U.S. DEPARTMENT OF JUSTICE

DRUG ENFORCEMENT ADMINISTRATION

www.dea.gov Washington, D.C. 20537

WALGREEN CO
28727 OREGON ROAD
ATTN: C II MANAGER
PERRYSBURG OH, 43551-0000

December 27, 2007

In reference to registration
RW0294493

Dear Registrant:

This letter is being sent to every entity in the United States registered with the Drug Enforcement Administration (DEA) to manufacture or distribute controlled substances. The purpose of this letter is to reiterate the responsibilities of controlled substance manufacturers and distributors to inform DEA of suspicious orders in accordance with 21 CFR 1301.74(b).

In addition to, and not in lieu of, the general requirement under 21 USC 823, that manufacturers and distributors maintain effective controls against diversion, DEA regulations require all manufacturers and distributors to report suspicious orders of controlled substances. Title 21 CFR 1301.74(b), specifically requires that a registrant "design and operate a system to disclose to the registrant suspicious orders of controlled substances." The regulation clearly indicates that it is the sole responsibility of the registrant to design and operate such a system. Accordingly, DEA does not approve or otherwise endorse any specific system for reporting suspicious orders. Past communications with DEA, whether implicit or explicit, that could be construed as approval of a particular system for reporting suspicious orders, should no longer be taken to mean that DEA approves a specific system.

The regulation also requires that the registrant inform the local DEA Division Office of suspicious orders when discovered by the registrant. Filing a monthly report of completed transactions (e.g., "excessive purchase report" or "high unit purchases") does not meet the regulatory requirement to report suspicious orders. Registrants are reminded that their responsibility does not end merely with the filing of a suspicious order report. Registrants must conduct an independent analysis of suspicious orders prior to completing a sale to determine whether the controlled substances are likely to be diverted from legitimate channels. Reporting an order as suspicious will not absolve the registrant of responsibility if the registrant knew, or should have known, that the controlled substances were being diverted.

The regulation specifically states that suspicious orders include orders of an unusual size, orders deviating substantially from a normal pattern, and orders of an unusual frequency. These criteria are disjunctive and are not all inclusive. For example, if an order deviates substantially from a normal pattern, the size of the order does not matter and the order should be reported as suspicious. Likewise, a registrant need not wait for a "normal pattern" to develop over time before determining whether a particular order is suspicious. The size of an order alone, whether or not it deviates from a normal pattern, is enough to trigger the registrant's responsibility to report the order as suspicious. The determination of whether an order is suspicious depends not only on the ordering patterns of the particular customer, but also on the patterns of the registrant's customer base and the patterns throughout the relevant segment of the regulated industry.

Registrants that rely on rigid formulas to define whether an order is suspicious may be failing to detect suspicious orders. For example, a system that identifies orders as suspicious only if the total amount of a controlled substance ordered during one month exceeds the amount ordered the previous month by a certain percentage or more is insufficient. This system fails to identify orders placed by a pharmacy if the pharmacy placed unusually large orders from the beginning of its relationship with the distributor. Also, this system would not identify orders as suspicious if the order were solely for one highly abused controlled substance if the orders never grew substantially. Nevertheless, ordering one highly abused controlled substance and little or nothing else deviates from the normal pattern of what pharmacies generally order.

When reporting an order as suspicious, registrants must be clear in their communications with DEA that the registrant is actually characterizing an order as suspicious. Daily, weekly, or monthly reports submitted by a registrant indicating "excessive purchases" do not comply with the requirement to report suspicious orders, even if the registrant calls such reports "suspicious order reports."

Lastly, registrants that routinely report suspicious orders, yet fill these orders without first determining that order is not being diverted into other than legitimate medical, scientific, and industrial channels, may be failing to maintain effective controls against diversion. Failure to maintain effective controls against diversion is inconsistent with the public interest as that term is used in 21 USC 823 and 824, and may result in the revocation of the registrant's DEA Certificate of Registration.

For additional information regarding your obligation to report suspicious orders pursuant to 21 CFR 1301.74(b), I refer you to the recent final order issued by the Deputy Administrator, DEA, in the matter of Southwood Pharmaceuticals Inc., 72 FR 36487 (2007). In addition to discussing the obligation to report suspicious orders when discovered by the registrant, and some criteria to use when determining whether an order is suspicious, the final order also specifically discusses your obligation to maintain effective controls against the diversion of controlled substances.

Sincerely,

Joseph T. Rannazzisi
Deputy Assistant Administrator
Office of Diversion Control

Recap of DEA visit to Perrysburg Distribution Center on 1/18/08

Attendees: Angie Francis, Diversion Unit Supervisor, DEA
Paula Albert, Diversion Investigator, DEA
Brian Leander, Walgreens Asset Protection
Tonia Ramos, Walgreens Asset Protection
Steve Kneller, Walgreens DC Operations Manager

Francis (DEA):

- The reason to visit was to research recent increases into 106's filed and to discuss and tour CII Operation.
- A complaint case was opened by DEA on our losses.
- DEA only requires registrant to file106 form
- Their role is to investigate and to ensure those responsible are prosecuted.

1. Area of concern: a. "CII" identified on tamper proof bag; suggested to remove
   b. UPS Label: CII FM's name as sender. Auditor name on receiver label
   -Problem if someone equates name with Perrysburg location.
2. CII Area: Gate into vault was not self-closing, self-locking which is DEA regulation. Albert stated they're giving us a warning on this. CII (20x20 sign) on side of cage(s) were removed by Kneller after DEA recommendation
3. Procedural: What is Walgreens procedure for investigating?
   a. When does it get reported and by whom?
   b. What are the investigative steps?
4. Suggestion: Freight Forward Facilities: suggested researching this option for Walgreens
   a. Packages leave PB on Fleet go to another facility owned by Walgreens. Controls can only stay at facility for 24 hours. Site doesn't need license but does need inspection by DEA.
5. Francis stated someone would be back to DC to meet with UPS.
6. Francis stated that they are gathering all 106 forms filed by all Walgreens (Stores and other DC's). Wants paper trail; records and reports for all 106 forms filed with DEA.

Leander: (Walgreens):

1. What we're doing, what we're evaluating at this point:
2. DHL: alternate courier, committed to already: in place 30-45 days
3. Evaluating delivering on our fleet to DC parent stores (750);
4. UPS in conjunction with Walgreens have used "salt" and die packages during investigations
5. Provided UPS Resolution sheet for investigations into losses.
6. Provided UPS contact information; Brian Woods, Regional Security Manager.
7. Suggestion made to send print screen of UPS package tracking information in lieu of spreadsheet that was sent with 106 form by CII FM. Francis agreed to the change.

What we (Walgreens) owes to DEA:

1. Repairs to gate going into CII vault has been assigned to Glenn Gmitter, Maintenance Manager; who stated this would be corrected by 2/1/08
2. Walgreens investigative steps: Tonia Ramos; completed by 2/1/08
3. UPS print outs to accompany DEA 106 form: Immediate. 1/18/08

Walgreen Discussion Items:

1. Label Change: remove names of Perrysburg DC employees and the possibility of removing "Walgreens".
2. Freight Forward Facility
3. Change in tamper proof bag to remove "CII" wording.
4. DHL vs. UPS flexibility: DCM and AP must coordinate before stores are switched.

U. S. Department of Justice
Drug Enforcement Administration

www.dea.gov

Washington, D.C. 20537

MAY 2 3 2003

Mr. Stephen J. Reardon
Director, Corporate Compliance
Cardinal Health
7000 Cardinal Place
Dublin, Ohio 43017

Dear Mr. Reardon:

This is in response to your correspondence dated April 30, 2003, regarding the substitution of a generic product for a brand name product pursuant to the receipt of a DEA-222 Order Form. You asked if there is an acceptable method of preventing this type of substitution by a supplier when the pharmacy requires a specific product.

Currently, the Drug Enforcement Administration's (DEA) policy allows a supplier to provide an identical generic controlled substance when a name brand product is ordered provided the customer agrees to accept the generic. As you state in your letter, many of your retail chain customers have agreed to accept generic substitution on a routine basis. However, in those instances when the purchaser will not accept a substitute product it would be acceptable, and advisable, to indicate on the order form that the name brand product is the only product acceptable. Wording such as you suggest, i.e.: "do not substitute," or any other clearly understood term that informs the supplier of the pharmacy's needs would not be in violation of the DEA regulations.

Your efforts to remain in compliance with federal regulations are appreciated. For further information on the DEA's Diversion Control Program, you may access our web site at www.DEAdiversion.usdoj.gov. If you have additional questions, feel free to contact Fred H. Shiel, R.Ph. in the Policy Unit at (202) 307-7296.

Sincerely,

Robert C. Nathanson

for Patricia M. Good, Chief
Liaison and Policy Section
Office of Diversion Control

U. S. Department of Justice
Drug Enforcement Administration
8701 Morrissette Drive
Springfield, Virginia 22152

www.dea.gov

DEC 29 2009

Steven C. Kneller
Walgreens Distribution Center Manager
28727 Oregon Road
Perrysburg, Ohio 43551

Dear Mr. Kneller:

This correspondence is in response to your letter dated May 22, 2009, to Robert L. Corso, Special Agent in Charge, Detroit Field Division, Drug Enforcement Administration (DEA). On October 9, 2009, the Detroit Field Division forwarded your inquiry to the Office of Diversion Control, Liaison and Policy Section, for a response. In your letter, you state that Walgreens Distribution Center (Walgreens) ships an average of 9,000 lines of the DEA Form 222 *(U.S. Official Order Form – Schedules I & II)* per day. You indicate that due to Walgreens daily volume, handwriting the date of shipment on each line hinders your operation and negatively impacts the physical well-being of employees due to the repetitive nature of the process.

Consequently, you are requesting an exception to 21 C.F.R. § 1305.13(b) as authorized by 21 C.F.R. § 1307.03. Title 21 C.F.R. § 1305.13(b) states that "A supplier ... **must** [emphasis added] record on Copies 1 and 2 the number of commercial or bulk containers furnished on each item and the date on which the containers are shipped to the purchaser." DEA has reviewed your request for an exception to permit Walgreens to record the date on the first completed line of each DEA Form 222 shipped, and then draw a vertical line from that date down to the last line completed on the DEA Form 222. To ensure the Controlled Substances Act requirement for complete and accurate records pursuant to 21 U.S.C. § 827, DEA denies your request for this exception.

Please note, that although 21 C.F.R. § 1305.13(b) states that the date on which the containers are shipped must be **recorded** on Copies 1 and 2 of the DEA Form 222, it does not require that the date be handwritten. Suppliers may use a date stamp for each line item shipped. Alternatively, DEA registered suppliers may utilize DEA's electronic equivalent to the DEA Form 222, the Controlled Substances Ordering System (CSOS). On April 1, 2005, DEA published a Final Rule titled *Electronic Orders for Controlled Substances* in the Federal Register. A copy is enclosed for your review. Additional information regarding this program may be obtained on DEA's e-commerce website at www.DEAecom.gov.

If you have any additional concerns regarding this matter, please contact this office at (202) 307-7297. For additional information regarding the DEA's Diversion Control Program, please visit our website at www.DEAdiversion.usdoj.gov.

Sincerely,

Mark W. Caverly
Chief, Liaison and Policy Section
Office of Diversion Control

Enclosure

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

21 CFR Parts 1305 and 1311

[Docket No. DEA–217F]

RIN 1117–AA60

Electronic Orders for Controlled Substances

AGENCY: Drug Enforcement Administration (DEA), Justice.

ACTION: Final rule.

SUMMARY: DEA is revising its regulations to provide an electronic equivalent to the DEA official order form, which is legally required for all distributions involving Schedule I and II controlled substances. These regulations will allow, but not require, registrants to order Schedule I and II substances electronically and maintain the records of these orders electronically. The regulations will reduce paperwork and transaction times for DEA registrants who handle, sell, or buy these controlled substances. This rule has no effect on patients' ability to receive prescriptions for controlled substances from practitioners, nor on their ability to have those prescriptions filled at pharmacies.

DATES: *Effective Date:* This rule is effective on May 31, 2005. The incorporation by reference of certain publications listed in the rule is approved by the Director of the Federal Register as of May 31, 2005.

FOR FURTHER INFORMATION CONTACT: Patricia M. Good, Chief, Liaison and Policy Section, Office of Diversion Control, Drug Enforcement Administration, Washington, DC 20537, Telephone (202) 307–7297.

SUPPLEMENTARY INFORMATION:

I. Background

DEA's Legal Authority for These Regulations

DEA enforces the Controlled Substances Act (CSA) (21 U.S.C. 801 *et seq.*), as amended. DEA regulations implementing this statute are published in Title 21 of the Code of Federal Regulations (CFR), Part 1300 to 1399. These regulations are designed to establish a framework for the legal distribution of controlled substances to deter their diversion to illegal purposes and to ensure that there is a sufficient supply of these drugs for legitimate medical purposes.

Requirements for Distributing Schedule I and II Controlled Substances

The CSA prohibits distribution of Schedule I and II controlled substances except in response to a written order from the purchaser on a form DEA issues (21 U.S.C. 828(a)). DEA issues Form 222 to registrants for this purpose, preprinting on each form the registrant's name, registered location, DEA registration number, schedules, and business activity. DEA serially numbers the forms and requires registrants to maintain and account for all forms issued. Executed and unexecuted Forms 222 must be available for DEA inspection. The CSA requires that executed Forms 222 be maintained for two years (21 U.S.C. 828(c)).

When ordering a Schedule I or II substance, the purchaser must provide two copies of the Form 222 to the supplier and retain one copy. Upon filling the order, the supplier must annotate both copies of the form with details of the controlled substances distributed, retain one copy as the official record of the distribution, and send the second copy of the annotated Form 222 to DEA. Upon receipt of the order, the purchasers must also annotate their copy, noting the quantity of controlled substances received and date of receipt.

Regulatory History

Although the paper-based regulatory structure limits diversion, it does not address or provide for the use of modern computer technologies. DEA issued more than six million individual order forms in fiscal year 2003. Because both the purchaser and supplier must maintain copies of the form for two years, the order system requires the maintenance of more than 24 million forms. Many, if not most, of the registrants using Form 222 place all their orders for Schedules III–V controlled substances electronically. Many suppliers receive electronic notice from their purchasers of their intention to place Schedule I and II orders, but the orders cannot be filled until the supplier receives the DEA-issued Form 222 from the purchaser. The processing of the Form 222 takes one to three days from the time the form is completed to the time the order is delivered; electronic orders can be processed and filled immediately.

DEA Pilot Project

Industry asked DEA to provide an electronic means to satisfy the legal requirements for order forms. DEA began discussions with the regulated industry regarding CSOS standards in 1999. On January 11, 2002, DEA published a notice in the **Federal Register** expressing its intent to conduct a pilot project to conduct performance verification testing of public key infrastructure enabled controlled substances orders. This pilot project was conducted in partnership with two industry associations—the Health Care Distribution Management Association and the National Association of Chain Drug Stores. A total of 22 DEA registrants were listed as initial pilot participants. Initial pilot objectives were to ascertain the level of compatibility and usability of CSOS standards for electronic controlled substances ordering applications and to test industry's ability to deploy these systems. All technical test objectives were successfully realized in early phases of the pilot with registrants demonstrating the ability to retrieve and manage their CSOS digital certificates. Where participants expressed difficulty or reported undue burden with processes (*e.g.*, with initial notarization requirements for enrollment) proposed technical standards were reviewed and modified, where possible, without compromising necessary nonrepudiation and security services objectives.

In August 2002, pilot participants began using CSOS certificates in simulated environments with DEA providing access to a test suite of CSOS certificates. Pilot participants demonstrated the ability to send, receive and validate digitally signed controlled substances orders in a test environment, and also demonstrated the ability to accurately reject orders, as appropriate. Pilot outcomes allowed DEA to identify and resolve potential challenges before the controlled substances ordering system was proposed. DEA continues to provide test resources to industry through the use of its pilot system, allowing continued refinement of CSOS applications.

Summary of Proposed Rule

On June 27, 2003, DEA issued a Notice of Proposed Rulemaking (NPRM) in which DEA proposed revisions to its regulations to allow electronic orders if those orders were signed using an electronic signature that met three criteria—authentication; non-repudiation, and record integrity (68 FR 38558). Because only digital signatures based on certificates issued by a Certification Authority as part of a public key infrastructure (PKI) meet all three criteria, DEA proposed requirements that apply to obtaining and using digital certificates.

registrant is authorized to order the schedules.

Attaching the digital certificate. One commenter expressed concern about the statements in the preamble that a digital certificate be attached to each order.

Because the digital certificate serves as the equivalent of the CSA-mandated form, the certificate, with its extension data, must be attached to each order. Including the certificate with each order ensures that, just as with the paper forms, an accurate copy of the DEA registration information for the customer is with the order. It should be noted that the requirement that the digital certificate be attached to the order applies to when the order is transmitted by the purchaser to the supplier. Once orders have been archived, each order does not have to have the specific digital certificate attached, as long as the certificate is associated with the order. Thus, an archive may have one copy of a specific certificate that is associated with a number of orders that have been archived, provided that retrieval of an order includes a copy of the certificate.

FIPS 140–1. Commenters noted that the proposed rule referenced FIPS 140–2, but did not mention FIPS 140–1, causing concern that systems validated and approved under 140–1 might not be allowed under the new standard. They were further concerned because the rule did not specify the security level required. Commenters stated that requiring a standard beyond security level 1 would cause difficulties for participants.

FIPS 140–2 grandfathers FIPS 140–1; any system validated and approved under FIPS 140–1 is considered to be approved and validated under FIPS 140–2. Therefore, the regulatory provision that implementations be certified under FIPS 140–2 incorporates, by reference, any implementations previously certified under FIPS 140–1. With respect to the security level required, DEA agrees with comments that Security Level 1 is appropriate and has included it in the final rule.

Commenters objected to the requirement that the private keys be stored on a FIPS-approved module. As DEA explained in the NPRM, government agencies must adopt FIPS requirements for any federal system, such as CSOS. DEA, therefore, must require that storage of keys be on FIPS-approved systems. While DEA encourages the use of smartcards, biometrics, or other secure hardware devices for private key storage within the CSOS architecture, use of such devices is voluntary. The regulations only require that the private key be stored on a FIPS-approved cryptographic module.

Power of Attorney. A number of commenters raised issues related to the power of attorney (POA) provisions. Several suggested that the existing requirement that the POA letter be signed by the person who signed the most recent registration application is impractical for companies that have national or regional distribution operations. Other commenters suggested that the application for a digital certificate, handled through the CSOS coordinator, could replace the POA letter and process.

The intent of this rulemaking is to establish an electronic means of satisfying the order form requirements—not to change the existing order form requirements. DEA did not propose to change the POA requirement or process, which was established to ensure that all activities by a registrant with respect to order forms be under the ultimate control of one responsible individual within the registrant. Any concerns regarding existing requirements with respect to POA will have to be considered in a separate action; they are beyond the scope of this CSOS rulemaking.

With respect to the suggestion that application for a digital certificate serve as a substitute for granting power of attorney, DEA wishes to note that the granting of power of attorney is an explicit legal act of assignment of authority from an authorized individual to another; accepting the application for a digital certificate as a substitution would make the assignment implicit, which would not be acceptable to DEA. Any assignment of the authority to obtain and execute order forms on behalf of a registrant must be an explicit legal act.

One commenter noted that the language in § 1305.12(d) that states that orders must be signed by a person authorized to sign an application for registration was wrong and should state that orders must be signed either by a person who is authorized to sign a registration application or a person granted POA to sign orders. DEA agrees and has changed the rule.

Tracking number. Several commenters stated that the format of the unique tracking number that a registrant assigns to an order was incorrect, that the last two digits of the year should come first. DEA agrees and has corrected the rule.

Order contents. Commenters suggested several changes to the requirements for order contents. DEA agrees that the complete address of the supplier could be provided by either the purchaser or the supplier and has changed the rule. Similarly, DEA agrees that the order could include either the National Drug Code (NDC) number or the drug name. DEA emphasizes that the system used to view the orders must provide the drug description if the NDC code is used in the order.

Linked records. Commenters objected to the use of the phrase "electronically linked" records because they think that links could be electronic or manual. In technical discussions with DEA, industry clarified that their concern was that DEA might interpret "electronically linked" to require active rather than passive links, where all order data are linked automatically. Passive links would allow the data to be stored in separate databases linked by one or more data elements common to all records.

DEA emphasizes that it is not requiring any specific type of link; DEA's only concern is that if it requests copies of orders (*e.g.*, for a particular customer or substance), the registrant must be able to produce the requested records (*i.e.*, both the electronic orders and the linked distribution records) upon request in a format that an agent can read and understand. DEA has revised the rule to clarify that "readable format" means that a person, not a computer, can easily read the documents.

Corrections. Several commenters identified changes needed to correct regulatory language. In § 1305.22(c)(1), DEA proposed that suppliers should verify the signature and order by "having" software that complies with Part 1311. The commenter recommended "using" instead of "having." DEA agrees and has made the change.

Commenters stated that the proposed language in § 1305.25(b) and (c) that requires the supplier to provide a reason for not filling the order was inconsistent with the existing rule. DEA agrees and has changed the language to clarify that a supplier must notify a purchaser that an order will not be filled, however, the supplier does not need to provide a reason for refusing to fill an order.

Commenters asked DEA to make the definition of digital certificate specific to CSOS. DEA disagrees. The definition is intended to be general and will cover more than CSOS certificates. In the regulatory text, however, DEA has added "CSOS" before digital certificate wherever the certificate is limited to the CSOS certificate.

One commenter asked whether "a registrant's recognized agent" was different from a CSOS coordinator. The two are the same; DEA has revised the

of the data may be imprecise due to changes in orders, but DEA needs frequent submissions of reports to account for all orders generated by a given purchasing registrant and as a means to identify and account for all outstanding orders for a given registrant.

Commenters also recommended changes to the information provided in the daily reports to make the data elements consistent with ARCOS data elements and to add four elements on the substances ordered. DEA agrees with the commenters. DEA will specify a format for the report that is consistent with the ARCOS reports plus the data fields on what was ordered. DEA notes that ARCOS is preparing to allow electronic filing of reports; when this occurs, DEA plans to develop a process by which the summary reports can be accepted as a substitute for ARCOS reporting for Schedule I and II substances, with the usual ARCOS provisions for filing corrections.

Adoption of new technologies. Commenters stated that it was unclear how DEA would evaluate new technologies and recommended that DEA develop a rapid means for evaluating and approving new technologies. DEA understands the commenters' concern, but approval of any new technology would be subject to the Administrative Procedure Act requirements for public notice and comment prior to adoption. Beyond the statutory mandates, DEA thinks it is vital that the regulated community have an opportunity to consider and discuss new methods to ensure that any new rules can be accommodated by existing systems. Although the development of this rule took several years, DEA believes that the time was well spent because discussions that DEA and industry held made it possible for all parties to identify potential problems and find solutions prior to publishing a regulation. DEA does not anticipate that review and recognition of suitable alternative technologies should take that long.

Audits. Comments expressed concern about the scope of the third-party audits and DEA audits. They specifically stated that the reports to DEA should not be included in the third-party audits.

DEA agrees with the commenters that the reports to DEA would not be part of third-party audits. The independent third-party audit is intended to ensure that the digital signature system functions properly for both the supplier and purchaser.

Reverse Distributors. Several commenters asked how the electronic order system will work for reverse distributors. DEA recognizes that the ordering system has different characteristics in reverse distribution and intends to address issues related to those distributions in a separate rulemaking.

Other Issues. Commenters objected to the mention of biometrics and smart cards. DEA notes that certificate holders may want to consider using biometric passwords or smart cards, but DEA is not requiring them to do so. Keys may be stored on any secure system provided that the storage module is approved under FIPS 140–2.

Commenters questioned the use of "system." DEA agrees with commenters that systems for creating and processing digitally signed orders may be one or more software systems. As noted above, DEA's concern is the integrity and availability of the records of orders, not the technologies and software used to create and store the information.

Commenters asked that DEA include a definition or description of the subscriber agreement. DEA does not believe that it is necessary to define the subscriber agreement. The DEA CA will provide the agreement, appropriately titled, to each certificate holder.

Commenters objected to the statement in the NPRM that the practical implementation of PKI systems is simple. DEA understands and explained in the NPRM that the technologies involved in PKI systems are complex, but from the user's standpoint, digital signatures are simple because so much of the work is actually done by machine. After authenticating themselves to the system and activating the key, the signer generally digitally "signs" the document with a single key stroke.

One commenter raised issues related to digital certificates for pharmacists for use in the electronic prescription system. This issue is beyond the scope of this notice; DEA will address the issue when it proposes its rule for electronic prescriptions.

A commenter noted that the five-year transition period used in the economic analysis may be optimistic. DEA recognizes that the electronic orders may phase in at a different rate; some registrants may continue to use Forms 222 indefinitely, as the rule allows. The five-year period was simply used to estimate costs to avoid understating those costs.

One commenter supported the proposed rule, but expressed the hope that pharmacies would not bear the cost of implementation. DEA notes that use of electronic orders is voluntary. DEA believes that the system will provide cost savings to both purchasers and suppliers, but no registrant is required to adopt electronic orders.

One vendor recommended that DEA adopt an approach more consistent with the vendor's technology. DEA is not dictating a particular technology or PKI implementation. Any approved system that meets the criteria for authentication, non-repudiation, and record integrity may be used.

Special Note Regarding Certificate Extension Data

Finally, following publication of the proposed rule, DEA modified the specification for the certificate extensions. Certain registrants had expressed concerns regarding using the certificates for other health care purposes because their DEA registration number appeared in plain text in the certificate, thus making it easily accessible to the recipient. To address this concern, DEA has modified the certificate profile to allow that, in lieu of listing the plain text DEA number, the DEA number extension will contain a hash value generated from the DEA number and the specific certificate subject distinguished name serial number using the SHA–1 hashing algorithm. Because the DEA number will no longer be available in plain text in the certificate, DEA is modifying the order format requirement in Section 1305.21 to require that the purchaser include their DEA registration number in the body of the order. Further, Section 1311.55 is being amended to require that a supplier must verify that the DEA number listed in the body of the order is the same as the DEA number associated with the certificate. The verification is necessary to avoid circumstances where a person who has been granted POA for multiple registered locations does not inadvertently sign an order with the wrong certificate/private key.

III. Discussion of the Final Rule

Except for the changes discussed above, DEA is adopting the rule as proposed. Part 1305 has been reorganized to place requirements that apply to all Schedule I and II orders in subpart A; these include old §§ 1305.01, 1305.02, 1305.03, 1305.04, which retain their numbers, old § 1305.07 (power of attorney), which is redesignated as § 1305.05, old § 1305.08 (persons entitled to fill orders), which is redesignated as § 1305.06, and old § 1305.16 (special procedures for filling certain orders), which is redesignated as § 1305.07. The remainder of old Part 1305 is subpart B, which covers the requirements for obtaining, executing, and filling orders on Form 222. Subpart B includes old §§ 1305.05 and 1305.06 (procedures for obtaining and executing

certificates are estimated to be $20 million. The annualized net benefit of the rule, therefore, is $264 million.

As discussed in the NPRM, DEA developed estimates of the time required for each step in the process of issuing and processing an order and used weighted wage rates based on the number of orders registrant groups are estimated to issue. DEA estimates that issuing and processing a Form 222 order costs purchasers about $26 and suppliers about $13. In contrast, issuing and processing a digitally signed order will cost about $2.60 for purchasers and $3.00 for suppliers. (These costs do not include the cost of obtaining a digital certificate or installing software, most of which are one-time costs.) The costs for a single registrant vary depending on the number of orders issued and filled. DEA estimates that annual costs for Form 222 orders range from $26 for a registrant who issues a single order to more than $184,000 for distributors who both issue and fill orders. The annual costs for electronic orders range from $2.60 to about $40,000. The initial registrant costs of obtaining a digital certificate range from $156 to about $600, varying with the number of applicants a registrant has.

Table 1 presents the total annual hours and costs for the Form 222 system for 2004 orders. Tables 2–4 present the total annual hours and costs for obtaining digital certificates, issuing electronic orders, and developing and installing software, if these activities occurred in a single year.

TABLE 1.—TOTAL ANNUAL HOURS AND COSTS FOR THE FORM 222 SYSTEM

[2004 orders]

	Hours	Labor	Capital	O&M	Total
Purchaser:					
Complete and send order	1,640,250	$139,323,000		$7,355,000	$146,677,000
Requisition order	3,124	265,000		23,000	288,000
Annotate order	328,050	27,865,000			27,865,000
File orders	109,350	3,087,000	$129,700	2,668,000	4,472,000
Supplier:					
Enter order	1,640,250	58,770,000			58,770,000
Annotate order	328,050	21,212,000			21,212,000
Compile and send to DEA	90,936	3,258,000		174,000	3,433,000
File orders	109,350	3,918,000	129,700	2,668,000	5,303,000
Total	4,249,360	257,698,000	259,000	12,887,000	270,844,000

TABLE 2.—TOTAL HOURS AND COSTS FOR DIGITAL CERTIFICATES

	Hours	Labor	O&M	Total
Purchaser:				
Complete application	58,950	$5,007,000		$5,007,000
Complete application—coordinator	78,755	6,689,000	$638,000	7,328,000
Generate keys	12,116	1,029,000		1,029,000
Learn to use signature	20,778	1,765,000		1,765,000
Renewal—one year	1,234	105,000		105,000
Renewal—3 year-annual	3,627	308,000		308,000
Supplier:				
Complete application	3,311	214,000		214,000
Complete application—coordinator	345	22,000	2,790	25,000
Generate keys	406	26,000		26,000
Learn to use signature	2,032	131,000		131,000
Renewal	406	26,000		26,000
Total	181,960	15,324,000	641,000	15,965,000

TABLE 3.—TOTAL HOURS AND COSTS FOR ELECTRONIC ORDERS

	Hours	Activities	Total cost
Purchaser:			
Sign orders	36,450	6,561,000	$3,096,000
Edit and archive	164,025	6,561,000	13,932,000
Supplier:			
Validate orders	27,338	6,561,000	1,768,000
Collect and send to DEA	5,473	109,460	354,000
Edit and archive	273,375	6,561,000	17,676,000
Total	506,661		36,826,000

processed through the central distribution office, which then transmits parts of the orders to the warehouses that hold specific items. The Form 222 system cannot take advantage of this arrangement because the paper must accompany the order. With electronic orders, DEA will allow a distributor with a central distribution system to divide an order and ship parts of the order from different distribution points. New orders will not need to be generated because the central computer system can track each item in the order and ensure that it is shipped to the appropriate registrant only once. DEA and the supplier will have the records necessary to maintain the closed system of control while allowing the supplier to take advantage of its own system of distribution.

A copy of the Economic Impact Analysis of the Electronic Orders Rule is available on the Diversion Control Program's Web site.

Regulatory Flexibility Act

The Regulatory Flexibility Act (5 U.S.C. 601–612) requires Federal agencies to determine whether regulations have a significant economic impact on a substantial number of small entities or have a disproportionate effect on small entities. DEA, as part of its economic analysis, considered the costs of the existing system and the electronic system on small entities. The annualized costs of the Form 222 system for the smallest entities (Narcotic Treatment Programs with less than $100,000 in revenues), are 1.66 percent of annual revenues; for these registrants, the annual costs of the electronic orders are about 0.24 percent of annual revenues. For most small entities affected by the rule, the cost of the electronic system will be less than 0.1 percent of revenues or sales. Consequently, the Deputy Administrator hereby certifies that this rulemaking has been drafted in accordance with the Regulatory Flexibility Act (5 U.S.C. 605(b)), has reviewed this regulation, and by approving it certifies that this regulation will not have a significant economic impact on a substantial number of small entities.

A copy of the small business analysis for this proposed rule, which is section 7 of the economic analysis, can be obtained from the Diversion Control Program web site or by contacting the Liaison and Policy Section, Office of Diversion Control, Drug Enforcement Administration, Washington, DC 20537, Telephone (202) 307–7297.

Small Business Regulatory Enforcement Fairness Act of 1996

This rule has been determined to be a major rule as defined by Section 804 of the Small Business Regulatory Enforcement Fairness Act of 1996. This rule will result in an annual effect on the economy of $100,000,000 or more, but will not impose a major increase in costs or prices; or significant adverse effects on competition, employment, investment, productivity, innovation, or on the ability of United States-based companies to compete with foreign-based companies in domestic and export markets. In fact, this rule will result in a significant reduction in the cost of ordering Schedule I and II controlled substances.

Paperwork Reduction Act

The Department of Justice (DOJ), Drug Enforcement Administration (DEA) submitted the following information collection requests to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act of 1995. Under the Paperwork Reduction Act, DEA is required to estimate the burden hours and other costs of any requirement for recordkeeping and reporting over a three-year period. Therefore, DEA proposed the revision of an existing collection of information *U.S. Official Order Forms for Schedules I and II Controlled Substances (Accountable Forms), Order Form Requisition, (OMB Control # 1117–0010)*, and the creation of a new collection of information *Reporting and Recordkeeping for Digital Certificates* under the Paperwork Reduction Act of 1995. This process is conducted in accordance with 5 CFR 1320.11. The Information Collection Request was submitted to the Office of Management and Budget for review under section 307 of the Paperwork Reduction Act.

Overview of U.S. Official Order Forms for Schedules I and II Controlled Substances (Accountable Forms), Order Form Requisition Information Collection

(1) Type of information collection: Revision of existing collection.

(2) The title of the form/collection: U.S. Official Order Forms for Schedule I and II Controlled Substances (Accountable Forms), Order Form Requisition.

(3) The agency form number, if any, and the applicable component of the Department sponsoring the collection:

Form No.: DEA Form 222, U.S. Official Order Forms for Schedule I and II Controlled Substances (Accountable Forms)

DEA Form 222a: Order Form Requisition

Applicable component of the Department sponsoring the collection: Office of Diversion Control, Drug Enforcement Administration, U.S. Department of Justice

(4) Affected public who will be asked or required to respond, as well as a brief abstract:

Primary: Business or other for-profit.

Other: Non-profit, state and local governments.

Abstract: DEA–222 is used to transfer or purchase Schedule I and II controlled substances and data are needed to provide an audit of transfer and purchase. DEA–222a Requisition Form is used to obtain the DEA–222 Order Form. Persons may also digitally sign and transmit orders for controlled substances electronically, using a digital certificate. Orders for Schedule I and II controlled substances are archived and transmitted to DEA; both the supplier and purchaser must retain records for two years.

(5) An estimate of the total number of respondents and the amount of time estimated for an average respondent to respond/reply: DEA estimates that the rule will affect 98,000 registrants. The average time for requisitioning Form 222 is 0.05 hours. The average time for completing, annotating and filing paper orders for purchasers is 0.317 hours. It is estimated that suppliers spend, on average, 0.317 hours annotating, entering and filing the DEA Forms 222. Suppliers spend, on average, 9 hours a month logging and tracking order forms and preparing the mailing to DEA. The average time for signing and annotating electronic orders is estimated to be 0.031 hours per order for purchasers; the average time for validating and annotating electronic orders is estimated to be 0.046 hours per order for suppliers, who also spend 0.05 hours every other business day sending reports to DEA.

(6) An estimate of the total public burden (in hours) associated with the collection: As registrants adopt the electronic ordering, the annual burden hours would average 2.5 million hours a year. During this period, DEA assumes that 20 percent of orders would be electronic in year 1, 60 percent in year 2, and 80 percent in year 3, with a 7 percent growth rate for orders per year.

Overview of Reporting and Recordkeeping for Digital Certificates Information Collection

(1) *Type of information collection:* New collection.

issue electronic orders for these substances. Persons not registered to handle Schedule I or II controlled substances and persons registered only to import controlled substances are not entitled to obtain Form 222 or issue electronic orders for these substances.

(b) An order for Schedule I or II controlled substances may be executed only on behalf of the registrant named on the order and only if his or her registration for the substances being purchased has not expired or been revoked or suspended.

§ 1305.05 Power of attorney.

(a) A registrant may authorize one or more individuals, whether or not located at his or her registered location, to issue orders for Schedule I and II controlled substances on the registrant's behalf by executing a power of attorney for each such individual, if the power of attorney is retained in the files, with executed Forms 222 where applicable, for the same period as any order bearing the signature of the attorney. The power of attorney must be available for inspection together with other order records.

(b) A registrant may revoke any power of attorney at any time by executing a notice of revocation.

(c) The power of attorney and notice of revocation must be similar to the following format:

Power of Attorney for DEA Forms 222 and Electronic Orders

_____
(Name of registrant)

_____
(Address of registrant)

_____
(DEA registration number)

I, _____ (name of person granting power), the undersigned, who am 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 Forms 222 and to sign orders for Schedule I and II controlled substances, whether these orders be on Form 222 or electronic, in accordance with 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 must 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 _____, (year), at _____.

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 or 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 _____, (year), at _____.

(d) A power of attorney must be executed by the person who signed the most recent application for DEA registration or reregistration; the person to whom the power of attorney is being granted; and two witnesses.

(e) A power of attorney must be revoked by the person who signed the most recent application for DEA registration or reregistration, and two witnesses.

§ 1305.06 Persons entitled to fill orders for Schedule I and II controlled substances.

An order for Schedule I and II controlled substances, whether on a DEA Form 222 or an electronic order, may be filled only by a person registered with DEA as a manufacturer or distributor of controlled substances listed in Schedule I or II pursuant to section 303 of the Act (21 U.S.C. 823) or as an importer of such substances pursuant to section 1008 of the Act (21 U.S.C. 958), except for the following:

(a) A person registered with DEA to dispense the substances, or to export the substances, if he/she is discontinuing business or if his/her registration is expiring without reregistration, may dispose of any Schedule I or II controlled substances in his/her possession with a DEA Form 222 or an electronic order in accordance with § 1301.52 of this chapter.

(b) A purchaser who has obtained any Schedule I or II controlled substance by either a DEA Form 222 or an electronic order may return the substance to the supplier of the substance with either a DEA Form 222 or an electronic order from the supplier.

(c) A person registered to dispense Schedule II substances may distribute the substances to another dispenser with either a DEA Form 222 or an electronic order only in the circumstances described in § 1307.11 of this chapter.

(d) A person registered or authorized to conduct chemical analysis or research with controlled substances may distribute a Schedule I or II controlled substance to another person registered or authorized to conduct chemical analysis, instructional activities, or research with the substances with either a DEA Form 222 or an electronic order, if the distribution is for the purpose of furthering the chemical analysis, instructional activities, or research.

(e) A person registered as a compounder of narcotic substances for use at off-site locations in conjunction with a narcotic treatment program at the compounding location, who is authorized to handle Schedule II narcotics, is authorized to fill either a DEA Form 222 or an electronic order for distribution of narcotic drugs to off-site narcotic treatment programs only.

§ 1305.07 Special procedure for filling certain orders.

A supplier of carfentanil, etorphine hydrochloride, or diprenorphine, if he or she determines that the purchaser is a veterinarian engaged in zoo and exotic animal practice, wildlife management programs, or research, and is authorized by the Administrator to handle these substances, may fill the order in accordance with the procedures set forth in § 1305.17 except that:

(a) A DEA Form 222 or an electronic order for carfentanil, etorphine hydrochloride, and diprenorphine must contain only these substances in reasonable quantities.

(b) The substances must be shipped, under secure conditions using substantial packaging material with no markings on the outside that would indicate the content, only to the purchaser's registered location.

Subpart B—DEA Form 222

§ 1305.11 Procedure for obtaining DEA Forms 222.

(a) DEA Forms 222 are issued in mailing envelopes containing either seven or fourteen forms, each form containing an original, duplicate, and triplicate copy (respectively, Copy 1, Copy 2, and Copy 3). A limit, which is

is sufficient for purposes of this paragraph.

(d) When a purchaser receives an unaccepted order, Copies 1 and 2 of the DEA Form 222 and the statement must be attached to Copy 3 and retained in the files of the purchaser in accordance with § 1305.17. A defective DEA Form 222 may not be corrected; it must be replaced by a new DEA Form 222 for the order to be filled.

§ 1305.16 Lost and stolen DEA Forms 222.

(a) If a purchaser ascertains that an unfilled DEA Form 222 has been lost, he or she must execute another in triplicate and attach a statement containing the serial number and date of the lost form, and stating that the goods covered by the first DEA Form 222 were not received through loss of that DEA Form 222. Copy 3 of the second form and a copy of the statement must be retained with Copy 3 of the DEA Form 222 first executed. A copy of the statement must be attached to Copies 1 and 2 of the second DEA Form 222 sent to the supplier. If the first DEA Form 222 is subsequently received by the supplier to whom it was directed, the supplier must mark upon the face "Not accepted" and return Copies 1 and 2 to the purchaser, who must attach it to Copy 3 and the statement.

(b) Whenever any used or unused DEA Forms 222 are stolen or lost (other than in the course of transmission) by any purchaser or supplier, the purchaser or supplier must immediately upon discovery of the theft or loss, report the theft or loss to the Special Agent in Charge of the Drug Enforcement Administration in the Divisional Office responsible for the area in which the registrant is located, stating the serial number of each form stolen or lost.

(c) If the theft or loss includes any original DEA Forms 222 received from purchasers and the supplier is unable to state the serial numbers of the DEA Forms 222, the supplier must report the date or approximate date of receipt and the names and addresses of the purchasers.

(d) If an entire book of DEA Forms 222 is lost or stolen, and the purchaser is unable to state the serial numbers of the DEA Forms 222 in the book, the purchaser must report, in lieu of the numbers of the forms contained in the book, the date or approximate date of issuance.

(e) If any unused DEA Form 222 reported stolen or lost is subsequently recovered or found, the Special Agent in Charge of the Drug Enforcement Administration in the Divisional Office responsible for the area in which the registrant is located must immediately be notified.

§ 1305.17 Preservation of DEA Forms 222.

(a) The purchaser must retain Copy 3 of each executed DEA Form 222 and all copies of unaccepted or defective forms with each statement attached.

(b) The supplier must retain Copy 1 of each DEA Form 222 that it has filled.

(c) DEA Forms 222 must be maintained separately from all other records of the registrant. DEA Forms 222 are required to be kept available for inspection for a period of two years. If a purchaser has several registered locations, the purchaser must retain Copy 3 of the executed DEA Form 222 and any attached statements or other related documents (not including unexecuted DEA Forms 222, which may be kept elsewhere under § 1305.12(e)), at the registered location printed on the DEA Form 222.

(d) The supplier of carfentanil, etorphine hydrochloride, and diprenorphine must maintain DEA Forms 222 for these substances separately from all other DEA Forms 222 and records required to be maintained by the registrant.

§ 1305.18 Return of unused DEA Forms 222.

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 as shown on the purchaser's registration) or is suspended or revoked under § 1301.36 of this chapter for all Schedule I and II controlled substances for which the purchaser is registered, the purchaser must return all unused DEA Forms 222 to the nearest office of the Administration.

§ 1305.19 Cancellation and voiding of DEA Forms 222.

(a) A purchaser may cancel part or all of an order on a DEA Form 222 by notifying the supplier in writing of the cancellation. The supplier must indicate the cancellation on Copies 1 and 2 of the DEA Form 222 by drawing a line through the canceled items and printing "canceled" in the space provided for number of items shipped.

(b) A supplier may void part or all of an order on a DEA Form 222 by notifying the purchaser in writing of the voiding. The supplier must indicate the voiding in the manner prescribed for cancellation in paragraph (a) of this section.

Subpart C—Electronic Orders

§ 1305.21 Requirements for electronic orders.

(a) To be valid, the purchaser must sign an electronic order for a Schedule I or II controlled substance with a digital signature issued to the purchaser, or the purchaser's agent, by DEA as provided in part 1311 of this chapter.

(b) The following data fields must be included on an electronic order for Schedule I and II controlled substances:

(1) A unique number the purchaser assigns to track the order. The number must be in the following 9-character format: the last two digits of the year, X, and six characters as selected by the purchaser.

(2) The purchaser's DEA registration number.

(3) The name of the supplier.

(4) The complete address of the supplier (may be completed by either the purchaser or the supplier).

(5) The supplier's DEA registration number (may be completed by either the purchaser or the supplier).

(6) The date the order is signed.

(7) The name (including strength where appropriate) of the controlled substance product or the National Drug Code (NDC) number (the NDC number may be completed by either the purchaser or the supplier).

(8) The quantity in a single package or container.

(9) The number of packages or containers of each item ordered.

(c) An electronic order may include controlled substances that are not in schedules I and II and non-controlled substances.

§ 1305.22 Procedure for filling electronic orders.

(a) A purchaser must submit the order to a specific supplier. The supplier may initially process the order (*e.g.*, entry of the order into the computer system, billing functions, inventory identification, etc.) centrally at any location, regardless of the location's registration with DEA. Following centralized processing, the supplier may distribute the order to one or more registered locations maintained by the supplier for filling. The registrant must maintain control of the processing of the order at all times.

(b) A supplier may fill the order for a Schedule I or II controlled substance, if possible and if the supplier desires to do so and is authorized to do so under § 1305.06.

(c) A supplier must do the following before filling the order:

(1) Verify the integrity of the signature and the order by using software that

Authority: 21 U.S.C. 821, 828, 829, 871(b), 958(e), 965, unless otherwise noted.

Subpart A—General

§ 1311.01 Scope.

This part sets forth the rules governing the use of digital signatures and the protection of private keys by registrants.

§ 1311.02 Definitions.

For the purposes of this chapter:

Biometric authentication means authentication based on measurement of the individual's physical features or repeatable actions where those features or actions are both unique to the individual and measurable.

Cache means to download and store information on a local server or hard drive.

Certificate Policy means a named set of rules that sets forth the applicability of the specific digital certificate to a particular community or class of application with common security requirements.

Certificate Revocation List (CRL) means a list of revoked, but unexpired certificates issued by a Certification Authority.

Certification Authority (CA) means an organization that is responsible for verifying the identity of applicants, authorizing and issuing a digital certificate, maintaining a directory of public keys, and maintaining a Certificate Revocation List.

CSOS means controlled substance ordering system.

Digital certificate means a data record that, at a minimum:

(1) Identifies the certification authority issuing it;

(2) Names or otherwise identifies the certificate holder;

(3) Contains a public key that corresponds to a private key under the sole control of the certificate holder;

(4) Identifies the operational period; and

(5) Contains a serial number and is digitally signed by the Certification Authority issuing it.

Digital signature means a record created when a file is algorithmically transformed into a fixed length digest that is then encrypted using an asymmetric cryptographic private key associated with a digital certificate. The combination of the encryption and algorithm transformation ensure that the signer's identity and the integrity of the file can be confirmed.

Electronic signature means a method of signing an electronic message that identifies a particular person as the source of the message and indicates the person's approval of the information contained in the message.

FIPS means Federal Information Processing Standards. These Federal standards, as incorporated by reference in § 1311.08, prescribe specific performance requirements, practices, formats, communications protocols, etc., for hardware, software, data, etc.

FIPS 140–2, as incorporated by reference in § 1311.08, means a Federal standard for security requirements for cryptographic modules.

FIPS 180–2, as incorporated by reference in § 1311.08, means a Federal secure hash standard.

FIPS 186–2, as incorporated by reference in § 1311.08, means a Federal standard for applications used to generate and rely upon digital signatures.

Key pair means two mathematically related keys having the properties that:

(1) One key can be used to encrypt a message that can only be decrypted using the other key; and

(2) Even knowing one key, it is computationally infeasible to discover the other key.

NIST means the National Institute of Standards and Technology.

Private key means the key of a key pair that is used to create a digital signature.

Public key means the key of a key pair that is used to verify a digital signature. The public key is made available to anyone who will receive digitally signed messages from the holder of the key pair.

Public Key Infrastructure (PKI) means a structure under which a Certification Authority verifies the identity of applicants, issues, renews, and revokes digital certificates, maintains a registry of public keys, and maintains an up-to-date Certificate Revocation List.

§ 1311.05 Standards for technologies for electronic transmission of orders.

(a) A registrant or a person with power of attorney to sign orders for Schedule I and II controlled substances may use any technology to sign and electronically transmit orders if the technology provides all of the following:

(1) *Authentication:* The system must enable a recipient to positively verify the signer without direct communication with the signer and subsequently demonstrate to a third party, if needed, that the sender's identity was properly verified.

(2) *Nonrepudiation:* The system must ensure that strong and substantial evidence is available to the recipient of the sender's identity, sufficient to prevent the sender from successfully denying having sent the data. This criterion includes the ability of a third party to verify the origin of the document.

(3) *Message integrity:* The system must ensure that the recipient, or a third party, can determine whether the contents of the document have been altered during transmission or after receipt.

(b) DEA has identified the following means of electronically signing and transmitting order forms as meeting all of the standards set forth in paragraph (a) of this section.

(1) Digital signatures using Public Key Infrastructure (PKI) technology.

(2) [Reserved]

§ 1311.08 Incorporation by reference.

(a) The following standards are incorporated by reference:

(1) FIPS 140–2, Security Requirements for Cryptographic Modules, May 25, 2001, as amended by Change Notices 2 through 4, December 3, 2002.

(i) Annex A: Approved Security Functions for FIPS PUB 140–2, Security Requirements for Cryptographic Modules, September 23, 2004.

(ii) Annex B: Approved Protection Profiles for FIPS PUB 140–2, Security Requirements for Cryptographic Modules, November 4, 2004.

(iii) Annex C: Approved Random Number Generators for FIPS PUB 140–2, Security Requirements for Cryptographic Modules, January 31, 2005.

(iv) Annex D: Approved Key Establishment Techniques for FIPS PUB 140–2, Security Requirements for Cryptographic Modules, February 23, 2004.

(2) FIPS 180–2, Secure Hash Standard, August 1, 2002, as amended by change notice 1, February 25, 2004.

(3) FIPS 186–2, Digital Signature Standard, January 27, 2000, as amended by Change Notice 1, October 5, 2001.

(b) These standards are available from the National Institute of Standards and Technology, Computer Security Division, Information Technology Laboratory, National Institute of Standards and Technology, 100

§ 1311.35 Number of CSOS digital certificates needed.

A purchaser of Schedule I and II controlled substances must obtain a separate CSOS certificate for each registered location for which the purchaser will order these controlled substances.

§ 1311.40 Renewal of CSOS digital certificates.

(a) A CSOS certificate holder must generate a new key pair and obtain a new CSOS digital certificate when the registrant's DEA registration expires or whenever the information on which the certificate is based changes. This information includes the registered name and address, the subscriber's name, and the schedules the registrant is authorized to handle. A CSOS certificate will expire on the date on which the DEA registration on which the certificate is based expires.

(b) The Certification Authority will notify each CSOS certificate holder 45 days in advance of the expiration of the certificate holder's CSOS digital certificate.

(c) If a CSOS certificate holder applies for a renewal before the certificate expires, the certificate holder may renew electronically twice. For every third renewal, the CSOS certificate holder must submit a new application and documentation, as provided in § 1311.25.

(d) If a CSOS certificate expires before the holder applies for a renewal, the certificate holder must submit a new application and documentation, as provided in § 1311.25.

§ 1311.45 Requirements for registrants that allow powers of attorney to obtain CSOS digital certificates under their DEA registration.

(a) A registrant that grants power of attorney must report to the DEA Certification Authority within 6 hours of either of the following (advance notice may be provided, where applicable):

(1) The person with power of attorney has left the employ of the institution.

(2) The person with power of attorney has had his or her privileges revoked.

(b) A registrant must maintain a record that lists each person granted power of attorney to sign controlled substances orders.

§ 1311.50 Requirements for recipients of digitally signed orders.

(a) The recipient of a digitally signed order must do the following before filling the order:

(1) Verify the integrity of the signature and the order by having the system validate the order.

(2) Verify that the certificate holder's CSOS digital certificate has not expired by checking the expiration date against the date the order was signed.

(3) Check the validity of the certificate holder's certificate by checking the Certificate Revocation List.

(4) Check the certificate extension data to determine whether the sender has the authority to order the controlled substance.

(b) A recipient may cache Certificate Revocation Lists for use until they expire.

§ 1311.55 Requirements for systems used to process digitally signed orders.

(a) A CSOS certificate holder and recipient of an electronic order may use any system to write, track, or maintain orders provided that the system has been enabled to process digitally signed documents and that it meets the requirements of paragraph (b) or (c) of this section.

(b) A system used to digitally sign Schedule I or II orders must meet the following requirements:

(1) The cryptographic module must be FIPS 140–2, Level 1 validated, as incorporated by reference in § 1311.08.

(2) The digital signature system and hash function must be compliant with FIPS 186–2 and FIPS 180–2, as incorporated by reference in § 1311.08.

(3) The private key must be stored on a FIPS 140–2 Level 1 validated cryptographic module using a FIPS-approved encryption algorithm, as incorporated by reference in § 1311.08.

(4) The system must use either a user identification and password combination or biometric authentication to access the private key. Activation data must not be displayed as they are entered.

(5) The system must set a 10-minute inactivity time period after which the certificate holder must reauthenticate the password to access the private key.

(6) For software implementations, when the signing module is deactivated, the system must clear the plain text private key from the system memory to prevent the unauthorized access to, or use of, the private key.

(7) The system must be able to digitally sign and transmit an order.

(8) The system must have a time system that is within five minutes of the official National Institute of Standards and Technology time source.

(9) The system must archive the digitally signed orders and any other records required in part 1305 of this chapter, including any linked data.

(10) The system must create an order that includes all data fields listed under § 1305.21(b) of this chapter.

(c) A system used to receive, verify, and create linked records for orders signed with a CSOS digital certificate must meet the following requirements:

(1) The cryptographic module must be FIPS 140–2, Level 1 validated, as incorporated by reference in § 1311.08.

(2) The digital signature system and hash function must be compliant with FIPS 186–2 and FIPS 180–2, as incorporated by reference in § 1311.08.

(3) The system must determine that an order has not been altered during transmission. The system must invalidate any order that has been altered.

(4) The system must validate the digital signature using the signer's public key. The system must invalidate any order in which the digital signature cannot be validated.

(5) The system must validate that the DEA registration number contained in the body of the order corresponds to the registration number associated with the specific certificate by separately generating the hash value of the registration number and certificate subject distinguished name serial number and comparing that hash value to the hash value contained in the certificate extension for the DEA registration number. If the hash values are not equal the system must invalidate the order.

(6) The system must check the Certificate Revocation List automatically and invalidate any order with a certificate listed on the Certificate Revocation List.

(7) The system must check the validity of the certificate and the Certification Authority certificate and invalidate any order that fails these validity checks.

(8) The system must have a time system that is within five minutes of the official National Institute of Standards and Technology time source.

(9) The system must check the substances ordered against the schedules that the registrant is allowed to order and invalidate any order that includes substances the registrant is not allowed to order.

(10) The system must ensure that an invalid finding cannot be bypassed or ignored and the order filled.

(11) The system must archive the order and associate with it the digital certificate received with the order.

(12) If a registrant sends reports on orders to DEA, the system must create a report in the format DEA specifies, as provided in § 1305.29 of this chapter.

(d) For systems used to process CSOS orders, the system developer or vendor must have an initial independent third-party audit of the system and an

Steve Kneller/LOG/Walgreens
02/05/2010 01:38 PM

To deborah.bish@walgreens.com
cc
bcc
Subject Fw: Form 222 for CII

Deb,

Print this off and keep it.

Steve

Steve Kneller
Walgreens
Distribution Center Manager
28727 Oregon Road
Perrysburg, Ohio 43551
419-662-4003 - direct line
419-662-4071 - fax

----- Forwarded by Steve Kneller/LOG/Walgreens on 02/05/2010 01:37 PM -----

Dan Coughlin/LOG/Walgreens
01/07/2010 10:05 AM

To Steve Kneller/LOG/Walgreens@Walgreens, rob.varno@walgreens.com, John Coman/LOG/Walgreens@Walgreens
cc Linda Rambo/LOG/Walgreens@Walgreens, Dwayne Pinon/Corp/Walgreens@Walgreens, Sharon Hann/LOG/Walgreens@WALGREENS
Subject Fw: Form 222 for CII

Redacted – Attorney Client Privileged

----- Forwarded by Dan Coughlin/LOG/Walgreens on 01/07/2010 09:01 AM -----

Dwayne Pinon/Corp/Walgreens
01/07/2010 08:54 AM

To Linda Rambo/LOG/Walgreens@Walgreens
cc Dan Coughlin/LOG/Walgreens@Walgreens, Gary Peters/Corp/Walgreens@Walgreens, Steve Kneller/LOG/Walgreens@Walgreens
Subject Re: Form 222 for CII Link

Redacted – Attorney Client Privileged

Redacted – Attorney Client Privileged

Dwayne A. Pinon, R.Ph.
Senior Attorney, Litigation & Regulatory Law
Walgreen Co.
104 Wilmot Road, MS #1447
Deerfield, IL 60015
(847) 315-4452
(847) 315-4660 (fax)

Redacted – Attorney Client Privileged

Linda Rambo/LOG/Walgreens

01/06/2010 05:36 PM

To Dwayne Pinon/Corp/Walgreens@Walgreens, Gary Peters/Corp/Walgreens@Walgreens

cc Dan Coughlin/LOG/Walgreens@Walgreens, Steve Kneller/LOG/Walgreens@Walgreens

Subject Form 222 for CII

Redacted – Attorney Client Privileged

Linda Rambo
Supply Chain & Logistics
Office: (847) 527-4366
Mobile: (847)863-2334

Watson

March 17, 2011

Ms. Deborah Bish
Walgreens Perrysburg Dist. Center
28727 Oregon Road
Perrysburg, OH 43551

Re: Fentanyl Transdermal Patch 25 mcg
Lot Number: 368924A
Watson File Number: 2011-03417

Dear Ms. Bish:

We have received your notification regarding a problem with the product listed above.

Our Quality Department has been notified of this event. Each lot of Fentanyl distributed by Watson Laboratories, Inc. must pass strict testing requirements; no lot would be released if these requirements are not met.

Maintaining the quality and integrity of our products is of the utmost importance to us. We appreciate your time and effort in bringing the matter to our attention as it will become a part of our database.

Sincerely,

Watson Drug Safety Department
800-272-5525