A Watson Pharma, Inc.

# Call Center Operations
# Licenses Administrator Operational Procedure

| | | | |
|---|---|---|---|
| **PROCEDURE:** | **License Maintenance**<br>**Create, Change License or Create, Change Listing/Exclusion for Controlled and Non-Controlled substance License** | | |
| **Written by:** | **Karen Schomer** | **Date:** | 05/03/04 |
| **Call Center Policy Number:** | **OPDLA 507200-01.08** | **Policy Effective Date** | May 3, 2004 |
| **Revision written by:** | **Larry Shaffer**<br>**Mary Moskello** | **Revision date:** | **April 04, 2007** |
| **CTM Transaction:** | **VX01N- License Create**<br>**VX02N- License Change**<br>**VB01- Create Listing / Exclusion**<br>**VB02- Change Listing / Exclusion**<br>**VE30- Existing Licenses**<br>**VE31- License Blocked Sales Orders**<br>**VCH1- Create Batch Search Strategy**<br>**VCH2- Change Batch Search Strategy** | **CTM Doc #** | |
| **Prerequisites SAP Transaction Code** | **VD01- Create Customer**<br>**VD02- Change Customer** | | |
| **Post requisites SAP Transaction Code** | | | |

**TABLE OF CONTENTS**

| | | | |
|---|---|---|---|
| **PROCEDURE:** | **Create, Change or Create Listing/Exclusion for Controlled and Non-Controlled substance License** | | |
| **Revision Number:** | **OPDLA 507200-01.08** | **Effective Date:** | May 5, 2004 |
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| | | | Page 3 of 20 |

## Purpose

Establish and maintain the proper method of applying licensing information on an account to ensure compliance with the Drug Enforcement Administration (DEA) licensing requirements and the Prescription Drug Marketing Act (PDMA), as well as, the National Association of Boards of Pharmacy.

## Scope

All Call Center Operations employee directly or indirectly responsible for customer account maintenance

## Procedure

Once a customer account has been opened, updated, or unblocked, the Customer Master Administrator will submit the account maintenance form, along with the SAP account number to the Licensing Administrator. The licensing information should be reviewed and verified for accuracy.

All information necessary for analysis, review and validation of a license must be submitted to the SAP Licensing Administrator.

The following information is verified against the current License for accuracy:

1. Customer Name
2. Ship-To Address

   Note: Ship-to address MUST match the License, however PDMA regulations policy to ship non-controlled sample products only to a facility that the requesting practitioner operates from. If the address of the licensed practitioner does not match the address of the practitioner's license. The License Administrator must obtain a copy of a voided Rx and/or a letter of authorization from the physician as proof that this is a facility the practitioner is operating from.
3. DEA number / State License
4. DEA expiration date / State License expiration date
5. Approved Drug Schedule(s)

Please take note: Accounts are not deleted or de-activated. When an account is no longer in use, i.e. per customer request, location has moved, or any other reasons, Customer Master will block the account and the License Administrator will expire all current licenses attached to the account.

## A. DRUG SUBSTANCES – Controlled:

### 1. DEA License

DEA license is required for orders containing controlled substances. The DEA license includes the DEA license number, DEA license expiration date and the approved drug schedules (2, 2N, 3, 3N, 4, 5).

| Schedule | Regulatory Definitions |
|---|---|
| 2 | High Potential for abuse. Use may lead to severe physical or psychological dependence. No renewals are permitted |
| 2N | *Same as above except, Non-narcotic* |
| 3 | Some potential for abuse. Use may lead to low to moderate physical dependence or high psychological dependence. Up to 5 renewals are allowed within 6 months. |
| 3N | *Same as above except, Non-narcotic* |
| 4 | Low potential for abuse. Use may lead to limited dependence either physically or psychologically. Up to 5 renewals are permitted within 6 months. |
| 5 | Subject to state and local regulation. Abuse potential is low; a prescription may not be required. |
| Rx | Prescription *(SAP requirement)* |

Verification of the DEA license number, DEA shipping address, and DEA expiration date and drug schedule can be made by:

a. Using The U.S. Department of Commerce National Technical Information Services (NTIS) Drug Enforcement Administration (DEA) website: http://deanumber.com/ (See Exhibit B).

b. Obtaining a photocopy of the DEA license certificate from the customer or on the website DEA.com.

If copy received from the customer does not exist according to the DEA website or the DEA license has expired, the SAP Licensing Administrator will leave the order on license block in SAP, until the appropriate documentation is received. The SAP Licensing Administrator will contact the customer or the CSR responsible for the account to request a photocopy of the DEA License. The License Administrator will update the account upon receipt of a valid DEA license to remove the block on the order in SAP. The SAP Licensing Administrator will also communicate and report back to the Customer Support department on the licensing status, if necessary.

If the photocopy of the DEA License is not received, the Licensing Administrator will contact the customer or the CSR responsible for the account a second time requesting the photocopy of the DEA license. If the photocopy of the DEA license is not received, the customer will be notified that the pending order will be cancelled until a valid DEA license is received. The License Administrator will communicate with the Customer Master to update the account with an overall

block until a valid license has been received. Once a valid license has been received the overall block will be removed.

*NOTE: A Wholesaler, Distributor, Exporter and Importer may file a "straight" II. This provision allows a registrant to register for only a class 2 schedule, but entitles the registrant to receive both 2 and 2N schedules. All other schedules (3, 3N, 4, 5) must be registered to receive shipment. Also, customers with a DEA license automatically receive schedule Rx.

Retail Outlets and Practitioners must register all schedules to receive shipment.

The check digit algorithm will determine the validity of a DEA number. The seventh digit of the DEA number is the Check Digit. Add the first, third, and fifth digits to equal SUM1. Add the second, fourth, and sixth digits and then multiply by 2 for Sum2. Add SUM1 + SUM2. The last digit of this total should equal the seventh (Check Digit) of the DEA #.

Note: On occasion DEA licenses with only 1 letter at the beginning (i.e. R10184159) may be submitted. These licenses are usually submitted by customers that have a name that starts with a number (i.e. 212 Pharmacy). The check digit algorithm can still be used by treating the first number as the 2nd letter of a typical DEA license. If necessary, the DEA can be called directly to verify the validity of a license.

| **DEA check digit algorithm** | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| For example: DEA License RW0184159 | | | | | | | | | |
| **DEA** | **First** | **Second** | **Third** | **Fourth** | **Fifth** | **Sixth** | **Seventh (check digit)** | **Results** | |
| **RW** | **0** | | **8** | | **1** | | **9** | **9** | **Sum1** |
| | | **1** | | **4** | | **5** | | **10 x 2 = 20** | **Sum2** |

## 2. Creating Exclusion Record

The only time a customer material exclusion is set up is when the customer requests to exclude schedules. The customer may request to exclude schedules because the facility does not have proper storage and/or when the customer does not wish to receive those schedules. When creating exclusions, if there is a need to delete schedule numbers, the entire line must be selected and the delete icon must be used.

## 3. Violations

The License Administrator will review and release sales orders pending licensing verification. This is critical in order to remain in compliance with the DEA, State and PDMA law as it pertains to the sales and distribution of pharmaceutical products.

*NOTE: On a monthly basis, the DEA registration file information is loaded, by the Information Systems group. The updated information is in accordance with information on file at the DEA. This is inclusive of DEA license expiration date and authorized schedules. However, the DEA registration file information may not be as current as the DEA website mentioned above. The most current data should be used. Please see the Information Systems group update process below:

**Monthly DEA License Update from NTIS CD Process**

1. **CD received via mail by Call center in Corona CA –** generally, the update CD for a particular month arrives anywhere from the 15th to the 25th of that month.

2. **Call Center notifies SAP SD Production Support –** Prod Support picks CD from Call Center.

3. **Prod Support executes a trial run in a test system –** this is not done to update the license values in the test system, rather to determine whether there are any format or data problems with the CD. In the past 14 months we have had circumstances in which a) dates on the CD were incorrectly formatted and b) schedule values on the CD were not valid (licenses with Schedule 1). It is important to discover these errors and request a replacement CD from NTIS prior to using the CD to update the production system.

4. **Prod Support executes the custom License Update program in the production system –** a brief summary of the functionality of the program:

   **Custom Program Name:** ZVI_DEA_LICENSE
   **Transaction Code:** ZVLICUPD

   The program selects all active DEA license records from the SAP system. Each record is then matched against the NTIS CD using DEA number, if found, the End Dates and schedules of the SAP license and the NTIS entry are compared. If they are identical, no updates are made in SAP. If they are different (i.e., new End Date, different schedules), the existing SAP license is expired and a new license is created using the values from the NTIS entry. If a match is not found, the SAP license is expired, as the validity of the license could not be confirmed from the NTIS CD.

   The program also dumps the full content of the NTIS CD into a custom SAP table ZVDEA for reference purposes. After completion of the job, the number of records in this table is compared to documentation received with the CD to confirm that the record counts match. This is done via transaction code ZVDEA.

If errors occur during the execution of the job, Prod Support will analyze and correct the errors. The job is usually executed Friday evening, so that errors can be resolved with limited impact to the business.

5. **Post Processing Reporting** – after processing is complete, Prod Support produces a listing of Expired and new licenses, using the SQVI Quickviewer query tool in SAP. The listing shows all licenses expired; and, if a new license was created (in the case of updates). This listing is sent to the License Team for review.

**Notes:** one issue regarding this process is that a time lag will always potentially exist between receipt/application of the CD and the actual status of the DEA licenses. The Licensing team has access to daily updated information on DEA licenses via the internet, including newly created licenses; they will capture and create/update licenses in the SAP system based on business requirements. However, as noted in the processing summary, if the CD does not contain a license (i.e., perhaps a license just created/approved in the past week, after the latest CD was mailed), the program will consider it invalid.

The Post Processing listing also contains information about the Created On date and Created by ID of a license. One possibility is for the License Team to review the list by the Created On date, so that expired licenses that were created most recently will be readily apparent. These are the most likely to have been created/updated after the CD was issued, and the License Team can manually update them before any business impact is realized. If the license continues to be missing from the CD month after month (requiring manual re-creation), this should be researched; supposedly, if it's not on the CD it's doesn't exist.

Licenses used on specific orders: this is not related to the update process in any way; however, this data is available via standard SAP transaction ENGK, using the Assigned Documents option under Alert Reporting. Among the search criteria available are license type, license number (internal SAP or external/DEA number), Sold-to customer and schedule number.

## 4. Licensing Issues

Whenever there is a discrepancy between the information on the licensing website and the account, for example, the customer has recently moved to another address, but the website still reflects the old address. The Customer Service Representative should then contact the customer to verify the correct information and obtain the supporting documents. If the account needs to be changed, the Customer Service Representative will need to fill out the appropriate form and forward to the Customer Master group. If the Customer Master group cannot update the address on the account within 24 hrs, then the Licensing group should EXPIRE the current license. Once the Customer Master group has followed their procedure to correct the address in SAP then the licensing group will validate the license according to standard procedures. If the customer has a new license number, then the current license should be expired immediately and a new license should be created according to standard procedures.

Validating Medical Prescriber's State Licenses

The License Administrator will validate the State License using the IMS website. Once the license has been faxed it will be printed for record retention. The License Administrator will create the license to reflect the IMS data.

In the event IMS is not up to date, the License Administrator can visit the respective state website and print a copy for record retention. If the state website and IMS reflect an expired license, the customer will need to provide an updated license.

If the state website reflects a valid license, but IMS reflects an expired license, a web inquiry will be submitted to IMS for validation. Once the validation is received from IMS, then the license can be created and the order released.

Exception: If the order is for Trelstar or an Indigent and the state website shows a valid license, then the license can be created and the order released using the state website printout. A web inquiry with IMS is still needed, but the order will not be held until the IMS validation is received.

## 5. Health Identification Number (HIN)

If the HIN is being used, the Contracts Department need only submit the HIN. No additional documentation is required. The License Administrator will populate the current date in the "valid from" field and 12/31/9999 in the "valid to" field. On the ExpContrClass tab there is no need to include schedule numbers when creating a HIN, this field will be left blank. On the Customers tab, the License Administrator will need to add the customer account number and then accept the license under the Status tab. Input the SAP internal license number on the spreadsheet provided by the Customer Master Group. Once all the HIN numbers have been created the updated spreadsheet needs to be forwarded to the Customer Master Group.

## 6. License blocks

The License Administrator will be responsible to ensure that pending sales orders on hold due to license violations are investigated. Once the investigation has been completed the License Administrator will take the appropriate action necessary to either release the sales order hold or notify the appropriate Order Entry representative regarding the necessary action required in order to update the license. For example, if the order went to License Block (VE31) and we noticed that the customer cannot receive 2 and 2N on their license, the Licensing group would notify the CSR responsible for that account (and Order Processing, if necessary) that the customer is not able to receive the product they ordered. This usually happens when it is an EDI order or sample order.

## 7. CII Schedule Drugs and SOMS blocks

**SOMS – Suspicious Order Monitoring System (Of Control Drugs Substances)**
The License Administrator will be responsible to ensure that pending sales orders on hold due to suspicious order violations (SOMS) are investigated. The License Administrator will execute VA05 to determine the value and priority of the orders blocked due to SOMS violations. An Order Processing Representative or

License Administrator will print the SOMS Form. The SOMS form contains Class of Trade (COT) averages and customer allowable/order and customer allowable/month.

The License Administrator will review the SOMS form to determine if customer contact is necessary. If customer contact is necessary, the License Administrator will contact the customer. If necessary, the customer contact information can be obtained from the CSR responsible for the account. The Licensing Administrator will contact the customer to confirm the quantity ordered. The customer will determine whether to: reduce the quantity, cancel the order, or provide a valid reason for the increase in order quantity or frequency.

The following procedure is used to identify if the order is at or over the allowance Watson gives the customer which will determine if the customer needs to be contacted.

Put the number that's in the "Order Quantity" column into the "Release Qty" column. Then, mathematically ADD the following columns "MTD Qty" plus the "Release Qty" to give you a total order quantity to date.

- If the "MTD Qty" plus the" Release Qty" is equal to or less than the "Customer allow/mth, then the reason code is "12" (Administration Release Customer Call Not Required).

- If the "MTD Qty" plus the "Release Qty" is greater than the "Customer Allow/mth , then the reason code is "01" (Increased Supply to new or existing customer/patient) and the customer should be contacted to obtain the reason for the increase. Reason code "01" (Increased Supply to new or existing customer/patient)", must have a 2nd signature of Supervisor level or above and a note containing the reason for the increase in order quantity or frequency.

- If the customer is called, the License Administrator will attach a note to the SOMS form which will include the customer contact name, phone number, reason for the increase in order quantity or frequency, and the SKU/Material number and description of the product released. If the same SKU/Material suspends again in the same month, the License Administrator will attach a copy of the original resolution to the SOMS investigation form. This process is for the current month and will need to be repeated at the start of each month.

Once this SOMS form is confirmed and verified, the License Administrator will release the SOMS violation block. Otherwise, the License Administrator will escalate the suspicious order (SOMS) to the next level. If the suspicious order (SOMS) gets to the point that DEA contact is necessary, then the License Administrator will contact the Watson Director, Controlled Substance Compliance. The Watson Director, Controlled Substance Compliance will contact the DEA.

Also please make note of the following:

- The 'Release Qty' column on the SOMS form will need to be filled in by the License Administrator; this is the quantity that the License Administrator releases. Usually the 'Release Qty' is the same as the 'Order Qty', unless the customer requests to reduce or cancel the order.

- If the customer decides to reduce or cancel the order, the Licensing group will notify the CSR responsible for that account (and Order Processing, if necessary) that the customer has decided to reduce or cancel the order.

- If the customer decides to reduce the order quantity, the order may come off of SOMS violation hold automatically once the change has been made. If the order appears on the VA05 list after the change, then the License Administrator will need to evaluate the SOMS form again per standard procedures. Also if the customer decides to cancel the order, then the order may come off of SOMS violation. The License Administrator will need to execute the VA05 again to verify the order is not on the VA05 list.

- Class 2 and 2N's are filed in a separate filing cabinet. The DEA requires all Class 2 and 2N's to be filed separately from the 3, 3N, 4 and 5. All SOMS are filed by the account name, account number, City and State, by most current date. If within the same day there are multiple SOMS, then the most current Sales Document number is filed on top.

  Also, there are four states Kansas, Kentucky, New York and Rhode Island which DO NOT allow CONTROLLED samples sent to ANY practioners.

## B. DEA License Renewal Maintenance:

At the beginning of the month, the License Administrator will use the "custlist" to find DEA licenses that are due to expire before the month end. The license Administrator will contact each customer to obtain a valid/updated DEA license. If the customer does not have a DEA license with an updated expiration date, then the DEA license in SAP will be expired on the expiration date shown in SAP. If updated DEA license is not received, the pending orders will be cancelled until a valid DEA license is received. The License Administrator will communicate with Customer Master to update the account with an overall block until a valid license has been received. Once a valid license has been received, the overall block will be removed and the license will be updated and the customer can re-submit any orders.

## C. License for One Time Customer:

The Customer Master group will create a one-time customer master template (shell) only once, as necessary. This shell will be used to create orders for one-time customers. A one-time customer shell will be used by order processing to create orders for situations where a permanent customer master record is not needed, such as Tradeshows or Replacement Orders. **A One-time customer shell SHOULD NEVER be used for any site order or control substance order. A Customer Master account must be set up in order to place these order types.** These templates do not include entry of financial (company-level) data; as such, its usage should be restricted to free of charge orders (i.e., samples, literature etc.). If the one-time customer shell is used to generate a sales order, this record will supply basic customer master information and requires the order processing user to input key fields (i.e., name, address etc). The Licensing group will create the appropriate license for a one-time customer and link the license to the one-time ship-to customer's sales order.

## D. Unlicensed Locations:

If a representative receives an order for prescription drugs for an unlicensed location, he/she must fax a Letter of Authorization (see Exhibit A) to a responsible licensed individual who will accept responsibility for non-controlled substance prescription (RX) drugs being shipped to that specific location.
Such customers may include:

- Dialysis Centers
- Universities
- Health Organizations
- Clinics
- Humanitarian Aid
- Family Planning/Planned Parenthood

Regardless of whether a doctor/Medical Director/Mid-Level Practitioner license address is the same as the facility or ship to address, a properly filled out Letter of Authorization is required.

In the event the Letter of Authorization is submitted with a Mid-Level Practitioner's license, the Licensing Administrator will verify that the Mid-Level practitioner is able to received Rx product by reviewing the Buzzeo PDMA quarterly spreadsheet by logging into the Dendrite website, State Monitor section.

Note: A Letter of Authorization is valid for one year only. Customer's Letters of Authorization can be found in the portal.

## E. Methamphetamine Control Act:

The License Administrator will create a virtual "MethAct" license in the format of MA and the business entity phone number (i.e. MA6029992002). Material Classification Rx prescription should be entered on the ExpContrClass tab. The License Administrator will "redetermine" the sales order (unblock) to the newly created MethAct license and the sales order will be released for delivery.

The License Administrator will check sales order document flow (VA03 Display Sales Order) to confirm a delivery document has been generated. The License Administrator will "Expire" the newly created MethAct license(s) once the order has shipped, usually the day after the license has been created. This will ensure a validation process is in place for future orders.

## F. Indigent Accounts:

Quarterlies (As of 4/2007, DaVita Healthcare is the only customer of this sort)

These customers place orders on a quarterly basis and the account should be created in the clinic's name. These clinics staff multiple physicians and seldom have their own licensees so licenses are generally linked at the order level, referencing the physician placing the order. A Letter of Authorization is needed as usual, and they are valid for one year. In the unlikely event that a clinic has its own license, the license may be linked at the customer master level.

Dailies

These customers place orders on a daily basis and the account should be created in the physician's name, even if his office is located in a hospital or clinic. If the physician wants to ship goods to numerous locations, a Sold-To should be created for the primary location and Ship-To's should be created for the additional locations. All accounts are to be linked to the same state license even if the address does not match the license as long as this does not violate PDMA regulations. Note: The Sold-To address is usually the address that is on the physician's state license, but the physician may choose not to ship goods to the address listed on the state license, in this case the physician will choose another address as the Sold-To. If, at a later time, the physician wants to ship goods to the address listed on the state license, that account may be created as a Ship-To and linked to the existing Sold-To.

### Trelstar and Indigents

- **Trelstar and Indigent orders are top priority and should be released as soon as possible following standard procedures.**

### Papsure Physician Address Changes:

**NOTE**: You do not need a license for Papsure orders, since the Material master record considers Papsure as an OTC product, therefore, the order should not be held up for a license.

## G. R&D Research and Development:

Shipments for prescription items to facilities for research and/or development purposes do not require licensing.

## Exhibit A – Unlicensed Location (Letter of Authorization)

WATSON PHARMA®

Date:
Account:

To: Watson Pharma

Attn:

Phone:

Fax:

I hereby authorize Watson Pharma, Inc. to ship orders of pharmaceuticals directly

to: _____

located at: _____

Utilizing my **State license number** _____

I am affiliated with the clinic and direct the use of pharmaceutical products in it.

By: _____

Print Name: _____

Title: _____

**State License Address:** _____

City/State: _____

Date: _____

****Note: If the doctor is no longer affiliated with the facility or does not authorize shipment of prescription drugs, he/she is required to notify the person named above at Watson Pharma, immediately.****

360 Mt. Kemble Avenue, P.O. Box 1953 Morristown, NJ 07962-1953·Tel :( 973)-355-8300 ·Fax 800-760-9224·Web Site.

www.watsonpharm.com

OPDCSS 507200-38F.01
08/29/06
E.David

## Exhibit B - NTIS National Technical Information Services

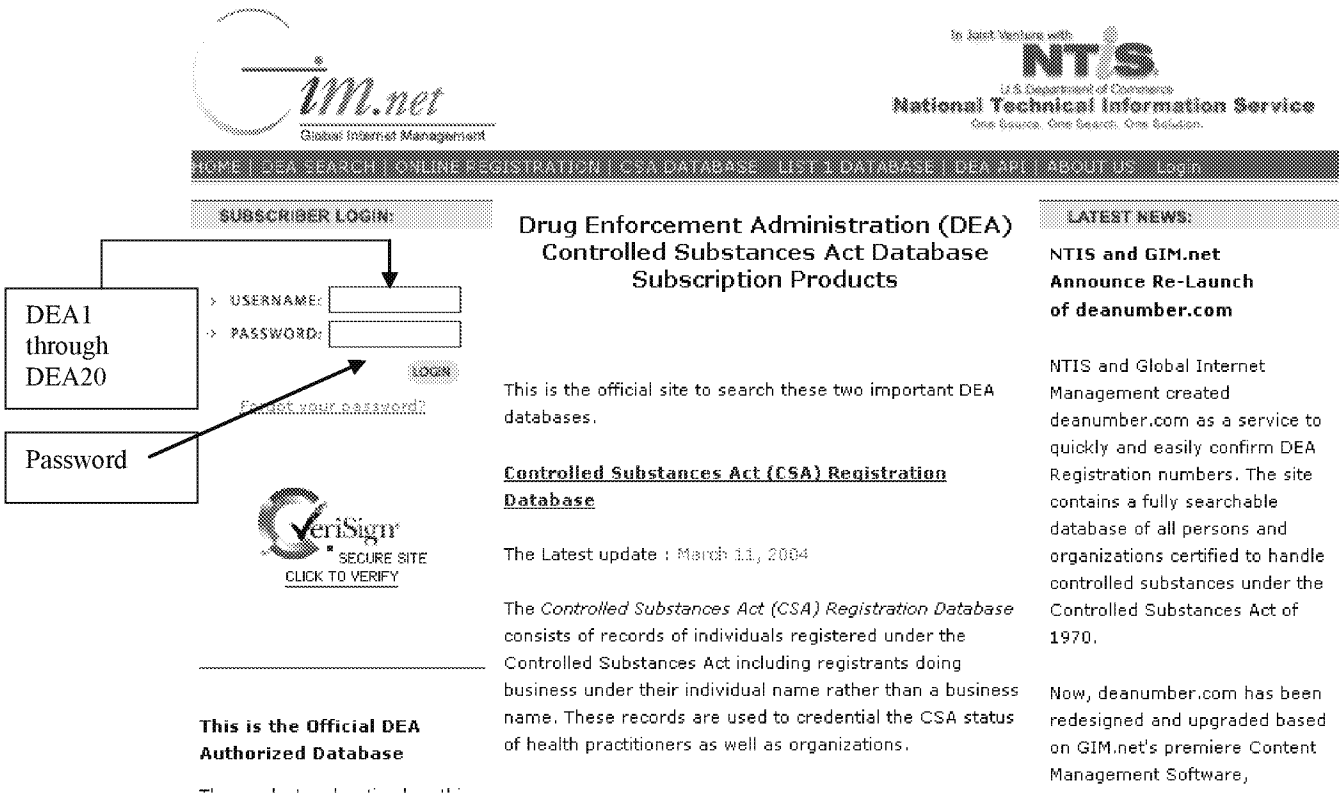

Exhibit B – NTIS continued…

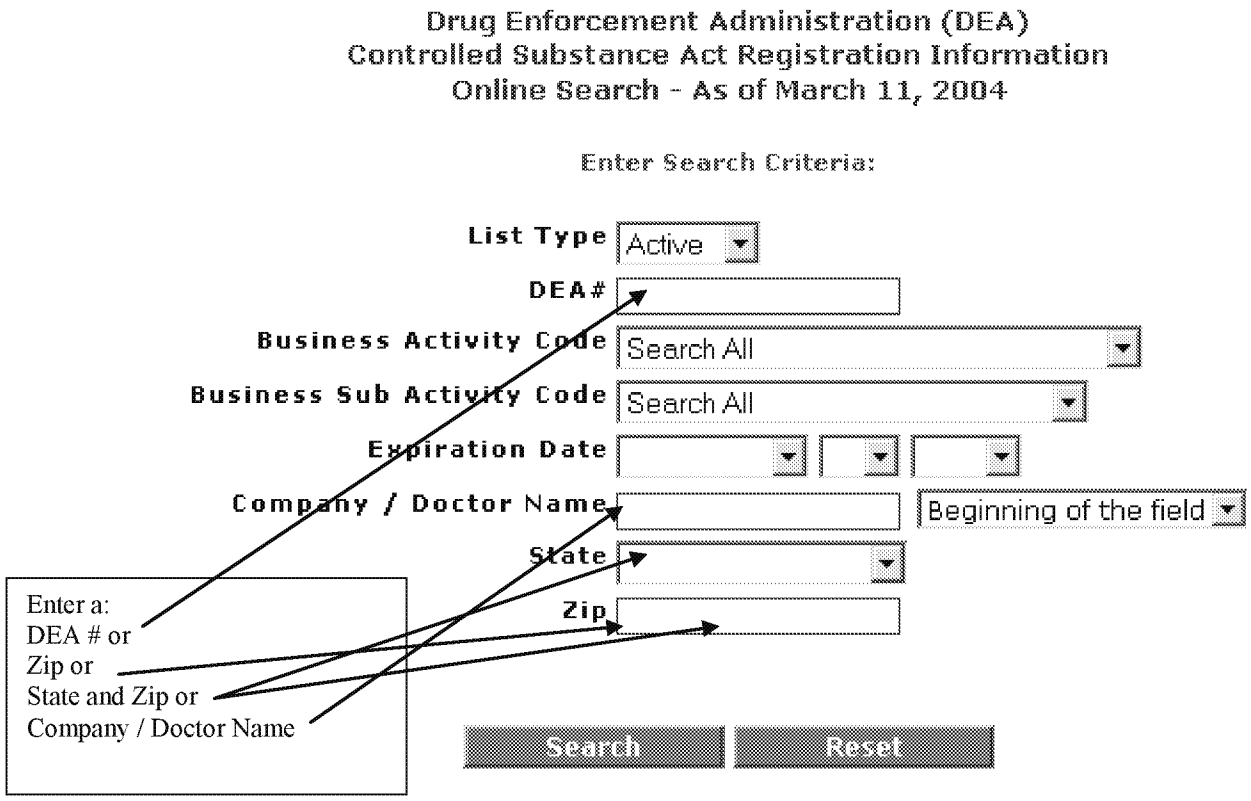

Exhibit B – NTIS continued…

| DEA Number | Exp. Date | Company Name | State | Zip |
|---|---|---|---|---|
| AC0393734 | 8/31/2005 | CITY PHARMACY INC | TN | 37745 |
| AT7665637 | 11/30/2005 | SUSONG PHARMACY | TN | 37745 |
| BS0143850 | 2/28/2007 | STUMM, HARRY J MD | TN | 37745 |
| BP3389093 | 3/31/2007 | PATTERSON, MARK DAVID MD | TN | 37745 |
| MM0369365 | 1/31/2005 | MCMILLIAN, JEFFREY OD | TN | 37745 |
| MR0852081 | 4/30/2005 | ROBBINS, MELISSA A FNP | TN | 37745 |
| MM0467426 | 1/31/2006 | MORRISON, REBECCA A PNP | TN | 37745 |
| MP0551033 | 3/31/2006 | PACE, NANCY L NP | TN | 37745 |
| MC0649472 | 8/31/2006 | CARRINO, THOMAS PA | TN | 37745 |
| BW8300220 | 5/31/2004 | WALGREEN CO | TN | 37745 |
| BT4966288 | 11/30/2004 | THE MEDICINE SHOPPE | TN | 37745 |
| AC0401202 | 12/31/2004 | REVCO DISCOUNT DRUG CTRS, INC | TN | 37745 |
| AR8276405 | 12/31/2004 | REVCO DISCOUNT DRUG CTRS, INC | TN | 37745 |
| BF8029589 | 9/30/2005 | FOOD CITY PHARMACY #606 | TN | 37745 |
| BH2489032 | 10/31/2005 | HOWARD'S PHARMACY | TN | 37745 |
| BR3339618 | 6/30/2006 | RITE AID OF TENNESSEE INC | TN | 37745 |
| BG8618689 | 9/30/2006 | GREENE COUNTY DRUG STORE, LLC | TN | 37745 |

Select the hyperlink that matches the DEA information you are searching for.

Exhibit B – NTIS continued…


**Current Date:** 3/15/2004 **Data File Release Date:** March 11, 2004

**Drug Enforcement Administration (DEA) Datafiles -Both**

**Registrant Profile**

***for***

| CITY PHARMACY INC | |
|---|---|
| Address: | 113 E CHURCH ST<br>GREENEVILLE, TN 37745 |
| State / Zip: | TN 37745 |
| DEA Number: | AC0393734 |
| Business Activity Code: | A |
| Drug Schedule: | 22N 33N 4 5 |
| Expiration Date: | 8/31/2005 |

Print Close

# *Call Center Operations*
# *Licenses Administrator Operational Procedure*

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| | | | Page 20 of 20 |