3/19/98

TRANSACTION		ITEM		DESCRIPTION		ASOC. ID NO.		CORRECTION		BILL		SHIP		INVOICE		INVOICE		MFG#		PO#		ADI		C/M#		SRC	
YYMM	IDNT.	CDE	DATE	NUMBER	NDC NUMBER	DESCRIPTION	ASOC. ID NO.	REG. NO.	BLANK FORM NO.	CORRECTION NUMBER	D C	QTY	ACCT #	SHIP ACCT#	INVOICE NUMBER	INVOICE DATE	INVOICE NUMBER	MFG#	MFG#	PO#	PO#	ADI	C/M#	SRC	SRC	SRC	SRC
9803	6499	P	3/19/98	181084	00034-0517-25	M5 CONTIN CR 100MG 25UD PFC C2	5570	FT0226820	973652612			12	000000	000000	0000000	0/0/00	0000000	05570	05570	49523	49523	50	0000000	0000000	0000000	0000000	0000000
9803	6503	S	3/19/98	104334	00074-3142-01	NEMBUTAL SOD 18.2MG 480ML C2	381914	UNKNOWN				1	000000	000000	0000000	0/0/00	0000000	05000	05000	00000	00000	50	0000000	0000000	0000000	0000000	0000000
9803	6650	S	3/19/98	148976	59630-0106-04	PRQTUSS 120ML GRAPE HOR C3	381914	AB3010763				2	381914	381914	4207012	98/03/19	4207012	00000	00000	00000	00000	50	0000000	0000000	0000000	0000000	0000000

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Guide to Handling ARCOS Transactions

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Field Name	Description	Definition	Function
YYMM	year and month	4 digit code to identify the year and month of the reporting period	reported to ARCOS to identify the reporting period
IDENT	transaction identifier	sequential number assigned by the reporting registrant to each transaction record	reported to ARCOS to identify the transaction
CDE	transaction code	single-character field which identifies each specific ARCOS-reportable activity. The entire list of available codes is on the next page.	reported to ARCOS to identify the activity
DATE	transaction date	the actual date on which the activity occurred	reported to ARCOS to identify the date of the activity
ITEM NUMBER	item number	number assigned by the company to a particular SKU	used by the division for research and identification purposes
NDC NUMBER	National Drug Code number	11-character code that identifies controlled substance products	reported to ARCOS to identify the item
DESCRIPTION	item description	description of the item including size, strength, and finished form	used by the division for research and identification purposes
ASSOC. ID NO.	associate identification number	number assigned by the company to the vendor or customer participating in the transaction	used by the division for research and identification purposes
ASSOC. DEA REG. NO.	associate DEA registration number	9-character field identifying the customer or supplier with which the transaction took place	reported to ARCOS to identify the other party in the transaction
BLANK FORM NO.	narcotic order form (DEA 222) number	9-character field for the number of the order form	reported to ARCOS for CII items
CORRECTION NUMBER	correction number	unique sequential number assigned by ARCOS to an erroneous transaction	reported to ARCOS for reprocessing a corrected transaction
DC	action indicator (formerly the delete indicator)	a single character field which initiates three different ARCOS data base operations	reported to ARCOS when deleting or revising previously submitted and accepted transactions, or when inserting unreported transactions from previous months.

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Guide to Handling ARCOS Transactions

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Field Name	Description	Definition	Function
QTY	quantity	numeric field containing the number of packages, weight, or volume being reported	reported to ARCOS to identify the quantity
BILL - ACCT #	Bill-to account number	customer number assigned by the company to the account that was invoiced for the product(s) in this transaction	used by the division for research and identification purposes
SHIP - ACCT #	Ship-to account number	customer number assigned by the company to the account that was delivered the product(s) in this transaction	used by the division for research and identification purposes
INVOICE NUMBER	invoice number	the number assigned to the invoice that reflects the sale to the customer	used by the division for research and identification purposes
INVOICE DATE	invoice date	the date the invoice was created. Usually matches the transaction date.	used by the division for research and identification purposes
MFG #	vendor number	number assigned to the vendor from whom the product was purchased	used by the division for research and identification purposes
PO#	purchase order number	number assigned to the order under which the product was purchased	used by the division for research and identification purposes
ADJ	inventory adjustment code	the code assigned to the adjustment to indicate the disposition of the inventory	used by the division for research and identification purposes
C/M#	credit memo number	the number assigned to the credit memo that reflects the return of the product from the customer	used by the division for research and identification purposes
SRC	source	identifies where the information came from that created the transaction record	used by the division for research and identification purposes

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Guide to Handling ARCOS Transactions

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TRANSACTION CODES

(FROM PAGE 5-6 OF THE ARCOS REGISTRANT HANDBOOK)

INVENTORY TRANSACTION CODES

- 1 SCHEDULE CHANGE INVENTORY
- 3 YEAR-END INVENTORY
- 4 YEAR-END IN-PROCESS INVENTORY (MANUFACTURERS ONLY)
- 5 SPECIAL INVENTORY
- 8 NO YEAR-END INVENTORY

ACQUISITION TRANSACTION CODES (INCREASES TO INVENTORY)

- P PURCHASE OR RECEIPT
- R RETURN
- V UNSOLICITED RETURN
- W RECOVERED WASTE (MANUFACTURERS ONLY)
- M MANUFACTURED (MANUFACTURERS ONLY)
- G GOVERNMENT SUPPLIED
- L REVERSING (MANUFACTURERS ONLY)
- J RETURN OF SAMPLE TO INVENTORY (MANUFACTURERS ONLY)

DISPOSITION TRANSACTION CODES (DECREASES TO INVENTORY)

- S SALE, DISPOSITION, OR TRANSFER
- Y DESTROYED
- T THEFT
- N NONRECOVERABLE WASTE (MANUFACTURERS ONLY)
- U USED IN PRODUCTION (MANUFACTURERS ONLY)
- Z RECEIPT BY GOVERNMENT (SEIZURES, SAMPLES, ETC.)
- Q SAMPLING (MANUFACTURERS ONLY)
- K USED ON PREPARATIONS (MANUFACTURERS ONLY)

MISCELLANEOUS TRANSACTION CODES

- F REORDER DEA-333 FORMS
- X LOST IN TRANSIT
- 7 NO ARCOS ACTIVITY FOR THE CURRENT REPORTING PERIOD

What To Do When A Report Is Received From ARCOS:

1. Place the ARCOS template over the error report to separate the columns of information.
2. Identify the time period of the errors.
3. Retrieve the monthly report for that time period, to be used as reference.
4. Review the error code and the necessary correction action.
5. Determine if the error needs to be resubmitted. (Is it an ARCOS reportable item? Does the record reflect an actual transfer of product?)
6. Research any information pertinent to the type of error (invoice, receiver, credit memo, narcotic blank, etc.)
7. Create correction transactions in the ARCOS Maintenance Menu of the computer system. These transactions should be made in the current month's tape and not in the month of the original submission.
8. Make any necessary changes to the customer/vendor file or item file that could prevent future errors.

EDIT ERRORS REPORT

DEPARTMENT OF JUSTICE
DRUG ENFORCEMENT ADMINISTRATION
ARCOS - 2
DAILY TRANSACTIONS PROCESSING

ERROR REPORT

THE MUNSTER COMPANY
1313 MOCKINGBIRD LANE
TRANSYLVANIA, PA 66613

ERRORS FOR CONTROL RECORD == > RM1313666*043098M

RM1313666S 5045800340500000192 RD01049599804757070428980000010200009804011749
E77 NDC NUMBER ISN'T ARCOS REPORTABLE. DON'T SUBMIT CORRECTED TRANSACTION.
CORRECTION NUMBER: 00000102

RM1313666P 0000802580100000020 PA30379829621567550407980000010300009804012347
E48 ASSOCIATE REGISTRANT NUMBER IS NOT A VALID DEA REGISTRANT NUMBER
CORRECTION NUMBER: 00000103

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Guide to Handling ARCOS Transactions

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Errors for Control Record

RM1313666 SUBMITTING REGISTRANT NUMBER
* ASTERISK
043098 LAST DATE OF THE REPORTING PERIOD REPORT MEDIA (T=TAPE)
M REPORTING FREQUENCY (M = MONTHLY)

LINE 1
RM1313666 REPORTING REGISTRANT NUMBER (DIVISION)
S TRANSACTION CODE
50458003405 NATIONAL DRUG CODE (11 DIGITS)
00000192 QUANTITY (8 DIGITS)
RD0104959 ASSOCIATE REGISTRATION NUMBER (CUSTOMER OR VENDOR)
980475707 DEA ORDER FORM NUMBER (BLANK NUMBER, 9 DIGITS)
042898 TRANSACTION DATE
00000102 CORRECTION NUMBER
00009804 YEAR/MONTH OF REPORT
011749 TRANSACTION IDENTIFIER

LINE 2
E48 ASSOCIATE REGISTRANT NUMBER IS NOT A VALID DEA REGISTRANT NUMBER

LINE 3
CORRECTION NUMBER: 00000102

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Guide to Handling ARCOS Transactions

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ERROR CODES

(FROM PAGE 7-5 OF THE ARCOS REGISTRANT HANDBOOK)

- E01 REPORTING REGISTRANT NUMBER DOESN'T MATCH THE ONE ON THE CONTROL RECORD
- E06 DELETE INDICATOR FIELD MUST BE BLANK OR MUST BE THE LETTERS "A", "D", OR "I"
- E07 DELETE INDICATOR FIELD MUST BE BLANK IF A CORRECTION NUMBER IS PRESENT
- E12 TRANSACTION DATE CONTAINS AN INVALID MONTH AND/OR AN INVALID DAY
- E13 TRANSACTION DATE MUST BE THE LAST DAY OF THE REPORT MONTH OR QUARTER
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- E47 ASSOCIATE REGISTRANT NUMBER CAN'T EQUAL REPORTING REGISTRANT NUMBER
- E48 ASSOCIATE REGISTRANT NUMBER IS NOT A VALID DEA REGISTRANT NUMBER
- E49 ASSOCIATE REGISTRANT NUMBER IS INVALID FOR THE TRANSACTION CODE
- E52 THE ORDER FORM NUMBER HAS NOT BEEN CORRECTLY ENTERED
- E53 THE ORDER FORM NUMBER IS REQUIRED FOR SCHEDULE 1 & 2 DRUGS
- E60 TRANSACTION CODE 1 - AN INVENTORY RECORD ALREADY EXISTS
- E61 TRANSACTION CODE 3 OR 8 - YEAR-END INVENTORY AMOUNT ALREADY EXISTS
- E75 THE NDC NUMBER IS INVALID, IT CONTAINS ONE OR MORE SPACES
- E76 THE NDC NUMBER IS NOT IN THE DRUG FILE
- E77 NDC NUMBER ISN'T ARCOS REPORTABLE. DON'T SUBMIT CORRECTED TRANSACTION

ARCOS Transaction Maintenance/AS400

Through the modified ARCOS Transaction Maintenance Menu, changes can be made not only to transactions from the current month, but also transactions to previous months. All of the maintenance must be done in the current reporting period to ensure that changes are added to the current month's tape.

Since transactions can now be from a variety of months (previous or current), the transaction ID will consist of the year/month (YYMM) and sequence number (Seq), as shown on the far left of each transaction.

Screen 1

From the ARCOS File Maintenance Menu, you must select the file type and enter the report reference date, as well as an access path. The file type can either be Monthly (M), Annual (A), or Special (S). A majority of the time, this selection will be M. The report reference date is the last date of the reporting period you have selected. For example, if you want to look at the records for May 1999, then you would enter M and 05311999. Through your selection of an access path, you make the determination of how the transactions are sorted. Entering a 'starting at' value can help to limit your search, but is not required. By leaving that field blank, the search will begin with the lowest value of your selected access path. The options for access path are:

- 1 = Corporate Item Number
- 2 = Blank Number
- 3 = NDC Number
- 4 = Customer Number
- 5 = Vendor Number
- 6 = DEA Number
- 7 = Sequence Number

Screen 2

After selecting the file type, the reference date, the access path and pressing enter, the next screen is displayed. The columns appearing on the screen are:

- Sel = select transaction to update
- Seq # = transaction ID
- Trans Date = transaction date
- Cd = transaction code
- Dc = action indicator (only used for late, adjusted, and deleted transactions)
- Cst/Vnd = customer or vendor number, depending on which access path was chosen
- NDC/Item # = NDC or item number, depending on which access path was chosen
- Quantity = transaction quantity
- ASS Reg # = Associate registration number (DEA number of the other party involved in this transaction)
- Blank # = order form number (required for CII transactions only)

If you choose a 'starting at' value in Screen 1, that equals a valid value for that access path, then that value will be highlighted in all of the transactions where it is included.

You can scroll through transactions with a higher value for the access path, but in order to view transactions with a lower value, you must enter another value into the 'start at' field at the top of the screen and press F8. This 'start at' value is associated with the access path code selected on Screen 1. To select an alternative access path, press F12 to return to Screen 1.

To make a change to a transaction, enter '2' in the 'Sel' column and press enter. This will display the Change/Delete Current window. Changes can be made to any fields that are underlined. After completing the changes, press 'enter' and the transaction will be verified for accuracy and will be updated in the file. This function can be used for any transaction in the current batch including the current month's transactions, as well as any added, late or corrected transactions that have been entered.

To delete a transaction, enter '4' in the 'Sel' column and press 'enter'. This will display the Change/Delete Current window. No information can be entered into this pop-up window. Press <enter> to accept the delete. This function can be performed for any transaction that is displayed in the current batch that is not already deleted, this includes the current month's transactions, as well as any added, late or corrected transactions that have been entered. Deleted transactions will be displayed with an 'X' in the Dc column.

To add (current month) transactions, press (F6). This will display the Add Transaction pop-up window will appear requesting the required information. After completing the window, press <enter> and the transaction will be checked for accuracy and a transaction ID will be assigned. This add function can only be used for transactions that have occurred in the current month. Adding transactions from previous months is done using F14.

To add late (previous months) transactions, press (F14). This will display the Late Transaction pop-up window will appear requesting the required information. *You must assign a transaction ID that includes the YYMM of the transaction and an original sequence number. The YYMM must be from a previous month.* After completing the window, press <enter> and the transaction will be checked for accuracy and will be added to the batch. Late transactions will be noted with an 'I' in the Dc column. This function can only be used for transactions that have occurred in previous months.

To add corrected (DEA specified) transactions, press (F15). This will display the Correction Transaction pop-up window will appear requesting the required information. These transactions are identified on the ARCOS-2 Error Report. *The correction transaction record must contain 1) all the fields that were correct on the original submission including the original transaction identifier, 2) the corrected field(s), and 3) the correction number.* The YYMM must be from a previous month. After completing the window, press <enter> and the transaction will be checked for accuracy and will be added to the batch. Corrected transactions will be noted with a correction number under the Corr# column. This function can only be used for transactions that have been identified as errors by the DEA and must not have occurred in the current month.

To adjust (previous months) transactions, press (F20) This will display the Adjustment, Deletion pop-up window will appear requesting the required information. This is to correct mistakes on previously submitted transactions. Once these are identified, wait until the error report is received from ARCOS. If the transaction appears on the error report, a correction must be made using F15. If the transaction does not appear on the error report and was accepted by ARCOS, an adjustment must be made using F20. The first record created will be coded 'D' in the Dc column. You will then be

prompted to adjust the transaction to reflect correct information. The second record will be coded 'A' in the Dc column.

To delete (previous months) transactions, press (F21) This will display the Delete, Previous pop-up window will appear requesting the required information. This is to delete transactions that were previously submitted but should not have been. The record will be coded D in the Dc column.

To unfold the screen, press (F10). This will expand a single transaction to two lines and include the customer name and the item description.

To select all transactions that meet a specified value in an access path, press (F7). This will put a '2' in the 'Sel' column. If the transactions span for more than one page, you must page forward to the last page of the highlighted transactions to select all of these transactions. If you press F7 without first paging forward, you will only select the specified transactions from the first page.

To mass update, press (F5). This will display the Mass Change pop-up window. From this window you have the option to change the NDC, DEA number or Blank number from the first transaction you selected to another value. It is recommended that mass changes only be made to the field that was selected in the access path.

ARCOS File Maintenance - HP

Overview

In General:

The ARCOS File Maintenance screen allows the user to enter ARCOS File corrections. The screen was developed to replace the manual submission of corrections on ARCOS FORM 333 which the DEA will no longer accept from registrants who submit monthly reports electronically.

With the ARCOS file maintenance screen you have the ability to 1) make changes, additions and deletions to transactions prior to submission to ARCOS, 2) make adjustments, additions and deletions to transactions after acceptance by ARCOS, and 3) make corrections to transactions rejected by ARCOS.

Detailed Procedures

The ARCOS File Maintenance Screen is located on the **DEAMENUB**. To access **DEAMENUB**, log on to the live account and enter the following at the prompt: **MENU DEAMENUB**

Select option #11, ARCOS File Maintenance. This will take you to the ARCOS File Maintenance screen.

Note: Previous knowledge regarding the use of QUICK screens is needed to proceed with the following procedures.

MODE:F ACTION: _____

DEA :RH0191318

ARCOS TRANSACTION MAINTENANCE

Trans. No.	Date	Cd	Dc	Order Form	H.D.C. No.	Quantity	Assoc. Ref#	Correct#
01	1	11/01/96	S	-	960224487	00024027402	3	AM1471515
02	2	11/01/96	S	-		00172564370	1	AM1471515
03	3	11/01/96	S	-	960224488	00074113403	10	AM1471515
04	4	11/01/96	S	-		00044072802	1	BB3984413
05	5	11/01/96	S	X		00785635001	1	BA3885160
06	6	11/01/96	S	-		00044072703	1	AT9562023
07	7	11/01/96	S	-		00044072803	1	AT9562023
08	8	11/01/96	S	-		60432045716	1	AT9562023
09	9	11/01/96	S	-		51079042099	1	BC3621047
10	10	11/01/96	S	-		50752029205	1	BS4696590
11	11	11/01/96	S	-		51079042020	1	AM2103454
12	12	11/01/96	S	-		50474090201	1	BK3045211
13	13	11/01/96	S	-		50474090760	2	AS3310315
14	14	11/01/96	S	-		50474090260	22	BN0963795
15	15	11/01/96	S	D	961420472	00008072901	1	AM5706861



This is a standard QUICK screen which allows the user to enter information needed to correct ARCOS transactions.

The Screen starts in find mode. The Screen will request the Trans ID to find or the user may hit enter to scan the file.

To change transactions

Changes to transactions may be made using the Find/Change command (F2). Once a transaction has been selected either by transaction identifier or by line number, the date field is erased for change. If no change is required, press <enter> and the next field will be erased and the date will reappear. Continue this process through the entire line, making change(s) where needed. When completed with the line, press F6 to update the file. The change function can be used for any transactions in the current batch including the current months transactions, as well as any transactions added from previous months.

To add (current month) transactions

Transactions for the current month can be added using the Add Trans Curr Mo command (F4). The system will assign the next available transaction number. You will be required to add the rest of the information, pressing <enter> to tab through the fields. When the record is complete, press F6 to update the file. The system will only accept a date within the current month. To add a transaction from a previous month, use F5.

To add late (previous months) transactions

Transactions for previous months can be added using the Add Trans Prev Mo command (F5). You will be required to assign the transaction number using the next sequential number for that previous months batch. You will also be required to add the rest of the information for that transaction, pressing <enter> to tab through the fields. When the record is complete, press F6 to update the file. The system will require that the transaction date be from a previous month.

To delete transactions

Transactions from the current month can be deleted using the Delete Trans command (F7). You will be required to identify the transaction by transaction identifier or line number. The transaction will be coded with an 'X' and will be excluded from the tape. You must press F6 to update the file.

To delete (previous months) transactions

Transactions from previous months can be deleted by using a two step process of adding a previous months transaction and changing the code. First, add a transaction from a previous month using F5, keying in all of the required fields, pressing <enter> to tab through the fields. When the record is complete, you have the option of updating or changing it. To change the record, type the line number of the transaction (1) in the 'action' field, then change the 'I' in the Dc column to 'D'. Press F6 to update the file.

To adjust (previous months) transactions

Transactions from previous months can be adjusted by using a deletion from a previous month, in combination with a previous month add and a change of the code. First, add a transaction from a previous month using F5, keying in all of the information from the original transaction, pressing <enter> to tab through the fields. When the record is complete, change the code in the Dc column from 'I' to 'D'. Press F6 to update the file. A second transaction then needs to be added, containing all the fields that were correct on the original submission including the original transaction identifier, the corrected fields, and the correction number. When the record is complete, change the code in the DC column from 'I' to 'A'. Press F6 to update the file.

To add corrected (DEA specified) transactions

Transactions for correction can be done using a previous month add, including a correction number, then deleting the 'I' code. First, add a transaction from a previous month using F5, keying in all of the information from the original transaction, pressing <enter> to tab through the fields. Remember to include the correction number assigned to the transaction on the ARCOS Error Report. When the record is complete, remove the code in the Dc column. Press F6 to update the file.

Screen Definitions

Field Name	Field Description
Trans No.	The ARCOS Transaction Identifier.
Date	The transaction date, format of MMDDYY. Do not enter slashes the screen with auto format the field.
Cd	Transaction Code. When in this field use Function key <F1> "HELP" for a list of acceptable transaction codes.
Dc	Delete Indicator. This field is used to mark ARCOS transactions for delete. When in this field use Function key <F1> "HELP" for a list of acceptable delete codes.
Order Form	The Order Form Number
N.D.C. No.	The National Drug Code number.
Quantity	The Quantity.
Assoc Reg#	The Associated DEA Registration Number.
Correct #	The ARCOS Correction Identifier.

Screen Definitions

Function Key	Label	Function Key Description
F1	HELP	This will give Help on the screen when used in the Action Box and will give help for a specific field when used in that field.
F2	Find / Change	This is used to find transaction by a Trans ID or to scan the file. After finding a transaction, enter the line number of the transaction to modify the data in a field.
F3	Find By Date	This function key will allow the user to retrieve all the transactions for a specific date.
F4	AddTrans Curr Mo.	This will allow the user to add a transaction for the current month.
F5	AddTrans Prev Mo.	The will allow the user to add a transaction for a prior month.
F6	Update	After changing, adding or deleting any transactions this function key MUST be used to permanently save the transaction.
F7	Delete Trans	This function key is used to mark a transaction for delete.
F8	Exit	This key will allow the user to exit from the screen.



DEA

COMPLIANCE MANUAL

APPENDIX B

Test and Training Manual for Distribution Center Employees Handling Controlled Substances

**TRAINING MANUAL
FOR EMPLOYEES
HANDLING
CONTROLLED
SUBSTANCES**

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INTRODUCTION

The Drug Enforcement Administration (DEA) is the primary federal law enforcement agency charged with combating drug abuse in this country. Established in 1973, it is a combination of the agencies formerly known as the Bureau of Narcotic and Dangerous Drugs, the Office for Drug Abuse Law Enforcement, the Office of National Narcotic Intelligence, and certain drug related elements of both the Bureau of Customs and the Office of Science and Technology. The intent of the amalgamation of agencies is to eliminate the piecemeal approach to the control of narcotics and dangerous drug and, by coordinating the effort, to control more effectively narcotic and dangerous drug activity and abuse.

Prior to this amalgamation of agencies, the laws on the control of drugs were collected and conformed into one piece of legislation, the Comprehensive Drug Abuse Protection Control Act of 1970 (the "Controlled Substance Act"). This act consolidated over 50 pieces of legislation that had been enacted in piecemeal fashion since 1914. The trust of this Controlled Substance Act is the improvement of the administration and regulation of manufacturing, distribution, and dispensing of controlled substances by establishing a "closed" system for legitimate drug handlers so that controlled drugs can be traced from their origin to their eventual user.

The act contains nine major control mechanisms that apply to the manufacture, purchase and distribution of substances subject to the act. They are:

- registration of handlers;
- record keeping requirements;
- manufacturing quotas;
- distribution restriction;
- limitations on imports and exports;
- conditions of storage of drugs;
- reports of transactions to the government; and
- criminal, civil and administrative penalties for violations.

Each of these mechanisms has a considerable impact upon the industry, especially the penalties and loss of registration provisions. Each violation of the act (which may be as little as misplacing one bottle of controlled substances) is punishable up to 15 years imprisonment and \$10,000 in fines. In addition, a relatively speedy administrative hearing can result in a finding of inadequate security. Such a finding could lead to loss of registration, effectively putting a company out of the controlled drugs distribution business. It has, therefore, become a cost justified good business practice to establish effective control measures in the first instance. DEA, like most other federal agencies, prefers voluntary rather than forced compliance.

12/28/99

Training Manual

1-1

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The DEA Diversion Control Program is responsible for implementing and maintaining controls over the distribution of legally produced controlled substances into the illegal market. The diversion control program operates through: periodic investigations to ensure that record keeping, reporting, and security requirements are being met; targeted investigations (for violative registrants); preregistration investigations; and organized system of destruction; manufacturing quotas; and drug scheduling (collection of abuse and diversion information). Periodic inspections are conducted as circumstances may require, based in part on the registrant's history of compliance and maintenance of effective controls to guard against the diversion of controlled substances.

This manual is intended as a resource to the Controlled Substance Act and Regulations. It is intended as a guide so that you can better understand DEA's function. Further, it is intended to help you learn to deal with the agency that has and tremendous impact on our business.

In addition to this manual, you should also have the following DEA publications available for ready reference:

**Code of Federal Regulations 21. Food and Drugs
Part 1300 to End – available from:**

Superintendent of Documents
U.S. Government Printing Office
Washington, D.C. 20402
(202) 783-3238

ARCOS Reporting Manual – available from:

United States Department of Justice
Drug Enforcement Administration
ARCOS Unit, P.O. Box 27273
Central Station
Washington, D.C. 20038-7273
(202) 307-8600

Note: The Automation of Reports and Consolidated Orders System (ARCOS) is the automated system developed by DEA to monitor selected controlled substances. ARCOS software enables the government to maintain a current and historical record of controlled substance inventories and transactions from the point of manufacture to the point of sale, distribution, or other disposition, and finally, to the dispensing (consumption) level.

INVENTORY

There are specific regulations with regards to inventory. DEA requires a biennial inventory, and a year-end ARCOS inventory. As company policy, periodic inventories are recommended. Unless otherwise specified, the general requirements pertain to each type of inventory. Refer to **Procedural Security** for additional information on the **Physical Verification of Controlled Substances**.

Biennial

(21 CFR 1304.11 (c))

Frequency. Every two years, the wholesaler is required to take a physical inventory of all controlled drug stocks on hand.

When. The regular biennial inventory date is every two years from the date the wholesaler initially became registered to distribute controlled substances. Thus, for all firms who were provisionally registered on May 1, 1971, the biennial inventory date is May 1st every odd year. For any firm registered after May 1, 1971, or which has been issued a new registration since May 1, 1971, the regular inventory date is two years from the initial date of registration, e.g., Firm A which first became registered on August 21, 1974, has a regular biennial inventory date of August 21 every even year. The wholesaler may take the inventory within four days of the inventory date if he/she notifies the DEA special agent in charge in advance.

Cardinal Health has received authorization from DEA for all Cardinal Health locations to conduct biennial inventories on December 31 of even numbered years.

Year-End ARCOS

(21 CFR 1304.33 (b))

Frequency. Every year, the wholesaler is required to take a physical inventory of all reportable controlled substances on hand.

When. The inventory should report the stock on hand as of the close of business on December 31st.

Reporting. A report of the inventory shall be filed with the ARCOS Unit of the Drug Enforcement Administration by January 15th of the following year.

Periodic
(21 CFR 1304.11)

Frequency. A daily count of controlled substances and narcotics having movement (sales, purchases, and returns) on the previous day should be conducted, and a monthly count of all controlled substances in the facility.

When. Counts should be conducted as close to the end of day processing so as not to interfere with the current day's business. The monthly count should be conducted as close to the same time each month as possible.

General Requirements

Newly Controlled Drugs. An initial inventory must be taken of all stocks on hand of a newly controlled drug on the effective date of control. Subsequently, the newly controlled drug will be reinventoried on the same date as all other controlled drugs. (21 CFR 1304.11 (d))

Note: Many wholesalers have been cited for missing the initial inventory date on newly controlled drugs. For example, anabolic steroids were controlled (Schedule III) effective February 27, 1991, and an initial inventory should have been taken on that date.

Drugs to Be Included. All controlled substances on hand as of the inventory date must be included. Returns, damaged goods, and any other drugs awaiting disposal must be inventoried.

Note: Wholesalers often overlook returns and drugs awaiting disposal in taking inventory.

Retention of Inventory Records. The record must be retained for two years from the date the inventory was taken and must be available for DEA inspection at the registered location where the inventory was made. (21 CFR 1304.04)

Note: State record keeping requirements may be more than two years and records should be maintained accordingly.

DEA REGISTRATION

Detecting Fraudulent Registration Numbers

A DEA registration number consists of a two-character prefix and a seven-character suffix which are determined as follows:

Prefix. 1st character is A or B for all practitioners, hospitals, pharmacies and teaching institutions; it is P or R for all other classes of registrants. M is used for mid-level practitioners (MLP). (Refer to **DEA Correspondence 8/25/93**). The 2nd character is the first letter of the registrant's last name if an individual, or the first letter in the first word of the name if a firm (Note, a "9" is inserted in this position if the firm's name begins with a number—e.g., "101 A Street, Inc.>").

Suffix. The suffix contains seven numeric characters, the seventh of which is a check digit that is determined as follows:

Add the number of the 1st, 3rd and 5th characters to twice the sum of the 2nd, 4th and 6th characters; if the total is a single-digit number, that number is the check digit; if the total is a two-digit number, the digit in the ones column is the check digit and is inserted in the seventh position.

Checking Expiration Dates

A system to verify the renewal of registration number can be standardized by expiration date because all registrations with the same second character in the prefix expire on the same date. The expiration dates for these characters are:

January 31	M	July 31	B
February 28	S	August 31	C, E
March 31	L, P	September 30	F, G
April 30	Q, R, 9	October 31	H, N
May 31	U, V, W, X, Y, Z	November 30	I, T
June 30	A, D	December 31	J, K, O

Note: Practitioners, hospitals, pharmacies, and teaching institutions re-register every three years. All others register annually.

DEA Registration Verification

(21 CFR 1301.74(a))

The wholesaler is responsible for verifying that customers possess a valid, current DEA Certificate of Registration (Exhibit J). DEA will not verify routinely, and it is left to the wholesaler to develop a system. There are several methods the wholesaler may use.

Cardinal's policy and procedure requires that new accounts provide a photocopy of a current DEA registration prior to being allowed to purchase controlled substances. A copy of the account's state license should be obtained at the same time.

Registration expiration dates for existing accounts are monitored on a monthly basis. Those accounts whose registration is due to expire are contacted either by letter, telephone, or sales representative and are requested to provide an updated copy of their registration (Exhibits K, L). A copy of the state license should also be requested.

In addition, the computer system prohibits the purchase of controlled substances by any customer who does not have a DEA registration number loaded into the computer system or whose registration has expired. The system also limits the purchase of controlled substances to the schedules for which the customer is registered.

Cardinal purchases, on a quarterly basis, a tape from the DEA of all current registrations. This tape is run against each division's customer database. The Quarterly DEA Exception Report (Exhibit N) is a listing of all customers in a division's database whose DEA number or expiration date does not match the DEA database. Review and maintenance of this report must be done to assure sales of controlled substances are only made to current registrants of the DEA.

Questioned Registrations

Whenever there is reason to question a customer's registration (i.e., the number does not pass the check digit, there is a question whether the registration includes the schedule(s) ordered or a pharmacy has changed hands and the new owner is using the old DEA number), further inquiry should be made to ensure that the customer is properly registered. The local DEA office will check this type of situation. Calls to the local DEA office should be documented on a Regulatory Agency Contact Form (Form #1).

Delayed Registration Renewal Certificates

From time to time, computer delays at DEA cause customer renewals to be late, even though renewal applications were submitted in a timely fashion. When the customer tells the wholesaler that this has occurred, the wholesaler should contact the local DEA office to confirm this fact and to authorize continued shipments. If the authorization is made by telephone, the wholesaler should write down the confirmation, including the name of the authorizing DEA official, the date, and the details of the authorization. Document this on a Regulatory Agency Contact Form. Refer to DEA Correspondence 9/7/93.

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Modification of DEA Registration

When a registrant moves to a new location, they must have the new location inspected by the DEA and obtain a new DEA registration with a corrected address. Many customers continue to use the old registration and expect that their controlled substance orders will be delivered to the new address. This is a violation of DEA regulations. Controlled substances can only be shipped to properly registered location and only to the address listed on the registration. (21 CFR 1301.51)

Transfer of Ownership

For a change of pharmacy ownership and continuing operation on a previous owner's DEA registration, the primary condition is that both the buyer and seller enter into a **Limited Power Of Attorney (Form #25)** that specifically sets forth the following:

- The seller agrees to allow the controlled substance activities of the pharmacy to be carried out under the seller's DEA registration;
- The seller agrees to allow the buyer to carry out the controlled substance activities of the pharmacy, including the ordering of controlled substances, as an agent of the seller;
- The seller acknowledges that, as the registrant, they will be held accountable for any violations of controlled substance laws which may occur; and
- The buyer agrees that the controlled substance activities of the pharmacy may be carried out under the seller's registration for no more than 45 days after the purchase date, which shall be recorded in the agreement.

Prior to selling product to the new owner, you should obtain a copy of the **Power Of Attorney** and file it with the copy of the previous owner's DEA registration certificate.

In addition, you must monitor the 45-day limit on controlled substance activity imposed as part of this policy. Refer to **DEA Correspondence 8/25/93**.

Termination of DEA Registration

(21 CFR 1301.52)

The closing of a facility requires that a DEA certificate of registration be terminated. At least 14 days prior to close and controlled substance transfer, submit a registered or certified letter, return receipt requested, to local DEA supervisor containing the following information:

- name, address, registration number of distribution center which is transferring the controlled substances and associated records and terminating the registration,
- name, address, registration number of distribution center to whom the controlled substances and associated records will be transferred,
- date of the controlled substance transfer and a description of the proposed transfer procedure,
- date and time of termination.

Contact state licensing agencies and follow their specific procedures for registration termination.

On the date of the transfer, a complete inventory of all controlled substances being transferred must be taken. A copy must be maintained with the records for each distribution center. The transfer must be documented as a purchase and sale. Purchase orders, 222's, invoices and receiving documents must be created.

The Corporate Compliance Department will arrange and supervise the transfer of all controlled substances.

Upon termination of the registration, submit to the regional DEA office by registered or certified mail, return receipt requested, a cover letter and the following:

- DEA Certificate of Registration,
- unused DEA Forms 222.

Chemical Registration

Any person or persons who distribute products covered by the Methamphetamine Control Act (ephedrine, pseudoephedrine, phenylpropanolamine) must have either a controlled substance registration or a chemical registration. They do not have to possess both registrations. Registrations must be renewed annually.

A DEA chemical registration number consists of a six character prefix and a three character suffix which are determined as follows:

Prefix. The prefix contains six numeric characters. There is no check digit as in a controlled substance registration.

Suffix. The suffix contains three alpha characters. The first is the first letter in the registrants name. The second is a random letter and the third identifies the activity of the registrant as listed below.

- W - Manufacturer
- Y - Distributor
- V - Retail Distributor
- X - Importer
- Z - Exporter

ORDER FORMS

(21 CFR 1305)

All transactions of Schedule I and II substances must be made on federal order forms - DEA Form 222 (Exhibit O). Any exceptions to this requirement must be approved by DEA on a case-by-case basis. Purchases from vendors and returns from customers are executed on order forms issued by Cardinal Health. Sales to customers are executed on order forms issued by the customer.

Obtaining and Executing Order Forms

Only persons registered to handle Schedule I and/or II substances may obtain order forms. Order forms may be executed only on behalf of the registrant named on the order form provided that the registrant **currently** is registered to handle the scheduled substances ordered.

When blanks are received from the DEA, the order form numbers should be logged on the DEA Narcotic Blank Log (Form #4), and kept in the vault for safekeeping, pending use.

Separate Records Requirement

DEA has taken the position that order forms are the primary record of Schedule II transactions and, therefore, that the maintenance of order forms in a separate file satisfies the requirement that records of Schedule II transactions be maintained separately. Secondary records (e.g., invoices accompanying order forms) are not required to be maintained separately.

Purchases and Returns of Schedule I and II substances

Procedure for Executing Order Forms

(21 CFR 1305.06)

- The purchaser simultaneously prepares and executes order forms in triplicate by means of interleaved carbon sheets which are part of the DEA Form 222. Order forms are prepared by use of a typewriter, pen or indelible pencil. A wholesaler may consider rejecting any Form 222 completed in pencil, indelible or not, as the identification of indelible over regular lead is tenuous at best.

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- Only one item is entered on each numbered line. There are 10 lines on each order form. Some registrants still are using the old five-line order forms, which are valid. If one order form is insufficient to include all items in an order, additional forms are used. The last line completed is noted on that form in the space provided. This number should correspond to the number of lines used. For example, if two lines are used on an order form to describe one item, the number of lines completed at the bottom is two.
- An item consists of one or more commercial or bulk containers of the same finished or bulk form and quantity of the same substance; a separate item is made for each commercial or bulk container of different finished or bulk form, quantity or substance. For each item, the form should show the name of the product ordered, the finished or bulk form of the product (e.g., 10-mg. tablet, 10-mg. concentration per fluid ounce or milliliter or U.S.P), the number of units or volume in each commercial or bulk container (e.g., 10 kilograms), the number of commercial or bulk containers ordered, and the name and quantity per unit of the controlled substance or substances contained in the product if not in pure form. The catalogue number of the product may be included at the discretion of the purchaser.
- The correct name and address of the supplier from whom the controlled substances are being ordered is entered on the form. Only one supplier may be listed on any one form.
- Each order form is signed and dated by a person authorized to sign a requisition for order forms on behalf of the purchaser pursuant to 21CFR 1305.05(c). The name of the purchaser, if different from the individual signing the order form, is inserted in the signature space. Unexecuted order forms may be kept and may be executed at a location other than the registered location printed on the form provided that all unexecuted forms are delivered promptly to the registered location upon an inspection of such location by any officer authorized to make inspection or to enforce any federal, state or local law regarding controlled substances.

Centralized Purchasing of Schedule II Drugs

When the ordering of schedule II drugs and the processing of the DEA Forms 222 is handled by Corporate Purchasing, the following steps are taken:

- Corporate Purchasing orders DEA Form 222's by contacting the appropriate DEA office or the DEA Registration Unit in Washington, D.C., or by completing a 222 Requisition Form.

Note: All 222 Requisition Forms received by the divisions should be forwarded to Corporate Purchasing.

- Order Form Books are received at the division.
- The division logs the order form numbers onto the **DEA Narcotic Blank Log**.
- Division retains adequate supply of order forms for emergency purchases and customer return buybacks and forwards remainder to Corporate Purchasing, along with a copy of the **DEA Narcotic Blank Log**.
- Corporate Purchasing receives and stores order forms in a secure area. Corporate Purchasing contacts division if numbers are out of sequence or an order form is missing.
- Corporate Purchasing creates Schedule II purchase order and completes order form according to DEA regulations (21 CFR 1305.06).
- Copy 1 (brown) and Copy 2 (green) copies of order form are mailed to the vendor; Copy 3 (blue) is mailed to the division. Corporate Purchasing makes copy of the order form for purchasing records.

Note: All three copies of voided order forms must be sent to the division.

- Corporate Purchasing adds order form numbers to purchase orders and transmits purchase order file to the division.
- Division receives Copy 3 (blue) copy of order form and records appropriate information onto **DEA Narcotic Blank Log**. Division contacts Corporate Purchasing if numbers are out of sequence or an order form is missing.

Power of Attorney

(21 CFR 1305.07)

Any purchaser may authorize one or more individuals, whether or not located at the registered location of the purchaser, to obtain and execute order forms on his/her behalf by executing a **Power of Attorney (Form #2)** for each such individual. The **Power Of Attorney** is signed by the same person who signed or was authorized to sign, the most recent application for registration or re-registration and by the individual being authorized to obtain and execute order forms. The power of attorney is filed with the executed order forms of the purchaser, and retained for the same period as any order form bearing the signature of the attorney. The power of attorney should be available for inspection together with other order form records. Any power of attorney may be revoked at any time by executing a **Notice Of Revocation (Form #3)**, signed by the person who signed (or was authorized to sign) the power of attorney or by a successor, or by whomever signed the most recent application for registration or re-registration, and filing it with the power of attorney being revoked.

Sales of Schedule I and II Substances

Procedure for Filling Order Forms

(21 CFR 1305.09)

- The purchaser submits copy 1 (brown) and copy 2 (green) of the order form to the supplier and retains copy 3 (blue) in his/her own files.

Note: Order forms given by customers to contract drivers for eventual delivery to the distribution center must be in a sealed envelope. The driver should have no knowledge of the contents of the order form. Refer to DEA Correspondence 07-18-96.

- The supplier fills the order, if possible and if the supplier desires to do so, and records on copies 1 (brown) and 2 (green) the number of commercial and bulk containers furnished on each item and the date on which such containers are shipped to the purchaser. If an order cannot be filled in its entirety, it may be filled in part and the balance supplied by additional shipments within 60 days after its execution by the purchaser, except as noted below.
- The controlled substances are shipped to the purchaser at the location printed by the administration on the order form, except as noted below.
- The supplier retains copy 1 (brown) of the order form for his/her own files and forwards copy 2 (green) to the special agent in charge of the DEA field office in the area in which the supplier is located. Copy 2 (green) is forwarded at the close of the month during which the order is filled; if an order is filled by partial shipments, copy 2 (green) is forwarded at the close of the month during which the final shipment is made or during which the 60-day validity period expires.
- The purchaser records on copy 3 (blue) of the order form the number of commercial or bulk containers furnished on each item and the dates on which such containers are received by the purchaser.

Note: Order forms submitted by registered procurement officers of the Armed Services Medical Procurement Agency for delivery to armed services establishments within the United States may be shipped to locations other than the location printed on the order forms, and in partial shipments at different times not to exceed six months from the date of the order, as designated by the procurement officer when submitting the order.

Note: DEA Policy is that the wholesaler or a "direct proprietary agent" of the wholesaler must have the order form in hand before the product is released. The direct proprietary agent can be a sales representative, a depot supervisor or a driver (not common or contract).

Substitutions

It is acceptable to substitute generic product for generic product, generic product for brand name product, or brand name product for generic product provided that the products are equivalent, the name and the NDC number of the actual product shipped are reflected on the order form, and the purchaser agrees to the substitution. Refer to DEA Correspondence 6/29/92.

Faxing Narcotic Order Forms

DEA, as a matter of policy, has stated that they will allow the faxing of order forms when it involves a direct transmission from the customer to the wholesaler; however, the order may not leave the distribution center until the original order form arrives at the distribution center or is in the possession of a direct proprietary agent of the wholesaler. DEA may grant approval in emergency situations on a case-by-case basis for shipping the order before receiving the order form.

The DEA is also not opposed to having order forms faxed from depots to the wholesaler when the following conditions are met:

- The original order forms, when delivered to the depot, are in the possession of an employee of the wholesaler who is familiar with order form regulations.
- The order forms and a DEA 222 Transmission Log (Form #5) are faxed to the division and order form receipt is verified to the log.
- Narcotic orders are not released at the depot unless there is a corresponding order form.
- The regulatory requirements for the processing of DEA Form 222 are strictly adhered to.

This procedure shall not be used unless the depot operation is supervised by a Cardinal employee, the Cardinal employee faxes the order forms, and the Cardinal employee maintains possession of the original order forms until the order forms are exchanged for the controlled substances.

DEA will not permit, under any circumstances, the faxing of order forms from contract carrier crossdock locations by contract carrier employees. Refer to DEA Correspondence 07-18-96 and 08-28-96.

The faxing of 222s for customers serviced by contract carriers must be handled as follows:

FROM THE CROSSDOCK:

1. Contract delivery drivers deliver original 222s in sealed envelopes to contract carrier crossdock supervisor.
2. Crossdock supervisor delivers sealed envelopes containing 222s to Cardinal crossdock employee.
3. Cardinal crossdock employee removes 222s from envelopes and completes DEA222 Transmission Log (Form #5).

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4. Cardinal employee faxes 222s to distribution center. This should be done using one transmission and the DEA222 Transmission Log should be the last page of the fax.
5. Fax is received in distribution center by Operations Manager or designee.
6. Operations Manager or designee verifies faxed 222s received with information on the DEA 222 Transmission Log. Faxed copies of 222s are checked for legibility and compliance and are processed according to DEA regulations.
 - a) If any discrepancies exist that would require 222s to be re-faxed, Operations Manager or designee contacts Cardinal crossdock employee.
7. Cardinal crossdock employee places original 222s in a sealed envelope for delivery to the distribution center.
8. Operations Manager or designee delivers faxed 222s to the vault.
9. Vault clerk fills orders and files faxed 222s. Orders are held until original 222s arrive at the distribution center and are compared to the orders.

FROM THE CUSTOMER:

1. Customer faxes 222 directly to the distribution center.
2. Operations Manager or designee checks 222 for legibility and compliance and processes according to DEA regulations.
 - a) If any discrepancies exist that would require 222 to be re-faxed, Operations Manager or designee contracts the customer.
3. Customer gives original 222 to contract delivery driver in a sealed envelope for delivery to distribution center.
4. Operations Manager or designee delivers faxed 222 to the vault.
5. Vault clerk fills order and files faxed 222. The order is held until the original 222 arrives at the distribution center and is compared to the order.

Preservation of Order Forms

(21 CFR 1305.13)

- The purchaser retains copy 3 (blue) of each filled order form. The purchaser also retains in his/her files all copies of each unaccepted or defective order form and any statements attached to them.

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- The supplier retains copy 1 (brown) of each order form that has been filled.
- Order forms must be maintained separately from all other records of inspection for two years (as are all records of controlled substance transactions). If a purchaser has several registered locations, copy 3 (blue) of the executed order forms and any attached statements or other related documents (not including unexecuted order forms which may be kept elsewhere pursuant to (21 CFR 1305.06 (d))) must be kept at the registered location printed on the order form.

Note: State record keeping requirements may be more than two years and records should be maintained accordingly.

Unaccepted and Defective Order Forms (21 CFR 1305.11)

Federal regulations applicable to the handling of such order forms are as follows:

- No Order Form shall be filled if it:
 - (1) Is not complete, legible, or properly prepared, executed, or endorsed; or
 - (2) Shows any alteration, erasure, or change of any description.
- If an Order Form cannot be filled for any reason under this section, the supplier shall return Copies 1 (brown) and 2 (green) to the purchaser with a statement as to the reason (e.g., illegible or altered). A supplier may for any reason refuse to accept the order; a statement that the order is not accepted shall be sufficient for purposes of this paragraph.
- When received by the purchaser, Copies 1 (brown) and 2 (green) of the Order Form and the statement shall be attached to Copy 3 (blue) and retained in the files of the purchaser in accordance with 21 CFR 1305.13. A defective Order Form may not be corrected; it must be replaced by a new Order Form in order for the order to be filled.
- Any information which is pre-printed on the order form may not be altered in any way.

Pursuant to these regulations, order forms should be returned to the customer under the following circumstances:

- The writing is illegible or it is otherwise impossible to identify a customer's registration number, items specified or quantities, or there is improper execution or endorsement.
- There are alterations, erasures, or changes resulting in questions regarding the identity of the customer, customer's registration number, items or quantities.
- Signatures are omitted.
- Sixty days have elapsed from the date of execution by the purchaser.
- The last line completed is greater than the last line specified.

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- The number of line items is greater than the total number of items specified.
- Customer voids a line.

Federal order forms which identify the customer's registration number, items and quantities, and which are properly signed but are incomplete or have minor errors may be corrected to the following extent:

- The supplier's name, address, city, state, or zip code may be added when omitted by the customer.
- The supplier's address, city, state or zip code may be corrected.
- The date of the order may be added when omitted. Whenever possible, the postal date on the envelope should be used.
- It is permitted to add or change hydrochloride, sulfate, phosphate, ampules, tablets, etc. if the customer's order is correct in all respects except that it is specified in error; for example, specifies capsules and the product requested is properly designated and supplied in tablets.
- A letter or digit in the National Drug Code designation may be corrected if the controlled substance is described correctly, or the strength stated may be corrected if the quantity of controlled substance is not increased in any way.
- Order forms may be accepted when the customer has sent all three copies of the form to the supplier, but the customer's copy must be forwarded to him in advance of the shipping product.
- Order forms received by the supplier without interleaf carbon may be accepted, but the supplier must insert a replacement carbon between the forms before making any entries on the form.
- If a form is received which lists a package amount which is unavailable, a lesser amount may be shipped (e.g. order is for package size 100, if unavailable may ship package size 50), or if a form is received which lists a package amount which is unavailable, different package sizes not to exceed the original amount may be shipped (e.g. ordered 1 x 1000, may ship 10 x 100).
- Lesser number of line items ordered than line items specified, if the supplier crosses out the remaining lines before filling the form.
- Last line completed has been incorrectly noted. The order form should not be rejected when it is clear that this is due to misinterpretation, rather than an attempt to facilitate diversion.

A single item must be canceled for the following reasons, but the balance of the order may be shipped:

- If the number of packages, size of package, or strength has been altered by the person preparing the order form.

- If the item requested is discontinued or not listed, or is a non-controlled substance or is a controlled substance other than a Schedule I or II controlled substance.
- Strength is dittoed on the order form rather than designated.
- Strength is omitted (except trademark items when National Drug Code number is listed).
- Size of package incorrectly stated (quantity may be reduced).
- Size of package omitted.
- When a multiple item order is properly prepared and complete in all other respects but a single item has a non-correctable defect, this item may be canceled in lieu of returning the order form to the customer.

Refer to DEA Correspondences 6/29/92, 12/16/92, 7/28/94, and 9/14/95 for regulatory interpretations.

Cancellation and Voiding of Order Forms

(21 CFR 1305.15)

- A purchaser may cancel part or all of an order on an order form by notifying the supplier in writing of such cancellation. The supplier indicates the cancellation on copies 1 (brown) and 2 (green) of the order form by drawing a line through the canceled items and printing "Canceled" in the space provided for number of items shipped.
- A supplier may void part or all of an order form by notifying the purchaser in writing of such voiding on an **Order Form Rejection Notification (Form #6)**. The supplier should keep a copy of the order form and the notification. The supplier indicates the voiding in the manner prescribed for cancellation in paragraph (a) of this section.
- No cancellation or voiding permitted by this section affects in any way contract rights of either the purchaser or the supplier.

Narcotic Order Form Review

The DEA has established specific criteria for the acceptance of Narcotic Order Forms. To assure that the appropriate personnel receive continuous training with respect to these regulatory requirements, the previous day's Narcotic Order Forms must be reviewed for compliance with DEA regulations. Complete a **Narcotic Order Review Form (Form #7)** for any order forms that were processed in violation of DEA regulations. Discuss violations and the appropriate responsive action with personnel involved. File the Narcotic Order Review Form with a copy of the corresponding DEA Form 222.

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Procedure for Endorsing Order Forms

(21 CFR 1305.10)

- An order form made out to any supplier who cannot fill all or part of the order within the time limitation set forth in 1305.09 may be endorsed to another supplier for filling. The endorsement is made only by the supplier to whom the order form was first made, states (in the space provided on the reverse sides of copies 1 (brown) and 2 (green) of the order form) the name and address of the second supplier, and is signed by the person authorized to obtain and execute order forms on behalf of the first supplier. The first supplier may not fill any part of an order on an endorsed form. The second supplier fills the order if possible and if the supplier desires to do so, in accordance with 21 CFR 1305.09(b),(c) and (d) including shipping all substances directly to the purchaser.
- Distribution made on endorsed forms is reported by the second supplier in the same manner as all other distributions except that where the name of the supplier is requested on the reporting form, the second supplier records the name, address and registration number of the first supplier.

Lost or Stolen Order Forms

(21 CFR 1305.12)

- If a purchaser ascertains that an unfilled order form has been lost, the purchaser should execute another in triplicate and a statement containing the serial number and date of the lost form, and stating that the goods ordered in the first order form were not received through loss of that order form. Copy 3 (blue) of the second order form and a copy of the statement are retained with copy 3 (blue) of the order form first executed. A copy of the statement is attached to copies 1 (brown) and 2 (green) of the second order form sent to the supplier. If the first order form subsequently is received by the supplier to whom it was directed, the supplier marks it as "Not accepted" and returns copies 1 (brown) and 2 (green) to the purchaser, who attaches it to copy 3 (blue) and the statement.
- Whenever any used or unused order forms are stolen or lost (besides in the course of transmission) by any purchaser or supplier, immediately upon discovery of the theft or loss, that person reports it to the local office of the Drug Enforcement Administration stating the serial number of each form stolen or lost. If the theft or loss includes any original order forms received from purchasers and the supplier is unable to state the serial numbers of such order forms, the supplier should report the date or approximate date of receipt and the names and addresses of the purchasers. If an entire mailing envelope of order forms is lost or stolen, and the purchaser is unable to state the serial numbers of the order forms it contained, the purchaser should report, in lieu of the numbers of the forms contained in the envelope, the date or approximate date the envelope was issued. If any unused order form reported lost or stolen subsequently is recovered or found, the Registration Unit should be notified immediately.

Return of Unused Order Forms

(21 CFR 1305.14)

If the registration of any purchaser terminates (because the purchaser dies, ceases legal existence, discontinues business or professional practice, or changes the name or address shown on the registration), or is suspended or revoked (pursuant to 21 CFR 1301.45 or 1301.46 of this chapter), the purchaser (or his/her executor) should return all unused order forms for controlled substances listed in Schedules I and II for which the purchaser is registered to the nearest DEA office.

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REQUIRED REPORTS TO DEA

Wholesalers are required to report regularly to DEA's ARCOS Unit all receipts and disposals of all Schedule I and II drugs and Schedule III narcotics. In addition, wholesalers are required to submit other reports to DEA under certain circumstances (e.g., drug thefts, drug destructions and suspicious orders).

ARCOS Reports

(21 CFR 1304.33)

Every wholesaler who handles controlled substances in Schedule I and II and/or narcotics in Schedule III must report to the ARCOS Unit, as follows:

When

Annual Inventory	To be taken on December 31
Initial Inventory	To be taken on the effective date that a substance becomes reportable
Transaction Reporting	Quarterly, or, with DEA permission, monthly

All reports are required to be submitted within 15 days after the end of the report period by certified or registered mail, return receipt requested.

Note: The Automation of Reports and Consolidated Orders System (ARCOS) is the automated system developed by DEA to monitor selected controlled substances. ARCOS software enables the government to maintain a current and historical record of controlled substance inventories and transactions from the point of manufacture to the point of sale, distribution, or other disposition, and finally, to the dispensing (consumption) level.

Refer to The ARCOS Reporting Manual (Appendix A) for additional information.

Optional ARCOS Reporting Modes

Registrants using punched card accounting machines or electronic data processing equipment should submit either card decks or magnetic tapes. Registrants without automated systems must use the Manual ARCOS OCR Form - DEA Form 333 - (Form #9).

Reporting ARCOS Data from Another Location

For authorization to report ARCOS data from other than a registered location, a central reporting identified must be obtained from the ARCOS unit at the above address.

DEA Order Forms

(21 CFR 1305.09 (d))

Copy 2 (green) of the order form shall be sent to the local DEA office at the close of the month during which the order was filled. If the order is filled by partial shipments, Copy 2 (green) shall be forwarded at the close of the month during which the final shipment is made or during which the 60-day validity period expires.

Drug Thefts/Losses

(21 CFR 1301.74(c))

The registrant notifies the DEA field office in that area of any theft or significant loss upon discovery of such theft or loss on Report of Theft or Loss of Controlled Substances -DEA Form 106- (Form #10). Reports must be submitted within seven (7) days of the incident. Reporting in-transit losses is the supplier's responsibility. Reporting responsibility for shipments for which you have a signed receipt lies with the customer.

The reporting of inventory variances on DEA form 106 must be carefully evaluated. The most recent DEA policy addressing this issue reads as follows: "DEA regulations require a registrant to maintain inventory records to track the flow of controlled substances but do not require the maintenance of perpetual inventories. If a firm elects to regularly track inventory balances and notes a theoretical discrepancy, the firm should make every effort to resolve it within a timely manner. If it is determined that an actual discrepancy is the result of a theft or significant loss of controlled drug product, then the nearest DEA field office must be notified immediately upon discovery and the theft or loss must be reported on a DEA Form 106." Variances which are the result of record keeping or order filling errors need not be reported.

Any ARCOS reportable items filed on DEA Form 106 should also be submitted to ARCOS.

Note: Some state agencies require copies of all DEA Forms 106 filed with DEA.

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Drug Destructions

(21 CFR 1307.21)

If a wholesaler wants to destroy certain controlled substances (e.g., damaged goods, returns, etc.), the wholesaler should notify the DEA special agent in charge on **Registrant Inventory of Drugs Surrendered - DEA Form 41 - (Form #11)** in triplicate. The special agent in charge will inform the wholesaler how the drug destruction will be handled. Where the wholesaler regularly disposes of controlled substances, the DEA special agent in charge can, upon request, authorize dispositions without prior approval provided that these dispositions are recorded fully and meet all conditions established by the special agent in charge. Destructions of reportable items must be submitted to ARCOS on **ARCOS OCR Form 333**.

Note: It is DEA's policy that if a state agency having jurisdiction over wholesalers has adopted disposal procedures for controlled substances, the wholesaler may follow these procedures in lieu of DEA requirements.

Cardinal has a contract with Reverse Management Systems to handle our destruction of unsaleable merchandise. The product is sold to Reverse Management Systems who in turn destroys it and files **DEA Form 41**. Refer to **DEA Correspondence 8/12/94** for additional information.

DEA Form 41 should also be used for documenting a liquid controlled substance loss when the container accidentally breaks. Any loss of an ARCOS reportable item must also be reported to ARCOS. The pieces of the broken bottle do not need to be retained as evidence of the accident. Refer to **DEA correspondence 11/17/97**.

Suspicious Orders

(21 CFR 1301.74(b))

Wholesalers are responsible for designing and operating a system that will disclose to the wholesaler suspicious orders. The wholesaler informs the DEA field office in that area of all suspicious orders. Suspicious orders include orders of unusual size, orders deviating from a normal pattern and orders of unusual frequency. DEA has no specific form for this.

Establishing Suspicious Order Criteria

Wholesalers should establish written criteria of what constitutes a suspicious order. DEA leaves it to the wholesaler to make this determination. The key for the wholesaler is to establish **reasonable** criteria based upon customer purchasing patterns and then to adhere to them in monitoring orders.

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Either a computerized or a manual system can be utilized depending upon the wholesaler's preference and capability.

Complying with 21 CFR 1301.74 (b) is a two-step process. First, each Cardinal Division submits to DEA on a monthly basis an Ingredient Limit Report (Exhibit M). This report is based on a computer program which monitors customer controlled substance purchases for a month and compares these purchases to predetermined averages or limits and if a customer's purchase quantities exceed the established parameters, the customer's activity is printed on the report.

Second, on a daily basis cage and vault personnel should be policing and identifying individual orders that appear excessive in relation to what other customers are buying and/or the customer's purchase history. In these situations, DEA should be notified, if possible, before the order is shipped and a copy of all such orders should be maintained in the division's suspicious order file along with a Regulatory Agency Contact Form (Form #1) noting any specific instructions from DEA.

In an effort to assist cage and vault personnel in identifying these orders, we have developed Dosage Limit Charts (Exhibit P). The products included on these charts are those commonly audited by DEA during their inspections of our facilities and those which have a high potential for diversion. The dosage limits were set by calculating average sales quantities for Knoxville's retail customers and Boston's hospital customer and multiplying by 3 for ARCOS reportable items and 5 for non-ARCOS items.

These charts should be posted in your cage and vault and the hospital and retail dosage limit quantities for particular items should be posted at the product locations.

STRUCTURAL SECURITY

Schedule II Controlled Substances

(21 CFR 1301.72)

Schedule II controlled substances are stored in a vault, the physical structure of which meets the following specifications or equivalent:

If grandfathered (a vault constructed before, or under construction on, September 1, 1971): substantial construction with a steel door and a combination or key lock.

A vault constructed after September 1, 1971: walls, floor and ceiling constructed of at least eight inches of reinforced concrete or other substantial masonry, reinforced vertically and horizontally with one half inch steel rods tied six inches on center, or the structural equivalent to such reinforced walls, floors and ceilings.

The door and frame unit of the vault (GSA approved, Class V) conforms to the following specifications, or the equivalent:

- 30 man minutes against surreptitious entry;
- 10 man minutes against forced entry;
- 20 man hours against lock manipulation; and
- 20 man hours against radiological techniques.

Refer to DEA Correspondence 2/14/94 for a change in the specifications for the GSA Class V vault door.

DEA will also approve, on a case by case basis, UL listed Class M modular vaults for the storage of Schedule II controlled substances.

If operations require the vault to remain open for frequent access, then it must be equipped with a 'day gate' that is self-closing and self-locking or the equivalent. If the operation requires only that the vault be opened infrequently, such as to remove material in the morning and return material at night, and is always relocked immediately after use, a 'day gate' is not required.

Schedule III, IV, and V Controlled Substance Storage

DEA regulations (21 CFR 1301.72(b)) provide that Schedule III through V controlled substances must be secured as follows:

- In a cage located within the building on the premises meeting the specifications in 1301.72(b)(4)(ii-iv) and Section 1301.72 (b)(3)(ii)(a)(b), which read as follows:

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21 CFR 1031.72(b)(4):

- A cage, located within a building on the premises, meeting the following specifications:
- Having walls constructed of not less than No. 10 gauge steel fabric mounted on steel posts, which posts are:
 - (a) At least one inch in diameter;
 - (b) Set in concrete or installed with lag bolts that are pinned or brazed; and
 - (c) Which are placed no more than 10 feet apart with horizontal one and one half inch reinforcements every sixty inches;
- Having a mesh construction with openings of not more than two and one half inches across the square.
- Having a ceiling constructed of the same material, or in the alternative, a cage shall be erected which reaches and is securely attached to the structural ceiling of the building. A lighter gauge mesh may be used for the ceilings of large enclosed areas if walls are at least 14 feet in height.
- Is equipped with a door constructed of No. 10 gauge steel fabric on a metal door frame in a metal door flange, and in all other respects conforms to all the requirements of 21 CFR 1301.72(b) (3)(ii)."

21 CFR 1301.72(b)(3):

- Is equipped with self-closing, self-locking doors constructed of substantial material commensurate with the type of building construction, provided, however, a door which is kept closed and locked at all times when not in use and when in use is kept under direct observation of a responsible employee or agent of the registrant is permitted in lieu of a self-closing, self-locking door. Doors may be sliding or hinged. Regarding hinged doors, where hinges are mounted on the outside, such hinges shall be sealed, welded or otherwise constructed to inhibit removal. Locking devices for such doors shall be either of the multiple-position combination or key lock type and:
 - (a) In the case of key locks, shall require key control which limits access to a limited number of employees, or;
 - (b) In the case of combination locks, the combination shall be limited to a minimum number of employees and can be changed upon termination of employment of an employee having knowledge of the combination
- The controlled substance section also provides:
The track holding sliding 10-gauge steel gates in place is adjusted to meet self-closing requirements and the track is "trapped" to prevent the gate from being lifted out of the track surreptitiously.
Alternate: Where swinging cage doors are installed, hinges are properly secured.

Note: Schedule III through V controlled substances may be stored with Schedule II controlled substances under security measures previously described for Schedule II controlled substances.

Non-controlled substances and other materials may be stored with Schedule III through V controlled substances in any of the secure storage areas required by 21 CFR 1301.72(b) provided that permission for such storage of noncontrolled items is obtained in advance in writing from the Special Agent in Charge of DEA for the area in which storage area is situated. Any such permission tendered must be upon the Special Agent's written determination that such non-segregated storage does not diminish security effectiveness for Schedule III through V controlled substances. This authorization should be posted, in plain sight, in the secured area. An additional copy of the authorization letter should be retained by division management.

Company Vehicles

Vehicles used for the delivery and pickup of controlled substances are equipped with proper vehicle locks including, when appropriate, padlocks for cargo doors.

ACCESS CONTROL

General Warehouse

It is the policy of Cardinal to limit access to the general warehouse to only those employees who have a full-time work assignment that requires their presence in the warehouse. Each division shall maintain a list of employees authorized to have warehouse access. This access shall be controlled by a Card Entry Access Control System.

Specifically excluded from warehouse access without a full-time escort are the following groups of people:

All visitors including:

- Vendor sale representatives
- Cardinal sales representatives
- Management employees except those directly responsible for supervision of employees whose duties require them to be in the warehouse to perform their jobs
- Office employees except those whose duties require their presence in the warehouse.

Signs should be posted on all warehouse entrances regarding limited access (Exhibit B).

Outside contractors shall be monitored through a cooperative effort of warehouse supervisory personnel and full-time warehouse employees.

Employees of Cardinal Health who require temporary access to the warehouse may be issued "temporary passes" controlled by the Division Manager or his/her designee.

Controlled Substance Area

DEA regulations related to accessibility to storage areas state:

"The controlled substances storage areas shall be accessible only to an absolute minimum number of specifically authorized employees. When it is necessary for employee maintenance personnel, non-employee maintenance personnel, business guests, or visitors to be present in or pass through controlled substances storage areas, the registrant shall provide for adequate observation of the area by an employee specially authorized in writing." (21 CFR 1301.72(d))

Division management maintains an **Access and Surveillance List (Form #16)** of those employees whose responsibilities include authorization to access the vault or cage during the open-for-business period. Only those individuals are assigned a key or knowledge of a combination. The authorized access list should be posted along with a **"Restricted Area" (Exhibit C)** sign on the door(s) of the vault and cage.

Temporary employees should never be allowed access to the cage or vault, supervised or unsupervised.

Computer System

The computer system should include security levels to prohibit access to certain files unless an employee's job responsibilities warrant access. Employees should keep passwords to themselves and periodically change them to prevent access by others. Access should be limited for inventory adjustments, customer licensing information and financial records.

Computer room access should be controlled and limited to only those employees who have a full time work assignment that requires access to the computer room.

PROCEDURAL SECURITY

Receiving

Upon receipt, controlled substance items are physically checked by a receiving clerk. The quantity and description of the materials received are checked against the packing list provided by the vendor and against the controlled substance purchase order. The paperwork is signed and dated by the receiving clerk.

Any variations in quantities or visible damage to cartons are subject to immediate investigation. The matter should be reported to the supervisor prior to the departure of the carrier's representative from the area.

The carrier's representative is required to sign a statement written on the receiving report, describing the shortage, damage, etc. The receiving procedures should be verified by the receiving department supervisor if the actual receiving is handled by a designated employee.

If a discrepancy is noted and cannot be reconciled, the manufacturer(s) is contacted immediately by telephone and confirmation of the shortage or damage is verified in writing on the appropriate form. The loss of controlled substances is to be promptly reported to DEA. Refer to **Drug Thefts/Losses within Required Reports to DEA**. The supplier is responsible for reporting in transit losses of controlled substances by the common or contact carrier selected pursuant to 21 CFR 1301.74 (e) upon discovery of such theft or loss. Thefts must be reported whether or not the controlled substances subsequently are recovered and/or the responsible parties are identified and action taken against them (21 CFR 1301.74c).

Immediately on verification of the order received, the controlled substances and the corresponding paperwork are placed in a rolling locked cage and moved to the vault or to the controlled substance cage. No controlled substances may be left in the receiving area overnight or during periods when the receiving area is not under adequate surveillance.

Stocking

Verify all products and quantities against paperwork. Date and sign each purchase order. Bring discrepancies to the attention of the supervisor immediately. Forward original paperwork to appropriate department for data entry. Retain a copy in the controlled substance area.

For Schedule II items, the product is also verified against Copy 3 (blue) of the DEA order form. The date received and quantity received columns of the order form are completed and the Narcotic Order Blank Log is also updated.

Order Filling

For Schedule III, IV, V controlled substances, the order filler picks the items and quantities as requested on the picking document. As items are picked, each line of the picking document is initialed. The completed order and paperwork is staged pending verification.

For Schedule II controlled substances, the order form - DEA Form 222 - is reviewed for accuracy, then matched to the picking document to make sure all items agree. The items and quantities are picked as requested on the picking document. The picking document is initialed as each item is picked. The completed order and paperwork is staged pending verification. The following fields on the order form must be filled in:

- Packages Shipped
- Date Shipped
- Supplier DEA Registration Number
- National Drug Code

Quality Control

All controlled substance orders should be double checked for accuracy. The quality control clerk matches the items against the picking document and initials the paperwork. The merchandise and copy of the picking document are put in a bag and sealed - preferably a heat-sealed poly bag. The other copy of the pick document is retained at the division per division policy. The outside of the package should be labeled with the name of the customer. There should be no marks identifying the contents as controlled substances. The order is then staged within the controlled substance area until shipped.

Shipping

While most regular orders are manifested on the shipping dock, controlled substance orders are manifested in the cage or vault. Controlled substance packages are not to be left unattended in the shipping department. Product may be placed in locked roll-around cages or left in the controlled substance area until the delivery person is on the premises and ready to sign for them.

Delivery

The driver is required to obtain a customer signature for any packages delivered. The proof of delivery (manifest) is then returned to the carrier or division and retained per division policy.

Returns from Customers

All returns of controlled substances must be accompanied by a return authorization. The shipments must be distinguished from the other returns without revealing their contents to the delivery drivers. Upon receipt at the distribution center, these returns are to be transferred to the controlled substance area, and processed daily, noting the actual date of receipt.

Returns of Schedule II drugs are discouraged. They must be handled by issuing an order form - DEA Form 222 - to the customer.

Partial returns of controlled substances are prohibited.

Returns to Vendors

Controlled substances returned to the vendor should be accompanied by a return authorization from the vendor and a debit memo from the division. Creating the debit memo should remove the product from inventory. Proof of delivery should be filed at the division with a copy of the debit memo.

Physical Verification of Controlled Substances

When taking an inventory, the following steps should be taken,

- Do not allow any product into or out of the area during the count or recount.
- Counts should be conducted from count sheet with the on hand quantities suppressed.
- Compare the inventory results with the current on-hand balance of each item.
- Recount any out-of -balance item.
- Run audit report for any out-of-balance item. The **Selected Item Audit Report (Exhibit I)** gives all movement - purchases, returns, sales and inventory adjustments - for a requested item during a specified time frame.
- Research the error, checking for orders picked but not invoiced, mispicks, etc.
- Make appropriate adjustments as errors causing variances are detected.
- The Distribution Center Manager should sign off on the count sheet that he has reviewed all exceptions and that variances have been explained.
- File DEA Form 106, on a timely basis, for any item that cannot be resolved.
- Create ARCOS transactions for any reportable items on DEA Form 106.

Inventory Adjustments

Inventory adjustments for controlled substances should only be made after a thorough research. Documentation should be kept on file to support any adjustments.

Breakage

Documentation of breakage occurring in the vault or cage or during delivery is strongly recommended by the DEA. Maintenance of a breakage report is designed to help control any possible intentional breakage for the purpose of removing contents. Concern should arise when the same item is broken repeatedly.

Opening and Closing

The distribution center should be opened by at least two employees. These employees should meet at a safe, well-lighted, off-site location. The employees should then proceed to the distribution center and one employee should enter the distribution center while the other employee waits outside for an "ALL'S CLEAR" signal (the moving of blinds or flickering of lights, etc.). This procedure should be reversed when closing the distribution center. If the utilization of two employees at opening and closing time is totally impractical, one employee opening or closing the facility alone must have security hardware such as a portable panic button.

SHIPPING

Controlled Substance Shipping Area

Schedule II controlled substance orders are retained in the vault until the driver assigned such delivery is ready to depart the premises. At that time, the order is delivered by the vault supervisor to the driver who signs a log, circling the order number of the merchandise on the manifest. The driver then loads the packets or container into the delivery vehicle.

Schedule III through V controlled substance orders in sealed containers are held in the cage or staged in the defined controlled substance staging area under the direct supervision of the shipping department supervisor or a closed-circuit TV surveillance system. The driver assigned to the specific orders signs for the controlled substance items on a log form, circling the order number of the merchandise, and then loads the order on the delivery vehicle.

No controlled substance orders awaiting shipment are left in the shipping dock during the closed period. Such unshipped orders must be returned to the controlled substance cage at the close of business. The shipping department supervisor makes a thorough search of the shipping area prior to his/her departure from that area at the end of the business day.

Shipping Destination

DEA regulations require that controlled substances be distributed only to persons who are properly registered with DEA to possess the controlled substances and that Schedule II controlled substances only be shipped to the purchases at the location printed on the order form (DEA Form 222). Emergency will call orders are an exception to the rule.

Company Delivery Vehicles

Company employees assigned to driving delivery vehicles are screened in accordance with 21 CFR 1301.90 and Cardinal's policy which requires all prospective employees to consent to a drug test and a criminal record check. Delivery Vehicle Security Rules (Form #17) are reviewed, and signed by drivers.

The drivers deliver the Schedule II through V controlled substance orders to the customers and obtain a customer signature on one copy of the delivery order, which the driver then attaches to his/her manifest as proof of delivery.

Common Or Contract Delivery Vehicles

The company selects common or contract carriers that provide adequate security to guard against in-transit losses.

Further, the company takes precautions to assure that shipping containers do not indicate contents are controlled substances so as to guard against storage or in-transit losses.

When distributing controlled substances through agents, the company provides and requires adequate security to guard against theft and diversion while the substances are being stored or handled by the agent or agents.

Delivery Vehicle Security Rules (Form #17) are provided to contract carriers for distribution to drivers. Rules are reviewed and signed by drivers.

Depots/Line Haul Shipments

The use of cross-dockings and line hauls means vehicles with larger quantities of controlled substances and other merchandise and increased vulnerability to theft and/or diversion during the run from the distribution center to the depot. To protect against internal theft that may go undetected until the orders get to the customer level, ensure that vehicle contents are checked and signatures obtained upon pickup and delivery and that line haul vehicles are secured with a numbered seal that must be cut off or broken upon arrival at the depot.

Seal Construction Specifications

Durability A seal must be strong enough to prevent accidental breakage during normal use.

Design The design must be sufficiently complex to make unauthorized manufacture of a replacement seal difficult.

Tamperproof The seal should provide readily visible evidence of tampering and prevent reconstruction after the seal is closed; that is, a seal needs construction to make simulated locking difficult.

Individually Identifiable Identification is best accomplished by embossing serial numbers and owner identification on each seal.

Seal Accountability Procedures

Record of Application Seal numbers are entered or written on transportation documents such as bills of lading and manifests.

Time of Application Trailers must be sealed immediately after the loading is completed. Roll-up-type doors must be sealed at the loading dock. Swing-out doors must be sealed immediately after the unit is far enough away to close the doors.

Verification Seal examination and verification at every stop such as docks and transfer points. Multiple stops require new seals. Persons receiving sealed shipments must examine the seal and record the number on appropriate documentation, such as a log. Retain broken seals until it is determined whether there are any discrepancies. If there are none, destroy the seal. If discrepancies are found, retain the seal pending investigation.

U.S. Postal Mailing And Delivery

DEA regulations applicable to the use of the U.S. postal services state: "Controlled substances including Schedule II may be sent in any quantity by registered mail, return receipt requested, from one DEA registrant to another DEA registrant. The packaging must be in plain outer containers and give no indication of the contents."

Will Call Orders

Verification calls are to be made to the person in charge of the licensed premises for whom the order is intended and the name and description of the person picking up the order and the items included in the order are obtained.

When the individual arrives to pick up the order, the shipping supervisor checks the individual's name by asking for the driver's license and comparing the description of that provided by the person in charge of the licensed premises.

The person picking up the orders signs a **Will Call Log (Form #18)** that is dated and initialed by the shipping supervisor. The driver's license number and the person's name are then recorded both on the packing slip and the will call log.

Note: Many wholesalers have discontinued will call orders for controlled substances to avoid this high risk diversion exposure.

PERSONNEL

Additional information is located in the Employee Handbook.

Pre-Employment Screening

Cardinal Health requires all prospective employees to sign a **Pre-Employment Waiver (Form #19)** consent to a physical examination, which includes a drug test, and to an investigation made of their background and fitness for the position for which they have applied.

Cardinal Health reserves the right to immediately dismiss any employee when the results of the physical examination or drug test show signs of substance abuse and/or the background investigation reveals a history of criminal activity or other information which would deem the employee unfit for the position.

Any information associated with the physical examination or background investigation will be gathered and held in the strictest confidence by Cardinal Health in accordance with all applicable laws.

It is recommended that employment should not commence until the results of the physical examination and drug test are received and reviewed by the appropriate management personnel of Cardinal Health.

Upon commencement of employment, the new employee will complete a **Post-Employment Security Data Information Sheet (Form #20)**. The completed sheet is sent to the Corporate Compliance Department to conduct a criminal record check.

Controlled Substance Requirements

When an employee is promoted or transferred it may be necessary to review his/her background, depending on the nature of the transfer or promotion. Anyone allowed unsupervised access to the cage or vault in order to perform job functions must complete the **Test for Distribution Center Employees Handling Controlled Substances (Appendix B)** as well as the **Post-Employment Security Data Information Sheet**. The test and form must then be submitted to the Corporate Compliance Department. The department will grade the test and each individual must pass with a score no lower than 88%. If an employee does not pass the test, he/she must re-take the test at a later date and must obtain a passing score. The employee should be advised that prior to his or her working inside the controlled substance area an in-depth background investigation will be performed. The results of this background check along with the individuals test score will be shared with division management. The background check should be performed prior to the distribution center manager assigning the employee to the controlled substance area.

Security Rules

The following list of security rules has been developed to promote a safe and secure working environment for all employees and to assure compliance with United States Drug Enforcement Administration Security Regulations.

- Possessing, dispensing, or using a controlled substance without a medical prescription or reporting to work or working under the influence of alcohol or a controlled substance without a medical prescription is strictly prohibited. If an employee requires medication which may affect their performance, they should notify their supervisor immediately. DEA regulations regarding this should be posted in the facility (**Exhibit D**).
- Defacing Company property or willful negligence resulting in damage due to mishandling of merchandise or destructive abuse of machines or other Company equipment is prohibited.
- Falsifying an employment application, time card, production record, or other documents for yourself, customers, or another employee is prohibited.
- Protection of Company property is a responsibility all employees must share. Any employee discovering theft, loss, or malicious damage has an obligation to report the incident immediately to his supervisor.
- Fighting or instigating a fight with an employee, customer, or supplier while on Company property is strictly prohibited. No permanent personnel action will be taken until there is a complete investigation by Management.
- Tampering with or breaching Company security systems or policies is prohibited.
- Theft or unauthorized removal or use of Company or another employee's property is prohibited.
- Possession of firearms or illegal weapons on Company property is prohibited.
- Employees must use their own card entry access card, and access cards should not be loaned to other employees. Lost access cards should be reported to Management immediately.
- Employees must use authorized employee entrance when entering and exiting the building and must use their own access card when doing so.
- Entrance and exits to the facility are to be closed at all times, unless being used for the purpose they are designed.
- All bags, boxes, lunch boxes, containers, etc., are subject to inspection when exiting the facility. Signs to this affect should be posted throughout the distribution center (**Exhibit E**). Random periodic inspections could serve as a deterrent to internal theft.

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- Locker assignments and locks will be issued by Cardinal Health. Personal locks are not allowed. Locks will be subject to inspection by Management at their discretion.
- Visitor's entering the distribution center should be asked to sign in on a **Visitor's Log (Form #21)**, indicating their name, who they represent, time in, time out, and who they are visiting at the distribution center. Each visitor should wear a badge and must be escorted during their stay.
- Warehouse access is limited to employees who have full-time assignments that require their presence in the warehouse.
- Coats and pocketbooks are not allowed in the warehouse.
- Employees are to adhere to the posted access list for the cage and vault area.
- A **Miscellaneous Security Log (Form #22)** should be used to document any minor security-related incidents that occur but do not need to be explained in detail.

Security rules should be distributed to all employees and a signature obtained to document receipt.

Violence Prevention Procedures

The sign entitled **Violence Prevention Procedures (Exhibit G)** should be posted in conspicuous locations throughout the distribution center. These procedures should be reviewed with distribution center employees on a routine, periodic basis. It is paramount that all employees know exactly what to do in case they are confronted with a possible violent situation. Additional copies of these signs may be obtained through the Corporate Compliance Department.

Driver Security Rules

Drivers are required to adhere to the following security rules:

- Test all vehicle locks each day and immediately report defects to a supervisor.
- Keep all merchandise in the rear of the truck. Leave nothing in the cab.
- Secure the truck when making a delivery. Roll up all windows, lock all doors and take the keys with you.
- Do not stop for stranded motorists. This could be a setup for a hijack. If you feel it is necessary to call for assistance, do so at your next stop.
- Make it a habit to check your rear view mirror to see if you are being followed. If you suspect that you are being followed, obtain a description of the vehicle, the license number and the occupants. Proceed to the local police station; if this is not possible, proceed to your next stop and call the local police or the office.
- If you break down, stay with your truck. Leave only to call for assistance.
- Avoid areas where the threat of theft is high (such as back doors and alleys). If something appears suspicious, do not stop.

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- In the event of a robbery:
 - a. Offer no resistance.
 - b. Stay calm.
 - c. Be observant.

Driver security rules should be distributed to all drivers and a signature obtained to document receipt.

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CAH SWE 019194

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Test for Employees Handling Controlled Substances

Name _____

Location _____

Date _____

January 12, 2000

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CAH SWE 019195

CAH_MDL_PRIORPROD_DEA07_01384058

P-09320_00164

Company Policy

Per the DEA Compliance Manual, anyone allowed unsupervised access to the cage or vault in order to pick controlled substances orders must complete the *Test for Employees Handling Controlled Substances* as well as the Post-Employment Security Data Information Sheet. The test and this form must then be submitted to the Corporate Compliance Department in Dublin, Ohio. Corporate Compliance will grade the test. Each individual must pass with a score no lower than 88%. If an employee does not pass the test, he/she must re-take the test at a later date and must obtain a passing score. The employee should be advised that prior to his or her working inside the controlled substance area, an in-depth background check will be performed. The results of this background check along with the individual's test score will be shared with the Distribution Center Manager. The background check must be performed prior the Distribution Center Manager assigning the employee to the controlled substance area.

Instructions

1. Complete the information requested on the cover page.
2. Answer all 33 questions completely.
3. Complete the form entitled "Post-Employment Security Data Information Sheet", which is included at the end of this test booklet. This form is utilized for the background investigation portion of this testing process. If this form is not completed in full, your authorization to work with controlled substances will be delayed.
4. Seal the booklet with the circle provided.
5. Return the test booklet to your supervisor or manager to be forwarded to the Corporate Compliance Department to be scored.
6. The Corporate Compliance Department will notify the Distribution Center Manager, in writing, of the test score results and completion of the background investigation. This notification memo should be maintained at the distribution center for audit purposes.
7. If you have any questions involving this test or the Company's written policy and procedure in regards to the handling of controlled substances, notify the Compliance Department at (614) 757-7109.

1) There must be an authorized access list for both the cage and the vault?

True _____ False _____

2) DEA form 41 is used in the reporting of _____.

3) The DEA schedules Drug Wholesalers for inspection every:

- a) Year
- b) 2 years
- c) 3 years
- d) They have no set schedule

4) Which color copy of the 222 Order Forms must be sent to the DEA each month?

- a) blue
- b) green
- c) brown
- d) none of the above

5) You are allowed to ship controls and narcotics to a customer who has moved as long as he notifies you by phone of his new address.

True _____ False _____

6) The DEA Form 106 is used for reporting _____ of controlled substances.

7) The cage and vault must be inventoried at a minimum of :

- a) daily for items with movement
- b) weekly for items with movement
- c) monthly for all items
- d) a and c
- e) b and c

8) You may fill a narcotic blank that has no signature?

True _____ False _____

9) The proper schedules listed on the vast majority of Narcotic Order Forms consist of Schedules (fill in the blanks):

10) An employee who has knowledge of drug diversion from his employer by a fellow employee has an obligation to report such information to a responsible official of the company?

True _____ False _____

11) A Narcotic Blank (DEA form 222) is good for _____ days from the date it was issued.

12) DEA fines are calculated at \$ _____ per violation.

13) It is not necessary to have someone double check your Narcotic Orders prior to them leaving the distribution center.

True _____ False _____

14) _____ is the name of the unit within the DEA that requires us to send a computer tape at the end of each month.

15) As a wholesale drug distributor governed by the Drug Enforcement Administration, Cardinal Health is required to report suspicious or excessive purchases of controlled substances.

True _____ False _____

16) Possession, use, sale or purchase of any illegal drug on the job is contrary to company policy and is grounds for immediate termination.

True _____ False _____

17) In order to accept a Schedule II return from a customer, the distribution center must first issue a narcotic blank to the customer.

True _____ False _____

18) What is a Contact sheet and when should it be used? _____

19) The day-gate doors to both the cage and the vault must be self-_____ and self-_____
_____ according to Federal Regulations.

20) Controlled Substances may be left outside the approved controlled substances area overnight as long as they are left in a locked roll-around cage.

True _____ False _____

21) You may store other items inside the vault as long as you have written permission from the DEA.

True _____ False _____

22) The rule book used by the DEA to enforce regulations on the drug wholesale industry goes by the initials "C.F.R.". These initials stand for:

23) The "Selected Item Audit Report" lists:

- a) All receipts of a controlled substance
- b) All sales of a controlled substance
- c) All controlled substance adjustments
- d) All transactions of a controlled substance

24) It is Cardinal Health, Inc.'s policy to thoroughly discourage returns of scheduled narcotics.

True _____ False _____

25) How often should the report entitled "Ingredient Limits Report" or "Suspicious Order Analysis" be generated at your Distribution Center?

- a) Daily
- b) Once a week
- c) Once a month
- d) Quarterly

26) Vault and Cage Morgue merchandise is dead inventory and does not need to be counted.

True _____ False _____

27) The responsibility of verifying a customer license rests with:

- a) The DEA
- b) The Distribution Center
- c) Corporate Headquarters
- d) Regional Headquarters

28) You may sign a 222 narcotic order form if the customer gives you permission over the phone.

True _____ False _____

29) Cardinal Health, Inc. has a manual entitled DEA Compliance Manual which contains answers to frequently asked questions about controlled substance procedures.

True _____ False _____

30) List 5 things to look for when reviewing a 222 Narcotic Order Form:

31) A customer calls your distribution center and asks you to fill an order involving one of his blanks but to send the controlled substances to another location. Is this a violation of the Code of Federal Regulations?

Yes _____ No _____

32) It is advisable that you use white-out or a pencil when working with DEA Form 222 (Narcotic Order Form) in case you make a mistake.

True _____ False _____

33) All visitors at your Distribution Center entering the cage or vault area must be escorted by an employee on the authorized access list?

True _____ False _____

Thank you for completing this test on the handling of controlled substances. Please return this test to your supervisor. He/She will send the test the Cardinal Health, Inc. Corporate Compliance Department in Dublin, Ohio for grading. Your Distribution Center Manager will be notified of your score as soon as your test is graded.

DEA COMPLIANCE MANUAL

APPENDIX C

DEA Field Offices

DEA Regional Offices



Atlanta Division

Richard B. Russell Federal Building
75 Spring Street, S.W., Suite 740
Atlanta, GA 30303
(404) 331-4401
Fax: (404) 331-7340

*Area Covered: Georgia, North
Carolina, South Carolina, Tennessee*

Charleston Resident Office

5900 Core Avenue
Suite 100
North Charleston, SC 29406
(803) 308-6660
Fax: (803) 308-6670

Charlotte Resident Office

Nine Woodlawn Green
Suite 200
Charlotte, NC 28217
(704) 344-6188
Fax: (704) 344-6795

Columbia Resident Office

Strom Thurmond Federal Building
1835 Assembly Street, Room 1472
Columbia, SC 29201
(803) 765-5251
Fax: (803) 765-5410

Columbus Resident Office

120 12th Street
Room 316
Columbus, GA 31902
P.O. Box 1565
Columbus, GA 31902
(706) 649-7850
Fax: (706) 649-7872

Greensboro Resident Office

1801 Stanley Road
Suite 201
Greensboro, NC 27407
(910) 547-4210
Fax: (910) 547-4215

Knoxville Resident Office

1721 Midpark Drive
3rd Floor
Knoxville, TN 37921
(423) 584-9364
Fax: (423) 584-8763

Memphis Resident Office

Morgan Keegan Tower, Suite 500
50 N. Front Street
Memphis, TN 38103
(423) 544-3396
Fax: (423) 544-3025

Nashville Resident Office

Estes Kefauver Building
801 Broadway, Room 500
Nashville, TN 37203
(615) 736-5988
Fax: (615) 736-2221

Savannah Resident Office

Smith Kelly Building
300 Drayton Street, Suite 401
Savannah, GA 31401
(912) 652-4286
Fax: (912) 652-4050

Wilmington Resident Office

Two Princess Street, Room 322
Wilmington, NC 28401
(910) 343-4513
Fax: (910) 343-4463

Chicago Division

John C. Kluczynski Federal
Building
230 S. Dearborn Street, Room 1200
Chicago, IL 60604
(312) 353-7875
Fax: (312) 886-8439

*Area Covered: Illinois, Indiana,
Minnesota, North Dakota,
Wisconsin*

Fargo Resident Office

One N. Second Street
Suite 302
Fargo, ND 58102
(701) 239-5331
Fax: (701) 239-5248

Green Bay Post of Duty (Brown County/MJG Unit)

PO Box 12734
Green Bay, WI 54307-2734
(414) 448-6241
Fax: (414) 448-6376

Indianapolis Resident Office

Minton-Capehart Federal Building
575 N. Pennsylvania St., Room 290
Indianapolis, IN 46204
(317) 226-7977
Fax: (317) 226-7703

Madison Post of Duty

PO Box 92812
Madison, WI 53701-0981
(608) 264-5111
Fax: (608) 264-5116

Merrillville Resident Office

1571 E. 85th Avenue, Suite 200
Merrillville, IN 46410
(219) 681-7000

Milwaukee Resident Office

1000 N. Water Street, Suite 1010
Milwaukee, WI 53202
(414) 297-3395
Fax: (414) 297-1169

Minneapolis Resident Office

Federal Building
110 S. Fourth Street, Room 402
Minneapolis, MN 55401
(612) 348-1700
Fax: (612) 348-1708

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DEA Regional Offices



Rockford Resident Office

420 W. State Street
Rockford, IL 61101
(815) 987-8034

Springfield Resident Office

Illinois Business Center
400 W. Monroe Street, Suite 302
Springfield, IL 62704
(217) 492-4504
Fax: (217) 492-4507

Dallas Division

1880 Regal Row
Dallas, TX 75235
(214) 640-0801
Fax: (214) 649-0895
*Area Covered: Oklahoma, Texas
(Northern)*

Fort Worth Resident Office

Fritz W. Lanham Federal Building
819 Taylor Street, Room 13A33
Fort Worth, TX 76102
(817) 978-3455
(817) 978-4128

Lubbock Resident Office

5214 68th Street, Suite 401
Lubbock, TX 79424
(806) 798-7189
Fax: (806) 794-3149

Midland Resident Office

1004 N. Big String, Room 225
Midland, TX 79701
(915) 686-0356
Fax: (915) 682-3016

Oklahoma City District Office

3909 N. Classen Blvd., Suite 100
Oklahoma City, OK 73118
(405) 424-2213
Fax: (405) 524-3448

Tulsa Resident Office

5100 E. Skelly Drive, Suite 570
Tulsa, OK 74135-6548
(918) 581-6391
Fax: (918) 581-6439

Tyler Resident Office

909 ESE Loop 323, Suite 280
Tyler, TX 75701
(903) 534-0472

Detroit Division

Rick Finley Federal Building
431 Howard
Detroit, MI 48226
(313) 234-4000
Fax: (313) 234-4141
*Area Covered: Kentucky, Michigan,
Ohio*

Cincinnati Resident Office

Federal Office Building
550 Main Street, Room 8504
Cincinnati, OH 45202
(513) 684-3671
Fax: (513) 684-3672

Cleveland Resident Office

Courthouse Square Development
310 Lakeside Avenue, #395
Cleveland, OH 44113
(216) 522-3705
Fax: (216) 522-3704

Columbus Resident Office

78 E. Chestnut Street
Columbus, OH 43215
(614) 469-2595
Fax: (614) 469-5788

Grand Rapids Resident Office

65 Monroe Center, N.W.
Grand Rapids, MI 49503
(616) 456-2541
Fax: (616) 456-2001

Lexington Resident Office

1500 Leestown Road, Room 308
Lexington, KY 40511
(606) 233-2479
Fax: (606) 233-2590

Louisville Resident Office

New Federal Building, Room 1006
600 Dr. Martin Luther King Place
Louisville, KY 40202
(502) 582-5908
Fax: (502) 582-5535

Saginaw Resident Office

301 E. Genessee, Fourth Floor
Saginaw, MI 48607
(517) 758-4133
Fax: (517) 758-4013

Toledo Resident Office

234 N. Summitt Street, Room 106
Toledo, OH 43603
(419) 259-6490
Fax: (419) 259-3725

Houston Division

333 W. Loop N.
Suite 300
Houston, TX 77024
(713) 681-1771
Fax: (713) 220-2378
Area Covered: Texas (Southern)

Alpine Resident Office

810 N. 2nd Street
Alpine, TX 79830
P.O. Box 1282
Alpine, TX 79820
(915) 837-3421
Fax: (915) 837-2701

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April, 1997

DEA Regional Offices



Austin Resident Office

9009 Mountain Ridge Drive
Austin, TX 78759
(512) 346-2486
Fax: (512) 346-0825

Beaumont Resident Office

350 Magnolia, Suite 290
Beaumont, TX 77701-1899
(409) 839-2461
Fax: (409) 839-2551

Brownsville Resident Office

1100 FM 802, Suite 200
Brownsville, TX 78521
(210) 504-4100
Fax: (210) 504-4118

Corpus Christi Resident Office

Wilson Plaza, Suite 300
606 N. Carancahua
Corpus Christi, TX 78476
P.O. Box 2443
Corpus Christi, TX 78403
(512) 888-0150
Fax: (512) 888-0199

Eagle Pass Resident Office

342 Rio Grande
Room 102
Eagle Pass, TX 78852
(210) 773-5378
Fax: (210) 773-3008

El Paso District Office

700 E. San Antonio Street
Suite D-701
El Paso, TX 79901
(915) 534-6400
Fax: (915) 534-6034

Galveston Resident Office

6000 Broadway, Suite 104
Galveston, TX 77551
(409) 766-3568
Fax: (409) 766-3570

Laredo Resident Office

4804 N. Bartlett, Building 1050
Laredo, TX 78041
P.O. Drawer 2307
Laredo, TX 78044-2307
(210) 722-5201
Fax: (210) 726-2221

McAllen District Office

1919 Austin Street
McAllen, TX 78501-7030
(210) 618-8400
Fax: (210) 618-8478

San Antonio District Office

10127 Morocco, Suite 200
San Antonio, TX 78216
(210) 525-2900
Fax: (210) 525-2930

Los Angeles Division

Roybal Federal Building
255 E. Temple Street, 20th Floor
Los Angeles, CA 90012
(213) 894-2650
Fax: (213) 894-4244
*Area Covered: California (Southern),
Hawaii, Nevada*

Hawaii District Office

Honolulu, HI 96813
P.O. Box 50163
Honolulu, HI 96850
(808) 541-1930
Fax: (808) 541-3048

Nevada District Office

Foley Federal Building & U.S.
Courthouse
300 Las Vegas Blvd. S., Suite 204
Las Vegas, NV 89101-0023
(702) 388-6635
Fax: (702) 388-6894

Orange County Resident Office

Federal Building
34 Civic Center Plaza
Santa Ana, CA 92712
PO Box 12609
Santa Ana, CA 92712
(714) 836-2892
Fax: (714) 836-2925

Reno Resident Office

300 E. Second Street, Suite 1320
Reno, NV 89501
(702) 784-5617
Fax: (702) 784-5679

Riverside District Office

6377A Riverside Avenue, Suite 220
Riverside, CA 92516-3162
(909) 276-6642
Fax: (909) 276-6269

Ventura Resident Office

770 Padeo Camarillo, 3rd Floor
Camarillo, CA 93010
(805) 383-6454
Fax: (805) 383-6464

Miami Division

8400 N.W. 53rd Street
Miami, FL 33166
(305) 590-4870
Fax: (305) 590-4500
*Area Covered: Nassau, Bahamas,
Florida*

Fort Lauderdale District Office

1475 W. Cypress Creek Rd., Ste. 301
Fort Lauderdale, FL 33309
(305) 356-7700

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DEA Regional Offices



Fort Meyers Resident Office

12730 New Brittany Blvd., Suite 501
Fort Myers, FL 33907
(941) 275-3662
Fax: (941) 275-8945

Gainesville Resident Office

235 S. Main Street, Suite 202
Gainesville, FL 32601
(352) 371-2077
Fax: (904) 375-4356

Jacksonville Resident Office

4077 Woodcock Drive, Suite 210
Jacksonville, FL 32207
(904) 232-3566
Fax: (904) 232-2501

Key Largo Resident Office

95360 Overseas Highway, Suite 6
Key Largo, FL 33037
P.O. Box 2930
Key Largo, FL 33037
(305) 852-7874
Fax: (305) 536-5485

Orlando Resident Office

Heathrow Business Center
300 International Pkwy., Suite 424
Heathrow, FL 32746
(407) 333-7000
Fax: (407) 333-7012

Panama City Resident Office

5323 W. Highway 98, Suite 215
Panama City, FL 32401
(904) 769-3407
Fax: (904) 769-4118

Tallahassee Resident Office

3384 Capitol Circle N.E.
Tallahassee, FL 32308
(904) 942-8417
Fax: (904) 942-8420

Tampa District Office

5426 Bay Center Drive
Tampa, FL 33609
(813) 228-1268
Fax: (813) 228-1281

West Palm Beach Resident Office

1818 S. Australian Ave., Suite 300
West Palm Beach, FL 33409
(561) 684-8000

Midwest Division

United Missouri Bank Building
7911 Forsyth Blvd., Room 500
St. Louis, MO 63105
(314) 425-3241
Fax: (314) 425-3245
*Area Covered: Illinois (Southern),
Iowa, Kansas, Missouri, Nebraska,
South Dakota*

Cape Girardeau Resident Office

339 Broadway, Room 158
Cape Girardeau, MO 63701
(573) 334-1534
Fax: (573) 335-4117

Des Moines Resident Office

Federal Building
210 Walnut Street, Room 937
Des Moines, IA 50309
(515) 284-4700
Fax: (515) 284-4920

Kansas City Resident Office

8600 Farley Street, Suite 200
Overland Park, KS 66212
(913) 236-3257
Fax: (913) 236-3186

Omaha Resident Office

Old Federal Building
106 S. 15th Street, Room 1003
Omaha, NE 68102
(402) 221-4222
Fax: (402) 221-4225

Sioux Falls Resident Office

Shriver's Building
230 S. Phillips Avenue, Suite 407
Sioux Falls, SD 57102
(605) 330-4421
Fax: (605) 330-4420

Springfield Resident Office

901 St. Louis Street, Suite 301
Springfield, MO 65806
(417) 831-3948
Fax: (417) 831-0607

Wichita Resident Office

1919 N. Amidon, Suite 330
Wichita, KS 67203
(316) 838-2500
Fax: (316) 838-9123

New England Division

50 Staniford Street, Suite 200
Boston, MA 02114
(617) 557-2100
Fax: (617) 557-2135
*Area Covered: Connecticut, Maine,
Massachusetts, New Hampshire,
Rhode Island, Vermont*

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DEA Regional Offices



Bridgeport Resident Office

915 Lafayette Blvd., Room 200
Bridgeport, CT 06604
(203) 579-5591
Fax: (203) 579-5530

Burlington Resident Office

P.O. Box 446
Williston, VT 05495
(802) 951-6777
Fax: (802) 951-6489

Cape Cod Resident Office

P.O. Box 708
Barnstable, MA 02630
(508) 362-2117
Fax: (508) 362-8303

Concord Resident Office

197 Loudon Road, Suite 300
Concord, NH 03301
(603) 225-1574
Fax: (603) 225-1543

Hartford Resident Office

Ribicoff Federal Office Building
450 Main Street, Room 628
Hartford, CT 06103
(203) 240-3233
Fax: (203) 240-3703

Logan Airport Task Force

One Harbor Side Drive, Suite 1095
Boston, MA 02128
(617) 561-5764
Fax: (617) 561-5772

Portland Resident Office

1355 Congress Street, Suite D
Portland, ME 04102
(207) 780-3331
Fax: (207) 780-3413

Providence Resident Office

Two International Way
Warwick, RI 02886
(401) 732-2550
Fax: (401) 739-2576

Springfield Resident Office

1441 Main Street, Suite 1000
Springfield, MA 01103
(413) 785-0284
Fax: (413) 785-0483

New Jersey Division

Peter Rodino Federal Building
970 Broad Street, Room 806
Newark, NJ 07102
(201) 645-6060
Fax: (201) 645-6297
Area Covered: New Jersey

Atlantic City Resident Office

Executive Plaza
2111 New Road, Suite 203
North Field, NJ 08225
(609) 383-3322
Fax: (609) 383-0884

Camden Resident Office

1000 Crawford Place, Suite 200
Mount Laurel, NJ 08054
(609) 757-5407
Fax: (609) 757-5006

New Orleans Division

Three Lakeway Center
3838 N. Causeway Blvd., Suite 1800
Metairie, LA 70002
(504) 840-1100
Fax: (504) 840-1103
*Area Covered: Alabama, Arkansas,
Louisiana, Mississippi*

Baton Rouge Resident Office

2237 S. Acadian Thruway, Suite 306
Baton Rouge, LA 70808
(504) 389-0254
Fax: (504) 389-0772

Birmingham Resident Office

234 Goodwin Crest, Suite 420W
Birmingham, AL 35209
(205) 290-7150
Fax: (205) 290-7157

Gulfport Resident Office

One Government Plaza, Suite 230
Gulfport, MS 39502
(601) 863-2992
Fax: (601) 868-3112

Jackson Resident Office

Dr. A. H. McCoy Federal Building
100 W. Capitol Street, Suite 1213
Jackson, MS 39269
(601) 965-4400
Fax: (601) 965-4401

Little Rock Resident Office

10825 Financial Parkway, Suite 317
Little Rock, AR 72211-3557
(501) 324-5981
Fax: (501) 324-6900

Mobile Resident Office

900 Western American Cir., Ste. 501
Mobile, AL 36609
(334) 441-5831
Fax: (334) 441-5289

Montgomery District Office

2720-A Gunter Park Drive, West
Montgomery, AL 36109
(334) 260-1150
Fax: (334) 223-4430

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FOIA Confidential
Treatment Requested By
Cardinal

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DEA Regional Offices



Shreveport Resident Office

401 Edwards, Suite 510
Shreveport, LA 71101
(318) 676-4080
Fax: (318) 676-4085

New York Division

99 10th Avenue
New York, NY 10011
(212) 337-3900
Fax: (212) 337-2799
Area Covered: New York

Albany Resident Office

Leo W. O'Brien Federal Building,
Room 930
Clinton Avenue & N. Pearl Street
Albany, NY 12207
(518) 431-4700
Fax: (518) 472-4525

Buffalo Resident Office

28 Church Street, Suite 300
Buffalo, NY 14202
(716) 551-4421
Fax: (716) 551-5160

Long Island Resident Office

175 Pinelawn Road, Suite 205
Melville, NY 11747
(516) 420-4500
Fax: (516) 420-6944

Rochester Resident Office

P.O. Box 14210
Rochester, NY 14614
(716) 263-3180
Fax: (716) 263-5870

Syracuse Resident Office

4600 W. Genesee Street
Syracuse, NY 13219
(315) 468-2772
Fax: (315) 468-2985

Philadelphia Division

William J. Green, Jr. Federal
Building
600 Arch Street, Room 10224
Philadelphia, PA 19106
(215) 597-9530
Fax: (215) 597-6063
Area Covered: Delaware,
Pennsylvania

Allentown Resident Office

504 W. Hamilton Street, Suite 2500
Allentown, PA 18101
(610) 770-0940
Fax: (610) 435-6854

Harrisburg Resident Office

228 Walnut Street, Room 579
Harrisburg, PA 17101
P.O. Box 887
Harrisburg, PA 17108-0887
(717) 782-2270
Fax: (717) 782-4851

Pittsburgh Resident Office

William S. Moorehead Federal Bldg.
1000 Liberty Ave., Room 1328
Pittsburgh, PA 15222
(412) 644-3390
Fax: (412) 644-4745

Scranton Post of Duty

401 N. Adams Plaza, Suite 305
Scranton, PA 18503
(717) 782-2270
Fax: (717) 341-9094

Wilmington Resident Office

One Rodney Square
920 King Street, Suite 404
Wilmington, DE 19801
(302) 573-6184
Fax: (302) 573-6296

Phoenix Division

3010 N. Second Street, Suite 301
Phoenix, AZ 85012-3055
(602) 664-5600
Fax: (602) 664-5611
Area Covered: Arizona

Nogales Resident Office

1370 W. Fairway Drive
Nogales, AZ 85621-3895
(520) 281-1727
Fax: (520) 281-1850

Sierra Vista Resident Office

500 Fry Blvd., Suite L14
Sierra Vista, AZ 85635-1840
PO Box 2169
Sierra Vista, AZ 85636-2169
(520) 458-3691
Fax: (520) 670-5025

Tucson District Office

3285 E. Hemisphere Loop
Tucson, AZ 85706-5014
(520) 573-5500
Fax: (520) 573-5632

Yuma Resident Office

3150 Windsor Avenue, Suite 202
Yuma, AZ 85365-4905
(602) 344-9550
Fax: (602) 344-1444

Rocky Mountain Division

115 Inverness Drive, East
Englewood, CO 80112
(303) 705-7300
Fax: (303) 705-7414
Area Covered: Colorado, New Mexico,
Utah, Wyoming

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DEA Regional Offices



Albuquerque District Office

301 Martin Luther King Blvd., N.E.
Albuquerque, NM 87102
(505) 766-8925
Fax: (505) 766-8960

Cheyenne Resident Office

J. C. O'Mahoney Federal Building
2120 Capitol Avenue, Room 7010
Cheyenne, WY 82001
(307) 772-2391
Fax: (307) 772-2399

Colorado Springs Resident Office

111 S. Tejon, Suite 306
Colorado Springs, CO 80903
P.O. Box 350
Colorado Springs, CO 80901
(719) 471-1749
Fax: (719) 471-3647

Glenwood Springs Resident Office

401 23rd Street, Suite 300
Glenwood Springs, CO 81601
(970) 945-0744
Fax: (970) 945-8247

Las Cruces Resident Office

Loretto Town Center
505 N. Main Street, Suite 350
Las Cruces, NM 88001
(505) 527-6950
Fax: (505) 527-6966

Salt Lake City Resident Office

American Plaza III
47 West 200 South, Suite 401
Salt Lake City, UT 84101
(801) 524-4156
Fax: (801) 524-5364

San Diego Division

4560 Viewridge Avenue
San Diego, CA 91950
(619) 585-4200
Fax: (619) 585-4224
Area Covered: California (Border Area)

Carlsbad Resident Office

5973 Avenida Encinas, Suite 220
Carlsbad, CA 92008
(619) 931-2666
Fax: (619) 931-5974

Imperial County Resident Office

2425 LaBrucherie Road
Imperial, CA 92251
(619) 355-0857
Fax: (619) 355-2946

San Ysidro Resident Office

406 Virginia Avenue
San Ysidro, CA 92173
(619) 662-7115

San Francisco Division

450 Golden Gate Avenue
San Francisco, CA 94102
P.O. Box 36035
San Francisco, CA 94102
(415) 436-7860
Fax: (415) 436-7810
Area Covered: California (Northern)

Fresno Resident Office

1260 M Street, Room 200
Fresno, CA 93720
(209) 487-5402
Fax: (209) 487-5287

Monterey Resident Office

2560 Garden Road, Suite 207
Monterey, CA 93940
P.O. Box 3182
Monterey, CA 93942-3182
(408) 648-3050
Fax: (408) 648-3056

Sacramento Resident Office

1860 Howe Avenue, Suite 250
Sacramento, CA 95825
(916) 566-7160
Fax: (916) 566-7177

San Jose Resident Office

One N First Street, Suite 405
San Jose, CA 95113
(408) 291-7235
Fax: (408) 291-7720

Seattle Division

220 W. Mercer, Suite 104
Seattle, WA 98119
(206) 553-5443
Fax: (206) 553-1576
Area Covered: Alaska, Idaho, Montana, Oregon, Washington

Anchorage Resident Office

555 Cordova Street, Suite 600
Anchorage, AK 99501
(907) 271-5033
Fax: (907) 271-3097

Billings Resident Office

303 N. Broadway, Suite 302
Billings, MT 59101
(406) 657-6020
Fax: (406) 657-6047

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DEA Regional Offices



Blaine Resident Office

165 Second Street
Blaine, WA 98230
P.O. Box 1680
Blaine, WA 98231
(360) 332-8692
Fax: (360) 332-5704

Washington, D.C. Division

400 Sixth Street, S.W., Suite 2558
Washington, DC 20024
(202) 401-7834
Fax: (202) 401-7061
Area Covered: District of Columbia,
Maryland, Virginia, West Virginia

Boise Resident Office

607 N. Eighth Street, Fourth Floor
Boise, ID 83702
(208) 334-1620
Fax: (208) 334-9253

Baltimore District Office

200 St. Paul Place, Suite 2222
Baltimore, MD 21202
(410) 962-4800
Fax: (410) 962-3470

Eugene Resident Office

Federal Building
211 E. Seventh Avenue, Room 230
Eugene, OR 97401
(541) 465-6861
Fax: (541) 465-6796

Charleston Resident Office

Union Square
2 Monongala, Suite 202
Charleston, WV 25302
(304) 347-5209
Fax: (304) 347-5212

Medford Resident Office

310 Sixth Street, Room B-3
Medford, OR 97501
(541) 454-4407
Fax: (541) 776-4263

Norfolk Resident Office

Federal Office Building
200 Granby Street, Room 320
Norfolk, VA 23510
(804) 441-3152
Fax: (804) 441-6639

Portland Resident Office

Green Wyatt Federal Building
1220 S.W. Third Avenue, Room 1525
Portland, OR 97204
(503) 326-3371
Fax: (503) 326-2341

Richmond Resident Office

8600 Staples Mill Road, Suite B
Richmond, VA 23228
(804) 771-2871
Fax: (804) 771-8167

Spokane Resident Office

1124 W. Riverside, Suite L300
Spokane, WA 99201
(509) 353-2964
Fax: (509) 353-2963

Roanoke Resident Office

210 Franklin Road, SW
Roanoke, VA 24011
(540) 857-2555

Yakima Resident Office

402 E. Yakima Avenue
Yakima, WA 97501
PO Box 4025
Yakima, WA 97501
(509) 454-4407
Fax: (509) 454-4413

D-12
April, 1997

DEA

COMPLIANCE MANUAL

APPENDIX D

Forms and Exhibits

FORMS AND EXHIBITS

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CAH SWE 019215

CAH_MDL_PRIORPROD_DEA07_01384078

P-09320_00184

FORM NAME: REGULATORY AGENCY CONTACT FORM

FORM NUMBER: DEA # 1

FUNCTION: Used to document regulatory agency visits, inspections, and contacts. Provides Corporate Compliance Department with a means to monitor regulatory agency activity on a national level.

DISTRIBUTION: This two part form is to be completed as needed for any and all agency contacts. One copy must be sent to the Corporate Compliance Department in Dublin by the 15th of the following month. One copy to file.



REGULATORY AGENCY CONTACT FORM

1. _____ / _____
Division Name Date Time

2. Contact was made with:
 D.E.A. Representative State Board of Pharmacy Representative
 FDA Representative Other _____
(Please indicate agency)

3. Contact was made by:
 Telephone Visit at Division Visit at Agency

4. Contact initiated by: Division Agency

5. NAME, ADDRESS, AND TELEPHONE NUMBER OF REPRESENTATIVE

(Name) (Title)

(Address) (Office working out of)

(City) (State) (Zip)

6. PURPOSE OF CONTACT (AUDIT, REQUESTING INFORMATION (include DEA's response), REPORTING SUSPICIOUS ORDERS, EXCESSIVE PURCHASES, ETC.)

7. IF INFORMATION OR RECORDS WERE PROVIDED, COMPLETE THE FOLLOWING:

Information Sent: _____
Delivery Method: _____
Sent/Delivered By: _____

8. FOLLOW-UP REQUIRED? Yes No

9. NAME OF EMPLOYEE COMPLETING THIS FORM: _____

(Date) (Signed)

WHITE - Division

YELLOW - Corporate Compliance

DJR 1301

FORM NAME:

POWER OF ATTORNEY FOR DEA ORDER FORMS

FORM NUMBER:

DEA #2

FUNCTION:

Used to authorize specific employees to obtain and execute order forms (DEA Form 222).

POWER OF ATTORNEY FOR DEA ORDER FORMS

(Division Name)
(Address)

(DEA Number)

I, _____ the undersigned, who is authorized to sign the current application for registration of the above-named registrant under the Controlled Substances Act or Controlled Substances Import and Export Act, have made, constituted, and appointed, and by these presents, do make, constitute and appoint _____ (name of attorney-in-fact), my true and lawful attorney for me in my name, place and stead, to execute applications for books of official order forms and to sign such order forms in requisition for Schedule I and II controlled substances, in accordance with section 308 of the Controlled Substances Act (21 U.S.C. 828) and Part 1305 of Title 21 of the Code of Federal Regulations. I hereby ratify and confirm all that said attorney shall lawfully do or cause to be done by virtue hereof.

(Signature of person granting power)

I, _____ (name of attorney-in-fact), hereby affirm that I am the person named herein as attorney-in-fact and that the signature affixed hereto is my signature.

(Signature of attorney-in-fact)

Witnesses:

1. _____
2. _____

Signed and dated on the _____ day of _____, 19 _____,
at _____.

FORM NAME:

NOTICE OF REVOCATION

FORM NUMBER:

DEA # 3

FUNCTION:

Used to revoke power of attorney.

NOTICE OF REVOCATION

The foregoing power of attorney is hereby revoked by the undersigned, who is authorized to sign the current application for registration of the above-named registrant under the Controlled Substances Act of the Controlled Substances Import and Export Act. Written notice of this revocation has been given to the attorney-in-fact _____ this same day.

(Signature of person revoking power)

Witnesses:

1. _____
2. _____

Signed and dated on the _____ day of _____, 19 ,
at _____.

FORM NAME: DEA NARCOTIC BLANK LOG

FORM NUMBER: DEA # 4

FUNCTION: Used to record the order form numbers from the blanks received from DEA. Further information is also logged as a blank is used.

DEA NARCOTIC BLANK LOG

DATE BLANKS REC'D BY DIVISION	BLANK NUMBER	HELD BY DIVISION	SENT TO PURCHASING	PO/MRA NUMBER	DATE BLANK USED	VENDOR / CUSTOMER NAME	DATE PRODUCT RECEIVED

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CAH SWE 019223

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CAH_MDL_PRIORPROD_DEA07_01384086
P-09320_00192

FORM NAME: DEA 222 TRANSMISSION LOG

FORM NUMBER: DEA # 5

FUNCTION: Used in conjunction with Faxing Narcotic Order Forms
to verify faxed order form quantity and information.

FORM NAME:

ORDER FORM REJECTION NOTIFICATION

FORM NUMBER:

DEA # 6

FUNCTION:

Used to comply with DEA regulation which requires written notification to a customer when all or part of their order form (DEA Form 222) has been rejected.

Date: _____
Name: _____
Telephone Number: _____

The Drug Enforcement Administration has established specific criteria for the acceptance of Federal Order Forms (DEA Form 222). In some cases, we are required to return the form to you and request a new or corrected form before shipping. In other cases, we can make minor changes and process the form for shipment.

Your Federal Order Form _____ was not complete and/or correct in all respects. We have handled this as follows:

The omission and/or error indicated below is such that we are not permitted to process this form.

- _____ Form is altered.
- _____ Our name and/or address is not acceptable as shown.
- _____ Sixty days have elapsed from date of execution.
- _____ Item listed is not a Schedule II product.
- _____ Item listed has been discontinued. It is still available in _____ NDC # _____.
- _____ Package size is incorrect.
- _____ Product description is incomplete.
- _____ Number of packages or size is omitted.
- _____ Lines completed less than actually ordered.
- _____ Signature omitted.
- _____ Line number _____ is voided.

If your form is being returned.

- _____ Reference our phone conversation.
- _____ Please submit a new form.
- _____ Please revise attached form and return.
- _____ See example attached.

Changes indicated below have been made (as permitted by DEA), and order has been shipped. This notice is for informational purposes only. No action on your part is required.

- _____ Our name and/or address has been completed as required.
- _____ Number of line items stated in box provided was more than actually listed. We lined out the blank line(s).
- _____ You sent all three copies to us. We are returning Copy 3 for your files.
- _____ We corrected the NDC number on line item number _____.
- _____ We modified the dosage form on line item number _____. You requested _____ but the product is only supplied as _____.
- _____ Substitution of different size package has been made on line item _____.
- _____ Total product supplied is equal to or less than original request.
- _____ Line item number _____ was not correctable. We cancelled this line and processed rest of order. Please submit new form for this item.

THANK YOU FOR YOUR COOPERATION.

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CAH SWE 019227

CAH_MDL_PRIORPROD_DEA07_01384090
P-09320_00196

FORM NAME: NARCOTIC ORDER REVIEW FORM

FORM NUMBER: DEA # 7

FUNCTION: Used to document order form (DEA Form 222) violations when orders are not filled according to DEA regulations.

**CARDINAL HEALTH
NARCOTIC ORDER REVIEW FORM**

During a routine review of customer DEA Forms 222, order form number _____ (copy attached) was found to be filled in violation of DEA regulations.

The omission and/or error is indicated below:

- | | |
|--|---|
| _____ Order Form Not Written in Ink
or Not Signed | _____ NDC #, Strength or Dosage
Form Incorrect |
| _____ Customer/Registration Number:
Unable to I.D. or Altered | _____ " Lines Completed" Box Not
Filled In |
| _____ 60 Day Lapse from Date of
Execution | _____ "Lines Completed" Box
Altered |
| _____ Item: Unable to I.D. or
Altered | _____ Lines Completed Less than
Lines Actually Ordered |
| _____ Size, Number of Packages
or Strength Altered, Incorrect
or Omitted | _____ Our Name and Address or Date
Omitted |
| _____ Strength Dittoed | _____ Item Discontinued or Not a
Schedule II |
| | _____ Customer Voided a Line |

The resulting action should have been:

- Void entire order form _____
- Void single line _____
- Fill in omission _____

Appropriate personnel have been reminded of the regulatory requirements regarding the filling of order forms that have not been properly prepared.

Signature

Date

FORM NAME: MCA TRANSACTION REPORT

FORM NUMBER: DEA # 8

FUNCTION: Used to document any excessive purchase or unusual loss or activity of ephedrine, pseudoephedrine, and phenylpropanolamine products.



CARDINAL HEALTH

MCA TRANSACTION REPORT

Excessive Purchase Loss or Theft DEA Request

Supplier:

Name: _____
Business Address: _____
City: _____
State: _____
Zip Code: _____
Business Telephone: _____

Purchaser:

Name: _____
Business Address: _____
City: _____
State: _____
Zip Code: _____
Business Telephone: _____
Identification: _____

Shipping Address (If different than purchaser address):

Street: _____
City: _____
State: _____
Zip Code: _____
Date of Shipment: _____

Product Description: _____

Quantity and Form of Packaging: _____

If Loss or Disappearance:

Date of Loss: _____
Type of Loss: _____

Description of Circumstances: _____

FORM NAME: **ARCOS TRANSACTION REPORTING**

FORM NUMBER: **DEA # 9**

FUNCTION: **Used to submit correction or additional transactions to
ARCOS**

Public reporting burden for this collection of information is estimated to average 1 hour per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, reviewing and reviewing the collection of data needed, sending comments and reviewing the information, including suggestions for reducing this burden, to the Drug Enforcement Administration, Records Management Section, Washington, D.C. 20038-8293, Office of Management and Budget, Paperwork Reduction Project No. 1117-0002, Washington, D.C. 20503.

INSTRUCTIONS FOR CODING FORM

1. Characters should be printed neatly and conform as closely as possible to examples below.
2. All fields in this transaction (except the transaction code (Field 2) and the date code (Field 3)) are capable of being duplicated without coding the entire field to accomplish this. It is necessary that each field (to most character in each field to be duplicated) be coded using an equal (+) sign. The equal sign is the only character which can be used for this purpose.

MAILING INSTRUCTIONS

Retain duplicate for your records.
Mail the Original of completed form to:
Drug Enforcement Administration
ARCOS
P.O. Box 28293
Washington, D.C. 20038 - 8293

**ARCOS TRANSACTION
REPORTING**

DRUG ENFORCEMENT ADMINISTRATION

0 1 2 3 4 5 6 7 8 9 A B C D E F G H I J K L M N O P Q R S T U V W X Y Z * = ~~K E M~~

REPORTING REGISTRATION NUMBER	FDC ANNUAL REPORT NUMBER	NATIONAL DRUG CODE LABEL CODE	NATIONAL DRUG CODE PRODUCT CODE	PUG CODE	QUANTITY (No. of Packages, Volume or Weight)	U W T	ASSOCIATE REGISTRATION NUMBER	DEA ORDER FORM NUMBER	LOT NUMBER (DEA USE ONLY)	STRENGTH	TRANSACTION DATE			TRANSACTION IDENTIFIER
											MO	DAY	YEAR	

Previous editions may be used.

DEA Form - 333
(Feb. 1981)

Use Page 1 of Transaction Form

FORM NAME: REPORT OF LOSS OR THEFT OF CONTROLLED
SUBSTANCES (DEA FORM 106)

FORM NUMBER: DEA #10

FUNCTION: Used to document and report to DEA any loss or theft of
controlled substances.

DISTRIBUTION: Original and one copy must be submitted to the local DEA
office. One copy to the Corporate Compliance Department
in Dublin. Copy(s) to state licensing agency as required.
One copy to file. Must be submitted within seven (7) days of
the incident

**U.S. DEPARTMENT OF JUSTICE / DRUG ENFORCEMENT ADMINISTRATION
REPORT OF THEFT OR LOSS OF CONTROLLED SUBSTANCES**

**OMB APPROVAL
No. 1117-0001**

Federal Regulations require registrants to submit a detailed report of any theft or loss of Controlled Substances to the Drug Enforcement Administration. Complete the front and back of this form in triplicate. Forward the original and duplicate copies to the nearest DEA Office. Retain the triplicate copy in your records. Some states may also require a copy of this report.

**DEA MANUAL AUTHORITY:
Diversion Investigators 5124
FFS: 630-02**

1. NAME AND ADDRESS OF REGISTRANT (Include ZIP Code)

ZIP CODE

--	--	--	--	--	--

2. PHONE NO. (Include Area Code)

3. DEA REGISTRATION NUMBER

2 hr. prefix

7 digit suffix

--	--

--	--	--	--	--	--	--	--

4. DATE OF THEFT OR LOSS

5. PRINCIPAL BUSINESS OF REGISTRANT (Check one)

- | | |
|--|--|
| <input type="checkbox"/> Pharmacy | <input type="checkbox"/> Distributor |
| <input type="checkbox"/> Practitioner | <input type="checkbox"/> Methadone Program |
| <input type="checkbox"/> Manufacturer | <input type="checkbox"/> Other (specify) |
| <input type="checkbox"/> Hospital/Clinic | |

6. COUNTY IN WHICH REGISTRANT IS LOCATED

7. WAS THEFT REPORTED TO POLICE?

YES NO

8. NAME AND TELEPHONE NUMBER OF POLICE DEPARTMENT (Include Area Code)

9. NUMBER OF THEFTS OR LOSSES REGISTRANT HAS EXPERIENCED IN THE PAST 24 MONTHS ?

10. TYPE OF THEFT OR LOSS (Check one and complete items below as appropriate)

- | | | |
|---|---|---|
| <input type="checkbox"/> Night break-in | <input type="checkbox"/> Employee pilferage | <input type="checkbox"/> Other (Explain) |
| <input type="checkbox"/> Armed robbery | <input type="checkbox"/> Customer theft | <input type="checkbox"/> Lost in transit (Complete Item 14) |

11. IF ARMED ROBBERY, WAS ANYONE:

KILLED? No Yes (How many) _____
INJURED? No Yes (How many) _____

12. PURCHASE VALUE TO REGISTRANT OF CONTROLLED SUBSTANCES TAKEN ?

\$

13. WERE ANY PHARMACEUTICALS OR MERCHANDISE TAKEN ?

No Yes (Est. Value)

\$

IF LOST IN TRANSIT, COMPLETE THE FOLLOWING:

A. Name of Common Carrier

B. Name of Consignee

C. Consignee's DEA Registration Number

D. Was the carton received by the customer ?

Yes No

E. If received, did it appear to be tampered with ?

Yes No

F. Have you experienced losses in transit from this same carrier in the past ?

No Yes (How Many) _____

15. WHAT IDENTIFYING MARKS, SYMBOLS, OR PRICE CODES WERE ON THE LABELS OF THESE CONTAINERS THAT WOULD ASSIST IN IDENTIFYING THE PRODUCTS ?

16. IF OFFICIAL CONTROLLED SUBSTANCE ORDER FORMS (DEA-222) WERE STOLEN, GIVE NUMBERS

17. WHAT SECURITY MEASURES HAVE BEEN TAKEN TO PREVENT FUTURE THEFTS OR LOSSES ?

PRIVACY ACT INFORMATION

AUTHORITY: Section 301 of the Controlled Substances Act of 1970 (PL 91-513).

PURPOSE: Report theft or loss of Controlled Substances.

ROUTINE USES: The Controlled Substances Act authorizes the production of special reports required for statistical and analytical purposes. Disclosures of information from this system are made to the following categories of users for the purposes stated:

A. Other Federal law enforcement and regulatory agencies for law enforcement and regulatory purposes.

B. State and local law enforcement and regulatory agencies for law enforcement and regulatory purposes.

EFFECT: Failure to report theft or loss of controlled substances may result in penalties under Section 402 and 403 of the Controlled Substances Act.

LIST OF CONTROLLED SUBSTANCES LOST

Trade Name of Substance or Preparation	Name of Controlled Substance in Preparation	Dosage Strength and Form	Quantity
1. Desoxyn	Methamphetamine Hydrochloride	5 Mg Tablets	3 x 100
2. Demerol	Meperidine Hydrochloride	50 Mg/ml Vial	6 x 30 ml
3. Robitussin A-C	Codeine Phosphate	2 Mg/cc Liquid	12 Pints
4.			
5.			
6.			
7.			
8.			
9.			
10.			
11.			
12.			
13.			
14.			
15.			
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35.			
36.			
37.			
38.			
39.			
40.			
41.			
42.			
43.			
44.			
45.			
46.			
47.			

I certify that the foregoing information is correct to the best of my knowledge and belief.

Signature _____ Title _____ Date _____

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CAH_MDL_PRIORPROD_DEA07_01384099
P-09320_00205

FORM NAME: **REGISTRANT'S INVENTORY OF DRUGS
SURRENDERED (DEA Form 41)**

FORM NUMBER: **DEA # 11**

FUNCTION: **Used to document and report to DEA the destruction and
disposal of controlled substances.**

DISTRIBUTION: **Two copies must be submitted to the local DEA office. One
copy to the Corporate Compliance Department in Dublin.
One copy to file.**

OMB Approval No. 1117-0007	DEPARTMENT OF JUSTICE / DRUG ENFORCEMENT ADMINISTRATION REGISTRANTS INVENTORY OF DRUGS SURRENDERED	PACKAGE No.
-------------------------------	--	-------------

The following schedule is an inventory of controlled substances which is hereby surrendered to you for proper disposition.

FROM: (Include Name, Street, City, State and ZIP Code in space provided below).

Signature of applicant or authorized agent
Registrant's DEA Number
Registrant's Telephone Number

NOTE: REGISTERED MAIL IS REQUIRED FOR SHIPMENTS OF DRUGS VIA US POSTAL SERVICE (see instructions on reverse of form)

NAME OF DRUG OR PREPARATION <small>Registrants will fill in Columns 1, 2, 3, and 4 Only.</small>	Number of Containers	CONTENTS <small>(Number of grams, tablets, ounces or other units per container)</small>	Controlled Substances Content, <small>(Each Unit)</small>	FOR DEA USE ONLY		
				DISPOSITION	QUANTITY	
					GMS.	MGS.
1	2	3	4	5	6	7

DEA Form - 41
(Jul. 1984)

Previous edition may be used.

* See instructions on reverse side.

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CAH SWE 019238

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CAH_MDL_PRIORPROD_DEA07_01384101
P-09320_00207

NAME OF DRUG OR PREPARATION	Number of Containers	CONTENTS (Number of grams, tablets, ounces or other units per container)	Controlled Substance Content (Each Unit)	FOR DEA USE ONLY				
				DISPOSITION	QUANTITY			
					GMS.	MGS		
1	2	3	4	5	6	7		
17								
18								
19								
20								
21								
22								
23								
24								

The controlled substances surrendered in accordance with Title 21 of the Code of Federal Regulations, Section 1307.21, have been received in _____ packages purporting to contain the drugs listed on this inventory and have been: ******(1) Forwarded tape-sealed without opening; (2) Destroyed as indicated and the remainder forwarded tape-sealed after verifying contents; (3) Forwarded tape-sealed after verifying contents.

DATE _____ 19 _____ DESTROYED BY: _____

** Strike out lines not applicable.

WITNESSED BY: _____

INSTRUCTIONS

- List the name of the drug in column 1, the number of containers in column 2, the size of each container in column 3, and in column 4 the controlled substance content of each unit described in column 3; e.g., morphine sulfate tabs., 3 pkgs., 100 tabs., 1/4 gr. (16 mg.) or morphine sulfate tabs., 1 pkg., 82 tabs., 1/2 gr. (32 mg.), etc.
- All packages included on a single line should be identical in name, content and controlled substance strength.
- Prepare this form in quadruplicate. Mail two (2) copies of this form to the Special Agent in Charge, under separate cover. Enclose one additional copy in the shipment with the drugs. Retain one copy for your records. One copy will be returned to you as a receipt. No further receipt will be furnished to you unless specifically requested. Any further inquiries concerning these drugs should be addressed to the DEA District Office which serves your area.
- There is no provision for payment for drugs surrendered. This is merely a service rendered to registrants enabling them to clear their stocks and records of unwanted items.
- Drugs should be shipped tape-sealed via prepaid express or registered mail to Special Agent in Charge, Drug Enforcement Administration, of the DEA District Office which serves your area.

PRIVACY ACT INFORMATION

AUTHORITY: Section 307 of the Controlled Substances Act of 1970 (P.L. 91-513).

PURPOSE: To document the surrender of controlled substances which have been forwarded by registrants to DEA for disposal.

ROUTINE USES: This form is required by Federal Regulations for the surrender of unwanted Controlled Substances. Disclosures of information from this system are made to the following categories of users for the purposes stated.

- Other Federal law enforcement and regulatory agencies for law enforcement and regulatory purposes.
- State and local law enforcement and regulatory agencies for law enforcement and regulatory purposes.

EFFECT: Failure to document the surrender of unwanted Controlled Substances may result in prosecution for violation of the Controlled Substances Act.

FORM NAME:

KEY LOG

FORM NUMBER:

DEA # 12

FUNCTION:

Used to list personnel who have been issued keys.

FORM NAME: KEY RECEIPT

FORM NUMBER: DEA # 13

FUNCTION: Used to document the transfer of a key from the company to an employee.

Cardinal Health

Key Receipt

Employee Name: _____ **Date:** _____

Department: _____ **Key Number:** _____

I understand that I am responsible for the proper use of the key and will take all reasonable precautions to prevent any misuse. I will immediately notify the Cardinal Health Corporate Security Department in the event of theft or any other loss of the key. I will not have any copies of the key made and will turn in the key to the Cardinal Health Corporate Security Department when my employment terminates for whatever reason.

Employee Signature: _____

FORM NAME: MONTHLY ALARM WALK TEST REPORT

FORM NUMBER: DEA # 14

FUNCTION: Used to document proper functioning of alarm system and to maintain records of false alarms. Provides Corporate Compliance Department with information that can be used to evaluate alarm company service and divisional compliance with Company security policies.

DISTRIBUTION: This two-part form is to be completed at the end of each month. One copy must be sent to the Corporate Compliance Department in Dublin by the 15th of the following month. One copy to file.



MONTHLY ALARM WALK-TEST REPORT

DIVISION _____ FOR THE MONTH OF _____

ALARM COMPANY'S NAME _____

NUMBER OF FALSE ALARMS IN THE PAST MONTH _____

LAST FALSE ALARM _____

CAUSE OF FALSE ALARM _____

CORRECTIVE ACTION TAKEN _____

INSTRUCTIONS

Please check the following alarm equipment and indicate that it is functioning properly by placing a mark in the space provided.

- _____ Alarm call-up list is up-to-date
- _____ Ambush/Duress code on control panel is functioning
- _____ Sensitivity of all motion detectors is set correctly
- _____ Boxes and shelves are NOT blocking motion detectors
- _____ Photoelectric beams have a clean line of sight
- _____ Door contacts and audible alarms are functioning properly
- _____ Vault alarm system is functioning properly (scheduled openings & closings)
- _____ All closed circuit television cameras are working properly
- _____ All closed circuit television camera monitors are working properly
- _____ All electronically controlled doors are functioning properly
- _____ All robbery buttons are functioning properly (battery back-ups on hand-held buttons are fresh)
- _____ All intercoms are working properly

Signature of employee completing form

Date

This form is to be completed at the end of each month. Copy must be sent to the Corporate Compliance Office by the 15th of the following month.

WHITE - Division

YELLOW - Corporate Compliance

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CAH_MDL_PRIORPROD_DEA07_01384108

P-09320_00214

FORM NAME: INCIDENT REPORT

FORM NUMBER: DEA # 15

FUNCTION: Used to document security-related incidents which occur and require a detailed explanation (i.e., theft, burglary, vandalism).

FORM NAME:

ACCESS AND SURVEILLANCE LIST

FORM NUMBER:

DEA # 16

FUNCTION:

Used to facilitate compliance with DEA regulation which requires written authorization for cage and vault access.

FORM NAME:

DELIVERY VEHICLE SECURITY RULES

FORM NUMBER:

DEA # 17

FUNCTION:

Used to document security measures required by delivery vehicle drivers.

DELIVERY VEHICLE SECURITY

The following rules are intended to promote safety and security for drivers and their delivery vehicles. They are to be complied with at all times.

1. Keep all merchandise in the rear of the truck. Leave nothing in the cab.
2. Secure the truck when making a delivery. Roll up all windows, lock all doors, and take the keys with you.
3. Do not stop for stranded motorists. This could be a setup for a hijack. If you feel it is necessary to call for assistance, do so at your next stop.
4. Make it a habit to check your rearview mirror to see if you are being followed. If you suspect that you are being followed, obtain a description of the vehicle, the license number and the occupants. Proceed to the local police station; if this is not possible, proceed to your next stop, and call the local police or the office.
5. If you break down, stay with your truck. Leave only to call for assistance.
6. Avoid areas where the threat of theft is high (such as back doors and alleys). If something appears suspicious, do not stop.
7. In the event of a robbery:
 - A. Offer no resistance.
 - B. Stay calm.
 - C. Be observant.

Driver Signature: _____

Witness Signature: _____

FORM NAME:

WILL CALL LOG

_ FORM NUMBER:

DEA # 18

FUNCTION:

Used to document the pickup of an order by a customer.

WILL CALL LOG

Customer Name _____

Customer Number _____ Invoice Number _____

Date _____ Time _____

Number of Boxes _____ Number of Bags _____

Courier Service Name _____

Drivers Name (Print) _____

Drivers Signature _____

Drivers License Number _____ State _____

Driver ID# (Cab Number, etc.) _____

WILL CALL LOG

Customer Name _____

Customer Number _____ Invoice Number _____

Date _____ Time _____

Number of Boxes _____ Number of Bags _____

Courier Service Name _____

Drivers Name (Print) _____

Drivers Signature _____

Drivers License Number _____ State _____

Driver ID# (Cab Number, etc.) _____

FORM NAME: CONSENT AND RELEASE

FORM NUMBER: DEA #19

FUNCTION: Used during employment application process to obtain applicant's consent for background investigation and drug screening.



CONSENT AND RELEASE:

PLEASE READ THIS NOTICE AND CONSENT FORM CAREFULLY BEFORE SIGNING. YOU WILL BE PROVIDED WITH A COPY OF THIS FORM AT ANY TIME UPON REQUEST.

NOTICE AND CONSENT CONCERNING CONSUMER REPORTS FOR EMPLOYMENT APPLICATIONS AND EMPLOYMENT PURPOSES.

This form, which you should read carefully, has been provided to you because Cardinal Health ("Cardinal Health") will request consumer reports or investigate consumer reports in connection with your application for employment or during the course of your employment with Cardinal Health, if any. These background checks, and/or investigations, will be performed by Cardinal Health, in whole or in part, at Cardinal Health's discretion.

Cardinal Health's applicant background checks and employee investigations will also include the use of consumer reporting agencies to gather and report information to Cardinal Health in the form of consumer or investigative consumer reports, as regulated by federal law. Such reports, if obtained, will be prepared by consumer reporting agencies and may contain information concerning your credit standing or worthiness, character, general reputation, personal characteristics, or mode of living. Cardinal Health is not a consumer-reporting agency.

The type of reports that may be requested from consumer reporting agencies under this policy include, but are not limited to; credit reports, criminal records (for the maximum period permitted by applicable state and federal law), court records, driving records, and/or summaries of educational and employment records and histories. The information contained in these reports may be obtained by a consumer reporting agency, from public records, or through personal interviews with co-workers, neighbors, friends, associates, current or former employers, or other personal acquaintances. Any information contained in such reports may be taken into consideration in evaluating your suitability for employment, promotion, reassignment or retention as an employee.

If Cardinal Health requests an investigative consumer report to be performed by a consumer reporting agency, as defined by federal law, you will receive a notice indicating that the report has been requested no later than three days after the request is made to the agency. This additional notice, if issued, will provide you with further information pertaining to federal law governing investigative consumer reports. You will not receive a notice if Cardinal Health or a person or entity other than a consumer-reporting agency performs the investigation.

Your consent is required by law before Cardinal Health may obtain a consumer report or investigative consumer report from a consumer reporting agency pertaining to your application for employment and thereafter, during the course of your employment, if any, at Cardinal Health's discretion. Your signature below indicates that you have read and understand that Cardinal Health may request and review a consumer report or investigative consumer report regarding your background, and that you consent to the release of reports to Cardinal Health for employment purposes. This information may also be considered for any future decisions concerning your employment, promotion, reassignment or retention as an employee of Cardinal Health. Your signature additionally reflects your understanding that such consent will remain in effect indefinitely until you revoke it in writing, as described below.

8.00

Refusal to consent to a consumer report or an investigative consumer report as required by this notice, or any other attempt to interfere or failure to cooperate with Cardinal Health's lawful investigation, may result in rejection of your application, withdrawal of an offer of employment, or corrective discipline; up to and including termination of employment.

CONSENT STATEMENT:

I have carefully read and understand this notice and consent form and, by my signature below, consent to the release of consumer or investigative consumer reports, as defined above, to Cardinal Health in conjunction with my application for employment. I further understand that this consent will apply during the course of my employment with Cardinal Health, should I obtain such employment, and that such consent will remain in effect until revoked in a written document signed by me.

In the event that I wish to refuse or revoke my consent, I understand that I may do so by: 1. Signing the "Refusal or Revocation of Consent Statement" below, or 2. Sending a signed statement, indicating that I revoke my consent for Cardinal Health to obtain a consumer report or investigative consumer report, and submitting to:

Cardinal Health
Human Resources
7000 Cardinal Place
Dublin, OH 43017

I certify that the information I have provided to Cardinal Health, on this consent and release form, is correct to the best of my knowledge and I understand that any falsifications, misrepresentations, and/or omissions may result in my disqualification for consideration of employment or, if subsequently employed, my dismissal.

Name of Applicant/Employee

Applicant/Employee Signature

Today's Date

REFUSAL OR REVOCATION OF CONSENT STATEMENT:

(DO NOT SIGN UNLESS YOU HAVE DECIDED THAT YOU WILL NOT CONSENT, OR WILL NO LONGER CONSENT, TO CARDINAL HEALTH OBTAINING A CONSUMER REPORT OR AN INVESTIGATIVE CONSUMER REPORT)

I do not consent to Cardinal Health obtaining consumer reports or investigative consumer reports about me in connection with my application for employment or for any other employment purposes. If I have previously granted my consent, I hereby revoke that consent and understand that such revocation will take effect immediately after Cardinal Health receives this written revocation and has actual knowledge to communicate the revocation to those employees or agents who request consumer reports for Cardinal Health.

Name of Applicant/Employee

Applicant/Employee Signature

Today's Date

8.00

FORM NAME: EMPLOYMENT SECURITY INFORMATION

FORM NUMBER: DEA # 20

FUNCTION: Used to conduct background investigations on new employees.



Submitted ___/___/___

EMPLOYMENT SECURITY INFORMATION

Division: _____ Supervisor: _____

Department: _____ Date of Hire _____

Name: _____ (First) _____ (Middle) _____ (Last)

Present Address: _____ (Street) _____ (City) _____ (State) _____ (Zip)

Time at residence: _____ County of Residence: _____ Telephone: () _____

Previous Name	(First)	(Middle)	(Last)
Previous Residence	(Street)	(City)	(State) _____ (Zip) _____
Time at previous residence	County of previous residence		

Social Security Number _____ Drivers License Number _____ State _____

Date of Birth _____ Place of Birth _____ Height _____ Weight _____
Eye Color _____ Color of Hair _____ Marital Status _____

8.00

<u>Education Verification</u> Institution/School	City	State	Dates Attended	Degree

Have you ever been convicted of a crime (felony or misdemeanor), or do you have any pending charges? * Yes ___ No ___

If yes, identify the crime, the date of the conviction, the court where the conviction occurred, and the disposition of the case. Please provide any details you feel are relevant.

Conviction of a crime will not automatically disqualify you from employment, but will be considered as a part of the overall evaluation of your qualifications for the position sought.

Do not include convictions for which the good has been expunged or sealed in the following states: Alaska, California, Colorado, Connecticut, Florida, Illinois, Kansas, Kentucky, Maryland, Massachusetts, Mississippi, New Jersey, New York, North Carolina, Oklahoma, Oregon, Rhode Island, Utah, Virginia, Vermont, and West Virginia.

Do not provide information about juvenile convictions in the following states: California, Connecticut, Florida, Georgia, Kansas, Maryland, New Jersey, Oklahoma, Oregon, and West Virginia.

In California, do not include information about misdemeanor convictions for which you successfully completed probation, which were otherwise discharged. Also, do not include information about convictions for possession of insubstantial amounts of marijuana if the conviction occurred more than 2 years before today's date.

In Massachusetts, do not include information about general misdemeanor convictions. You may respond "No" to the question in any of the following circumstances: you were arrested but not convicted; you have only a conviction for a misdemeanor conviction for drunk driving, simple assault, speeding, minor traffic violations, arrays of disorderly conduct, or the peace; you have a misdemeanor conviction where the date of conviction or any resulting incarceration occurred more than 2 years prior to today's date; or you have a sealed conviction in a state where the conviction is sealed or expunged.

Waiver: I hereby authorize Cardinal Health, its subsidiaries or affiliates, and the Drug Enforcement Administration to make a complete investigation of me, my former business relations and employment, and any business organization or any other person to give full information and records about me. I hereby release Cardinal Health its subsidiaries, affiliates, officers, employees, informants and the Drug Enforcement Administration from liability arising from this investigation. Discovery of false information on this sheet may lead to discharge of my employment with Cardinal Health or its subsidiaries or affiliates.

Signature _____ Today's Date _____ 8.00

FORM NAME:

VISITOR LOG

FORM NUMBER:

DEA # 21

FUNCTION:

Used to document any visitor's entering the facility.

FORM NAME:

MISCELLANEOUS SECURITY LOG

FORM NUMBER:

DEA # 22

FUNCTION:

Used to document any minor security-related incidents that occur but do not need to be explained in detail (i.e., false alarms, open doors, alarm not set, etc.).

FORM NAME: DEA INSPECTION REPORT

FORM NUMBER: DEA # 23

FUNCTION: Used to document an inspection made by the DEA.

DEA INSPECTION REPORT

This form is to be completed by the Division Manager or his designee and forwarded to the Corporate Compliance Department upon completion of a DEA inspection.

DIVISION: _____

DATE: _____

A. General Information

- 1. Initiation Date _____
- 2. Leader Compliance Investigator _____
- 3. DEA Office _____
- 4. Closing Date -- Exit Interview _____
- 5. Total On-Site Days _____
- 6. Total On-Site Person Hours _____

B. Inventory Accountability Audit

- 1. Number of items audited _____

a) Description and class of items audited:

- 2. Audit timeframe in months _____
- 3. Number of items in variance _____

C. Inspection Focal Points (Check all that apply)

- 1. Background information
- 2. Biennial Inventory
- 3. Recordkeeping
- 4. DEA Form 222
- 5. Physical Security
- 6. Procedural Security
- 7. Shipping/Receiving Procedures
- 8. Registration Verification/Customers
- 9. ARCOS
- 10. Suspicious Order Monitoring
- 11. Destructions
- 12. Losses/Thefts
- 13. Pre-Employment Screening
- 14. Will Calls
- 15. Powers of Attorney
- 16. Other _____

D. Comments

Please document any significant comments, questions, criticisms made by the inspector during the inspection and exit interview and attach to this report.

**E. Resolution (to be completed by Corporate Compliance Department)
Please attach all related documentation.**

- 1. DEA Follow-Up
- 2. DEA Letter of Admonition
- 3. DEA Citation
- 4. Memorandum of Understanding
- 5. Informal Hearing
- 6. Formal Hearing
- 7. Court Proceeding
- 8. Consent Order
- 9. Total Violations Acknowledged in M.O.U.
- 10. Fines Sought
- 11. Fines Paid
- 12. Resolution Date

Yes	<input type="checkbox"/>	No	<input type="checkbox"/>
Yes	<input type="checkbox"/>	No	<input type="checkbox"/>
Yes	<input type="checkbox"/>	No	<input type="checkbox"/>
Yes	<input type="checkbox"/>	No	<input type="checkbox"/>
Yes	<input type="checkbox"/>	No	<input type="checkbox"/>
Yes	<input type="checkbox"/>	No	<input type="checkbox"/>
Yes	<input type="checkbox"/>	No	<input type="checkbox"/>
Yes	<input type="checkbox"/>	No	<input type="checkbox"/>

\$			

\$			

Signature and Title of Person Completing Form

Date

Division Manager's Signature

Date

FORM NAME: DEA ON-SITE BACKGROUND INFORMATION PACKAGE

FORM NUMBER: DEA # 24

FUNCTION: Used to provide DEA Investigators with company background information during DEA audits.

DEA ON-SITE BACKGROUND INFORMATION PACKAGE

SECTION I

FIRM'S BACKGROUND

- A. **Company Name:** _____
Address: _____

- Telephone Number:** () _____
Fax Number: () _____
- B. **Type of Firm:** _____
- C. **Corporate Headquarters:** _____

- D. **State of Incorporation:** _____
- E. **Subsidiaries:** _____
- F. **Corporate Officers: (See attached)**
- G. **Principle Management Personnel:**
(List all personnel and include the following information)
- Name:** _____
Title: _____
Length of Service: _____
- H. **Type of Business:** _____
- I. **Distribution Area:** _____
- J. **Methods of Distribution (Delivery Companies):** _____

- K. Hours of Operation: _____
- L. Number of Employees: _____
- M. How long at present location: _____
- N. Controlled substance sales as percentage of total sales: _____

SECTION II LICENSES AND REGISTRATIONS
 (attach copies of DEA registration and State licenses).

- A. DEA (See attached):
- B. State (See attached):

SECTION III
 (Briefly describe when inventories are taken and where records are maintained).

- A. Biennial Inventories: _____

- B. Periodic Inventories: _____

SECTION IV RECORDS / REPORTS
 (briefly describe the types of records and where maintained)

- A. Purchase Records: _____

- B. Sales Records: _____

- C. Return Records: _____

D. **DEA Form 222 - (blue & brown):** _____

E. **Power of Attorney:** _____

F. **DEA Form 106:** _____

G. **DEA Form 41:** _____

H. **ARCOS Records:** _____

I. **Suspicious/Excessive Customer Purchases:** _____

J. **Customer DEA Registrations and Verifications:** _____

SECTION V

PROCEDURES

(Briefly describe how the following is accomplished with respect to controlled substances).

A. **Receiving:**

B. **Order Filling:**

C. **Shipping:**

D. **Returns:**

SECTION VI

SECURITY

A. **Structure of Building:**

B. **Structure of Vault:**

C. **Structure of Cage:**

D. **Alarm Company:
Address:**

E. **Type of Alarm Hardware:**

F. **Type of Circuit (McCulloh Loop, etc.):**

G. **Notification Procedures:**

H. Who Responds:

I. Response Time:

Alarm Company: _____
Law Enforcement: _____
Distribution Center Personnel: _____

J. Persons with Alarm Keys/Passes:
(List all personnel and include the following information):

Name: _____ Title _____
Length of Service: _____

K. Persons with Access to Vault:
(List all personnel and include the following information)

Name: _____ Title _____
Date of Birth: _____ SS# _____

L. Persons with Access to Cage:
(List all personnel and include the following information)

Name: _____ Title _____
Date of Birth: _____ SS# _____

M. Employee Screening procedures (Describe hiring practices):

Cardinal Health, Inc.: DEA Registered Locations

<i>Distribution Center</i>	<i>Address</i>	<i>DEA Number</i>
Whitmire Dist. Corp. DBA Cardinal Health	7301 Los Volcanes Rd. NW Albuquerque NM 87121	RW0234928
Whitmire Distribution Corp. DBA Cardinal	914 Marcon Blvd. Allentown PA 18103	RW0191938
Whitmire Distribution Corp. DBA Cardinal	801 C St. N.W., Suite B Auburn WA 98001	RW0191813
Whitmire Distribution Corp. DBA Cardinal	2353 Prospect Dr. Aurora IL 60504	RW0231908
Whitmire Distribution Corp. DBA Cardinal	4770 (U) Forest St. Denver CO 80216	RW0192017
Whitmire Distribution Corp. DBA Cardinal	13188 Lakefront Drive Earth City MO 63045	RW0192106
Marmac Distributors, Inc. DBA Cardinal Health	4 Craftsman Road East Windsor CT 06088	RM0125484
Whitmire Distribution Corpora DBA Cardinal	3238 Dwight Road Elk Grove CA 95758	RW0236009
Whitmire Distribution Corp. DBA Cardinal	4 Gibrault Ct. Greensboro NC 27407	RW0243903
Ohio Valley-Clarksburg, Inc. DBA Cardinal Health	6540 Port Road Groveport OH 43125	RR0248179
Whitmire Distribution Corp. DBA Cardinal	7052 Grand Blvd. Ste. 112 Houston TX 77054	RW0191407
Whitmire Distribution Corp. DBA Cardinal	2901 Enloe St. Hudson WI 54106	RW0243725
Whitmire Distribution Corp. DBA Cardinal	7601 NE Gardner Avenue Kansas City MO 64120	RW0191926
Chapman Southeast, Inc. DBA Cardinal Health	2512 West Cott Blvd Knoxville TN 37931	RC0238104

Wednesday, January 05, 2000

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<i>Distribution Center</i>	<i>Address</i>	<i>DEA Number</i>
Cardinal Southeast, Inc DBA Cardinal Health	2045 Interstate Drive Lakeland FL 33805	RC0182080
CORD Logistics	1135 Heil Quaker Blvd. Ste. 100 LaVergne TN 37086	RC0229965
Cardinal Southeast, Inc. DBA Cardinal Health	1240 Gluckstadt Road Madison MS 39110	RC0221236
National Specialty Services, Inc.	556 Metroplex Dr. Nashville TN 37211	RN0184363
Whitmire Distribution Corp. DBA Cardinal	1351 Doubleday Ontario CA 91761	RW0192168
Daly, James W. Inc. DBA Cardinal Health	11 Centennial Drive Peabody MA 01960	RD0108200
Packaging Coordinators, Inc.	3001 Red Lion Road Philadelphia PA 19114	RP0225284
Whitmire Distribution Corp. DBA Cardinal	3821 East Broadway Phoenix AZ 85040	RW0224294
Whitmire Distribution Corp. DBA Cardinal	4422 South 38th Place Phoenix AZ 85040	RW0191940
Cardinal Southeast, Inc. DBA Cardinal Health	42 Ross Road Savannah GA 31405	RS0187612
Whitmire Distribution Corp. DBA Cardinal	955 West 3100 South South Salt La UT 84119	RW0191419
Cardinal Syracuse, Inc. DBA Cardinal Health	6012 Molloy Rd. Syracuse NY 13211	PC0003044
Whitmire Distribution Corp. DBA Cardinal	27680 Avenue Mentry Valencia CA 91355	RW0216449
Whitmire Distribution Corp. DBA Cardinal	7500 Mars Drive Waco TX 76712	RB0196522
Ohio Valley-Clarksburg, Inc. DBA Cardinal Health	71 Mil-Acres Dr. Wheeling WV 26003	RO0153609
National PharmPak Services, Inc.	3450 East Pike Zanesville OH 43701	RN0209583

Wednesday, January 05, 2000

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FOIA Confidential
Treatment Requested By
Cardinal

CONFIDENTIAL

CAH SWE 019274

CAH_MDL_PRIORPROD_DEA07_01384137
P-09320_00243

<i>Distribution Center</i>	<i>Address</i>	<i>DEA Number</i>
Williams Drug Dist., Inc.	1000 Linden Ave. Zanesville OH 43701	PT0186038
National PharmPak Services, Inc	850 Airport Distribution Drive Zanesville OH 43701	RN0244967
National PharmPak Services, Inc	1000 Linden Avenue Zanesville OH 43701	RN0231427

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FOIA Confidential
Treatment Requested By
Cardinal

CONFIDENTIAL

CAH SWE 019275

CAH_MDL_PRIORPROD_DEA07_01384138

P-09320_00244

FORM NAME: LIMITED POWER OF ATTORNEY

FORM NUMBER: DEA # 25

FUNCTION: Used for a change of pharmacy ownership and continuing operation on a previous owner's DEA registration.

LIMITED POWER OF ATTORNEY

(Name of Registrant)
(Address of Registrant)
(DEA Registration Number)

WHEREAS, _____ (hereinafter referred to as "Seller") and _____ (hereinafter referred to as "Buyer"), have executed a Purchase Agreement dated _____ and related documents, all with the intent of transferring a pharmacy _____ currently known as _____ (the "Pharmacy") and _____

WHEREAS, the transfer referred to in said Purchase Agreement is to take place, _____ or has taken place, on or about _____ and _____

WHEREAS, the parties to the Purchase Agreement and this Power of Attorney desire that the business carried on at _____ shall continue without interruption while BUYER obtains a DEA registration and the various licenses necessary in the State of _____ and until the transfers referred to in said Purchase Agreement take place; and _____

WHEREAS, such licenses are currently possessed by the Seller.

NOW, THEREFORE, in consideration of the mutual covenants and promises contained in the Purchase Agreement and related documents, and in an effort to implement the same, I, _____, who is authorized to sign the current application for registration of the above-named registrant under the Controlled Substances Act or Controlled Substances Import and Export Act, have made, constituted, and appointed, and by these presents do make, constitute, and appoint _____, my true and lawful attorney for me in my name, place, and stead, to execute applications for books of official order forms and to sign such order forms in accordance with Section 309 of the Controlled Substances Act (21 U.S.C. 828) and Part 305 or Title 21 of the Code of Federal Regulations for _____ Pharmacy located at _____ Such appointment shall authorize buyer to take all actions permitted by the undersigned pursuant to the aforesaid licenses, with respect to the management of the Pharmacy. I hereby ratify and confirm all that said Attorney-in-Fact shall lawfully do or cause to be done by virtue hereof, including the use of the DEA number of Seller until such time as a new DEA number and State pharmacy licenses are issued from the proper federal and state authorities.

IT IS FURTHER UNDERSTOOD that after the Closing Date in the Purchase Agreement, at such time as the undersigned no longer owns the assets of the pharmacy aforementioned, the operation of said pharmacy shall be solely in the control of Buyer and that nothing herein shall be construed so as to cause Buyer to be deemed the employee of the undersigned for any reason whatsoever, and that no action taken by Buyer shall give rise to any liability of the undersigned to any third party.

It is agreed by both parties that this appointment of Attorney-in-Fact shall terminate on the first to occur of Buyer obtaining all necessary licenses to operate the Pharmacy, or , 199 . (Power of Attorney cannot extend beyond 45 days of closing.)

By: _____

I, _____, accept the foregoing appointment, and I represent and warrant that I am a registered pharmacist, licensed to practice pharmacy in the State of _____, and I am the person named herein as Attorney-in-Fact and, that the signature affixed hereto is my signature.

By: _____

FORM NAME: DEA AND ARCOS DIVISION AUDIT RECAP

FORM #: DEA # 26

FUNCTION: Used to facilitate compliance with DEA record keeping and reporting requirements and assist the Corporate Compliance Department in monitoring divisional compliance and identifying potential problem areas.

DISTRIBUTION: This form is to be completed at the end of each month. One copy must be sent to the Corporate Compliance Department. One copy to your group office if applicable. One copy must remain on file at the division.



DEA & ARCOS DIVISION AUDIT RECAP

te _____

Division _____

1.	DP Number	Product	Counts		Variance
			Actual	OOH	
_____	_____	_____	_____	_____	_____
_____	_____	_____	_____	_____	_____
_____	_____	_____	_____	_____	_____
_____	_____	_____	_____	_____	_____

Discrepancies to counts and follow-up action taken: _____

- 2. Morgue - no controlled substances in morgue or in staging area for customer returns.
COMPLIANCE Yes _____ No _____
- 3. Receiving Area - No controlled substances left out or unattended in receiving.
COMPLIANCE Yes _____ No _____
- 4(a). Review of prior month's brown customer purchase copy of narcotic blanks.*
COMPLIANCE Yes _____ No _____
- 4(b). Review of prior month's DEA green copy of form 222.
COMPLIANCE Yes _____ No _____
- Review of prior month's blue receiving copy of narcotic blanks for purchases
COMPLIANCE Yes _____ No _____
- Division Manager or designee has approved and initialed blanks for excessive customer purchases.
COMPLIANCE Yes _____ No _____
- 7. DEA form 106 submitted timely to DEA for variances, losses or thefts.
Date variance occurred _____ Date loss/theft occurred _____
Date form 106 was submitted _____ Date form 106 was submitted _____
(attach copy of Form 106)
- 8. DEA Form 41 submitted for destruction and verification of ARCOS submission.
COMPLIANCE Yes _____ No _____
- 9. Excessive purchase report on file with copies of contact sheets sent to state and local DEA offices.
COMPLIANCE Yes _____ No _____
- 10. ARCOS and DEA Submission control form with return receipt copy, from prior month.
COMPLIANCE Yes _____ No _____
- 11(a). Month-end physical cycle counts for vault and cage with no variances.
VARIANCES Yes _____ No _____ If no, how many new variances this month? _____
- 11(b). Compliance to follow-up variance procedures.
Yes _____ No _____
- 12. ARCOS errors report researched and resubmitted.
Yes _____ No _____

Attach copies of blanks found not to be in compliance.

Division Manager's Signature _____

Program : QINVE240J WHITMIRE DIST CORP - MILWAUKEE Run Date: 12/30/94
Report : QINVE246R CONTROLLED SUBSTANCES INVENTORY Run Time: 19:49
Whse No.: 3034 Page: 1

The following report contains a complete inventory of Controlled Substances stocked at this distribution center warehouse at the close of business 12-30-94, in compliance with the Code of Federal Regulations:

#1304.13 BIENNIAL INVENTORY, and

ARCOS ANNUAL INVENTORY

Benjamin H. ...
Dist Center Manager
Date: 12/30/94

Stew Krave
Witness
Date: 12/30/94

60A*42	088-749	242	XANAX 100	TABS 0.25MG	A
60A*51	258-350	118	APAP/COD 1000	#3 TABS 30/300	A
60A*52	859-001	19	ALPRAZOLAM 500	TABS 1MG	A
60B*21	097-403	39	WYGESIC 100	TABS 65/650	A
60B*22	088-757	228	XANAX 100	TABS 0.5 MG	A
60B*23	076-252	12	P. ORINAL	TABS	A

- STOP -
ANY UNAUTHORIZED PERSONNEL
REQUESTING ENTRY INTO THE
WAREHOUSE SHOULD BE
INSTRUCTED TO RESPOND TO
THE FRONT DOOR OF THE
DISTRIBUTION CENTER

RESTRICTED AREA AUTHORIZED PERSONNEL ONLY

**UNAUTHORIZED PERSONNEL ENTERING THIS AREA WILL
BE SUBJECT TO SEVERE DISCIPLINARY ACTION
INCLUDING DISCHARGE**

**THIS ANNOUNCEMENT MADE NECESSARY BY INCREASED
STATE AND FEDERAL RESTRICTIONS PERTAINING TO
THE HANDLING AND CONTROL OF DANGEROUS DRUGS.**

EXHIBIT C

**RULES AND REGULATIONS AS PUBLISHED BY
THE DRUG ENFORCEMENT ADMINISTRATION
EFFECTIVE APRIL 17, 1975**

1301.91 Employee Responsibility to Report Drug Diversion

Reports of drug diversion by fellow employees is not only a necessary part of an overall employee security program but also serves the public interest at large. It is, therefore, the position of DEA that an employee who has knowledge of drug diversion from his employer by a fellow employee has an obligation to report such information to a responsible security official of the employer. The employer shall treat such information as confidential and shall take all reasonable steps to protect the confidentiality of the information and the identity of the employee furnishing information. A failure to report information of drug diversion will be considered in determining the feasibility of continuing to allow an employee to work in a drug security area. The employer shall inform all employees concerning this policy.

1301.92 Illicit Activities by Employees

It is the position of DEA that employees who possess, sell, use or divert controlled substances will subject themselves not only to State or Federal prosecution for any illicit activity, but shall also immediately become the subject of independent action regarding their continued employment. The employer will assess the seriousness of the employee's violation, the position of responsibility held by the employee, past record of employment, etc., in determining whether to suspend, transfer, terminate or take other action against the employee.

**ANYONE CARRYING
PERSONAL PACKAGES,
LUNCHBOXES, LUNCHBAGS,
OR PERSONAL CLOTHING
INTO THE WAREHOUSE WILL
BE SUBJECT TO SEARCH ON
LEAVING THE PREMISES**

**This announcement made necessary by increased State
and Federal restrictions pertaining to the handling and
control of dangerous drugs**



**VIOLENCE PREVENTION PROCEDURES
IN CASE OF ROBBERY**

DO

REMEMBER, THE SAFETY OF YOU AND YOUR EMPLOYEES IS THE NUMBER ONE CONCERN.

KEEP IT SHORT AND SMOOTH. The longer the robbery takes, the more nervous the robber becomes.

- Handle the entire procedure as if you were making a sale to a customer.
- The average robbery takes less than two minutes.

OBEY THE ROBBER'S ORDERS. Robbers seldom hurt people who cooperate with them.

- Let the robber know that you intend to obey.
- If you are not sure of what the robber is telling you to do, ask.
- Keep calm and observe what the robber looks like and what he is wearing. Remember exactly what he says.
- Try to get the robber out of the building as soon as possible.

TELL THE ROBBER ABOUT ANY POSSIBLE SURPRISES.

- If you must reach for something or move in any way, tell the robber what to expect.
- If someone is in the cage or vault.
- If the alarm system must be turned off, tell the robber.

CALL THE POLICE. Do not hang up until they tell you to do so. Notify the Cardinal Health, Inc. Compliance Department as soon as possible.

- Keep their numbers near the phone.
- Stay on the phone until they tell you they understand and have all the information they need.
- Keep at least one line into the division open for incoming calls.
- Write down a description of the robber and what they said.
- Protect the crime scene. Discontinue business until the police are finished. Do not touch any evidence.

DON'T

DON'T ARGUE WITH THE ROBBER.

- Give him all the cash and merchandise he wants.
- Remember, the robber has the upper hand – follow instructions.

DON'T FIGHT WITH THE ROBBER.

- The merchandise is not worth risking physical harm.
- Trying to overtake a robber is foolish, not heroic.

DON'T USE WEAPONS.

- Weapons breed violence.

DON'T CHASE THE ROBBER.

- You could be mistaken as the robber by the police.

**CHART II
TABLE OF OFFENSES AND PENALTIES
UNDER THE CONTROLLED SUBSTANCES ACT**

EXHIBIT H

	<u>First Offense</u>	<u>Second Offense</u>
REGISTRANT OFFENSES (COMMERCIAL) COMMITTED KNOWINGLY	Max: 1 yr., \$25,000	Max: 2 yrs., \$50,000
OTHER COMMERCIAL VIOLATIONS	Max: \$25,000 (civil fine)	Max: \$50,000 (civil fine)
DISTRIBUTION OF I & II SUBSTANCES NOT PURSUANT TO ORDER FORM, FALSE RECORDS, COMMUNICATIONS VIOLATION, ETC.	Max: 4 yrs., \$30,000	Max: 8 yrs., \$60,000
FELONY VIOLATOR AND ORGANIZER OR LEADER IN CONTINUING CRIMINAL ENTERPRISE (SUBSTANTIVE OFFENSE)	Max: Life, \$100,000 Profits, Assets Min: 10 yrs.	Max: Life, \$200,000 Profits, Assets Min: 20 yrs.
UNLAWFUL DISTRIBUTION, POSSESSION WITH INTENT TO DISTRIBUTE, MANU- FACTURE, ETC. (INCLUDES REGISTR- TRANTS) NARCOTICS IN SCHEDULES I & II	Max: 15 yrs., \$25,000	Max: 30 yrs., \$50,000 Special Parole: 6 yrs.
NONNARCOTIC SCHEDULE I, II AND ALL III SUBSTANCES	Max: 5 yrs., \$15,000	Max: 10 yrs., \$30,000
SCHEDULE IV SUBSTANCES	Max: 3 yrs., \$10,000	Max: 6 yrs., \$20,000
SCHEDULE V SUBSTANCES	Max: 1 yr., \$5,000	Max: 2 yrs., \$10,000
UNLAWFUL IMPORTATION OR EXPOR- TATION		
NARCOTICS IN SCHEDULES I & II	Max: 15 yrs., \$25,000	Max: 30 yrs., \$50,000
NONNARCOTIC SCHEDULE I & II AND ALL III SUBSTANCES	Max: 5 yrs., \$15,000	Max: 10 yrs., \$30,000
SCHEDULE IV SUBSTANCES	Max: 5 yrs., \$15,000	Max: 10 yrs., \$30,000
DANGEROUS SPECIAL DRUG OFFENDER WHO (A) IS AN ADULT AND (B) IS CHARGED WITH FELONY, AND 1) HAS TWO CONVICTIONS AND HAS SERVED TIME IN PRISON, OR 2) DEALS REG- ULARLY FOR PROFIT OR 3) IS AN ORGANIZER OF CONSPIRACY. (SEN- TENCING PROVISION)	Max: 25 yrs. Same fine otherwise prescribed	None
<u>SIMPLE POSSESSION OR DISTRIBUTION OF ANY CONTROLLED SUBSTANCE FOR NO</u>	Max:	Max:

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CAH_MDL_PRIORPROD_DEA07_01384151
P-09320_00257

05 11/02/95 N S S I N C.
SELECTED ITEM AUDIT REPORT

EM-035530 CHLORAL HYD 500MG SYR 100UD C4 100 EA EA VENDOR-11860 UDL LABORATORIES

DEA#- PO BOX 10319
ROCKFORD, IL 611313019

REIVED FROM- 1/01/95 TO-11/02/95

P.O. #	QTY	ORD	REC	DATE	REC	DEA #	VENDOR (IF DIFFERENT FROM ABOVE)	019616
1479400	1		1	7/12/95			JAMES W. DALY, INC., PO BOX 6041, PEABODY, MA	019616
1491400	1		1	7/20/95			JAMES W. DALY, INC., PO BOX 6041, PEABODY, MA	019616
1546800	1		1	8/07/95			JAMES W. DALY, INC., PO BOX 6041, PEABODY, MA	019616
1554600	2		2	8/09/95			CARDINAL SYRACUSE, 6012 MOLLOY ROAD, SYRACUSE, NY	13211

REDIT RETURNS

EMO #	RETRN	STOCK	VEND	CUST	CRD DATE	CUSTOMER	DEA #
20549	1	1			8/03/95	ROBERT E HAWKINS DMD, 4201 SOUTH CLOVERLEAF, ST PETERS, MO	63376
21019	1	1			8/10/95	ROBERT E HAWKINS DMD, 4201 SOUTH CLOVERLEAF, ST PETERS, MO	63376

USTOMER SALES

VOICE SHIP DATE	QTY	CUSTOMER	DEA #
46168 95/01/04	1	HIGH DESERT MEDICAL GROUP, 43845 N 10TH ST WEST, STE 2B, LANCASTER, CA	93534
67384 95/07/13	1	ROBERT E HAWKINS DMD, 4201 SOUTH CLOVERLEAF, ST PETERS, MO	63376
60331 95/06/30		ROBERT E HAWKINS DMD, 4201 SOUTH CLOVERLEAF, ST PETERS, MO	63376
74154 95/07/24	1	ROBERT E HAWKINS DMD, 4201 SOUTH CLOVERLEAF, ST PETERS, MO	63376
83528 95/08/08	1	JAMES WILLMOT CLINIC, 100 MEDICAL CENTER DRIVE, WOODRUFF, SC	293881
81569 95/08/03		JAMES WILLMOT CLINIC, 100 MEDICAL CENTER DRIVE, WOODRUFF, SC	293881
85953 95/08/10	1	ROBERT E HAWKINS DMD, 4201 SOUTH CLOVERLEAF, ST PETERS, MO	63376

ADJUSTMENTS

QUANTITY-	DATE-	ADJUSTMENT CODE-	MINUS VERIFICATION	TEXT-EXPIRED MERCHANDISE
19	2/24/95			
QUANTITY-	DATE-	ADJUSTMENT CODE-	CREDIT RETURNS AUTHORIZED SCRIP	TEXT-CUSTOMER RETURN
1	8/03/95			

CONTROLLED SUBSTANCES REGISTRATION CERTIFICATE
UNITED STATES DEPARTMENT OF JUSTICE
DRUG ENFORCEMENT ADMINISTRATION
WASHINGTON, D.C. 20537

Controlled Substances Act as hereinafter reads in part as follows:
304. (a) A registration pursuant to section 303 to manufacture, distribute, or dispense a controlled substance may be suspended or revoked by the Attorney General upon a finding that the registrant:
(1) has materially falsified any application filed pursuant to or required by this title or title II;
(2) has been convicted of a felony under this title or title II or any other law of the United States, or of any State, relating to any substance defined in this title as a controlled substance; or
(3) has had his State license or registration suspended, revoked, or denied by competent State authority and is no longer authorized by State law to engage in the manufacturing, distribution, or dispensing of controlled substances.

DEA REGISTRATION NUMBER	THIS REGISTRATION EXPIRES	FEE PAID
RW0191685	05-31-96	\$439.00

SCHEDULES	BUSINESS ACTIVITY	DATE ISSUED
2,3,3N,4,5	DISTRIBUTOR	04-20-95

WHITMIRE DISTRIBUTION CORP DBA CARDINAL HEALTH 3530 PAN AMERICAN FWY NE ALBUQUERQUE, NM	87107
--	-------

THIS CERTIFICATE IS NOT TRANSFERABLE ON CHANGE OF OWNERSHIP, CONTROL, LOCATION, BUSINESS ACTIVITY, OR VALID AFTER THE EXPIRATION DATE.

✓

speedigram®

FROM
BAILEY DRUG COMPANY, INC.
1000 LINDEN AVE.
ZANESVILLE, OH 43701

DEAR VALUED CUSTOMER,

ACCORDING TO OUR RECORDS, YOUR DEA REGISTRATION EXPIRES ON 8/31/95.
IN ORDER TO CONTINUE TO PROCESS YOUR CONTROLLED SUBSTANCE
ORDERS. PLEASE PROVIDE US WITH A COPY OF YOUR RENEWED DEA
REGISTRATION.

AT THIS TIME, WE ARE ALSO REQUESTING A COPY OF YOUR CURRENT STATE
LICENSE.

PLEASE SEND YOUR COPY TO THE ATTENTION OF LOREN TODD.

THANK YOU.

TO
20211
THE CLEVELAND CLINIC PHCY #2
CRILE BLDG-2ND FLOOR
2049 E. 100TH ST.
CLEVELAND, OH 44106

EXHIBIT L

December 1, 1995

DEAR VALUED CUSTOMER:

Our records indicate that your D.E.A. Registration Certificate expires as of

_____.

Please provide us with a copy of your current Registration Certificate as soon as possible to avoid service interruption of Controlled Substance Items.

A self-addressed envelope is enclosed for your convenience.

Thank you in advance for your prompt attention to this matter.

Sincerely,

Division Manager

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CAH SWE 019292

CAH_MDL_PRIORPROD_DEA07_01384155

P-09320_00261

**CARDINAL HEALTH
DEA REGISTRATION VERIFICATION FORM**

Dear Customer:

The Code of Federal Regulations (21 CFR 1301.74(a)) requires that we maintain your current DEA and State registration numbers in our files. Please allow our sales representative to transcribe the pertinent information.

DEA CONTROLLED SUBSTANCES REGISTRATION CERTIFICATE

Customer Name: _____

Address: _____

Registration Number: ___/___ ___/___/___/___/___/___/___
 Two letter prefix Seven letter suffix

Expiration Date: _____

(Circle permitted schedules 2 2N 3 3N 4 5)

STATE REGISTRATION CERTIFICATE

Registration (License) Number: _____

Expiration Date: _____

SIGNATURE

(Cardinal Health Sales Representative)

Solemons Company
Suspicious Order Monitoring
Arcos Report
For Hospitals/Managed Care

In Date 11/08/95 16:46:05
Inth 1 Oct 95
Sector Used: 2.0

Order Date Order Number Item Number HCD Number Item Description Marc Code Qty Sold Item Grams Total Grams

Customer: 1073 AMERICAN MEDICAL BILLING SERV 409A PLEASANT HOME RD AUGUSTA GA 30907 DEA DA4479019

Ingredient: 9193 HYDROCODONE BITARTRATE

10/30/95	2236093	103783	102-174505	HYDROCODN W/APA	3R	1	1.51125	1.51125
10/02/95	2216837	103783	102-174505	HYDROCODN W/APA	3R	1	1.51125	1.51125
10/11/95	2223938	116870	456-060101	BANCAP-HC 100S	3R	1	.30270	.30270
10/02/95	2216837	148976	59630-010004	PROTUSS LIQ 40Z	3R	1	.07161	.07161
10/13/95	2225790	155501	50474-092501	LORTAB 2-5MG 10	3R	1	.15135	.15135
10/11/95	2223938	169533	50474-090916	LORTAB ELIXIR P	3R	1	.14323	.14323
10/31/95	2237143	231178	60951-064070	HYDROCODONE/APA	3R	1	.45405	.45405
10/17/95	2227771	231178	60951-064070	HYDROCODONE/APA	3R	1	.45405	.45405
10/05/95	2219561	231178	60951-064070	HYDROCODONE/APA	3R	1	.45405	.45405

Customer Total: 5.05354
Ingredient Limit: 4.86380

Ingredient: 9308 MORPHINE SULFATE.SM20

10/23/95	2231056	116384	0-064901	MORPH SUL 2MG 1	2	2	.01504	.03008
10/19/95	2229180	127721	641-016825	MORPH SUL INJ 5	2	1	.11750	.11750
10/30/95	2235780	133809	54-378563	MORPHINE SUL 10	2	2	.75200	1.50400
10/19/95	2229185	144667	641-234541	MORPH SUL INJ 1	2	5	.22568	1.12800
10/31/95	2236852	145056	34-052302	HSIR 0/S COMC 2	2	2	1.80400	3.60800
10/16/95	2226768	181087	34-051410	HS CONTIN 15MG	2	1	1.12800	1.12800
10/02/95	2216465	181087	34-051410	HS CONTIN 15MG	2	1	1.12800	1.12800
10/31/95	2236852	234445	34-051410	HSIR 15MG 100S	2	1	1.12800	1.12800
10/31/95	2236852	234446	34-051910	HSIR 30MG 100S	2	1	2.25600	2.25600

Customer Total: 13.53318
Ingredient Limit: 12.24846

Ingredient: 9801 FENTANYL CITRATE

10/16/95	2226768	104563	50458-003505	DURAGESIC 75MCG	2	1	.03750	.03750
10/05/95	2219549	104365	50458-003505	DURAGESIC 75MCG	2	2	.03750	.07500
10/16/95	2226768	104365	50458-003405	DURAGESIC 50MCG	2	3	.02500	.07500
10/05/95	2219549	104365	50458-003405	DURAGESIC 50MCG	2	2	.02500	.05000
10/02/95	2216465	104365	50458-003405	DURAGESIC 50MCG	2	3	.02500	.07500
10/30/95	2235780	204368	50458-003305	DURAGESIC 25MCG	2	3	.01250	.03750
10/16/95	2226768	204368	50458-003305	DURAGESIC 25MCG	2	3	.01250	.03750
10/02/95	2216465	204368	50458-003305	DURAGESIC 25MCG	2	3	.01250	.03750

Customer Total: .42500
Ingredient Limit: .27236

CUSTOMER DEA EXCEPTION REPORT

CUJUB2U
CARDINAL P AVANNAH

CUST #	CUSTOMER	ADDRESS	CITY / STATE	ZIP	DEA NUMBER	DEA EXP. DATE
02955-0	SOUTHSIDE PHARMACY	2711 OLD SAVANNAH ROAD	AUGUSTA GA	30906	AS1926952	02/28/97
18062-0	SCOTT'S PHARMACY	WAYNE & 15TH STREET	ALMA GA	31510	AS2009579	02/28/99
18074-0	SMITH'S DRUG STORE	P. O. BOX 388	WILLISTON SC	29853	AS2146303	02/28/97
02800-0	SAUERS DRUG STORE	2303 SKIDAWAY ROAD	SAVANNAH GA	31404	AS4879512	02/28/94
02710-0	ROGERS DRUG STORE	1429 NEWCASTLE ST.	BRUNSWICK GA	31520	AS5386087	02/28/99
11360-0	STRANGE DRUG CO	122 S JEFFERSON ST	DUBLIN GA	31021	AS8995295	02/28/97
18065-0	SCOTTIE DISCOUNT DRUG	9 S. FOREST AVE.	HARTWELL GA	30643	AS9319725	02/28/97
03795-0	ST. NICHOLAS PHARMACY	3105 BEACH BLVD.	JACKSONVILLE FL	32207	AS9486742	02/28/99
02595-0	PROFESSIONAL PHARMACY	103 PROFESSIONAL CTR	EASTMAN GA	31023	AT9068520	11/30/96
03028-0	THE PRESCRIPTION SHOP	413 MEMORIAL AVE.	ALLENDALE SC	29810	AT9435113	11/30/93
18297-0	WIL-BUN PHARMACY	3365 TAMERA LANE	ORANGEBURG SC	29115	AW0345252	09/31/94
03270-0	WRIGHT'S DRUG STORE	217 MAIN STREET	TIFTON GA	31794	AW1171343	05/31/97
18289-0	WILLIAMS DRUG PRESC. C	101 SOUTH MAIN STREET	HEMINGWAY SC	29554	AW3096737	05/31/94
17020-0	AKINS PHARMACY	104-A SOUTHEAST BROAD DRUG CO.	LYONS GA	30436	BA1599440	06/30/94
17094-0	BERKELEY PORT CITY	2750 SPEISSEGER	N. CHARLESTON SC	29406	BB1150907	07/31/93
17063-0	BAKER PARK PHARMACY	(BILL TO ONLY)	N. CHARLESTON SC	29405	BB1649954	07/31/97
03360-0	T-2 MEDICAL, INC.	1 N. BROOKS ST	ALPHARETTA GA	30202	BC1795080	08/31/94
17259-0	CLARENDON DRUGS, INC.	1941 SAVAGE ROAD SUI	CHARLESTON SC	29102	BC1929415	08/31/95
01481-1	CAREMARK PHARMACY SER	1200 WOODRUFF RD. UNI	GREENVILLE SC	29407	BC2498435	08/31/96
01482-2	CAREMARK INC.	116 WEST RICHARDSON A	SUMMerville SC	29483	BC3517705	08/31/95
17666-0	COMP-RX-CARE INC.	9143 PHILLIPS HIGHWAY	JACKSONVILLE FL	32256	BC4058473	08/31/96
01480-0	CAREMARK PHARMACY SER	S. PALMETTO AVE.	DENMARK SC	29042	BD3555387	06/30/96
01725-0	DANIEL'S PALMETTO PHA	7634 A-2 SOUTH RAIL R	N. CHARLESTON SC	29406	BD3974121	06/30/97
01790-0	DOCTOR'S MED SUPPLY &	1203 GREENVILLE HIGHW	LYMAN SC	29365	BD3995959	06/30/97
01720-0	DARYL'S DISCOUNT DRUG	1100 EISENHOWER DRIVE	SAVANNAH GA	31406	BE0201462	08/31/96
10439-0	ECKERD'S #2710	229 GENERAL SCREVEN D	HINESVILLE GA	31313	BE0277954	10/14/94
10422-0	ECKERD DRUG #2702	373 WASHINGTON STREET	WALTERSBORO SC	29488	BF3238436	09/30/95
02090-0	HOTT'S PHARMACY	401 NORTH AVE.	ATHENS GA	30601	BG3396947	09/30/95
17513-0	GATEWAY PHARMACY	P. O. BOX 219	HARTWELL GA	30643	BH0365266	10/31/96
17491-0	HAILEY'S DRUG STORE	ASST IS CLOSED	DO NOT USE GA	31326	BH2234742	10/31/92
10626-0	HARDEN'S PHARMACY	9440-3 PHILLIPS HWY	JACKSONVILLE FL	32256	BH2733459	10/31/96
02048-8	HEALTH INFUSION INC.	9-F HUNTER RD.	HILTON HEAD SC	29925	BI2513706	11/30/96
17563-0	ISLAND PHCY SERVICES	3 BLACKSTOCK ROAD	INMAN SC	29349	BI2900721	11/30/94
02130-0	INMAN DRUGS INC.	1210 E DERENNE AVE	SAVANNAH GA	31406	BI3012781	11/30/94
10402-0	INFUSION THERAPIES	P.O. BOX 989	JOHNSONVILLE SC	29555	BJ1231517	12/31/93
17639-0	JOHNSONVILLE PHARMACY	D/B/A HESS FAMILY DRU	DAKWOOD GA	30566	BJ2760076	12/31/96
17633-0	JOHN BECK PHCY SERVIC	CLINIC	JACKSONVILLE FL	32209	BJ2770065	12/31/96
03589-0	JACKSONVILLE FACULTY	D/B/A FAMILY DRUGS	DAKWOOD GA	30566	BJ2867577	12/31/94
17634-0	JOHN BECK PHARM. SERV	3624 J. DEWEY GRAY CI	AUGUSTA GA	30909	BL0157758	03/31/94
02226-0	WESTSIDE PHARMACY	4704 AUGUSTA ROAD	GARDEN CITY GA	31418	BL3872808	12/31/94
10803-0	LIFELINE PHARMACY	554-D. MEMORIAL DR EXT	GREER SC	29631	BM0497241	01/31/97
17791-0	MCLESKY TODD DRUG	62 CHESTNUT STREET	ELBERTON GA	30635	BM2062646	/
17743-0	MADDEN'S PRESC. SHOP	265 KING ST	CHARLESTON SC	29401	BM2303282	01/31/96
11277-0	SCOTTIE DISCOUNT DRUG	D/B/A COMPREHENSIVE	SAVANNAH GA	31406	BM2434330	01/31/93
02292-0	KIMBERLY QUALITY CARE	306 MAIN STREET	BLACKVILLE SC	29817	BM2441094	01/31/96
02294-0	MAIN STREET PHARMACY	25 HOSPITAL CTR. BLVD	HILTON HEAD SC	29926	BM3942249	01/31/97
02416-0	MEDICAL PAVILION PHCY	2444 MAYPORT RD. #11	JACKSONVILLE FL	32233	BM1575387	10/31/94
02480-0	NAVACARE PHARMACY-MAYP	660 SPARTAN BLVD	SPARTANBURG SC	29301	BP1111599	03/31/96
02565-0	PHAR - MOR #104	2441 WHISKEY ROAD SOU	AIKEN SC	29801	BP2269389	03/31/96
02566-0	PHAR - MOR #210					

See Reverse of PURCHASER'S Copy for Instructions		No order form may be issued for Schedule I and II substances unless a completed application form has been received. (21 CFR 1305.04).			OMB APPROVAL No. 1117-0010	
TO: (Name of Supplier) JAMES W. DALY, INC.				STREET ADDRESS 11 CENTENNIAL DRIVE		
CITY and STATE PEABODY, MA 01961			DATE 11/06/92		TO BE FILLED IN BY SUPPLIER SUPPLIERS DEA REGISTRATION No.	
TO BE FILLED IN BY PURCHASER						
Line No.	No. of Packages	Size of Package	Name of Item	National Drug Code	Packages Shipped	Date Shipped
1	1	100	PERCODAN XXXTABS			
2	1	500	PERCOCET NNNTABS 5/325			
3	1	118 ML	OPIUM TINCTURE LIQD			
4	1	100	CODEINE SULFATE XXXTABS 15MG			
5	1	500 ML	ROXICET ORAL SOLN 5MG			
6	1	100	MS CONTIN CR TABS 15MG			
7						
8						
9						
10						
6		NO. OF LINES COMPLETED		SIGNATURE OF PURCHASER OR HIS ATTORNEY OR AGENT <i>T. Rich Collins</i>		
Date Issued 10-30-92		DEA Registration No. 8W3397951		Name and Address of Registrant WALGREEN EASTERN CO INC, C2823 DBA: WALGREENS 641 WESTERN AVE LYNN, MA 01505		
Schedules 2,2N,3,3N,4,5		Registered as a RETL PHARMACY		No. of this Order Form 522380221		
DEA Form - 222 (Aug. 1990)		U.S. OFFICIAL ORDER FORMS - SCHEDULES I & II DRUG ENFORCEMENT ADMINISTRATION SUPPLIER'S Copy 1			46408031	

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P-09320_00265

**Excessive Purchases
Schedule II**

EXHIBIT P

<u>Product</u>	<u>Strength</u>	Dosage Limit	
		<u>Hospital</u>	<u>Retail</u>
Codeine Sulf	All	800 Tabs	400 tabs
Dextroamphetamine (Dexedrine, Dextrastat)	All	700 Tabs/Spans	800 Tabs/Spans
Desoxyn	All	300 Tabs/Grad	500 Tabs/Grad
Hydromorphone (Dilaudid)	All	900 Tabs	500 Tabs
Methadone (Dolophine)	All	2000 Tabs	700 Tabs
Meperidine (Demerol, Meprozone, Mepergan Fortis)	All	600 Tabs	400 Tabs
Methlyphenidate (Ritalin)	All	800 Tabs	800 Tabs
Morphine Sulfate (MS Contin, MSIR, Oramorph)	All	600 Tabs	500 Tabs
Oxycodone/Acet (Tylox, Roxilox, Roxicet, Percocet, Endocet)	All	3800 Tabs/Caps	1200 Tabs/Caps
Oxycodone/Asa (Percodan, Endodan, Roxiprin)	All	500 Tabs	500 Tabs
Oxycodone (Oxcontin, Roxicodone)	All	800 Tabs	600 Tabs

Excessive Purchases Schedule III, IV, V

EXHIBIT P

<u>Product</u>	<u>Strength</u>	<u>Dosage Limit</u>	
		<u>Hospital</u>	<u>Retail</u>
Acetamenophen w/Cod (Tylenol w/Cod, Phenaphen)	All	1400 Tabs	1300 Tabs
Alprazolam (Xanax)	All	1400 Tabs	2500 Tabs
Butalbital Compound (Florinal w/Cod, Fioral, Fioricet w/ Cod)	All	500 Tabs/Caps	500 Tabs/Caps
Aspirin w/Cod	All	300 Tabs	400 Tabs
Clorazephate (Klonopin)	All	1000 Tabs	800 Tabs
Clorazephate (Tranxene)	All	700 Tabs	1300 Tabs
Diazepam (Valium)	All	1000 Tabs	2500 Tabs
Dexfenfluramine (Redux)	All	400 Caps	500 Caps
Diphenoxylt/Atropine (Lomotil, Lonox)	All	1600 Tabs	7500 Tabs
Dronabinol (Marinol)	All	300 Tabs	400 Tabs
Fenfluramine HCL (Pondimin)	All	800 Tabs	1700 Tabs
Hydrocodone (Anexsia, Dolaset, Hydrocet, Hycodan, Hyphen, Lorcet, Lortab, Zydone, Vicodin)	All	1200 Tabs/Caps	800 Tabs/Caps
Lorazepam (Ativan)	All	1200 Tabs	2400 Tabs
Meprobamate (Miltown, Equanil)	All	600 Tabs	1400 Tabs
Phentermine (Ionamin, Fastin, Adipex-P)	All	600 Tabs	1100 Tabs
Pentazoline (Talwin, Talacen)	All	700 Tabs	700 Tabs
Propoxyphene (Darvon, Darvocet, Propacet)	All	1100 Tabs	1900 Tabs
Temazepam (Restoril)	All	700 Caps	800 Tabs

Exhibit Q

Error Correction

In the following examples, assume the worst case — the order was shipped to the customer. Also assume the shelf count confirms the error.

Although these examples only address shipping errors involving Schedule II controlled substances, certain portions of the corrective action processes also apply to shipping errors involving Schedule III-V controlled substances which must be handled in a similar fashion.

Example 1: A customer orders Ritalin 5mg 100. The order is keyed as Ritalin 10mg 100. The order filler picks Ritalin 10mg 100. **Customer receives and is invoiced for the wrong item.**

Corrective Action:

- Request the customer submit a blank for the mispicked item (Ritalin 10mg 100). Have the customer back date the blank to reflect the original order date.
- Review the blank for accuracy, record the actual ship date, change the blank number in the ARCOS record. The blank number cannot be changed on the invoice.
- Key in the original blank with the correct item (Ritalin 5mg 100). Pick, bill, and ship the product. Attach a legible statement, preferably typed, to the original blank which reflects the correct NDC, ship quantity and date. Create an invoice and ARCOS record for the correct item.
- If the customer wants to return the mispicked item (Ritalin 10mg 100), issue a blank to the customer to buy back the product. Upon receipt, issue credit to customer.

Example 2: A customer orders Ritalin 5mg 100. The order is keyed as Ritalin 5mg 100. The order filler picks Ritalin 10mg 100. **Customer gets wrong item, but is invoiced for the right item.**

Corrective Action:

- Have the customer submit a blank for the mispicked item (Ritalin 10mg 100). Have the customer back date the blank to reflect the original order date.
- Review the blank for accuracy, record the actual ship date. Key in an order for the mispicked item (Ritalin 10mg 100), but do not ship the product. The customer will receive an invoice, but no product.
- Ship the correct product (Ritalin 5mg 100) from the original blank. The customer will get product, but no invoice.
- Change the ship dates of the products in the ARCOS records. The original invoice cannot be changed to reflect the actual ship date.

ERRORS.doc

5/25/99

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CAH SWE 019299

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- If the customer wants to return the mispicked item (Ritalin 10mg 100), issue a blank to the customer to buy back the product. Upon receipt, issue credit to the customer.

Example 3: A customer orders 5xRitalin 5mg 100. The order is keyed as 10xRitalin 5mg 100. The order filler picks 10xRitalin 5mg 100. **Customer was billed for and received more than what he ordered.**

Corrective Action:

- Request the customer submit a blank for the additional product. Have customer back date the blank to reflect the original order date.
- Review the blank for accuracy, record actual ship date of product.
- Correct the ARCOS record to show correct ship quantity for original blank. The blank number and ship quantity cannot be changed on the invoice. Create another ARCOS record to show ship quantity, date, and blank number of overshipment.
- Correct the ship quantity on the original blank by drawing a line through the incorrect quantity and entering the correct quantity.
- If the customer wants to return the extra product, issue a blank to the customer. Upon receipt of the overshipment, issue credit to the customer.

Example 4: A customer orders 5xRitalin 5mg 100. The order is keyed as 5xRitalin 5mg 100. The order filler picks 10xRitalin 5mg 100. **Customer received more than what he ordered or was billed.**

- Request the customer submit a blank for the additional product. Have customer back date the blank to reflect the original order date.
- Review the blank for accuracy, record the actual ship date of the product.
- Key in an order for the overshipment, but do not ship product. Reference the actual ship date in the text field of the order.
- Modify the ARCOS record to show the correct ship date of the product.

PAGE: 1

CARDINAL - SYRACUSE

RUN DATE: 7/14/99 7:54:53

(DETAIL)

MCA Dosage Limit Report

MONTH : JUN 1999

Invoice : JUN 1999 Invoice Item NDC Description Item Form Qty Sold Item Dosage Total Dosage

Date Number Number Number Description Item Form Qty Sold Item Dosage Total Dosage

Customer: 349902 WILKES-BARRE GEN HOSP RT140- N. RIVER & AUBURN ST. WILKES BARRE PA 18764-0000 DEA Lic: AW2452655

INGREDIENT: 002 PSEUDOPHEDRINE TYLENOL SINUS MAX STRN 24 TB 8 24 192

Customer: 620188 GEO NOTCHAN DETENTION CTR 15-15 HAZEN STREET EAST ELMHURST NY 11370-0000 DEA Lic: AM62232525

INGREDIENT: 003 PHENYLPROPANOLINE DIMETAPP EXT 100 UD 2277-64 TB 10 100 1,000

*** END OF REPORT ***



EXHIBIT II

SUSPICIOUS ORDER REPORTING SYSTEM OF 1998 For Use in automated tracking systems

The Current Calculation Being Used for List I Chemicals and Schedule II - V Controlled Substances

Terms & Definitions

This formula is used to calculate the quantity which, if exceeded in one month, constitutes an order which may be considered excessive or suspicious.

- 1) Add purchase quantities for the last 12 months for all customers within same Distribution Center and for customer type (Hospital, Pharmacy or Other) for any List I chemical containing item stocked by the Distribution Center.
- 2) Add Customer months for every record used in above total. (Months within the last 12 that customer purchases of the item were not zero).
- 3) Divide total quantity purchased by the total customer months.
- 4) Then multiply by the factor below to give the maximum amount that the customer can order per month before showing up on the suspicious order report.

Note: Factor equals 3 for C-II and C-III Controlled Substances Containing List I Chemicals and 8 for C-III N-V Controlled Substances and non-Controlled OTC products containing List I chemical items.

- 5) At the end of each month, a report will be transmitted to DEA (separate reports for List I Chemicals and Schedule II - V Controlled Substances) of all purchases of List I Chemicals and/or C-II-V Controlled Substances and List I containing OTC items by any customer whose purchase quantities exceed the parameters (above) any (2) consecutive months or in three (3) of any moving six (6) month period.

Using a computer to manage and report on high volume transaction business activities with extremely short order cycles times (receipt to delivery) is the only viable, cost effective methodology for the reporting of orders which may be considered excessive or suspicious.

SOTF Report Appendix A: 4



**FOIA Confidential
Treatment Requested By
Cardinal**

CONFIDENTIAL

CAH SWE 019303

CAH_MDL_PRIORPROD_DEA07_01384166

P-09320_00272

DEA COMPLIANCE MANUAL

APPENDIX E

Methamphetamine Control Act Products

ndc	ac	descrip	form	misc1	vendor	nc	dp number	ch	descrip	type
00083-0145-37	83014537	ACUTRIM II	TAB	75MG CR	CIBA SELF MEDICATION		159840	1396779	ACUTRIM II TB 40 MAX-STRN	40 PPA
00083-0188-17	83018817	ACUTRIM	TAB	75MG CR	CIBA SELF MEDICATION		20974	2048494	ACUTRIM TB 75MG 20 16-HR 018817	40 PPA
00083-0188-37	83018837	ACUTRIM	TAB	75MG CR	CIBA SELF MEDICATION		20982	2048503	ACUTRIM TB 75MG 40 16-HR	40 PPA
00603-0136-06	603013609	DIETRIM ES	TAB	75MG ES	QUALITEST		872938	2149177	DIETRIM ES TB 20	40 PPA
00904-2436-39	904243639	MEGA-TRIM	TAB	75MG CR	MAJOR PHARMACEUTICALS		371904	1474393	MEGA-TRIM CL 40	40 PPA
10425-00201	1042500201	SUP ODRINEX	TAB	25MG	FOX PHARMACAL INC		474401	1791148	ODRINEX SUPER TAB 110S	40 PPA
10425-00202	1042500202	SUP ODRINEX	TAB	25MG	FOX PHARMACAL INC		474398	1376920	ODRINEX SUPER TAB 50S	40 PPA
72959-18021	7295918021	THINZ-SPAN	TAB	75MG TR	ALVA-AMCO		331805	1505692	THINZ SPAN DIET CAP 21S	40 PPA
73865-69126	7386569126	HUNGREX PLUS	TAB	75MG TR	ALVA-AMCO		4804	1077148	HUNGREX PLUS TAB H7 126S	40 PPA
73865-74800	7386574800	PERMATHENE	CAP		ALLEGHANY		12802	1254706	PERMATHENE TRL DIET CAP 4BS	40 PPA
00671-1236-60	671123660	UNI-SLIM	CAP		URL		593087	1495449	UNI-SLIM CAP 20S	42 PPA
94604-0317-10	9460431710	GRAPEFRUIT	CAP	DIET	NAT-RUL HEALTH PRODUCTS		915645	2377133	GRAPEFRUIT DIET TAB 100S	42 PPA
37205-0109-60	37205010960	COLD	TAB	8-75 TR	LEADER BRAND PRODUCTS		968722	2256278	LDR COLD CAPS 20CT	70 PPA
37205-0116-26	37205011626	TRIACTING	SYP	1-6.25/5	LEADER BRAND PRODUCTS		928330	2313021	LDR TRIACTING SYRUP 4OZ 11026	70 PPA
37205-0140-26	37205014026	TRIACTING	SYP	MULT-	LEADER BRAND PRODUCTS		928293	2313005	LDR TRIACTING MULT-SYMP 4OZ 14526	70 PPA
37205-0182-26	37205018226	TRIACTING	SOL	EXCEPT	LEADER BRAND PRODUCTS		928275	2312998	LDR TRIACTING EXCEPT 4OZ 18226	70 PPA
37205-0308-62	37205030862	BROMATAPP	TAB	12-75 ER	LEADER BRAND PRODUCTS		968693	1793430	LDR BROMATAPP EXT RLF TAB 24CT	70 PPA
37205-0451-62	37205045162	DIBROMM	TAB	12-75 ER	LEADER BRAND PRODUCTS		933481	2312981	LDR PSEUDO COLD & ALLERGY TB 24CT	70 PPA
37205-0482-52	37205048252	COLD	CAP	8-75 CR	LEADER BRAND PRODUCTS		17843	1376375	LDR COLD CAPS 10CT	70 PPA
37205-0484-60	37205048460	EFFER COLD	TAB	RELIEF	LEADER BRAND PRODUCTS		963909	1783448	LDR EFF COLD TAB 20CT 49460	70 PPA
37205-0501-73	37205050173	COLD & FLU	CAP	SEVERE	LEADER BRAND PRODUCTS		968749	1759232	LDR COLD & FLU SEVERE CF 16CT	70 PPA
37205-0860-73	37205086073	ALLERHIST-D	TAB		LEADER BRAND PRODUCTS		927244	2312924	LDR ALLERHIST-D 16CT 86073	70 PPA
37205-0939-26	37205093926	COLD & COUGH	LIQ	DM	LEADER BRAND PRODUCTS		968692	1798143	LDR COLD & COUGH DM ELIXIR 4OZ	70 PPA
37205-0844-26	37205084426	COLD & ALLER	ELX	2-12.5/5	LEADER BRAND PRODUCTS		968684	1239185	LDR COLD & ALLERGY ELIX 4OZ	70 PPA
37205-0965-34	37205096534	TUSSIN CF	SYP		LEADER BRAND PRODUCTS		965219	2302933	LDR TUSSIN CF SR 8OZ	70 PPA
00031-8677-22	31867722	ROBITUSSIN	SYP	CF	WHITEHALL ROBINS HEALTHCARE		678597	1833789	ROBITUSSIN-CF SR 12OZ	80 PPA
00031-8677-25	31867725	ROBITUSSIN	SYP	CF	WHITEHALL ROBINS HEALTHCARE		326429	1303767	ROBITUSSIN CF SR 16OZ	80 PPA
00086-0051-10	86005110	PROPAGEST	TAB	25MG	CARNICK		158852	1300722	PROPAGEST TB 100	80 PPA
00472-0712-94	472071294	BROMANATE DM	LIQ		ALPHARMA		790923	2371649	BROMANATE DM EL 120ML AF	80 PPA
00472-1562-16	472156216	THREAMINE	SOL		BARRE-NATIONAL		735493	2195683	THREAMINE EXP RT	80 PPA
00536-0390-90	536039090	BROMALINE	ELX	2-12.5/5	RUGBY		652407	1158211	BROMALINE OTC EL 384OZ	80 PPA
00536-2192-75	536219275	TRI-DEC	DRO	PED	RUGBY		771627	1395078	TRI-DEC PED DR 1OZ	80 PPA
00536-2193-97	536219397	TRI-DEC	SYP	PED	RUGBY		771635	1394782	TRI-DEC CHILD SR 4OZ	80 PPA
00536-2345-85	536234585	BROMALINE	ELX	2-12.5/5	RUGBY		860931	1185842	BROMALINE ORAL SL 480ML	80 PPA
00536-2682-97	536268297	TRIPHENICOLD	SYP	MULT-	RUGBY		861847	1649946	TRIPHENICOLD MULTI SYM LO 4OZ RUG	80 PPA
00536-3389-35	536338935	BROMALINE	TAB	PLUS	RUGBY		680940	1325760	BROMALINE PLUS TABS 24	80 PPA
00536-4879-01	536487901	COLD	TAB	EXPECT	RUGBY		639582	1624949	COLD TAB 100S W/EXPECT	80 PPA
00904-0214-12	904021412	DIMAPHEN	TAB	TIMED	MAJOR PHARMACEUTICALS		675520	2163673	DIMAPHEN TB 12	80 PPA
00904-0216-24	904021624	DIMAPHEN	TAB		MAJOR PHARMACEUTICALS		598750	2164002	DIMAPHEN TB 24	80 PPA
00904-0331-20	904033120	THERA-HIST	SYP	2-12.5/5	MAJOR PHARMACEUTICALS		707821	2164457	THERA-HIST SR 4OZ	80 PPA
00904-0713-00	904071300	DIMAPHEN	ELX	2-12.5/5	MAJOR PHARMACEUTICALS		749370	2162816	DIMAPHEN ELIXIR 4OZ	80 PPA
00904-0713-28	904071328	DIMAPHEN	ELX	2-12.5/5	MAJOR PHARMACEUTICALS		698741	2163996	DIMAPHEN ELIX 4OZ	80 PPA
00927-0033-63	927003363	SINAPILS	TAB	2-12.5/5	MAJOR PHARMACEUTICALS		710555	2162675	DIMAPHEN EL 384OZ	80 PPA
00927-0133-63	927013363	SINAPILS	TAB		PFEIFFER		935298	1488519	SINAPILS TB 36	80 PPA
00927-0532-24	927053224	TRIN-NEFRIN	TAB	2-12.5/5	PFEIFFER		935298	1488519	SINAPILS TB 36	80 PPA
54092-0041-05	54092004105	PYROXATE	TAB	2-12.5/5	ROBERTS PHARMACEUTICAL		23186	1488535	TRIN-NEFRIN X/S TAB 24S	80 PPA
60793-0007-08	60793000708	DIMEPHENYL	ELX	25-5/5ML	KING PHARMA		86072	1188739	PYROXATE CAP 500S	80 PPA
00047-2917-23	47291723	HYDROMINE	SYP	EXCEPT	WARNER CHILCOTT		569755	2032896	Hydromint 25 mg 1602	999 PPA
00084-0463-01	84046301	TIMED COLD	CAP	4-75 CR	WARNER CHILCOTT		466808	2032712	Hydromint SR 25 mg 1602	999 PPA
00084-0609-04	84060904	TRISTINE	SYP	2-12.5/5	AMERICAN PHARMACEUTICAL CO.		466956	1843390	UN Timed Cold CP 10	999 PPA
00084-0609-04	84060904	TRISTINE	SOL	EXPECT	AMERICAN PHARMACEUTICAL CO.		466948	1842756	UN Tristine SR 120 ML	999 PPA
00084-0621-32	84062132	ALLERGY/COLD	ELX		AMERICAN PHARMACEUTICAL CO.		628767	2417871	UN Tristine EX 120 ML	999 PPA
00093-0110-01	93011001	RHINEX D-LAY	TAB	SA	GATE		373281	2117871	UN Allergy and Cold EL 120 ml	999 PPA
00093-0110-10	93011010	RHINEX D-LAY	TAB	SA	GATE		577928	1999036	Rhinex D-Lay SA 100	999 PPA
00182-1495-40	182149540	NEW DECONGES	SYP	PED	GOLDLINE		127663	1479567	Tri-Phenamine 480 ML	999 PPA
00182-6065-37	182606537	COLD & ALLERGY	ELX		GOLDLINE		757209	2639573	Cold and Allergy 120 ml	999 PPA

nc	ntc	descrp	form	misc	vendor	No	C	DP number	ch	descrip	depr	type	code
00045-0473-50	45047350	SINE-AID	TAB	MAX STR	MCNEIL CONSUMER			651125	1114586	SINE AID MS TAB 50S 473-50	7	PSE	S
00045-0476-06	45047606	TYLENOL COLD	POW	& FLU	MCNEIL CONSUMER			694347	1830405	TYLENOL COLD PACKET 6S 47606	7	PSE	S
00045-0480-20	45048020	TYLENOL SIN	CAP	MAX-STR	MCNEIL CONSUMER			694363	1830363	TYLENOL SINUS GELCAP 24S MS 48020	7	PSE	S
00045-0480-40	45048040	TYLENOL SIN	CAP	MAX-STR	MCNEIL CONSUMER			694371	1830355	TYLENOL SINUS GELCAP 60S MS 48040	7	PSE	S
00045-0616-20	45061620	TYLENOL COLD	TAB	NO-	MCNEIL CONSUMER			786900	1612324	TYLENOL COLD GELCAP 24S NDROW	7	PSE	S
00045-0616-40	45061640	TYLENOL COLD	TAB	NO-	MCNEIL CONSUMER			786918	1612332	TYLENOL COLD GELCAP 40S NDROW	7	PSE	S
00045-0841-10	45084110	TYLENOL FLU	TAB	NO-	MCNEIL CONSUMER			858285	1021310	TYLENOL FLU GELCAP 10S	7	PSE	S
00045-0841-20	45084120	TYLENOL FLU	TAB	NO-	MCNEIL CONSUMER			858293	1021302	TYLENOL FLU GELCAP 20S	7	PSE	S
00054-4743-25	54474325	PSEUDOEPHEDR	TAB	30MG	ROXANE			308102	1285540	PSEUDOEPHEDR HCL TB 30MG 100 ROX	7	PSE	S
00054-8743-25	54874325	PSEUDOEPHEDR	TAB	30MG	ROXANE			141313	1168792	PSEUDOEPHEDR HCL TB 30MG 100UD	7	PSE	S
00069-0102-61	68010261	SINGLET	TAB	2.5-60MG	WARNER WELLCOME			491942	1168416	SINGLET TAB 100S 10261	7	PSE	S
00081-0018-12	81001812	ACTIFED	TAB	2.5-60MG	WARNER WELLCOME			17949	1168004	ACTIFED TAB 12S 21052	7	PSE	S
00081-0018-24	81001824	ACTIFED	TAB	2.5-60MG	WARNER WELLCOME			17957	1168020	ACTIFED TAB 24S 21055	7	PSE	S
00081-0018-48	81001848	ACTIFED	TAB	2.5-60MG	WARNER WELLCOME			17964	1289743	ACTIFED TAB 48S 21047	7	PSE	S
00081-0018-55	81001855	ACTIFED	TAB	2.5-60MG	WARNER WELLCOME			17957	1289743	ACTIFED TB 100 21018	7	PSE	S
00081-0080-20	81008020	ACTIFED PLUS	TAB	2.5-60MG	WARNER WELLCOME			648973	1700145	ACTIFED PLUS TAB 20S 21080	7	PSE	S
00081-0080-40	81008040	ACTIFED PLUS	TAB	2.5-60MG	WARNER WELLCOME			648965	1700152	ACTIFED PLUS TAB 40S 21081	7	PSE	S
00081-0082-20	81008220	ACTIFED PLUS	TAB	2.5-60MG	WARNER WELLCOME			648949	1700160	ACTIFED CL COLD/SINUS 20	7	PSE	S
00081-0082-40	81008240	ACTIFED PLUS	TAB	2.5-60MG	WARNER WELLCOME			648957	1700178	ACTIFED PLUS CAPL 40S 21083	7	PSE	S
00081-0081-24	81008124	ACTIFED	KIT	SINUS	WARNER WELLCOME			948748	1622539	ACTIFED SINUS DAYNGT TB 24 21091	7	PSE	S
00081-0083-24	81008324	ACTIFED	KIT	SINUS	WARNER WELLCOME			781142	1622521	ACTIFED SINUS DYNGTE CAP 24S 21093	7	PSE	S
00081-0094-02	81009402	ACTIFED ALL	KIT	SINUS	WARNER WELLCOME			66385	2316685	ACTIFED DISTRIBUTION PACK 18PC DL	7	PSE	S
00081-0677-13	81067713	SUDAFED COLD	CAP	/DAYNITE	WARNER WELLCOME			864005	1710672	SUDAFED CLD/CGH LOCP 18 22677	7	PSE	S
00081-0677-20	81067720	SUDAFED COLD	CAP	/COUGH	WARNER WELLCOME			864013	1710680	SUDAFED CLD/CGH LOCP 20 22678	7	PSE	S
00081-0768-24	81076824	SUDAFED SIN	TAB	XS	WARNER WELLCOME			594865	1503150	SUDAFED SINUS TAB 24S 22786	7	PSE	S
00081-0768-24	81076824	SUDAFED SIN	TAB	XS	WARNER WELLCOME			594849	1503158	SUDAFED SINUS CL 24 22788	7	PSE	S
00081-0773-13	81077313	SUDAFED COLD	TAB	SINUS	WARNER WELLCOME			739227	1130954	SUDAFED SEVERE COLD TAB 10S 22773	7	PSE	S
00081-0773-20	81077320	SUDAFED COLD	TAB	SINUS	WARNER WELLCOME			739235	1131960	SUDAFED SEVERE COLD TAB 20S 77320	7	PSE	S
00081-0802-20	81080220	SUDAFED COLD	TAB	SEVERE	WARNER WELLCOME			739200	1131952	SUDAFED SEVERE COLD (SEE 2394658)	7	PSE	S
00081-0862-82	81086282	SUDAFED COLD	TAB	SEVERE	WARNER WELLCOME			101087	2354983	SUDAFED SEVERE COLD SR 4OZ KID 22863	7	PSE	S
00081-0865-24	81086524	SUDAFED	TAB	15MG/5M	WARNER WELLCOME			235989	1127059	SUDAFED TB 30MG 24 22855	7	PSE	S
00081-0865-48	81086548	SUDAFED	TAB	30MG	WARNER WELLCOME			62850	2226886	SUDAFED TB 30MG 36PC IRC DL 66524	7	PSE	S
00081-0865-55	81086555	SUDAFED	TAB	30MG	WARNER WELLCOME			19046	1351402	SUDAFED TB 30MG 48S 22854	7	PSE	S
00081-0868-55	81086855	SUDAFED	TAB	60MG	WARNER WELLCOME			19062	1026657	SUDAFED TB 30MG 100 22866	7	PSE	S
00081-0870-24	81087024	SUDAFED PLUS	TAB	Apr-60	WARNER WELLCOME			19003	1026655	SUDAFED TB 60MG 100	7	PSE	S
00081-0870-48	81087048	SUDAFED PLUS	TAB	Apr-60	WARNER WELLCOME			120502	1137314	SUDAFED COLD/ALLERGY TB 24 22879	7	PSE	S
00081-0875-82	81087582	SUDAFED	TAB	Apr-60	WARNER WELLCOME			101125	2354975	SUDAFED SR 4OZ CHILD COUGH&COLD	7	PSE	S
00081-9600-01	81960001	SUDAFED	SYP	COUGH	WARNER WELLCOME			102695	2389021	SUDAFED SEVERE COLD TAB 12S 22780	7	PSE	S
00081-9600-02	81960002	SUDAFED	TAB	SEV	WARNER WELLCOME			102741	2389013	SUDAFED SEVERE COLD CAP 12S 22790	7	PSE	S
00083-0250-78	83025078	EFIDAC/24	TAB	SEV	WARNER WELLCOME			101958	2394658	SUDAFED SEVERE COLD CAP 24S 22782	7	PSE	S
00083-0250-93	83025093	EFIDAC/24	TAB	SEV	WARNER WELLCOME			850373	1830975	EFIDAC-24 TB 12	7	PSE	S
00085-0147-01	85014701	DRIXORAL CLD	TAB	ALLERG	CIBA SELF MEDICATION			77585	1830983	EFIDAC-24 TB 6	7	PSE	S
00085-0147-02	85014702	DRIXORAL CLD	TAB	ALLERG	SCHERING-PLOUGH			77585	1112416	DRIXORAL TB COLD&ALLERGY 10	7	PSE	S
00085-0147-03	85014703	DRIXORAL CLD	TAB	ALLERG	SCHERING-PLOUGH			77593	1095017	DRIXORAL SA TAB 100S 147-02	7	PSE	S
00085-0147-04	85014704	DRIXORAL CLD	TAB	ALLERG	SCHERING-PLOUGH			256299	1125517	DRIXORAL TB COLD&ALLERGY 20	7	PSE	S
00085-0147-05	85014705	DRIXORAL CLD	TAB	ALLERG	SCHERING-PLOUGH			143650	2562999	DRIXORAL CLD/ALLERGY TB 72Z TRLSZ	7	PSE	S
00085-0147-09	85014709	DRIXORAL CLD	TAB	ALLERG	SCHERING-PLOUGH			606855	1208586	DRIXORAL SA TAB 40S 147-05	7	PSE	S
00085-0147-10	85014710	DRIXORAL CLD	TAB	ALLERG	SCHERING-PLOUGH			939498	1392851	DRIXORAL TRL 2S 72PC DL147-09	7	PSE	S
00085-0184-05	85018405	CHLOR-TRIMET	TAB	8-120 CR	SCHERING-PLOUGH			831794	1461284	CHLOR TRIM TB 10 DECON 12HR	7	PSE	S
00085-0261-03	85026103	DRIXORAL	TAB	COLD/FL	SCHERING-PLOUGH			533645	1432103	DRIXORAL TB COLD&FLU 12	7	PSE	S
00085-0261-04	85026104	DRIXORAL	TAB	COLD/FL	SCHERING-PLOUGH			539544	1432111	DRIXORAL TB COLD&FLU 24	7	PSE	S
00085-0261-06	85026106	DRIXORAL	TAB	COLD/FL	SCHERING-PLOUGH			36760	1500131	DRIXORAL PL TRUSZ DL261-06PPR 49	7	PSE	S
00085-0261-07	85026107	DRIXORAL	TAB	COLD/FL	SCHERING-PLOUGH			831728	1508555	DRIXORAL PLUS TAB 48S 261-07	7	PSE	S
00085-0261-08	85026108	DRIXORAL	TAB	COLD/FL	SCHERING-PLOUGH			839985	1465368	DRIXORAL PL CLD&FLU DISP PK 18X25	7	PSE	S
00085-0261-09	85026109	DRIXORAL	TAB	COLD/FL	SCHERING-PLOUGH			5872	1100015	DRIXORAL PLUS TR 18X25 DL26109	7	PSE	S
00085-0508-01	85050801	DRIXORAL ND	TAB	120MG	SCHERING-PLOUGH			651150	1717453	DRIXORAL TAB 10S NO DROW 508-01	7	PSE	S

ndc	dc	descrip	form	misc1	vendor	DP number	chf	descrip	date	i type
00031-8603-46	31860346	ROBITUSSIN	CAP	NIGHT-	WHITEHALL ROBINS HEALTHCARE	938459	2380749	ROBITUSSIN NIGHT TMLIQ-GEL 12S		9PSE
00085-1900-02	85190002	DRIXORAL	CAP	CGH/CON	SCHERING-PLOUGH	940073	2254449	DRIXORAL CGH/CONGST SEE 2132090		9PSE
00122-0810-66	122081066	SEUDO-TABS	TAB	30MG	REXALL	655780	2159424	SEUDO-TABS TB 24 RXC		9PSE
00122-0840-66	122084066	SEUDO-LIQUID	LIQ	30MG/5M	REXALL	655775	2159437	SEUDO-LIQ 40Z RXC		9PSE
00122-0856-66	122085666	SINUSTABS	TAB	6-120 CR	REXALL	655791	2159418	SINUSTABS TB 30 RXC		9PSE
00472-1139-94	472113994	NITE TIME CO	LIQ	CHILD	BARRE-NATIONAL	806200	2208718	NITE-TIME CHILD 40Z NAT		9PSE
00472-1470-93	472147093	NITE TIME CO	LIQ	CHILD	ALPHARMA	980447	2288690	NITE TIME COLD FM LQ 100Z ALM		9PSE
00573-1244-10	573124410	DRISTAN COLD	CAP	COUGH	WHITEHALL ROBINS HEALTHCARE	939084	2380723	DRISTAN CLD&CGH LIQ-GEL 12S		9PSE
00879-0450-04	879045004	PSEUDOEPHEDR	SYP	30MG/5M	HALSEY DRUG	924733	2212611	PSEUDOEPHEDR HCL SR 120ML HLS		9PSE
00879-0499-04	879049904	TRIPROSED	SYP	11.25-30	HALSEY DRUG	924750	2212637	TRIPROSED SR 120ML HLS		9PSE
00879-0499-16	879049916	TRIPROSED	SYP	11.25-30	HALSEY DRUG	924768	2212645	TRIPROSED SR 480ML HLS		9PSE
00904-0217-86	904021786	FLU/COLD/	POW	COUGH	MAJOR PHARMACEUTICALS	877158	2309124	MAJOR FLU COLD & COUGH PW 6 MJR		9PSE
00904-5054-60	904505460	SUDGEST	TAB	PLUS	MAJOR PHARMACEUTICALS	707546	2204576	PSEUDOGEST PLUS TB 60-4MG 100 MJR		9PSE
00904-5056-24	904505624	SINUS RELIEF	TAB	MAX STR	MAJOR PHARMACEUTICALS	500879	2517167	SINUS RELIEF TB 24 MS MJR		9PSE
00904-0108-01	60814010801	ANTHIST NAS	TAB	2.5-60MG	MAJOR PHARMACEUTICALS	894508	2379499	UL DECONGESTANT LNG ACTING TAB 24S		9PSE
00814-0108-10	60814010810	ANTHIST NAS	TAB	DECONG	REXALL MANAGED CARE	894516	2212884	ANTHIST NASAL DECONGEST TAB 1M		9PSE
00814-0108-24	60814010824	ANTHIST NAS	TAB	DECONG	REXALL MANAGED CARE	894486	2212908	ANTHIST NASAL DECONGEST TAB 24S		9PSE
00814-0108-30	60814010830	ANTHIST NAS	TAB	DECONG	REXALL MANAGED CARE	894494	2212892	ANTHIST NASAL DECONGEST TAB 30S		9PSE
00885-0901-02	885090102	CHLOR-TRIMET	TAB	Apr-60	SCHERING-PLOUGH	719200	1410240	CHLOR-TRIM D 4MG TRL SZ DL90102		44PSE
00677-0992-01	677099201	SINUS IMPROV	TAB	URL	URL	410918	1494426	HYDROCORTISIN OINT .5% 10Z URL		49PSE
37205-0001-05	37205000105	PEDIA RELIEF	DRO	7.5/8ML	LEADER BRAND PRODUCTS	963976	2303220	LDR PEDIA RELIEF DROPS .50Z 00105		70PSE
37205-0003-26	37205000326	PEDIA RELIEF	LIQ	CGH/COL	LEADER BRAND PRODUCTS	963966	2303236	LDR PEDIA RELIEF COUGH-COLD 40Z		70PSE
37205-0042-26	37205004226	TRIACTING	LIQ	NITE TIM	LEADER BRAND PRODUCTS	928291	2313013	LDR TRIACTING NITE TIME 40Z 04226		70PSE
37205-0085-52	37205008552	MULTI-SYMPTO	CAP	COLD&C	LEADER BRAND PRODUCTS	965405	2302941	LDR MULTI-SYMPTOM C&C GEL 10CT		70PSE
37205-0207-62	37205020762	PAIN RELIEF	CHW	COLD+C	LEADER BRAND PRODUCTS	372870	2474690	LDR PAIN RELIEVER C&C CHEW 24		70PSE
37205-0211-62	37205021162	PAIN RELIEF	TAB	COLD	LEADER BRAND PRODUCTS	461725	2507051	LDR PAIN RELIEVER COLD CP 24		70PSE
37205-0230-53	37205023053	DAY-TIME	CAP	COLD/FL	LEADER BRAND PRODUCTS	965308	2362580	LDR DAY-TIME SOFTGELS 12CT		70PSE
37205-0376-62	37205037662	SINUS PAIN	TAB	MAX STR	LEADER BRAND PRODUCTS	965162	1795257	LDR FLU COUGH & COLD 6CT		70PSE
37205-0385-62	37205038562	ALLERGY/SINU	TAB	COLD STR	LEADER BRAND PRODUCTS	965200	1363936	LDR SINUS PAIN RELIEVER CL 24		70PSE
37205-0400-71	37205040071	MULTI SYMPTO	TAB	MAX STR	LEADER BRAND PRODUCTS	965391	1364447	LDR SINUS/ALLERGY PAIN RELV 24		70PSE
37205-0410-53	37205041053	NIGHT-TIME	CAP	COLD/FL	LEADER BRAND PRODUCTS	965421	1745595	LDR MULTI-SYMPTOM COLD TAB 50CT		70PSE
37205-0445-62	37205044562	SINUS	TAB	30MG	LEADER BRAND PRODUCTS	965146	1795586	LDR NIGHT TIME SOFTGEL 12CT		70PSE
37205-0450-78	37205045078	HISTA-TABS	TAB	30MG	LEADER BRAND PRODUCTS	963984	1388107	LDR PSEUDOEPHEDRINE TAB 24CT		70PSE
37205-0537-53	37205053753	TUSSIN SEVER	TAB	CONGES	LEADER BRAND PRODUCTS	965340	1376506	LDR HISTA TAB 24CT		70PSE
37205-0875-30	37205087530	NIGHT-TIME	LIQ	SEVERE	LEADER BRAND PRODUCTS	964026	1963198	LDR TUSSIN S/C LIQU-CAP 12S 53753		70PSE
37205-0875-38	37205087538	NIGHT-TIME	LIQ	COLD	LEADER BRAND PRODUCTS	965456	2312973	LDR PSEUDO SEVERE COLD 10CT		70PSE
37205-0880-30	37205088030	NIGHT-TIME	LIQ	COLD	LEADER BRAND PRODUCTS	965464	1388065	LDR NIGHT TIME REGULAR 60Z		70PSE
37205-0880-38	37205088038	NIGHT-TIME	LIQ	COLD	LEADER BRAND PRODUCTS	965448	1239169	LDR NIGHT TIME REGULAR 100Z		70PSE
37205-0975-26	37205097526	DIXAPHEDRINE	TAB	6-120 CR	LEADER BRAND PRODUCTS	927376	1460377	LDR NIGHT TIME CHERRY 60Z		70PSE
00031-1653-70	31165370	DIMACOL	TAB	XS	WHITEHALL ROBINS HEALTHCARE	545287	2302925	LDR TUSSIN PE SR 40Z		80PSE
00081-0768-48	81076848	SUDAFED SIN	TAB	SINUS	WARNER WELLCOOME	694857	1085455	DIMACOL CAPLET 500S 1653-70		80PSE
00081-0768-48	81076848	SUDAFED	TAB	SINUS	WARNER WELLCOOME	694830	1507870	SUDAFED SINUS TAB 48S 22767		80PSE
00081-0685-78	81068578	SUDAFED	TAB	30MG	WARNER WELLCOOME	120489	1507888	SUDAFED SINUS CAPLET 48S 22769		80PSE
00121-0421-04	121042104	PSEUDOEPHEDR	CAP	30MG/5M	PHARMACEUTICAL ASSOCIATES	783021	1084740	SUDAFED TB 30MG 500X2 INSTUT		80PSE
00182-1361-11	182136111	NIGHTTIME	SYP	COLD	GOLDLINE	842664	2170793	PA-PSEUDOEPHEDRINE HCL SYRUP 40Z		80PSE
00451-4600-50	451460050	GUAITAB	TAB	60-400MG	MURO	745979	1698224	NIGHT TIME COLD CP 12 SFTGEL GLD		80PSE
00472-1517-94	472151794	DECOFED	SYP	30MG/5M	ALPHARMA	356948	2411304	GUAITAB 100S MURO		80PSE
00536-2303-75	536230375	KIDKARE DECO	DRO	7.5/8ML	RUGBY	771651	1395425	KIDKARE DECON DR 10Z RG RUG		80PSE
00536-2310-97	536231097	KIDKARE	LIQ	CGH/COL	RUGBY	771660	1395193	KIDKARE/CGH/COLD LQ 40Z RG RUG		80PSE
00904-0250-24	904025024	TRIPRO/PSE	TAB	2.5-60MG	MAJOR PHARMACEUTICALS	698270	2163760	APRODINE TB 24 MJR		80PSE
00904-0250-60	904025060	TRIPRO/PSE	TAB	2.5-60MG	MAJOR PHARMACEUTICALS	698288	2163798	APRODINE TB 100 MJR		80PSE
00904-0250-61	904025061	TRIPRO/PSE	TAB	2.5-60MG	MAJOR PHARMACEUTICALS	749087	2162625	APRODINE TB 100 UD MJR		80PSE

24

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DEA COMPLIANCE MANUAL

APPENDIX F

DEA Correspondence



U.S. Department of Justice
Drug Enforcement Administration

Washington, D.C. 20537

JUN 25 1992

Ms. Sherry Haber
National Wholesale Druggist Association
105 Oronoco Street
Alexandria, Virginia 22314

Dear Ms. Haber:

It has been brought to the attention of the Drug Enforcement Administration (DEA) that some confusion exists regarding the proper completion of the DEA Form 222 with respect to the "number of lines completed." This letter is written to help alleviate some of the confusion.

Title 21 of the Code of Federal Regulations (CFR), section 1305.06(b) states that only one item shall be entered on each numbered line. It further states that the total number of items ordered shall be noted on the order form in the space provided. On the current version of the DEA Form 222, the aforementioned "space provided" is termed "number of lines completed." When the above requirements are followed to the letter, there is no discrepancy between the number of items ordered and the number of lines completed.

Problems in interpretation have been encountered when the purchaser either uses more than one line to describe an item or voids an item. In the first instance, the correct interpretation would be to list the number of items ordered on the form in the space labeled "number of lines completed." The DEA Form 222 will be revised in its next printing to rename the heading "number of items ordered."

The issue of voided lines on the order form is perhaps a bit less clear cut in its interpretation. In strictly interpreting the regulations, the only conclusion which can be reached which is not open for interpretation is that a supplier may not fill an order form which "shows any alteration, erasure, or change of any description" (21 CFR 1305.11(2)). In fact, instructions provided on the reverse side of the DEA Form 222 advise the purchaser

Ms. Sherry Haber

Page Two

not to make erasures or alterations. They state that if an error should be made, all copies of the form should be voided and kept on file.

In addition, the regulations imply that only a supplier, not a purchaser, may void an item on a DEA Form 222. Section 1305.15(a) of the regulations states:

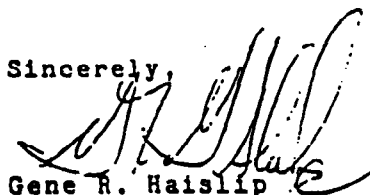
A purchaser may cancel part or all of an order on an order form by notifying the supplier in writing of such cancellation. The supplier shall indicate the cancellation on Copies 1 and 2 of the order form by drawing a line through the canceled items and printing "canceled" in the space provided for number of items shipped.

Consequently, the supplier is the only individual that has the authority to indicate the cancellation on the order form.

A separate but related issue has also been raised regarding generic substitution of order forms. DEA policy does not preclude generic substitution of identical products provided that the name and National Drug Code number of the actual product shipped is reflected on the form. Therefore, it would be acceptable to make a substitution provided that the customer agrees to accept a generic rather than a brand name product, the generic product of a manufacturer other than the one specified or a brand name product rather than a generic one. Therefore, the purchaser will not be required to submit a new DEA Form 222 to accommodate such a change.

Please disseminate the enclosed information to the members of your organization in an effort to dispel any problems they are perhaps encountering with the form. Thank you for your attention to this matter.

Sincerely,



Gene R. Haislip
Deputy Assistant Administrator
Office of Diversion Control

TO: Clarence Crisp/Cdc
Paul Exley/Ovc
Ron Franks/Bos
Rick Gliot/Cdc
Ben Jones/Zan
Geoff Kirkham/Har
- Carol Verrastro/Buf
Pete Westermann/Syr

DATE: June 29, 1992
FROM: Steve Reardon/Bos *Steve*
SUBJ: Order Forms (DEA Form 222)

CC: George Bennett

At a recent NWDA/DEA meeting that I attended, DEA issued the attached letter to further clarify their position on the proper completion of DEA Form 222 with respect to number of lines completed, voided or canceled lines, and generic substitutions. The regulatory interpretations are as follows:

- When two lines are used on an order form to describe one item, the number of lines completed at the bottom should be one. If two lines are used to order one item and "two" is entered in the number of lines completed, the order form must not be filled.
- A customer cannot void or cancel a line on the order form. If an order form is received from a customer with a voided or canceled line, the order form is considered defective and cannot be filled. Only a supplier may void an item on DEA Form 222. The customer may cancel a line by notifying the supplier in writing.
- It is acceptable to substitute generic product for generic product, generic product for brand name product, or brand name product for generic product provided that the products are equivalent, the name and the NDC number of the actual product shipped are reflected on the order form, and the purchaser agrees to the substitution.

Please read the letter for the specifics of these interpretations and pass the information on to the appropriate personnel in your division. Your customers should be notified regarding the consequences of their voiding or canceling a line.

DEA has informed their local offices of these interpretations, and you can expect regulatory enforcement to be consistent with the information contained in the letter.

If you have any questions, please call.

Attachment



TO: Clarence Crisp/Cdc
Paul Exley/Ovc
Ron Franks/Bos
Rick Gliot/Cdc
Ben Jones/Zan
Geoff Kirkham/Har
- Carol Verrastro/Buf
Pete Westermann/Syr

DATE: June 29, 1992
FROM: Steve Reardon/Bos *Steve*
SUBJ: Order Forms (DEA Form 222)

CC: George Bennett

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- When two lines are used on an order form to describe one item, the number of lines completed at the bottom should be one. If two lines are used to order one item and "two" is entered in the number of lines completed, the order form must not be filled.
- A customer cannot void or cancel a line on the order form. If an order form is received from a customer with a voided or canceled line, the order form is considered defective and cannot be filled. Only a supplier may void an item on DEA Form 222. The customer may cancel a line by notifying the supplier in writing.
- It is acceptable to substitute generic product for generic product, generic product for brand name product, or brand name product for generic product provided that the products are equivalent, the name and the NDC number of the actual product shipped are reflected on the order form, and the purchaser agrees to the substitution.

Please read the letter for the specifics of these interpretations and pass the information on to the appropriate personnel in your division. Your customers should be notified regarding the consequences of their voiding or canceling a line.

DEA has informed their local offices of these interpretations, and you can expect regulatory enforcement to be consistent with the information contained in the letter.

If you have any questions, please call.

Attachment

TO: John Dewees
Paul Exley
Ron Franks
Rick Gliot
Ben Jones
Willard Lawrence
Doug Pace
- Carol Verrastro
Pete Westermann

DATE: December 16, 1992

FROM: Steve Reardon

SUBJ: DEA Form 222

CC: George Bennett
Clarence Crisp

Please be advised that DEA has made changes on DEA Form 222 (sample attached). They are as follows:

- "No. of Lines Completed" has been changed to "No. of Items Ordered (Must Be Ten or Less)"
- Instruction #8 on the reverse side was changed *from*:

8. Enter the number of items ordered — this should correspond to the number of lines used. If this number has not been entered, the form will be returned to you for completion before the supplier is allowed to fill it.

TO:

8. Enter the number of *different* items ordered — this *generally* should correspond to the number of lines used. If a number has not been entered, the form will be returned to you for completion before the supplier is allowed to fill it.

These changes were made in an attempt to facilitate compliance with 21 CFR 1305.06(b) which reads:

- (b) Only one item shall be entered on each numbered line. There are ten lines on each order form. If one order form is not sufficient to include all items in an order, additional forms shall be used. Order forms for carfentanil etorphine diprenorphine shall contain only these substances. The total number of items ordered shall be noted on that form in the space provided.

Please pass this information on to the appropriate personnel in your division. If you have any questions, please call.

Attachment



U.S. Department of Justice

Drug Enforcement Administration

Washington, D.C. 20537

APR 25 1993

Mr. Dan White
Director, Distribution Projects
and Regulatory Affairs
McKesson Drug Company
One Post Street
San Francisco, California 94104-5296

Dear Mr. White:

Reference is made to your recent letter in which you asked for clarification of the Drug Enforcement Administration's (DEA) policy regarding the "Number of Items Ordered" box on DEA Forms 222.

We had hoped to eliminate much of the confusion regarding the proper completion of order forms by changing the heading for this box from "Number of Lines Completed" to "Number of Items Ordered," but based upon your inquiry and others we have received, it is apparent that some confusion still exists.

In your letter, you cited as an example an instance where a purchaser has used five lines on a DEA Form 222 to order controlled substances. Line #1 and line #4 both contain entries for the same product and package size, i.e. "1 x 100 Ritalin Tab 5mg." You asked whether the "Number of Items Ordered" would be "five" or "four."

Section 1305.06 (c) of Title 21 of the Code of Federal Regulations (CFR) specifies that "An item shall consist of one or more commercial or bulk containers of the same finished or bulk form and quantity of the same substance; a separate item shall be made for each commercial or bulk container of different finished or bulk form, quantity or substance." It is our position, therefore, that in the example you cited, four items were ordered. If the purchaser in this case had erroneously indicated that five items had been ordered (most likely based on the fact that five lines had been completed), we would deem this to be a minor error which could be corrected.

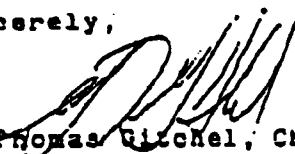
Mr. Dan White

Page Two

It has always been our intent to keep all of our Diversion Investigators knowledgeable about interpretations of the Controlled Substances Act and implementing regulations as well as DEA policy. If you are aware of any inconsistencies in our field offices' interpretation of the CSA, the regulations or DEA policy, please bring it to Ms. Carter's or my attention so the situation can be rectified.

If I can be of further assistance, please let me know.

Sincerely,



G. Thomas Mitchell, Chief
Liaison and Policy Section
Office of Diversion Control



U.S. Department of Justice
Drug Enforcement Administration

Washington, D.C. 20537

MAY 18 1993

Ms. Diane P. Goyette
Director of Regulatory Affairs
National Wholesale Druggists' Association
P.O. Box 2219
Reston, Virginia 22090-0219

Dear Ms. Goyette:

This is in response to your letter of March 8, 1993, regarding the issues raised at the National Wholesale Druggists' Association's (NWDA) Regulatory Affairs Working Group meeting in San Antonio.

The issues raised at the meeting are important and we look forward to continuing to work with the NWDA on matters concerning compliance with Federal and state laws and regulations governing controlled substances. We have relayed the working group's concerns regarding consistency in the Drug Enforcement Administration's interpretation of policy to all of our field offices. We have also reminded them that responses to policy questions should be made in writing if requested by the registrant.

Thank you for allowing members of the Office of Diversion Control staff to meet with you. We believe that by sharing concerns and ideas to prevent the diversion of legitimate controlled substance, both DEA's mission and NWDA's needs will be met.

Sincerely,

G. Thomas Gitchel, Chief
Liaison and Policy Section
Office of Diversion Control

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U.S. Department of Justice
Drug Enforcement Administration

(C)

JUN 23 1993

Mr. Larry L. Holland
Corporate Director
Security and Regulatory Compliance
Alco Health Services Corporation
P.O. Box 959
Valley Forge, Pennsylvania 19482

Dear Mr. Holland:

This is in response to your letter of April 22, 1993, in which you question the use of a former owner's Drug Enforcement Administration (DEA) registration by the new owner following the purchase of a pharmacy. There have been certain instances recently which have resulted in our reevaluating the circumstances under which these procedures may be used.

It is DEA's policy that upon purchasing a pharmacy the new owner must obtain a new DEA registration prior to dispensing controlled substances. However, we recognize that there may be occasions when, due to circumstances beyond the new owner's control, issuance of the appropriate state permits and, consequently, the new DEA registration may be delayed. In such situations, it may be permissible for the new owner to continue the business of the pharmacy under the previous owner's registration, provided certain conditions are met by both new and old owners.

The primary condition is that both the buyer and seller enter into a power of attorney that specifically sets forth the following:

1. The seller agrees to allow the controlled substance activities of the pharmacy to be carried out under the seller's DEA registration;
2. The seller agrees to allow the buyer to carry out the controlled substance activities of the pharmacy, including the ordering of controlled substances, as an agent of the seller;

Mr. Larry L. Holland

Page Two

3. The seller acknowledges that, as the registrant, they will be held accountable for any violations of controlled substance laws which may occur; and

4. The buyer agrees that the controlled substance activities of the pharmacy may be carried out under the seller's registration for no more than 45 days after the purchase date, which shall be recorded in the agreement.

In addition, the buyer must notify the appropriate local DEA office of the proposed use of the seller's DEA registration and, if requested, furnish a copy of the agreement. Should circumstances warrant, the local DEA office may withhold permission for the buyer to use the seller's registration number. The buyer cannot automatically assume that they will be authorized to utilize the seller's registration to conduct controlled substance activities.

With respect to your concerns regarding good faith verifications under such conditions, the best approach is to require that a copy of the power of attorney be provided with the copy of the registration certificate.

I trust the above adequately addresses your concerns. If you have any further questions or comments, please do not hesitate to contact this office at (202) 307-7297.

Sincerely,



G. Thomas Gitchel, Chief
Liaison and Policy Section
Office of Diversion Control

TO: Tom Blaylock/*National Specialty Serv.* DATE: June 29, 1993
John Dewees/*Marmac* FROM: Steve Reardon/*Daly*
Paul Exley/*Ohio Valley* SUBJ: DEA Policy
Ron Franks/*Daly*
Rick Gliot/*Chapman*
Ben Jones/*Bailey*
Brian Landry/*Mississippi*
-Doug Pace/*Florida*
John Roth/*Solomons*
Carol Verrastro/*Ellicott*
Pete Westermann/*Syracuse*

CC: George Bennett/*Dublin*

Typically, local DEA offices are willing to provide registrants with regulatory policy interpretations but are hesitant to put these interpretations in writing. However, according to the attached letter, the field offices have recently been instructed to respond to policy questions in writing if requested by the registrant. In response to this new directive from Washington, our policy should be to ask for all interpretations of DEA regulations and policies or approvals of procedures for your operation to be put in writing. This practice will protect us against potential violations that could result when being inspected by DEA investigators who disagree with the interpretation or are new to the local office. If the local office is hesitant to put something in writing, please feel free to provide them with a copy of this letter or contact me, and I will handle it.

If you have any questions, please call.

Attachment

TO: Sales and Operations Personnel
Linda Zarlengo

DATE: August 25, 1993

FROM: Steve Reardon *[Signature]*

CC: George Bennett
Pete Westermann

SUBJ:

**Change of Pharmacy Ownership:
DEA Policy**

Change of pharmacy ownership and continuing operation on a previous owner's DEA registration is an issue which has created ongoing confusion and inconvenience for us and our customers because of varying local DEA interpretations as to whether or not this is allowed.

DEA Headquarters recently documented DEA's official policy in the attached letter, which states that continued operation is permissible when certain conditions are met by both the current and previous owners.

The primary condition is that both the buyer and seller enter into a power of attorney that specifically sets forth the following:

1. The seller agrees to allow the controlled substance activities of the pharmacy to be carried out under the seller's DEA registration;
2. The seller agrees to allow the buyer to carry out the controlled substance activities of the pharmacy, including the ordering of controlled substances, as an agent of the seller;
3. The seller acknowledges that, as the registrant, they will be held accountable for any violations of controlled substance laws which may occur, and
4. The buyer agrees that the controlled substance activities of the pharmacy may be carried out under the seller's registration for no more than 45 days after the purchase date, which shall be recorded in the agreement.

Prior to selling to the new owner, you should obtain a copy of the power of attorney and file it with the copy of the previous owner's DEA registration certificate.

In addition, you must monitor the 45-day limit on controlled substance activity imposed as part of this policy.

If you have any questions, please call.

Attachment



Cardinal Health

TO Sales and Operations Personnel

DATE August 25, 1993

CC: George Bennett

FROM: Steve Reardon *SR*

SUB:

Mid-Level Practitioners (MLPs)

The Drug Enforcement Administration (DEA) published a final rule in the June 4 Federal Register establishing a new category of DEA registrants, *mid-level practitioners (MLPs)*. The rule defines MLP as "an individual practitioner... other than a physician, dentist, veterinarian, or podiatrist, who is licensed, registered, or otherwise permitted by the United States or the jurisdiction in which he/she practices, to dispense a controlled substance in the course of professional practice." Examples of MLPs include nurse practitioners, nurse midwives, nurse anesthetists, clinical nurse specialists, and physician assistants.

MLPs will now be registered with DEA, but their authority to prescribe, dispense, and order controlled substances is granted by the state in which they practice and varies greatly among the states and types of MLPs (see attached). The final rule places responsibility for verifying this authority on the supplier, a complicated task at best.

I don't believe MLPs represent a significant new class of customers who would generate large volume sales and, because of the compliance difficulties posed by the authority verification responsibility, recommend that we do not sell directly to them. However, if this turns out not to be the case, we can reevaluate this position.

Please pass this information along to the appropriate staff in your division. If you have any questions, please call.

NOTE: The new MLP registration number will begin with the letter "M" rather than the letters "A" or "B" currently used for traditional practitioners.

Attachment

Distribution:

Denzel Bibey
Dave Blaylock
Tom Blaylock
Jim Bonanni
Terry Brown
Chip Caney
John Dewees

Paul Exley
Rick Gliot
Pat Jensen
Lindsley Keeton
John Kilgour
Les Killebrew
Brian Landry

Bernie Livingston
Gene Morrow
Patrick O'Connor
Doug Pace
Alan Phair
Sherry Rahn
John Roth

Roy Stromski
Jeff Tuller
Mike Vaughan
Carol Verrastro
Pete Westermann



Dwight A. Steffensen, Chairman of the Board
Ronald J. Streck, President & CEO

National Wholesale Druggists' Association

P.O. Box 2219, Reston, VA 22090-0219 Fax # 703/787-6930
1821 Michael Faraday Drive, Suite 400, Reston, VA 22090-5348 • 703/787-0000

August 20, 1993

TO: Active Member CEO's
Government Affairs Committee
Regulatory Affairs Working Group

FROM: Diane Goyette
Director of Regulatory Affairs

Robin Pollini
Regulatory Analyst

SUBJECT: DEA Mid-level Practitioner Rule: Information on State Prescribing Authority

As previously reported to you, the Drug Enforcement Administration (DEA) published a final rule in the June 4 *Federal Register* establishing a new category of DEA registrants. Under this rule, mid-level practitioners (MLPs), such as physician assistants and nurse practitioners, will obtain and use their own DEA numbers to prescribe, dispense and order controlled substances, subject to state requirements. The rule went into effect on July 1, 1993. We have attached a copy of a June 1993, *Government Update* article outlining the new regulations (Attachment A).

MLPs will now be registered with DEA, but their authority to dispense controlled substances is granted by the state in which they practice. The final rule places the responsibility for verifying the degree of the MLP's authority to order and prescribe controlled substances on pharmacists, wholesalers and other parties in the distribution chain. Because prescribing authority varies so widely among states and types of MLPs, wholesalers need to be familiar with the restrictions imposed by each state that they service.

NWDA has developed the enclosed materials to familiarize you with the MLP prescribing authority in each state. We hope you will find them helpful in determining your obligations under the new DEA rule. The materials are based on information received from the National Association of Boards of Pharmacy, the American Academy of Physician Assistants, the American Nurses Association and various state authorities. In addition to the *Government Update* article, we have included the following:

Mid-Level Practitioner Prescribing Authority by State Chart (Attachment B) - This chart provides information on the prescribing authority, per state, for the following MLPs: doctors of homeopathy, physician assistants, advanced registered nurse practitioners, "other nurses" and optometrists. This is only a partial list, containing information on the

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more commonly encountered MLPs. It should be noted that other practitioners may be covered under the MLP rule. For the purposes of this chart, the term "other nurses" includes clinical nurse specialists, nurse midwives, certified registered nurse anesthetists and various nurse practitioner specialists.

The chart takes each state and assigns the five MLP groups a number representing their prescribing authority under that state's regulations. MLPs with independent prescribing authority (category 1) or limited prescribing authority (category 3) are probably of the most concern to you as a wholesaler because these MLPs have the greatest degree of authority to prescribe. Dependent prescribing authority (category 2) in some states may also be of concern. A description of the categories appears at the beginning of the chart.

Notes on Dependent and Limited Mid-Level Practitioner Prescribing Authority, by State (Attachment C) - These notes accompany the chart to provide additional information on dependent and limited prescribing authority for physician assistants and nurses. Accordingly, each category 2 and 3 listing on the chart has a corresponding explanation in the notes. Many of the chart entries for other nurses "vary." Where this variation could not be covered in the notes, you will need to contact the state for more information.

State Contact Listings (Attachment D) - Because there are so many different types of MLPs and the prescribing authority for each of these MLPs varies widely by state, you may need to supplement the enclosed information by contacting the states for more information. The contacts at the state Boards of Pharmacy and state licensing agencies listed in this package should be able to answer any questions that you have regarding MLP prescribing authority.

We hope that the enclosed materials will assist you in responding to the requirements of the new DEA mid-level practitioner rule. As new information becomes available we will update these materials for your use. If you have questions regarding the enclosed materials or the mid-level practitioner rule, please contact Robin Pollini, NWDA Regulatory Analyst, Ext. 242.



GOVERNMENT



Update.

National Wholesale Druggists' Association PO Box 2219, Reston, VA 22090 • 703/787-0000

Vol. 13 No. 6
June 1993

DEA Now Registers MLPs

Changes Could Pose New Burdens For Pharmacists, Wholesalers

The Drug Enforcement Administration (DEA) published a final rule in the June 4 *Federal Register* establishing a new category of DEA registrants. Under the new rule, which goes into effect on July 1, 1993, mid-level practitioners (MLPs) will obtain and use their own DEA numbers in dispensing controlled substances, subject to restrictions imposed by their state of practice.

The final rule defines an MLP as "an individual practitioner...other than a physician, dentist, veterinarian, or podiatrist, who is licensed, registered, or otherwise permitted by the United States or the jurisdiction in which he/she practices, to dispense a controlled substance in the course of professional practice." DEA considers "dispensing" to include administering, prescribing and directly dispensing — delivering to the ultimate user — controlled substances. Examples of MLPs include nurse practitioners, nurse midwives, nurse anesthetists, clinical nurse specialists and physician assistants.

Until now, MLPs have used the DEA number of their supervising practitioner or institution, again subject to state requirements. The new MLP registration numbers will begin with the letter "M" rather than the letters "A" or "B," currently used for traditional practitioners, so they can be identified as a separate registration category.

Although MLPs now will be registered with DEA, their authority to dispense controlled substances is granted by the state in which they practice and varies widely. In the final rule, DEA acknowledges that verifying MLP dispensing authority will pose difficulties, but notes that it will be the responsibility of pharmacists, wholesalers and other parties in the distribution chain to contact the appropriate state officials to verify the degree of dispensing authority an MLP has been granted.

The burden of this verification is expected to fall primarily on pharmacists, who most commonly will receive orders for controlled substances in the form of individual prescriptions from MLP prescribers. However, drug wholesalers also can expect to handle orders for controlled substances bearing the M-designated DEA number. The unique number format should alert wholesalers to the fact that an MLP customer may or may not be authorized to order controlled substances in a given state. Since this authority varies so widely, wholesalers need to be familiar with the restrictions imposed by each state it services.

NWDA currently is compiling information on the states' laws governing MLPs, and will distribute this information to members as soon as it is complete.

ATTACHMENT B

MID-LEVEL PRACTITIONER (MLP) PRESCRIBING AUTHORITY BY STATE

This table provides information on state prescribing authority for a limited number of mid-level practitioners (MLPs). Please note that for the purposes of this chart, the term "other nurses" includes clinical nurse specialists, nurse practitioners and various nurse practitioner specialists. The codes used to describe the authority granted in each state are as follows:

- 1 - Independent prescribing authority: The MLP has independent authority to order or prescribe controlled and non-controlled substances.
- 2 - Dependent prescribing authority: The MLP may order or prescribe certain controlled substances under the supervision of a physician. See the notes that accompany this table for specific requirements by state.
- 3 - Limited prescribing authority: The MLP's prescribing authority is limited to certain types of drugs. See the notes that accompany this table for specific restrictions by state.
- 4 - The MLP may not order or prescribe controlled and non-controlled substances.
- "vary" - Prescribing authority varies among different types of nurses. Contact the state for more information.

STATE	DOCTOR OF HOMEOPATHY	PHYSICIAN ASST	ADVANCED REGISTERED NURSE PRACTITIONERS	OTHER NURSES	OPTOMETRISTS
Alabama	4	4	4	4	4
Alaska	4	2	1	2	4
Arizona	1	2	1,2	4	1
Arkansas	1	4	4	4	1
California	4	4	3	vary	4
Colorado	4	2	2	vary	4
Connecticut	4	4	2	vary	4

STATE	DOCTOR OF HOMEOPATHY	PHYSICIAN ASST	ADVANCED REGISTERED NURSE PRACTITIONERS	OTHER NURSES	OPTOMETRISTS
Delaware	4	4	4	4	4
District of Columbia	4	2	2	2	1
Florida	4	4 (see notes)	2	4	1
Georgia	4	4	4 (see notes)	4	1
Hawaii	4	4	4	4	4
Idaho	4	2	1	vary	1
Illinois	4	4	4	4	4
Indiana	4	4	4	4	1
Iowa	4	2	3	4	1
Kansas	4	2	2	4	1
Kentucky	4	4	4	4	3,4
Louisiana	4	4	4	4	4
Maine	4	2	2	vary	4
Maryland	4	4	2	vary	4
Massachusetts	4	2	4	vary	4
Michigan	4	2	2	2	4
Minnesota	4	2	2	vary	4
Mississippi	4	4	2	vary	4
Missouri	4	2	4	4	1

STATE	DOCTOR OF HOMEOPATHY	PHYSICIAN ASST	ADVANCED REGISTERED NURSE PRACTITIONERS	OTHER NURSES	OPTOMETRISTS
Montana	4	3	1	vary	1
Nebraska	4	2	2	2	1
Nevada	1	2	2	4	4
New Hampshire	4	2	1	vary	4
New Jersey	4	4	4	vary	3
New Mexico	4	2	2	vary	1
New York	4	2	1	vary	4
North Carolina	4	2	2	vary	1
North Dakota	4	2	2	2	1
Ohio	4	4	4	vary	1
Oklahoma	4	4	4	4	3
Oregon	4	2	1	vary	1
Pennsylvania	4	4	4	4	4
Puerto Rico	4	4	4	4	4
Rhode Island	4	2	3	vary	1,4
South Carolina	4	2 (see notes)	2	vary	4
South Dakota	4	2	2	4	1
Tennessee	4	4	2	vary	1
Texas	4	2	2	vary	1

STATE	DOCTOR OF HOMEOPATHY	PHYSICIAN ASST	ADVANCED REGISTERED NURSE PRACTITIONERS	OTHER NURSES	OPTOMETRISTS
Utah	4	2	2	vary	2
Vermont	4	2	1	vary	4
Virginia	4	4 (see notes)	2	vary	1,4
Washington	4	2	1	1	4
West Virginia	4	2	3	4	4
Wisconsin	4	2	4	4	4
Wyoming	4	2	1,2 (see notes)	4	4

ATTACHMENT C
NOTES ON DEPENDENT AND LIMITED PRESCRIBING AUTHORITY BY STATE

- AK - Physician Assistants:** PAs may prescribe Schedules III-V controlled substances.
- Nurses:** Advanced registered nurse practitioners (ARNPs) have independent prescribing authority. The Board of Nurses may limit the types of drugs that they can prescribe in accordance with their education and experience.
- AZ - Physician Assistants:** PAs may prescribe Schedules II-III in a limited 48-hour supply, and Schedules IV-V in a 34-day supply. All prescriptions must contain the name of the supervising physician.
- Nurses:** Nurse practitioners (NPs) have full prescriptive and dispensing authority upon application and fulfillment of criteria established by the Board of Nursing. NPs may prescribe Schedule II and III drugs (limited to a 48-hour supply per patient) and Schedule IV and V (a one-month supply with no refills per patient). Other drugs may be refilled five times or up to one year.
- CA - Nurses:** NPs who have satisfactorily completed at least six months of MD-supervised experience in furnishing drugs or devices, who have satisfactorily completed a course in pharmacology and who have been issued a furnishing number by the Board of Nursing may furnish certain drugs or devices incidental to the provision of family planning services.
- CO - Physician Assistants:** Physicians may delegate limited prescribing authority to certified PAs. PAs may issue prescriptions for non-controlled substances only.
- Nurses:** NPs may write prescriptions for select drugs pursuant to an established protocol.
- CT - Nurses:** Nurse practitioners, clinical specialists, nurse midwives and nurse anesthetists may apply for prescriptive practice privileges. ARNPs must apply for licensure in order to prescribe. Dispensing privileges are also granted to ARNPs functioning in public clinics.
- DC - Physician Assistants:** PAs may sign prescriptions for non-controlled substances on Rx pads that contain the name of the supervising physician and PA.
- Nurses:** DC provides dependent prescriptive authority for NPs, nurse midwives and nurse anesthetists for Class II-V drugs according to existing federal laws.
- FL - Physician Assistants:** Legislation passed in 1992 grants PAs dependent authority to prescribe drugs according to a formulary. Although the legislation has been passed, the mechanisms for implementing the legislation will not be fully in place until early fall.
- Nurses:** NPs have dependent prescriptive privileges for non-controlled substances.
- GA - Nurses:** Although nurses have no prescribing authority, a 1989 law states that through a protocol a physician may delegate to a nurse in advanced practice the authority to order controlled substances and dangerous drugs.

ID - Physician Assistants: PAs may write prescriptions as agents of their supervising physicians by applying to the board for prescription-writing authority. The board-approved formulary is limited to 24 categories of legend drugs (antibiotics, non-narcotic analgesics, contraceptives, topical and local anesthetics, etc.).

Nurses: Prescribing is allowable for approved NPs based upon a formulary in the rules; NPs may not prescribe controlled substances.

IA - Physician Assistants: Physicians may delegate the function of prescribing drugs, controlled substances, and medical devices to a licensed PA. PAs may prescribe Schedules II-V controlled substances, except Schedule II stimulants and other depressants. PAs may order Schedule II stimulants and depressants with the prior approval and direction of a physician, and may request, receive and supply sample drugs and medical devices.

Nurses: Nurses may write prescriptions for non-controlled substances under an established protocol.

KS - Physician Assistants: PAs may issue prescription orders orally by telephone for Schedule II controlled substances in an emergency. The supervising physician must provide a written prescription within 72 hours. PAs may orally by telephone transmit prescription orders for Schedules III, IV and V controlled substances, as well as non-controlled substances, which may also be prescribed in writing.

Nurses: NPs may prescribe under jointly adopted protocols between the nurse and physician.

ME - Physician Assistants: Physicians may authorize PAs to prescribe or dispense controlled substances. Authorized PAs may issue prescriptions for categories of drugs on the board-approved formulary, which excludes Schedule II controlled substances. All parenterals except insulin are excluded unless prescribed for administration within a hospital, clinic, physician's office or nursing home. The amount of scheduled drugs that may be prescribed may be no more than 100 dose units or a 90-day supply, whichever is less.

Nurses: Prescriptive authority is approved by the Board of Medicine. Limits in prescribing formulary by exclusion (i.e., narcotics).

MD - Nurses: NPs prescribe medications as agreed upon in writing with physicians.

MA - Physician Assistants: PAs may write prescriptions for legend drugs and controlled substances (Schedules II-V). Prescriptions and medication orders must be issued in accordance with guidelines developed by each PA and supervising physician.

MI - Physician Assistants: Physicians may delegate to PAs the prescription of drugs other than controlled substances. The supervising physician's name must be indicated in connection with each individual prescription.

Nurses: Physicians may delegate the prescribing of drugs to RNs, excluding controlled substances.

MN - Physician Assistants: Physicians may delegate to PAs the authority to prescribe and administer legend drugs and medical devices that are appropriate to the practice. This delegation must be approved by the board. Physician and PA must have an internal protocol that lists the drugs and medical devices the PA may prescribe or administer.

Nurses: NPs have prescriptive authority when delegated to do so under a written agreement with a physician. Nurse midwives also have authority to prescribe.

MS - Nurses: NPs have statutory prescriptive authority granted by the Board of Nursing. This authority is based on the accepted protocol, which lists the treatments and medications the NP expects to prescribe in his or her practice. NPs are not allowed to prescribe controlled substances.

MO - Physician Assistants: The regulations do not impose restrictions on the types of drugs that PAs can prescribe. This is left to the discretion of the supervising physician.

MT - Physician Assistants: PAs may prescribe, dispense and administer drugs to the extent authorized by the rules of the medical board and/or the physician's utilization plan. Authority granted to the PA may include Schedule III, IV and V controlled substances, and Schedule II with a 48-hour limit. The medical board does not permit PAs to prescribe thrombolytics.

NE - Physician Assistants: PAs can only prescribe medications as an agent of a supervising physician. The PA may prescribe medications in the name of the supervising physician if the authority has been assigned by the physician (Schedule II controlled substances used for pain control are limited to a 72-hour supply). Prescription label must bear the name of both the PA and the supervising provision.

Nurses: ARNPs have dependent authority based on a practice agreement with their supervising physician.

NV - Physician Assistants: PAs may prescribe poisons, dangerous drugs or devices, but not controlled substances. PAs must be registered with the Board of Pharmacy.

Nurses: ARNPs may prescribe if certified by the Board of Nursing.

NH - Physician Assistants: Prescriptions transmitted by PAs must be based on patient-specific orders from the supervising physician or on written protocols. All Rx for controlled substances must contain the supervising physician's DEA number with the PA's state license number as a three-digit suffix.

NM - Physician Assistants: PAs may prescribe, administer and distribute dangerous drugs other than controlled substances provided it is done under physician supervision and within medical board-approved guidelines and formulary. The formulary lists 70 types of drugs PAs may prescribe.

Nurses: NPs have prescriptive privileges with their own signature in accordance to written protocols with physician supervision.

NY - Physician Assistants: Physicians may assign prescribing authority to registered PAs. PAs may not prescribe controlled substances.

NC - Physician Assistants: PAs are authorized by law to write prescriptions under conditions specified by the state board of medical examiners. PAs may prescribe drugs from a medical board-approved formulary that excludes controlled substances and parenteral preparations except insulin, immunizations, serum, epinephrine and benadryl. A prescription may not indicate a refill except birth control pills and may be for no more than 100 dosage units or a one-month supply.

Nurses: ARNPs may prescribe non-controlled substances under the supervision of a physician.

ND - Physician Assistants: PAs may prescribe controlled substances, except Schedule II, as agents of their supervising physicians.

Nurses: The Board of Nursing is responsible for delegating prescribing authorities. Once approved by the Board, nurses may prescribe drugs under the supervision of a physician. The types of drugs that a nurse can prescribe are determined by their area of expertise (six practice areas) designated by the Board.

OR - Physician Assistants: Physicians may delegate to PAs the authority to administer and dispense limited emergency medications and to prescribe. The medical board's Physician Assistants Committee is authorized to review applications for prescribing and dispensing privileges and to recommend a formulary that may include all or part of Schedules III through V. To prescribe Schedules II through V controlled substances, PAs must be registered with DEA.

PA - Physician Assistants: Regulations are currently under development that would allow PAs to prescribe and dispense drugs at the direction of licensed physicians. The rules include a formulary that excludes Schedules I and II controlled substances. Until the regulations are promulgated PAs have no prescribing authority.

RI - Physician Assistants: PAs may write prescriptions and medical orders. PAs employed by physicians, HMOs or other health care delivery organizations may prescribe legend medications and Schedule V controlled substances, medical therapies, device and diagnostics according to guidelines established by their employers. Guidelines are updated annually. PAs prescribing controlled substances must register with the state drug control division and with DEA.

Nurses: NPs have prescriptive authority for legend drugs but not for controlled substances.

SC - Physician Assistants: Regulations are currently under development that would grant PAs dependent authority to prescribe Schedule V controlled substances. The regulations would also establish a formulary and appropriate protocols. Until these regulations are developed and implemented PAs have no prescribing authority.

Nurses: Nurses are certified through the Board of Nursing for dependent prescribing authority.

SD - Physician Assistants: PAs can communicate information regarding Schedules III-V drugs to the pharmacy either in writing or by phone. PAs must act as agents of physicians to issue prescriptions for controlled substances; the physician decides on drug, dosage, amount and length of therapy.

Nurses: Certified NPs may prescribe under a practice agreement with the supervising physician. NPs act as the agent of the primary supervising physician in providing and prescribing, except for Schedule II controlled substances.

TN - Nurses: Certified NPs may apply to the Board of Nursing for a "certificate of fitness" with privileges to write and sign prescriptions and/or issue non-controlled legend drugs.

TX - Physician Assistants: Physicians may authorize PAs to administer, provide or carry out a prescription drug order (i.e., complete a prescription pre-signed by the supervising physician) in medically underserved areas.

Nurses: ARNPs have prescriptive authority under standing orders or protocols; prescriptions must be "presigned." To be authorized to prescribe the ARNP must serve certain medically underserved populations.

UT - Physician Assistants: PAs may, in accordance with an approved utilization plan, prescribe Schedule IV and V controlled substances for a period not to exceed seven days.

Nurses: All NPs who practice with a physician can apply for prescriptive privileges in accordance with protocols between the NP and physician. NPs can prescribe controlled substances III-V.

VT - Physician Assistants: PAs may prescribe only drugs selected by the supervising physician from the board-approved drug list. The board's approved drug list contains 25 categories. Some categories, such as heavy metal antagonists, antineoplastics, coagulation agents, cardiovascular drugs and oxytoxic, require additional protocols describing in detail the conditions under which the PA will be prescribing. The physician may delegate the prescribing of controlled substances in any of the categories.

VA - Physician Assistants: Regulations are currently being developed that would give PAs dependent authority to prescribe non-controlled substances. The regulations will include a formulary of specific drugs and devices a PA may prescribe under a written protocol with the supervising physician.

Nurses: ARNPs may prescribe most Schedule VI drugs under the supervision of a licensed physician.

WA - Physician Assistants: PAs may issue written or oral prescriptions when approved by the board and assigned by the supervising physician. Prescriptions for drugs in Schedule II-V may be issued for patients under the care of the sponsoring physician.

WV - Physician Assistants: PAs in all settings may issue prescriptions at the direction of their supervising physician. A state formulary excludes Schedule I and II controlled substances, anticoagulants, antineoplastics, radiopharmaceuticals, general anesthetics, and radiographic contrast materials. Drugs listed under Schedule III are limited to a 72-

hour supply without refill. Medical board rules exclude parenterals, except insulin and epinephrine, from the formulary.

Nurses: ARNPs have limited authority to prescribe, including some controlled substances.

- WI - Physician Assistants: Supervising physicians may direct a PA to prepare a prescription order for non-controlled substances if the PA prepares the prescription order only in patient situations specified and described in written protocols; the PA consults directly with the physician, when practicable, prior to preparing a prescription; and the prescription contains the name and address of the physician and PA.
- WY - Physician Assistants: PAs may prescribe medications as an agent of the supervising physician, except for Schedule I and II controlled substances. When prescribing controlled substances the supervising physician's DEA number is used.

Nurses: Current legislation states that nurses have prescribing and dispensing capabilities under a "collaborative agreement" with a physician. The Attorney General is currently in the process of determining whether this "collaborative agreement" constitutes independent or dependent prescribing authority. Until the issue is resolved nurses do not have prescriptive authority for controlled substances.

TO: Tom Blaylock/*National Specialty Serv.* DATE: September 7, 1993
John Dewees/*Marmac* FROM: Steve Reardon *SR*
Paul Exley/*Ohio Valley* SUBJ: DEA Registrations
Rick Gliot/*Chapman*
Pat Jensen/*Syracuse*
Ben Jones/*Bailey*
Brian Landry/*Mississippi*
Doug Pace/*Florida*
John Roth/*Solomons*
Roy Stromski/*Daly*
Carol Verrastro/*Ellicott*

CC: George Bennett/*Dublin*
Pete Westermann/*Dublin*
Linda Zarlengo/*Dublin*

At a recent meeting with DEA in Washington, D.C., Jim Pacella, DEA's Policy Unit Chief, discussed DEA registration verification issues with NWDA's Regulatory Affairs Committee. The points Mr. Pacella made are summarized as follows:

- Local DEA offices have been instructed not to verify DEA registrations verbally via the telephone. The reason is that certain wholesalers were using this as the sole means of verifying their customers' DEA registration numbers. Despite these instructions, however, I am aware of local offices that continue to verify numbers over the telephone. My recommendation is that if, in emergency situations, your local DEA office will provide this service, then you should continue to use it as long as the verification is documented on a Regulatory Agency Contact Form. This method, however, should not replace your existing Registration Verification Procedure.
- Local DEA offices should not be verbally issuing DEA registration numbers upon inspections of new registrants. DEA's policy is that a person is not registered until the registration certificate is issued. Although DEA Washington denies it, I know that local DEA offices continue this practice. Again, if your local DEA offices operate in this manner, you should take advantage and service your customer as long as you document the verification and request from your customer a copy of the certificate immediately upon receipt.

- A 60-90 day registration renewal grace period exists during which time you can continue to sell to customers who have yet to receive their renewed registration. I would recommend that you obtain a copy of the customer's renewal application and processed check if possible.
- For those accounts who operate on a physician's DEA registration, the physician's name should also appear on the records for that account; i.e., the invoice should show:

ABC Clinic
Dr. John Smith

If you have any questions regarding these issues, please call.



U.S. Department of Justice
Drug Enforcement Administration

②

Washington, D.C. 20537

NOV 29 1993

Ms. Diane P. Goyette
Director of Regulatory Affairs
National Wholesale Druggists' Association
1821 Michael Faraday Drive
Suite 400
Reston, Virginia 22090-5348

Dear Ms. Goyette:

This is in response to your correspondence of November 4, 1993, requesting information on any written clarification of security issues prepared by the Drug Enforcement Administration concerning specifications for cages and security containers. The Office of Diversion Control (OD) routinely disseminates security information to its field offices as part of its effort to insure uniform interpretation and application.

Recently, two security notices were prepared and distributed to the field Diversion Investigators. One addressed the new GSA specification revision for Class 5 security containers and the other addressed the cage configuration utilized for the storage of Schedule III-V controlled substances. The following is a synopsis of those two notices:

Class V Security Containers: This notice covered the General Services Administration's (GSA) specification revisions for improved, manipulation-resistant combination locking devices used on GSA Class 5 and 6 security containers and vault doors. This revision was intended to counter surreptitious entry using an auto-dialing device and/or radiological or emanations analysis. As a result, the specifications were changed to read as follows: "20 man-hours against surreptitious entry; 30 man-minutes against covert entry; and 20 man-hours against radiological techniques."

This notice further stated that only one lock, the Mas-Hamilton X-07, meets the new specifications without modifications. It further explained that the security

Ms. Diane P. Goyette

Page Two

standards listed in 21 CFR 1301.72(a)(1)(i) and 1301.72(a)(3)(ii) have not been revised to agree with the new GSA specifications.

- Lastly, the notice re-emphasized the fact that the regulations do not require a registrant to utilize a GSA Class 5 container. Instead, the regulations spell out the minimum security requirements for a security container or vault door used for the storage of Schedule I and II controlled substances. There are several security containers which, when equipped with a Group 1-R three position dial-type combination lock, meet the current Federal requirements.

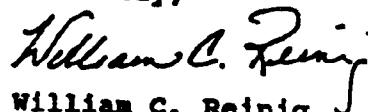
Schedule III-V Cage Specifications: This notice clarified the construction specifications for cages utilized for the storage of Schedule III-V controlled substances. As described in 21 CFR Section 1301.72(b)(4)(ii), a cage's mesh construction cannot have openings greater than 2 1/2" across the square. The confusion existed with the phrase "across the square" which is not a standard size measurement used by cage manufacturers to describe mesh fabric. The industry measurement for mesh size is the minimum distance between the wires forming the parallel sides of the mesh.

Some field offices were interpreting this measurement to be the diagonal distance from corner to corner, while other offices were using the distance between the parallel sides of the mesh configuration. A size comparison of the two options shows a substantial mesh size difference.

Based on this comparison and the intent of this regulation, it was decided that the 2 1/2" measurement has to be interpreted as the greatest point of separation in the mesh configuration. Another way of describing this regulation requirement is that the mesh size cannot exceed 1 3/4" by industry standards.

I trust that the above information adequately addresses your request. If you have any additional questions, please do not hesitate to contact this office.

Sincerely,



William C. Reinig
Security Specialist
Office of Diversion Control

TO Tom Blaylock
Brendan Connolly
Paul Exley
Ben Jones
David Kozaczka
Brian Landry
George Oughterson
Doug Pace
John Roth
Roy Stromski
Mike Vaughan
Carol Verrastro

DATE February 14, 1994

FROM Steve Reardon

SUBJ DEA Security Issues

CC: George Bennett
Pete Westermann

Attached, for your information and your DEA file, is a letter from Bill Reinig, DEA Diversion Security Specialist, to Diane Goyette, NWDA Director of Regulatory Affairs. The purpose of the letter is to summarize two security notices recently distributed to DEA field offices. One addressed a new GSA Class V specification for vault door construction; the other, controlled substance cage construction.

Evidently, as a result of the change in the GSA Class V vault door specifications, some local DEA offices were requiring vault doors of this new design. Reinig, in the letter, explains that while the GSA description did change, DEA regulations do not automatically require use of a GSA Class V door. Several different designs can meet DEA requirements. The cage construction section is self-explanatory.

If you have any questions, please call.

Attachment



Cardinal Health, Inc.
INTEROFFICE MEMORANDUM

To: Martin Alires/Syracuse
Bill Becker/Florida
Brendan Connolly/Ellicott
Mike Davison/Behrens-Lubbock
John Dewees/Marmac
Paul Exley/Ohio Valley
Jack George/Behrens-Waco
Ben Jones/Chapman
Les Killebrew/Mississippi
Harry Myers/Humiston Keeling
George Oughterson/PRN
John Roth/Solomons
Roy Stromski/Daly
Loren Todd/Bailey

CC: Joe Neary/Whitmire
Pete Westermann/Dublin

From: Steve Reardon *Steve*

Date: July 28, 1994

Re: Order Forms (DEA Form 222)

Attached for your information and your DEA file is a letter issued by DEA to further clarify their position on the proper completion of DEA Form 222 with respect to number of lines completed. The regulatory interpretation is as follows:

- When a purchaser has used five lines on a DEA Form 222 to order controlled substances, and two lines contain entries for the same product and package size, the number of items ordered would be four. If the purchaser erroneously indicated that five items had been ordered, DEA would deem this a minor error which could be corrected.

Please read the letter for the specifics of this interpretation and pass the information on to the appropriate personnel in your division.

If you have any questions, please call.

Attachment



Cardinal Health, Inc.
INTEROFFICE MEMORANDUM

To: Distribution

From: Steve Reardon, Joe Neary

Date: August 12, 1994

Re: Reverse Management Systems (3CI) Waste Disposal Program

Cardinal Health, Inc., has entered into an agreement with Reverse Management Systems (3CI) to dispose of our non-hazardous waste, including controlled substances, legend drugs, OTC items, and aerosols. Reverse Management Systems is registered with the Drug Enforcement Administration in Schedules II, III, IV and V, the Texas Department of Health, and the Texas Department of Public Safety. This registrant status allows them to receive and take possession of controlled substances and legend drugs for the purpose of disposal via incineration.

The pricing schedule is as follows:

1-24,999	pounds	\$.045/lb.
25T-74,999	pounds	\$.043/lb.
75T-99,999	pounds	\$.041/lb.
> 100 T	pounds	\$.039/lb.

The total pounds will be counted over a twelve-month period that will start with our first shipment. The steps to facilitate this process are outlined on the following page.

It is strongly recommended that this service be our sole method of disposal so that we may take advantage of volume discounts and assure compliance with applicable Federal, State, and local regulations. We believe that Reverse Management Systems (3CI) can provide us with a simple, efficient, and economical means to manage pharmaceutical waste. Please contact Joe Neary or me if, for some reason, you do not intend to utilize this service.

If you have any questions, please call.

Attachment



Cardinal Health, Inc.

PREPARING PRODUCT FOR DESTRUCTION

STEP ONE:

To arrange for destruction, contact:

Mr. Dennis Ingles, Operations Manager
Reverse Management Systems
DEA Number RE0196611
201 San Augustine Street
Center, Texas 75935

1-800 RX REVERSE (797-3837), or Fax 1-409-598-9539

STEP TWO:

Reverse Management Systems will provide you with DEA 222 Forms for your Schedule II products.

STEP THREE:

Create a debit memo or zero dollar invoice to Reverse Management Systems. This will serve as documentation of the transfer and create required records (ARCOS, etc.).

STEP FOUR:

When preparing product for shipment:

1. Verify that each return is packed according to the products on the schedule II form.
2. Segregate, and package separately, all other schedules from the legend products.
3. Pack aerosols separately.
4. Note that legend and OTC product do not need to be packaged in any special order.
5. Notify Reverse Management Systems by telephone or fax as to when shipment will be made.
6. Attach an A.O.D. tag to the top of the box for all orders to be shipped UPS. All other shipments must have some other proof of delivery receipt.
7. Include a copy of the debit memo or invoice with the shipment.

STEP FIVE:

Upon completion of the products' incineration, you will receive the following receipts:

- a) A copy of the completed DEA Form 41.
- b) A detailed burn report, itemizing each box with third party verification.
- c) An invoice detailing the amount based on per pound price.
- d) Documentation showing the accurate weight and the actual destruction, by incineration date, verified by third party municipality.



CARDINAL HEALTH, INC.
MEMORANDUM

TO: Division Managers / Directors of Operation
FROM: Steve Reardon *Steve*
DATE: June 28, 1995
SUBJECT: Regulatory Reminder
CC: Michael Proulx
Joe Neary
Art Hammerschmidt
Carol Verrastro

When providing back-up delivery service to another division's customers there are licensing and record keeping issues that must be addressed in order to assure compliance with applicable regulatory requirements. These requirements are as follows:

LICENSING:

Transactions between divisions (except in Georgia and Ohio) qualify for an intra-company exemption, and state licensure is not required. Shipping prescription drugs and/or controlled substances direct to customers within a state requires licensure in most instances. The attached sheet identifies where Cardinal divisions are currently licensed and lists those states where out-of-state licensure is not required. This should assist you in identifying where to go for back-up.

RECORD KEEPING:

If you ship prescription drugs and/or controlled substances directly to another division's customer, your records (invoices, computer-generated sales history reports, ARCOS reports, etc.) must show that customer as the recipient of the product. The Prescription Drug Marketing Act (PDMA) and DEA regulations require wholesalers to maintain records of all transactions regarding the receipt and distribution of prescription and controlled drugs. These records must identify the "ship to" location.

We understand the importance of being able to provide this service to our customers. Our intention is not to restrict your ability to do so. Our purpose is to inform you of the regulatory requirements that must be met when doing so.

Joe Neary and I will work with our MIS groups to explore system support for the record keeping issues. In the interim, we are open to suggestions.

I hope this memorandum clearly identifies the issues at hand. If you have any questions or comments, please contact the Corporate Compliance Department at (614) 799-6050.



U.S. Department of Justice

Drug Enforcement Administration

Washington, D.C. 20537

SEP 14 1995

Ms. Diane Goyette
National Wholesale Druggists'
Association (NWDA)
Director of Regulatory Affairs
P.O. Box 2219
Reston, Virginia 22090-0219

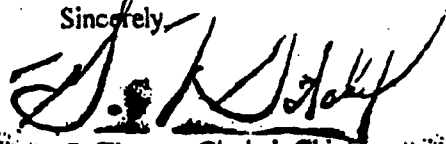
Dear Ms. Goyette:

The Drug Enforcement Administration (DEA) is pleased to announce that the DEA Form 222 (U.S. Official Order Form - Schedule I and II) used to purchase controlled substances from DEA registrants has been changed for clarification purposes. The former line entitled "Number of Lines Completed" has been changed to "Last Line Completed".

This change was made as a result of requests made by DEA registrants to avoid confusion associated with the former requirement for an entry to be made for "number of lines completed". The new forms are already being distributed. Supplies of the old forms should continue to be used until they are depleted.

Please advise your membership of this change. We have enclosed a sample article which may be used for your publications. It is hoped that this change will obviate many problems associated with the former design of the form. If you have any further questions, please contact the Liaison and Policy Section at (202) 307-7297.

Sincerely,


G. Thomas Gitchel, Chief
Liaison and Policy Section
Office of Diversion Control

Enclosure

DEA CHANGES ORDER FORM (DEA-222)

The Drug Enforcement Administration (DEA) has announced that, at the request of registrants, a change has been made to the U.S. Official Order Form for Schedule I and II controlled substances (DEA-222). This change has been made for clarification purposes and involves the replacement of the line entitled "Number of Lines Completed" with "Last Line Completed".

The instructions pertaining to the change which appear on the reverse of each individual form indicate under item "8" the following: "Enter the last line completed - this generally should correspond to the number of lines used. If a number has not been entered, the form will be returned to you for completion before the supplier is allowed to fill it."

While DEA hopes that this clarification will eliminate much of the confusion the language of this part of the order form has caused some registrants over the years, they realize that errors will still occur due to misinterpretation. When it is clear to the supplier that the number of the last line completed has been incorrectly noted due to misinterpretation, rather than an attempt to facilitate diversion, the DEA form 222 should not be rejected.

The new clarified forms have already begun to be distributed although old forms should continue to be used until depleted.

Name of PURCHASER'S Company for correspondence		No order form may be issued for Schedule I and II substances unless a properly completed copy of this form is received by the supplier.		DEA APPROVAL Rev. 11-17-87	
To: Name of Supplier		City and State		Date	
TO BE FILLED IN BY PURCHASER		TO BE FILLED IN BY SUPPLIER		SUPPLIER'S DEA REGISTRATION NO.	
1	2	3	4	5	6
No. of Packages	Name of Package	Name of Sub	Amount Being Ordered	Package Strength	Sub. Weight
1					
2					
3					
4					
5					
6					
7					
8					
9					
10					
← LAST LINE COMPLETED (MUST BE 10 OR LESS)		SIGNATURE OF PURCHASER OR ATTORNEY OR AGENT			
Name of Supplier		DEA Registration No.		Name and Address of Supplier	
Signature		Date		City and State	
Registered on or before		No. of this Order Form		Date	
DEA Form 222 Oct. 1987		U.S. OFFICIAL ORDER FORM - SCHEDULES I & II DRUG ENFORCEMENT ADMINISTRATION		55690014	

VOID

See Reverse of PURCHASER'S Copy for Instructions
 No order form may be issued for Schedule I and II substances unless a completed application form has been received. (21 CFR 1305.04)
 OMB APPROVAL No. 1117-0010

TO: (Name of Supplier) **CARDINAL**
JAMES W. DALY, INC.
 STREET ADDRESS
11 Centennial drive

CITY and STATE
Peabody, MA 01960
 DATE
2/1/93
 TO BE FILLED IN BY SUPPLIER
 SUPPLIER'S DEA REGISTRATION No.

TO BE FILLED IN BY PURCHASER						TO BE FILLED IN BY SUPPLIER	
L I N E N O.	No. of Packages	Size of Package	Name of Item	National Drug Code	Packages Shipped	Date Shipped	SUPPLIER'S DEA REGISTRATION No.
2	6	100	MS Contin 80 mg Tablets				
3	5	10	Morphine Sulf. Inj. 250 mg				
4			Add-Vantage Vial 10 ml				
5	1	100	Ritalin 5 mg tablets				
6							
7							
8							
9							
10							

5 LAST LINE COMPLETED (MUST BE 10 OR LESS)
 SIGNATURE OF PURCHASER OR ATTORNEY OR AGENT *John Doe*

Date issued 11-25-92
 Schedules 2,2N,3,3N,4,5
 Registered as a Pharmacy
 DEA Registration No. XXXXXXXXX
 No. of this Order Form 987654321
 Name and Address of Registrant
 Your Pharmacy
 100 Main Street
 Anytown, USA 12345

DEA Form -222 (Oct. 1992)
 U.S. OFFICIAL ORDER FORMS - SCHEDULE I & II
 DRUG ENFORCEMENT ADMINISTRATION
 SUPPLIER'S Copy 1
 46455319

FOIA Confidential
 Treatment Requested By
 Cardinal

CAH SWE 019364

CONFIDENTIAL

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U.S. Department of Justice
Drug Enforcement Administration

Washington, D.C. 20537

JUL 18 1996

Ms. Diane Goyette
Director of Regulatory Affairs
National Wholesale Druggists Association
P.O. Box 2219
Reston, Virginia 22090-0219

Dear Ms. Goyette:

Thank you for your letter of April 29, 1996, voicing your organization's satisfaction with the April 17, 1996 semi-annual meeting with your membership. I know I speak for all Drug Enforcement Administration (DEA) personnel present at that meeting, in conveying their appreciation for the information presented and the cooperation received.

There are several issues that have been long-standing and we would like to bring you up to date with current activities. The proposed rule on freight forwarding has cleared DEA and is ready to be forwarded to the Department of Justice (DOJ) and the Office of Management and Budget (OMB) for their approval. The DEA ARCOS Unit has resolved the problem of "inadvertent under-reporting" that was attributed to differences in National Drug Code Numbers (NDC) pertaining to sizes. The ARCOS Unit has been able to take care of this problem internally without any further involvement of ARCOS participants.

The last issue centers around delivery of Schedule II order forms by drivers and the associated distribution scenarios. DEA has carefully reviewed the scenarios discussed at the April 17, 1996, meeting and has approved the following circumstances in which driver handling of Schedule II Order Forms (DEA Form 222) will be permitted, and the circumstances under which we will allow DEA Forms 222 to be transmitted by facsimile. DEA will permit the driver to handle DEA Forms 222 provided they are carried in a sealed envelope. DEA will permit the "faxing" of DEA Forms 222 by the customer to the DEA registered distribution center, in order to facilitate the expedient filling of the DEA Form 222. The distributor may prepare the order

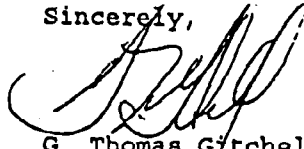
Ms. Diane Goyette

Page Two

from the facsimile and then compare the prepared order with the controlled substances, when the original DEA Form 222s arrive with the driver. Under no circumstances will DEA permit the driver to have the sole responsibility for reconciliation of the pre-prepared order with the actual DEA Form 222. DEA also does not approve of the scenario that allows the driver to "fax" the copy of the order form at the cross-docking facility. The cross-docking facility should only be used for the temporary storage of controlled substances in transit and DEA will not recognize any other activity, such as "faxing", at the facility. Further, the driver should have no knowledge as to the contents of the DEA Form 222. Also, it is the opinion of DEA that allowing the drivers to be responsible for sole reconciliation of Schedule II orders does not provide the "special handling" of Schedule II orders that the Controlled Substances Act mandates and the diversion possibilities presented by this scenario are obviously more plentiful.

Please convey this decision to your membership. We will inform all of our field offices of this approved procedure, in the hope that it will prevent admonishments such as the one that one of your members was given for allowing the driver to transport the DEA Forms 222. As always, it was a pleasure meeting with you and your membership. If you have any questions, please contact the Liaison and Policy Section at (202) 307-7297.

Sincerely,



G. Thomas Gitchel, Chief
Liaison and Policy Section
Office of Diversion Control



U.S. Department of Justice
Drug Enforcement Administration

Washington, D.C. 20537

AUG 28 1996

Ms. Diane Goyette
Director of Regulatory Affairs
P.O. Box 2219
Reston, Virginia 22090-0219

Dear Ms. Goyette:

Reference is made to our recent meeting regarding the facsimile transmission of DEA forms 222 from retail pharmacies to distributors. As I advised you at that time, the Drug Enforcement Administration (DEA) will permit the facsimile transmission of an executed DEA form 222 directly from a retail pharmacy to a distributor to facilitate filling of an order, provided that the facsimile copy is compared with the original copy prior to shipping the order. It is acceptable, although in our view, not desirable, to permit a proprietary driver, acting as an agent/employee of the distributor, to "fax" a DEA form 222 on behalf of the pharmacy, to the distribution center. The practice of allowing common or contract carriers to "fax" DEA forms 222 to distribution centers, however, is not in the public interest and does not effectively guard against diversion.

We realize that distribution centers adopted procedures for facsimile transmission of DEA forms 222 to expedite delivery of controlled substances to their customers. Nevertheless, we are very concerned that a practice that enables common or contract truck drivers, who are subject to only limited security checks and controls, to know exactly what a particular shipment of drugs will contain, poses a significant threat of diversion.

We urge your members, therefore, to cease this practice as soon as possible. It has been represented that the practice of "faxing" DEA forms 222 by common and contract carriers is widespread and well-established in many of your members' distribution centers. Therefore DEA will recognize a transition period until December 31, 1996 to discontinue this practice.

If you have any questions, please let me know.

Sincerely,

G. Thomas Gitchell, Chief
Liaison and Policy Section
Office of Diversion Control



U. S. Department of Justice

Drug Enforcement Administration
Office of Diversion

Washington, D.C. 20537

NOV 17 1997

Diane P. Goyette, Director
Regulatory Affairs
National Wholesale Druggists' Association
P.O. Box 2219
Reston, Virginia 20195-0219

Dear Ms. Goyette:

This is in response to your letter of August 13, 1997, regarding the proper procedure for documenting liquid controlled substance loss through accidental breakage of its container.

1. You ask whether such loss should be reported using a DEA Form-41, "Registrants Inventory of Drugs Surrendered," or a DEA Form-106, "Report of Theft or Loss of Controlled Substances."

When a bottle containing a controlled substance is accidentally broken, the registrant should report the loss on a DEA Form-41. The DEA Form-41 is used to report the disposal of controlled substances in the registrant's possession. As you are aware, DEA requires that the loss be reported in order to account for all dispositions of the controlled substance within the closed distribution system. Any remaining controlled substance, with the container labeling, should be disposed of in accordance with Title 21, Code of Federal Regulations (21 CFR), Section 1307.21. A registrant should use a DEA Form-106 to report an unaccounted for loss, a theft or a loss in transit.

2. You also ask what a distributor should use in the "Associated Registrant Number" and "DEA Order Form Number" fields of the ARCOS report.

The DEA ARCOS Reporting Manual states that the registrant, in accounting for the loss on an ARCOS report, should place a code "Y" in the transaction field, and the DEA Area Office Registration Number in the "Associated Registrant Number" field. The "DEA Order Form Number" field should remain blank.

3. And lastly, you inquire whether DEA requires a distributor to keep the pieces of broken bottle as evidence of the incident.

DEA does not require a registrant to keep the broken bottle pieces as evidence of the incident, but does require that the loss be documented as outlined above.

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Treatment Requested By
Cardinal

CONFIDENTIAL

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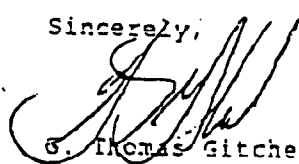
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Diane P. Goyette

Page 2

I trust that the foregoing adequately answers your questions. If we may be of further assistance, please do not hesitate to contact this office at (202) 307-7297.

Sincerely,



G. Thomas Gitchel, Chief
Liaison and Policy Section
Office of Diversion Control

Divisional Licensure By State

Alabama Calumet City Cord Logistics Jackson Knoxville Lakeland NSS-Abuquerque NSS-Nashville PharmPak Savannah	Alaska Auburn Out of State Licensure Not Required	Arizona Phoenix Out of State Licensure Not Required	Arkansas Cord Logistics Jackson Kansas City Lakeland NSS-Abuquerque NSS-Nashville St. Louis Williams Drug	California Auburn Calumet City Cord Logistics National PharmPak NSS-Nashville Ontario Sacramento Union City Valencia	Colorado Albuquerque Cord Logistics Denver Lakeland NSS-Nashville PharmPak Williams Drug
Connecticut Allentown Boston Cord Logistics Hartford Lakeland NSS-Abuquerque NSS-Nashville PharmPak Syracuse Williams Drug	Delaware Allentown Boston Cord Logistics Lakeland NSS-Abuquerque NSS-Nashville Syracuse Williams Drug	Dist. of Col. Allentown Cord Logistics NSS-Abuquerque NSS-Nashville Wheeling	Florida Calumet City Cord Logistics Jackson Knoxville Lakeland NSS-Nashville PharmPak Savannah Syracuse Williams Drug Winston-Salem	Georgia Auburn Boston Calumet City Cord Logistics Denver Knoxville NSS-Abuquerque NSS-Nashville PharmPak Phoenix Sacramento	Georgia cont'd. Salt Lake City Savannah Waco Wheeling Winston-Salem Williams Drug
Hawaii Out of State Licensure Not Required	Idaho Auburn Cord Logistics Lakeland Salt Lake City Williams Drug NSS-Nashville	Illinois Calumet City Chicago Cord Logistics Kansas City Lakeland Milwaukee NSS-Abuquerque NSS-Nashville PharmPak St. Louis Williams Drug	Indiana Calumet City Chicago Cord Logistics NSS-Nashville PharmPak St. Louis Williams Drug	Iowa Calumet City Chicago Cord Logistics Kansas City Lakeland NSS-Abuquerque NSS-Nashville Minneapolis Williams Drug	Kansas Cord Logistics Kansas City Lakeland NSS-Nashville PharmPak Williams Drug

Divisional Licensure By State

Kentucky	Louisiana Cord Logistics Jackson Knoxville Lakeland NSS-Albuquerque NSS-Nashville PharmPak Waco Williams Drug	Maine Allentown Boston Cord Logistics Lakeland NSS-Albuquerque NSS-Nashville PharmPak Syracuse Williams Drug	Maryland Allentown Boston Cord Logistics Lakeland NSS-Albuquerque NSS-Nashville PharmPak Wheeling Williams Drug	Massachusetts Boston Out of State Licensure Not Required	Michigan Calumet City Chicago Cord Logistics Lakeland Milwaukee NSS-Albuquerque NSS-Nashville PharmPak Syracuse Williams Drug Zanesville
Minnesota Calumet City Cord Logistics Lakeland Minneapolis NSS-Albuquerque NSS-Nashville PharmPak Williams Drug	Mississippi Cord Logistics Jackson Knoxville Lakeland NSS-Albuquerque NSS-Nashville PharmPak Williams Drug	Missouri Auburn Chicago Cord Logistics Denver Houston Jackson Kansas City Knoxville Lakeland	Missouri cont'd NSS-Nashville Phoenix Sacramento Salt Lake City St. Louis Williams Drug Winston-Salem PharmPak	Montana Auburn Cord Logistics Denver Lakeland NSS-Albuquerque NSS-Nashville Salt Lake City Williams Drug	Nebraska
Nevada Cord Logistics Lakeland NSS-Albuquerque NSS-Nashville Phoenix Sacramento Salt Lake City Valencia Williams Drug	New Hampshire Allentown Boston Cord Logistics Lakeland NSS-Albuquerque NSS-Nashville Williams Drug	New Jersey Out of State Licensure Not Required	New Mexico Albuquerque Cord Logistics Lakeland NSS-Albuquerque NSS-Nashville Waco PharmPak Williams Drug	New York Allentown Boston Cord Logistics Lakeland NSS-Nashville PharmPak Syracuse Williams Drug	North Carolina Cord Logistics Knoxville Lakeland NSS-Albuquerque NSS-Nashville PharmPak Savannah Wheeling Williams Drug Winston-Salem
				Out of State Licensure Not Required	

Divisional Licensure By State

North Dakota	Ohio	Ohio cont'd.	Oklahoma	Oregon	Pennsylvania
Cord Logistics Lakeland Minneapolis NSS-Abuquerque NSS-Nashville PharmPak Williams Drug	Auburn Boston Calumet City Cord Logistics Denver Jackson Knoxville Lakeland	NSS-Abuquerque NSS-Nashville PharmPak Phoenix Salt Lake City Syracuse Wheeling Williams Drug	Cord Logistics Kansas City Lakeland NSS-Abuquerque NSS-Nashville PharmPak Syracuse Waco Williams Drug	Auburn Cord Logistics NSS-Abuquerque NSS-Nashville PharmPak Salt Lake City Williams Drug	Allentown Out of State Licensure Not Required
Rhode Island	South Carolina	South Dakota	Tennessee	Texas	Utah
Allentown Boston Cord Logistics Lakeland NSS-Abuquerque NSS-Nashville PharmPak Syracuse Williams Drug	Out of State Licensure Not Required	Cord Logistics Lakeland Minneapolis NSS-Nashville Williams Drug	Cord Logistics Jackson Knoxville Lakeland NSS-Abuquerque NSS-Nashville PharmPak St. Louis Syracuse Williams Drug	Abuquerque Boston Cord Logistics Houston NSS-Abuquerque NSS-Nashville PharmPak Waco Williams Drug	Salt Lake City Out of State Licensure Not Required
Vermont	Virginia	Washington	West Virginia	Wisconsin	Wyoming
Allentown Boston Cord Logistics Lakeland NSS-Abuquerque NSS-Nashville	Allentown Cord Logistics Knoxville Lakeland NSS-Abuquerque NSS-Nashville Wheeling Winston-Salem Williams Drug	Auburn Cord Logistics NSS-Abuquerque NSS-Nashville PharmPak Spokane Williams Drug	Allentown Boston Cord Logistics Knoxville NSS-Abuquerque NSS-Nashville PharmPak Wheeling Williams Drug Winston-Salem	Calumet City Lakeland Milwaukee Minneapolis NSS-Abuquerque NSS-Nashville PharmPak Cord Logistics Williams Drug	Cord Logistics Denver NSS-Nashville Salt Lake City

6/8/98

3

Divisional Distribution By State

Alabama Cord Jackson Knoxville National PharmPak Savannah Williams Drug	Alaska Auburn Cord NSS-Nashville	Arizona Cord National PharmPak Nss-Nashville Phoenix Williams Drug	Arkansas Cord Jackson Kansas City NSS-Nashville St. Louis Williams Drug	California Auburn Cord National PharmPak NSS-Nashville Ontario Sacramento Union City Valencia Williams Drug	Colorado Albuquerque Cord Denver National PharmPak NSS-Nashville Williams Drug
Connecticut Allentown Boston Cord Hartford National PharmPak Williams Drug	Delaware Allentown Cord NSS-Nashville Williams Drug	Dist. of Col. Allentown Cord NSS-Nashville Wheeling	Florida Cord Jackson Knoxville Lakeland National PharmPak NSS-Nashville Savannah Williams Drug	Georgia Cord Knoxville National PharmPak NSS-Nashville Savannah Williams Drug	Hawaii Cord NSS-Nashville Ontario
Idaho Auburn Cord NSS-Nashville Salt Lake City Williams Drug	Illinois Aurora Cord Kansas City Lombard Milwaukee National PharmPak NSS-Nashville St. Louis Williams Drug	Indiana Aurora Cord Lombard National PharmPak NSS-Nashville St. Louis	Iowa Aurora Cord Kansas City Lombard Minneapolis NSS-Nashville	Kansas Cord Kansas City National PharmPak NSS-Nashville Williams Drug	Kentucky Cord Knoxville NSS-Nashville St. Louis Wheeling Williams Drug

Divisional Distribution By State

Louisiana	Maine	Maryland	Massachusetts	Michigan	Minnesota
Cord Jackson Knoxville National PharmPak NSS-Nashville Waco Williams Drug	Allentown Boston Cord Hartford National PharmPak NSS-Nashville Williams Drug	Allentown Cord National PharmPak NSS-Nashville Wheeling Williams Drug	Allentown Boston Cord Hartford National PharmPak NSS-Nashville Williams Drug	Aurora Cord Lombard Milwaukee National PharmPak NSS-Nashville Williams Drug	Cord National PharmPak NSS-Nashville Minneapolis Williams Drug
Mississippi	Missouri	Montana	Nebraska	Nevada	New Hampshire
Cord Jackson Knoxville National PharmPak NSS-Nashville Williams Drug	Cord Kansas City Lombard National PharmPak NSS-Nashville St. Louis Williams Drug	Cord Denver NSS-Nashville Salt Lake City Williams Drug	Cord Denver Kansas City National PharmPak NSS-Nashville	Cord NSS-Nashville Phoenix Sacramento Salt Lake City Valencia Williams Drug	Allentown Boston Cord Hartford NSS-Nashville Williams Drug
New Jersey	New Mexico	New York	North Carolina	North Dakota	Ohio
Allentown Boston Cord Hartford National PharmPak NSS-Nashville Williams Drug	Albuquerque Cord National PharmPak NSS-Nashville Waco Williams Drug	Allentown Boston Cord Hartford National PharmPak NSS-Nashville Williams Drug	Cord Knoxville National PharmPak NSS-Nashville Savannah Wheeling Winston-Salem Williams Drug	Cord Minneapolis NSS-Nashville Williams Drug	Aurora Cord Knoxville National PharmPak NSS-Nashville Wheeling Williams Drug

Divisional Distribution By State

Oklahoma	Oregon	Pennsylvania	Rhode Island	South Carolina	South Dakota
Cord Kansas City National PharmPak NSS-Nashville Waco Williams Drug	Auburn Cord National PharmPak NSS-Nashville Salt Lake City Williams Drug	Boston Cord National PharmPak NSS-Nashville Pennsylvania Syracuse Wheeling Williams Drug	Allentown Boston Cord Hartford National PharmPak NSS-Nashville	Cord NSS-Nashville Savannah Williams Drug Winston-Salem	Minneapolis NSS-Nashville Cord Williams Drug
Tennessee	Texas	Utah	Vermont	Virginia	Washington
Cord Jackson National PharmPak NSS-Nashville Williams Drug	Albuquerque Cord Houston National PharmPak NSS-Nashville Waco Williams Drug	Cord National PharmPak NSS-Nashville Salt Lake City Spokane Williams Drug	Allentown Boston Cord Hartford NSS-Nashville	Allentown Cord Knoxville NSS-Nashville Wheeling Winston-Salem Williams Drug	Auburn Cord National PharmPak NSS-Nashville Spokane
West Virginia	Wisconsin	Wyoming			
Allentown Cord Knoxville National PharmPak NSS-Nashville Wheeling Williams Drug	Aurora Cord Milwaukee Minneapolis National PharmPak NSS-Nashville Williams Drug	Cord Denver NSS-Nashville Salt Lake City			