DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. DEA–217N]

RIN 1117–AA60

Electronic Orders for Controlled Substances: Notice of Meeting

AGENCY: Drug Enforcement Administration (DEA), Justice.

ACTION: Notice of meeting.

SUMMARY: The Drug Enforcement Administration (DEA) will hold a public meeting to provide technical details regarding the use of digital signatures and public key infrastructure (PKI) technology within DEA's system for electronic orders for Schedule I and II controlled substances.

DATES: Wednesday, May 18, 2005, 9 a.m. until 4:30 p.m.

ADDRESSES: Sheraton National Hotel, 900 South Orme Street, Arlington, VA 22204.

Persons wishing to attend this meeting, space permitting, must provide attendee information to the Liaison and Policy Section, Office of Diversion Control, Drug Enforcement Administration, via e-mail to *mandy.a.healy@usdoj.gov,* or via facsimile at (202) 353–1079 as specified below. Persons wishing to attend the meeting must provide this information to the Liaison and Policy Section no later than Monday, May 16, 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:

Background

In a separate Final Rule published in today's **Federal Register**, the Drug Enforcement Administration (DEA) is implementing regulations regarding the electronic transmission of Schedule I and II controlled substances orders from purchasers (DEA-registered distributors, pharmacies and practitioners) to suppliers (DEA-registered manufacturers and distributors) and the electronic retention of records pertaining to those orders. DEA is requiring that these electronic orders be conducted using public key infrastructure (PKI) technology, including the use of digital certificates issued by the DEA Bridge Certification Authority.

This meeting is being held to provide information to interested persons including systems vendors and developers regarding industry's development of electronic systems which conform to the standards and regulations DEA is implementing. Persons interested in learning about the development of such PKI-based systems using DEA's standards may attend this meeting, so long as space permits.

Background and Supporting Documents

Supporting documents regarding DEA's system to permit the electronic transmission of Schedule I and II controlled substances orders and the electronic retention of records pertaining to those orders, including the Certificate Policy, Certificate Profile, applications to obtain a digital certificate from the DEA Bridge Certification Authority, and other pertinent materials may be found within the Electronic Commerce Initiatives/CSOS section on the Diversion Control Program Web site: *http://www.deadiversion.usdoj.gov/ecomm/index.html,* and DEA's E-Commerce Web site: *http://www.deaecom.gov.*

Meeting Registration

Persons wishing to attend this meeting must provide the following information to the Liaison and Policy Section, Office of Diversion Control, Drug Enforcement Administration, via e-mail or facsimile as listed above:

Name: _____
Title: _____
Company/Organization: _____
Address: _____
Telephone: _____
E-mail address: _____

Dated: March 29, 2005.

William J. Walker,

Deputy Assistant Administrator, Office of Diversion Control.

[FR Doc. 05–6505 Filed 3–31–05; 8:45 am]

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Federal Register

Friday,
April 1, 2005

Part II

Department of Justice

Drug Enforcement Administration

21 CFR Parts 1305 and 1311

Electronic Orders for Controlled Substances and Notice of Meeting; Final Rule and Notice

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.

DEA proposed allowing regulated entities who are eligible to order Schedule I and II controlled substances to issue and process electronic orders if those orders are signed using a digital certificate issued by a Certification Authority run by DEA; the approach is called the Controlled Substance Ordering System or CSOS. Use of electronic orders is optional; registrants may continue to issue orders on Form 222.

DEA proposed minor organizational revisions to the existing requirements in Part 1305 to create subparts. Subpart A includes those requirements that apply to all orders. Subpart B covers the requirements for handling Form 222 orders. Other than minor editorial changes to make the regulations easier to read, the existing requirements for paper orders are unchanged. A new subpart C was proposed to cover the requirements for issuing and filling electronic orders. These requirements parallel those for Form 222 orders, but include some differences based on the different constraints on the two systems. For example, the regulation specifies the data elements required on an electronic order; because these elements are part of the Form 222, they are not specified for paper orders. Orders submitted on paper must be filled by a single registered location because the original order form must be maintained at the distribution location in support of the distribution; electronic orders may be divided and filled from separate registered locations owned by the same company, since the order can be retrieved directly in verifiable form at each distributing location.

In addition to its revision of Part 1305, DEA proposed a new Part 1311 that includes the requirements for obtaining, storing, using, and renewing digital certificates. Registrants and people granted power of attorney by registrants to sign orders will be eligible to obtain digital certificates. A registrant must appoint a CSOS coordinator who will serve as that registrant's recognized agent regarding issues pertaining to issuance of, revocation of, and changes to digital certificates issued under that registrant's DEA registration. These individuals serve as knowledgeable liaisons between one or more DEA registered locations and the CSOS Certification Authority (CA). The coordinators will collect applications, ensure that they include all of the required information, and send them to the CA. Part 1311 also specifies the requirements that the digital signature software will have to meet to ensure that it is capable of creating and validating digitally signed orders.

Procedures for Obtaining a Digital Certificate

Procedures for enrolling to obtain a digital certificate are available on the DEA Diversion Control Program Web site, *http://www.deadiversion.usdoj.gov,* and on the DEA E-Commerce Web site at *http://www.deaecom.gov.* Applicants can download the Diversion PKI CSOS Enrollment document and the CSOS Subscriber's Manual for guidance on enrollment procedures. DEA will begin accepting applications to obtain digital certificates May 31, 2005. Upon receiving a completed application DEA estimates that it will take the Certification Authority 10 business days to process the application. DEA's Certification Authority will maintain a support line to assist applicants and subscribers with issues pertaining to certificate enrollment, issuance, revocation, and renewal.

PKI and Digital Certificates

A public key infrastructure is comprised of a Certification Authority, which must verify the identity of applicants before issuing digital certificates, and public-private key pairs. PKI systems are based on asymmetric cryptography: the holder of the digital certificate has a private key, which only the certificate holder can access, and a public key, which is available to anyone. What one key encrypts, only the other key can decrypt. It is computationally infeasible for the two keys to be derived from each other. Only one public key will validate signatures made using its corresponding private key. Because the private key is held by only one person, it is that person's responsibility to ensure that it is not divulged or compromised.

The DEA Certification Authority (CA) will issue digital certificates, which will serve as an electronic equivalent of the Form 222. DEA must serve as the CA because a digital certificate is the functional equivalent of a Form 222 that the CSA requires DEA to issue. In the same manner as DEA pre-prints the registration information on the paper order forms that are issued to registrants, DEA will enter the registration information in extensions within the certificates that are issued to registrants and those granted power of attorney by registrants.

As DEA explained in the NPRM, the process of digitally signing an order is technically complicated (the software uses several complex algorithms to create an encrypted digest of the text), but the user needs only to activate the key and then enter one or two key strokes to sign an order or validate it. Existing electronic order systems will have to be PKI-enabled, which can be done with commercially available toolkits. DEA has been working with industry to develop systems and procedures that allow PKI-enabling existing systems to reduce the cost of implementation.

CSOS Certificates

All of the information currently preprinted on the Form 222 will be part of the extension data of the CSOS digital certificate, which will be included with each order that is digitally signed. Attaching the digital certificate, with the registration information in the extension data, to an electronic order signed with the digital signature is the functional equivalent to DEA pre-printing the registrant information on the paper forms, thus creating an electronic equivalent of the Form 222.

A CSOS certificate will be valid until the DEA registration under which it is issued expires or until the CSOS CA is notified that the certificate should be revoked. Certificates will be revoked if the certificate holder is no longer authorized to sign Schedule I and II orders for the registrant, if the information on which the certificate is based changes, or if access to the private key has been compromised or lost.

II. Discussion of Comments on the NPRM

DEA received 11 comments on its proposed rule. Commenters included the major trade associations representing pharmacies and distributors as well as individual companies and one vendor. This section summarizes the comments and provides DEA's response.

Listed schedules. Several commenters were concerned with proposed rule language that implied that the digital certificate would include extension data that indicated the schedules the certificate holder rather than the registrant was authorized to order. The commenters stated that it would be an additional burden on suppliers if they had to verify the eligibility of the signer, as well as the registrant, to order specific schedules.

DEA has revised the rule language to clarify that only the registrant's authorized schedules will be included in the extension data. If a registrant limits an individual's signing authority, it is incumbent on the registrant to ensure that the individual does not sign orders for schedules he/she is not authorized to order. The supplier is not required to verify information on schedules beyond confirming that the

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

rule to replace registrant's recognized agent with CSOS coordinator.

Central Ordering. A commenter asked whether the § 1305.22(f) requirement to ship to the registered location of the purchaser allowed for shipment to a different registered location if the order was issued by a central ordering facility. A number of firms issue orders for all their registered locations from a central location which may not, itself, be registered. Each order, however, can be for only one specific registered location and the supplier must ship to that location. If the registered location identified within the order deviates from that identified within the digital certificate, the supplier cannot fill the order; a new order must be requested from the purchaser.

Commenters also recommended that for central processing of orders that DEA allow either the central location or the location filling part of the order to create the record. DEA agrees that either location may create the record and has revised the rule. DEA's concern is not with the creation of the record, but with its maintenance. The registrant that distributes a controlled substance must maintain a full record of the order and make it available for DEA on request.

One commenter raised the issue of linking a single certificate to multiple locations. As DEA explained in the NPRM, DEA understands the concern and has taken steps to reduce the burden for individuals who hold keys for many locations, but to serve as an equivalent of a Form 222, each digital certificate must be specific to a single registered location.

Endorsed, lost, and canceled orders. Commenters questioned whether the proposed rule for endorsing electronic orders could be implemented, noting that the requirements were confusing and cumbersome. DEA has reviewed this issue and agrees with the commenters that endorsing electronic orders in a manner that provides adequate safeguards may be technically too complicated. Consequently, DEA has decided to not allow endorsement of electronic orders. Because orders are rarely endorsed and the almost instantaneous communication of electronic orders and confirmations mean that a purchaser will learn that the supplier cannot fill all or part of an order shortly after the order is submitted, DEA does not expect this to pose any significant problem for registrants. The purchaser can quickly issue a new electronic order to another supplier for any items the first supplier cannot fill. Finally, if the order is originally submitted to a firm that processes orders centrally, the central processing supplier can fill the order from multiple locations without endorsement.

Commenters also stated that the meaning of § 1305.26 on lost orders was confusing and requested that only the purchaser maintain records of lost orders. DEA agrees and has revised the rule to specify that a supplier need maintain only those orders that the supplier fills.

Commenters stated that suppliers should not be required to maintain records of orders that are canceled. DEA agrees. Suppliers are only required to maintain records of orders that they fill. Suppliers need not return the electronic order to the purchaser, however, the supplier must notify the purchaser of the cancellation of the order. Commenters also said that purchasers should be able to use any method to notify the supplier that an order was canceled. DEA disagrees. Notification of an order cancellation must be written so that the purchaser can maintain a verifiable record. Written notification includes paper, facsimile, or electronically transmitted notifications such as e-mail; notification by telephone is not allowed.

Validity of a signature. Commenters asked whether it was feasible to determine whether a signature was valid at the time of signing. Commenters were particularly concerned that, if there was a delay in processing an order, they should be able to reject an order if the signature was no longer valid at the time of shipping.

The purpose of the requirement for consistent time systems is to allow suppliers to determine whether a signature was valid at the time of signing. If a digital signature was valid on Friday when the order was signed, but expired on Monday, DEA considers that the order is valid. Unless DEA or the purchaser has notified a supplier that orders issued by a specific person should not be filled, an order signed with a digital certificate that was valid at the time of signing is a valid order. A registrant may choose not to fill the order for any reason; if registrants want to require that the signature still be valid at the time of filling, they may do so. Suppliers have the option of imposing more stringent standards. As a secondary note, DEA wishes to stress that once a supplier has validated a signature on an order, it is not necessary to re-validate the signature prior to actually shipping the order to the purchaser.

Time period for reporting key compromise or loss of privilege. Commenters objected to the requirement that they report loss, theft, or compromise of the key within 24 hours of such loss, theft, or compromise, and that they report a certificate holder's loss of signing privilege within six hours. They also stated that they wanted to be able to report loss of signing privilege in advance (*e.g.*, when they learn an employee will be leaving the firm on a certain date). They stated that the 24-hour and 6-hour time frames were unrealistic and could result in notifications filed outside of business hours.

Registrants may notify the CA in advance of revocations. DEA agrees that the 24-hour period should be within 24 hours of substantiation of key compromise, etc., and has changed the rule. On the 6-hour notification, DEA disagrees with the commenters. DEA believes it is important that the CA be notified as soon as someone's signing privileges are revoked. The digital certificate is the equivalent of a Form 222—a former employee still in possession of their digital certificate and keys would have all they needed to generate orders that would be otherwise indistinguishable from legitimate orders. In the paper world, this concern does not exist since a former employee would no longer have access to the order forms and, thus, could not engage in any mischief. DEA notes that the CA will be staffed 24/7 so there is no need to wait until the next business day. An e-mail to the CA that is digitally signed by the coordinator or registrant will be sufficient notification.

Certification Authority. Commenters raised concerns about the DEA CA being run by a contractor and asked about the safety of information. DEA emphasizes that although a contractor may be used to carry out the day-to-day operations of the CA, the contractor will operate under direct DEA supervision and control. All Federal contractors are subject to the same legal requirements as government employees in regard to protection of information. DEA may use information submitted in its investigations, but the information would not be released for other purposes.

Reports to DEA. Commenters objected to the requirement that suppliers file reports on orders with DEA every other business day. They stated that this frequency of filing would not provide them with an opportunity to review and correct minor discrepancies. With paper orders, DEA knows which registrants have executed Form 222, which provides a control on the system. DEA needs frequent reports on electronic orders because it has no other means of determining who is ordering and in what volume. DEA recognizes that some

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

Forms 222), which are redesignated as §§ 1305.11 and 1305.12, and old §§ 1305.09–1305.15, which are redesignated as §§ 1305.13–1305.19. These sections include specific references to orders on Form 222.

Subpart C covers the requirements for electronic orders.

Section 1305.21 specifies that an electronic order must be signed with a CSOS digital certificate and that the order may include substances other than Schedule I and II controlled substances. The section specifies the data fields that must be included in electronic orders.

Section 1305.22 specifies procedures for filling electronic orders.

Section 1305.23 covers endorsing electronic orders. As discussed above, endorsement of electronic orders will not be allowed.

Section 1305.24 covers central processing of orders. These requirements are also different for electronic orders because with electronic orders, the supplier may have multiple registered locations fill parts of an order provided that the supplying company owns and operates all of the locations filling an order.

Sections 1305.25 and 1305.26 specify the requirements for handling unaccepted and defective electronic orders and lost orders.

Section 1305.27 covers preservation of electronic orders.

Section 1305.28 covers canceling and voiding electronic orders.

Section 1305.29 specifies the requirements for reporting electronic orders to DEA. Suppliers may submit either a copy of the order and its linked records or a report in a format DEA specifies. DEA intends that the report will be identical to the ARCOS report in format with four additional data elements: the NDC number, quantity, unit, and strength ordered.

New Part 1311 covers the requirements for digital certificates. Subpart A includes the scope, definitions, standards for electronic orders, and incorporations by reference. Subpart B covers the requirements for obtaining and using CSOS digital certificates.

Section 1311.10 specifies who is eligible to obtain a CSOS certificate; § 1311.15 covers the limitation of certificates to the schedules authorized for the DEA registration under which the certificate is issued. The revised section states that the registrant is responsible for ensuring that any person whose signing authority the registrant limits abides by those limits.

Section 1311.20 specifies the requirements for CSOS coordinators.

Section 1311.25 specifies the requirements for obtaining a CSOS certificate.

Section 1311.30 provides the requirements for using and storing a digital certificate.

Section 1311.35 specifies the number of certificates needed.

Section 1311.40 specifies when a new certificate must be obtained.

Section 1311.45 specifies requirements for registrants that grant power of attorney authority.

Section 1311.50 specifies requirements for recipients handling electronic orders prior to filling them.

Section 1311.55 specifies software requirements for handling electronic orders.

Section 1311.60 specifies recordkeeping requirements.

PART 1305.—DISTRIBUTION TABLE

Old section	New section
1305.01—Scope of part 1305	1305.01—Scope of part 1305.
1305.02—Definitions	1305.02—Definitions.
1305.03—Distributions requiring order forms	1305.03—Distributions requiring order forms.
1305.04—Persons entitled to obtain and execute order forms	1305.04—Persons entitled to obtain and execute order forms.
1305.05—Procedure for obtaining order forms	1305.11—Procedure for obtaining DEA Forms 222.
1305.06—Procedure for executing order forms	1305.12—Procedure for executing DEA Forms 222.
1305.07—Power of attorney	1305.05—Power of attorney.
1305.08—Persons entitled to fill order forms	1305.06—Persons entitled to fill DEA Forms 222.
1305.09—Procedure for filling order forms	1305.13—Procedure for filling DEA Forms 222.
1305.10—Procedure for endorsing order forms	1305.14—Procedure for endorsing DEA Forms 222.
1305.11—Unaccepted and defective order forms	1305.15—Unaccepted and defective DEA Forms 222.
1305.12—Lost and stolen order forms	1305.16—Lost and stolen DEA Forms 222.
1305.13—Preservation of order forms	1305.17—Preservation of DEA Forms 222.
1305.14—Return of unused order forms	1305.18—Return of unused DEA Forms 222.
1305.15—Cancellation and voiding of order forms	1305.19—Cancellation and voiding of DEA Forms 222.
1305.16—Special procedure for filling certain order forms	1305.07—Special procedure for filling certain DEA Forms 222.

Incorporation by Reference

The following standards are incorporated by reference:

- FIPS 140–2, Security Requirements for Cryptographic Modules.
- FIPS 180–2, Secure Hash Standard.
- FIPS 186–2, Digital Signature Standard.

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 Bureau Drive, Gaithersburg, MD 20899–8930 and are available at *http://csrc.nist.gov/.*

V. Required Analyses

Executive Order 12866

This regulation has been drafted and reviewed in accordance with Executive Order 12866, ''Regulatory Planning and Review'', Section 1(b), Principles of Regulation. It has been determined that this is a ''significant regulatory action'' under Executive Order 12866, Section 3(f), Regulatory Planning and Review, and accordingly this rule has been reviewed by the Office of Management and Budget.

DEA has conducted a cost-benefit analysis of the rule, which the Office of Management and Budget has reviewed. The Economic Impact Analysis for the proposed rule was posted on the Diversion Control Program Web site. That analysis has been updated to account for the number of orders expected in 2004 (6,561,000), the first year of implementation, and to adjust registrant estimates based on data from DEA's ARCOS reporting system. DEA estimates that about 98,000 registrants order Schedule I and II controlled substances and will apply for about 145,000 digital certificates. Over ten years, DEA estimates that electronic orders will reduce the annualized cost of Schedule I and II orders by $284 million; the annualized costs of digital

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

TABLE 4.—TOTAL HOURS AND COSTS FOR THE ELECTRONIC ORDER SOFTWARE

	Hours	Labor	O&M	Total
Purchaser:				
Install—chains	8,680	$666,000		$666,000
Install software—other	314,408	13,010,000		13,010,000
Install—practitioner	43,940	1,818,000		1,818,000
Supplier:				
Install software	280	11,600		11,600
Software Developer:				
Development	103,600	9,700,000		9,700,000
Maintenance	89,000	3,683,000		3,683,000
Upgrades	17,800	1,367,000		1,367,000
Audit	2,314	96,000	$593,000	689,000
Total	580,022	30,352,000	593,000	30,945,000

To estimate costs over the first ten years, DEA assumed that implementation would be phased in over the first five years (*i.e.*, it would be five years before all registrants were using the electronic order system). Based on discussions with industry, the phase-in was estimated to occur at 20 percent in the first year, 40 percent in the second, 20 percent in the third, and 10 percent each in the fourth and fifth years. DEA made the conservative estimate that orders would phase in at the same rate as digital certificates. Because a few distributors and large chain drug stores supply and order a large proportion of the drugs, it is likely that orders will phase in more quickly than digital certificates will. A faster phase-in will increase the net benefits; a slower rate would lower the benefits.

DEA also assumed that the number of orders would increase seven percent annually. The seven percent increase is based on the average annual increase in orders over the last seven years. The total cost of both systems was estimated using a seven percent and a three percent discount rate. Table 5 presents the ten-year total cost of orders under the Form 222 system, the electronic system, and the combined systems as the electronic system is phased in over the first five years as well as the annualized cost of the three systems over ten years. Table 6 presents the costs of digital certificates and software needed to create digitally signed orders.

TABLE 5.—TOTAL COST OF ORDERS OVER TEN YEARS

[Present value]

	Paper system	Electronic system	Combined phase-in
Total (7%)	$2,699,913,000	$298,086,000	$704,112,000
Annualized (7%)	384,407,000	42,441,000	100,250,000
Total (3%)	3,223,440,000	363,653,000	781,438,000
Annualized (3%)	377,886,000	42,631,000	91,608,000

TABLE 6.—TOTAL COSTS OF DIGITAL CERTIFICATES AND SOFTWARE OVER 10 YEARS

[Present value]

	New costs
Total (7%)	$149,308,000
Annualized (7%)	21,258,000
Total (3%)	172,093,000
Annualized (3%)	20,275,000

In addition to the cost savings, electronic orders will also provide a number of other benefits that cannot be quantified. Purchasers will be able to create and send single unified controlled substance orders to their suppliers. With Forms 222, purchasers must create the separate Form 222 for the Schedule I and II controlled substances and complete other orders for all other controlled substance purchases from a particular supplier. If a purchaser needs more than 10 Schedule I or II substances, multiple Forms 222 must be completed because the form is limited to ten items. With the electronic orders, they will be able to submit a single order covering all controlled substance and other prescription drugs being purchased from the supplier. The combined orders should reduce the orders that need to be logged, tracked, and handled by both purchasers and suppliers.

Electronic orders should also bring faster receipt of controlled substances. Under the present system, the purchaser has the choice of sending the order by overnight service at considerable cost, mailing it and waiting several days, or sending the order back with the delivery truck, which may not be returning directly to the distributor. In most cases, the purchaser is likely to have to wait at least two days and possibly four or five days when the order is mailed or is shipped back by truck. If the distributor that receives the order cannot fill it, the distributor may endorse it to another distributor and ship it on to another distribution point, further delaying the final shipment. Electronic orders will be received almost instantly and can be shipped the same day. This speed may allow purchasers to order only when they need an item and limit the quantity of controlled substances that they stock. Limiting the quantity of Schedule I and II controlled substances in stock reduces the possibility of diversion and the cost of security.

With the Form 222, if a supplier cannot fill all of an order, the supplier may endorse the entire order over to another supplier. The order cannot be divided and filled in part by one supplier and in part by a second, even if both suppliers belong to the same company. Because each location holds a separate registration, a distributor with multiple locations must maintain stocks of all Schedule I and II controlled substances at each location to be able to fill orders for these substances from that location. Some distributors have created centralized systems where all orders are

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.

(2) *The title of the form/collection:* Reporting and Recordkeeping for Digital Certificates.

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

Form No.:

DEA Form 251: CSOS DEA Registrant Certificate Application.

DEA Form 252: CSOS Principal Coordinator/Alternate Coordinator Certificate Application.

DEA Form 253: CSOS Power of Attorney Certificate Application.

DEA Form 254: CSOS Certificate Application Registrant List Addendum.

CSOS Certificate Revocation.

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: Persons use these forms to apply for DEA-issued digital certificates to order Schedule I and II controlled substances. Certificates must be renewed upon renewal of the DEA registration to which the certificate is linked. Certificates may be revoked and/or replaced when information on which the certificate is based changes.

(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 and 145,000 certificate holders. The average time for completing the application for a digital certificate to order controlled substances is estimated to be from 0.72 hours to 1.24 hours. Certificate renewal is estimated to take 0.083 hours.

(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 48,500 hours a year. During this period, DEA assumes that 80 percent of the certificate holders will apply for certificates.

If additional information is required regarding these collections of information, contact: Brenda E. Dyer, Department Clearance Officer, Information Management and Security Staff, Justice Management Division, United States Department of Justice, Patrick Henry Building, Suite 1600, 601 D Street, NW., Washington, DC 20530.

Executive Order 12988

This regulation meets the applicable standards set forth in Sections 3(a) and 3(b)(2) of Executive Order 12988 Civil Justice Reform.

Executive Order 13132

This rulemaking does not preempt or modify any provision of state law; nor does it impose enforcement responsibilities on any state; nor does it diminish the power of any state to enforce its own laws. Accordingly, this rulemaking does not have federalism implications warranting the application of Executive Order 13132.

Unfunded Mandates Reform Act of 1995

This rule will not result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of $114,540,000 (inflation-adjusted to 2003) or more in any one year, and will not significantly or uniquely affect small governments. Therefore, no actions were deemed necessary under the provisions of the Unfunded Mandates Reform Act of 1995.

List of Subjects

21 CFR Part 1305

Drug traffic control, Reporting requirements.

21 CFR Part 1311

Administrative practice and procedure, Certification authorities, Controlled substances, Digital certificates, Drug traffic control, Electronic signatures, Incorporation by reference, Prescription drugs, Reporting and recordkeeping requirements.

■ For the reasons set out above, 21 CFR Part 1305 is revised, and Part 1311 is added as follows:

■ 1. Part 1305 is revised to read as follows:

PART 1305—ORDERS FOR SCHEDULE I AND II CONTROLLED SUBSTANCES

Subpart A—General Requirements

Sec.

Subpart B—DEA Form 222

Subpart C—Electronic Orders

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

Subpart A—General Requirements

§ 1305.01 Scope of part 1305.

Procedures governing the issuance, use, and preservation of orders for Schedule I and II controlled substances are set forth generally by section 308 of the Act (21 U.S.C. 828) and specifically by the sections of this part.

§ 1305.02 Definitions.

Any term contained in this part shall have the definition set forth in the Act or part 1300 of this chapter.

§ 1305.03 Distributions requiring a Form 222 or a digitally signed electronic order.

Either a DEA Form 222 or its electronic equivalent as set forth in subpart C of this part and Part 1311 of this chapter is required for each distribution of a Schedule I or II controlled substance except for the following:

(a) Distributions to persons exempted from registration under Part 1301 of this chapter.

(b) Exports from the United States that conform with the requirements of the Act.

(c) Deliveries to a registered analytical laboratory or its agent approved by DEA.

(d) Delivery from a central fill pharmacy, as defined in § 1300.01(b)(44) of this chapter, to a retail pharmacy.

§ 1305.04 Persons entitled to order Schedule I and II controlled substances.

(a) Only persons who are registered with DEA under section 303 of the Act (21 U.S.C. 823) to handle Schedule I or II controlled substances, and persons who are registered with DEA under section 1008 of the Act (21 U.S.C. 958) to export these substances may obtain and use DEA Form 222 (order forms) or

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

based on the business activity of the registrant, will be imposed on the number of DEA Forms 222, which will be furnished on any requisition unless additional forms are specifically requested and a reasonable need for such additional forms is shown.

(b) Any person applying for a registration that would entitle him or her to obtain a DEA Form 222 may requisition the forms by so indicating on the application form; a DEA Form 222 will be supplied upon the registration of the applicant. Any person holding a registration entitling him or her to obtain a DEA Form 222 may requisition the forms for the first time by contacting any Division Office or the Registration Section of the Administration. Any person already holding a DEA Form 222 may requisition additional forms on DEA Form 222a, which is mailed to a registrant approximately 30 days after each shipment of DEA Forms 222 to that registrant, or by contacting any Division Office or the Registration Section of the Administration. All requisition forms (DEA Form 222a) must be submitted to the DEA Registration Section.

(c) Each requisition must show the name, address, and registration number of the registrant and the number of books of DEA Forms 222 desired. Each requisition must be signed and dated by the same person who signed the most recent application for registration or for reregistration, or by any person authorized to obtain and execute DEA Forms 222 by a power of attorney under § 1305.05.

(d) DEA Forms 222 will be serially numbered and issued with the name, address, and registration number of the registrant, the authorized activity, and schedules of the registrant. This information cannot be altered or changed by the registrant; any errors must be corrected by the Registration Section of the Administration by returning the forms with notification of the error.

§ 1305.12 Procedure for executing DEA Forms 222.

(a) A purchaser must prepare and execute a DEA Form 222 simultaneously in triplicate by means of interleaved carbon sheets that are part of the DEA Form 222. DEA Form 222 must be prepared by use of a typewriter, pen, or indelible pencil.

(b) Only one item may be entered on each numbered line. An item must consist of one or more commercial or bulk containers of the same finished or bulk form and quantity of the same substance. The number of lines completed must be noted on that form at the bottom of the form, in the space provided. DEA Forms 222 for carfentanil, etorphine hydrochloride, and diprenorphine must contain only these substances.

(c) The name and address of the supplier from whom the controlled substances are being ordered must be entered on the form. Only one supplier may be listed on any form.

(d) Each DEA Form 222 must be signed and dated by a person authorized to sign an application for registration or a person granted power of attorney to sign a Form 222 under § 1305.05. The name of the purchaser, if different from the individual signing the DEA Form 222, must also be inserted in the signature space.

(e) Unexecuted DEA Forms 222 may be kept and may be executed at a location other than the registered location printed on the form, provided that all unexecuted forms are delivered promptly to the registered location upon an inspection of the location by any officer authorized to make inspections, or to enforce, any Federal, State, or local law regarding controlled substances.

§ 1305.13 Procedure for filling DEA Forms 222.

(a) A purchaser must submit Copy 1 and Copy 2 of the DEA Form 222 to the supplier and retain Copy 3 in the purchaser's files.

(b) A supplier may fill the order, if possible and if the supplier desires to do so, and must 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. If an order cannot be filled in its entirety, it may be filled in part and the balance supplied by additional shipments within 60 days following the date of the DEA Form 222. No DEA Form 222 is valid more than 60 days after its execution by the purchaser, except as specified in paragraph (f) of this section.

(c) The controlled substances must be shipped only to the purchaser and the location printed by the Administration on the DEA Form 222, except as specified in paragraph (f) of this section.

(d) The supplier must retain Copy 1 of the DEA Form 222 for his or her files and forward Copy 2 to the Special Agent in Charge of the Drug Enforcement Administration in the area in which the supplier is located. Copy 2 must be forwarded at the close of the month during which the order is filled. If an order is filled by partial shipments, Copy 2 must be forwarded at the close of the month during which the final shipment is made or the 60-day validity period expires.

(e) The purchaser must record on Copy 3 of the DEA Form 222 the number of commercial or bulk containers furnished on each item and the dates on which the containers are received by the purchaser.

(f) DEA Forms 222 submitted by registered procurement officers of the Defense Supply Center of the Defense Logistics Agency for delivery to armed services establishments within the United States may be shipped to locations other than the location printed on the DEA Form 222, and in partial shipments at different times not to exceed six months from the date of the order, as designated by the procurement officer when submitting the order.

§ 1305.14 Procedure for endorsing DEA Forms 222.

(a) A DEA Form 222, made out to any supplier who cannot fill all or a part of the order within the time limitation set forth in § 1305.13, may be endorsed to another supplier for filling. The endorsement must be made only by the supplier to whom the DEA Form 222 was first made, must state (in the spaces provided on the reverse sides of Copies 1 and 2 of the DEA Form 222) the name and address of the second supplier, and must be signed by a person authorized to obtain and execute DEA Forms 222 on behalf of the first supplier. The first supplier may not fill any part of an order on an endorsed form. The second supplier may fill the order, if possible and if the supplier desires to do so, in accordance with § 1305.13(b), (c), and (d), including shipping all substances directly to the purchaser.

(b) Distributions made on endorsed DEA Forms 222 must be reported by the second supplier in the same manner as all other distributions except that where the name of the supplier is requested on the reporting form, the second supplier must record the name, address, and registration number of the first supplier.

§ 1305.15 Unaccepted and defective DEA Forms 222.

(a) A DEA Form 222 must not be filled if either of the following apply:

(1) The order is not complete, legible, or properly prepared, executed, or endorsed.

(2) The order shows any alteration, erasure, or change of any description.

(b) If a DEA Form 222 cannot be filled for any reason under this section, the supplier must return Copies 1 and 2 to the purchaser with a statement as to the reason (*e.g.*, illegible or altered).

(c) A supplier may for any reason refuse to accept any order and if a supplier refuses to accept the order, a statement that the order is not accepted

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

complies with Part 1311 of this chapter to validate the order.

(2) Verify that the digital certificate has not expired.

(3) Check the validity of the certificate holder's certificate by checking the Certificate Revocation List. The supplier may cache the Certificate Revocation List until it expires.

(4) Verify the registrant's eligibility to order the controlled substances by checking the certificate extension data.

(d) The supplier must retain an electronic record of every order, and, linked to each order, a record of the number of commercial or bulk containers furnished on each item and the date on which the supplier shipped the containers to the purchaser. The linked record must also include any data on the original order that the supplier completes. Software used to handle digitally signed orders must comply with part 1311 of this chapter.

(e) If an order cannot be filled in its entirety, a supplier may fill it in part and supply the balance by additional shipments within 60 days following the date of the order. No order is valid more than 60 days after its execution by the purchaser, except as specified in paragraph (h) of this section.

(f) A supplier must ship the controlled substances to the registered location associated with the digital certificate used to sign the order, except as specified in paragraph (h) of this section.

(g) When a purchaser receives a shipment, the purchaser must create a record of the quantity of each item received and the date received. The record must be electronically linked to the original order and archived.

(h) Registered procurement officers of the Defense Supply Center of the Defense Logistics Agency may order controlled substances for delivery to armed services establishments within the United States. These orders may be shipped to locations other than the registered location, and in partial shipments at different times not to exceed six months from the date of the order, as designated by the procurement officer when submitting the order.

§ 1305.23 Endorsing electronic orders.

A supplier may not endorse an electronic order to another supplier to fill.

§ 1305.24 Central processing of orders.

(a) A supplier that has one or more registered locations and maintains a central processing computer system in which orders are stored may have one or more of the supplier's registered locations fill an electronic order if the supplier does the following:

(1) Assigns each item on the order to a specific registered location for filling.

(2) Creates a record linked to the central file noting both which items a location filled and the location identity.

(3) Ensures that no item is filled by more than one location.

(4) Maintains the original order with all linked records on the central computer system.

(b) A company that has central processing of orders must assign responsibility for filling parts of orders only to registered locations that the company owns and operates.

§ 1305.25 Unaccepted and defective electronic orders.

(a) No electronic order may be filled if:

(1) The required data fields have not been completed.

(2) The order is not signed using a digital certificate issued by DEA.

(3) The digital certificate used had expired or had been revoked prior to signature.

(4) The purchaser's public key will not validate the digital signature.

(5) The validation of the order shows that the order is invalid for any reason.

(b) If an order cannot be filled for any reason under this section, the supplier must notify the purchaser and provide a statement as to the reason (*e.g.*, improperly prepared or altered). A supplier may, for any reason, refuse to accept any order, and if a supplier refuses to accept the order, a statement that the order is not accepted is sufficient for purposes of this paragraph.

(c) When a purchaser receives an unaccepted electronic order from the supplier, the purchaser must electronically link the statement of nonacceptance to the original order. The original order and the statement must be retained in accordance with § 1305.27.

(d) Neither a purchaser nor a supplier may correct a defective order; the purchaser must issue a new order for the order to be filled.

§ 1305.26 Lost electronic orders.

(a) If a purchaser determines that an unfilled electronic order has been lost before or after receipt, the purchaser must provide, to the supplier, a signed statement containing the unique tracking number and date of the lost order and stating that the goods covered by the first order were not received through loss of that order.

(b) If the purchaser executes an order to replace the lost order, the purchaser must electronically link an electronic record of the second order and a copy of the statement with the record of the first order and retain them.

(c) If the supplier to whom the order was directed subsequently receives the first order, the supplier must indicate that it is ''Not Accepted'' and return it to the purchaser. The purchaser must link the returned order to the record of that order and the statement.

§ 1305.27 Preservation of electronic orders.

(a) A purchaser must, for each order filled, retain the original signed order and all linked records for that order for two years. The purchaser must also retain all copies of each unaccepted or defective order and each linked statement.

(b) A supplier must retain each original order filled and the linked records for two years.

(c) If electronic order records are maintained on a central server, the records must be readily retrievable at the registered location.

§ 1305.28 Canceling and voiding electronic orders.

(a) A supplier may void all or part of an electronic order by notifying the purchaser of the voiding. If the entire order is voided, the supplier must make an electronic copy of the order, indicate on the copy ''Void,'' and return it to the purchaser. The supplier is not required to retain a record of orders that are not filled.

(b) The purchaser must retain an electronic copy of the voided order.

(c) To partially void an order, the supplier must indicate in the linked record that nothing was shipped for each item voided.

§ 1305.29 Reporting to DEA.

A supplier must, for each electronic order filled, forward either a copy of the electronic order or an electronic report of the order in a format that DEA specifies to DEA within two business days.

■ 2. Part 1311 is added to read as follows:

PART 1311 ''DIGITAL CERTIFICATES

Subpart A—General

Sec.

Subpart B—Obtaining and Using Digital Certificates for Electronic Orders

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

Bureau Drive, Gaithersburg, MD 20899–8930 and are available at *http://csrc.nist.gov/*.

(c) These incorporations by reference were approved by the Director of the Federal Register in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies may be inspected at the Drug Enforcement Administration, 600 Army Navy Drive, Arlington, VA 22202 or at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call (202) 741–6030, or go to: *http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html*.

Subpart B—Obtaining and Using Digital Certificates for Electronic Orders

§ 1311.10 Eligibility to obtain a CSOS digital certificate.

The following persons are eligible to obtain a CSOS digital certificate from the DEA Certification Authority to sign electronic orders for controlled substances.

(a) The person who signed the most recent DEA registration application or renewal application and a person authorized to sign a registration application.

(b) A person granted power of attorney by a DEA registrant to sign orders for one or more schedules of controlled substances.

§ 1311.15 Limitations on CSOS digital certificates.

(a) A CSOS digital certificate issued by the DEA Certification Authority will authorize the certificate holder to sign orders for only those schedules of controlled substances covered by the registration under which the certificate is issued.

(b) When a registrant, in a power of attorney letter, limits a certificate applicant to a subset of the registrant's authorized schedules, the registrant is responsible for ensuring that the certificate holder signs orders only for that subset of schedules.

§ 1311.20 Coordinators for CSOS digital certificate holders.

(a) Each registrant, regardless of number of digital certificates issued, must designate one or more responsible persons to serve as that registrant's CSOS coordinator regarding issues pertaining to issuance of, revocation of, and changes to digital certificates issued under that registrant's DEA registration. While the coordinator will be the main point of contact between one or more DEA registered locations and the CSOS Certification Authority, all digital certificate activities are the responsibility of the registrant with whom the digital certificate is associated. Even when an individual registrant, *i.e.*, an individual practitioner, is applying for a digital certificate to order controlled substances a CSOS Coordinator must be designated; though in such a case, the individual practitioner may also serve as the coordinator.

(b) Once designated, coordinators must identify themselves, on a one-time basis, to the Certification Authority. If a designated coordinator changes, the Certification Authority must be notified of the change and the new responsibilities assumed by each of the registrant's coordinators, if applicable. Coordinators must complete the application that the DEA Certification Authority provides and submit the following:

(1) Two copies of identification, one of which must be a government-issued photographic identification.

(2) A copy of each current DEA Certificate of Registration (DEA form 223) for each registered location for which the coordinator will be responsible or, if the applicant (or their employer) has not been issued a DEA registration, a copy of each application for registration of the applicant or the applicant's employer.

(3) The applicant must have the completed application notarized and forward the completed application and accompanying documentation to the DEA Certification Authority.

(c) Coordinators will communicate with the Certification Authority regarding digital certificate applications, renewals and revocations. For applicants applying for a digital certificate from the DEA Certification Authority, and for applicants applying for a power of attorney digital certificate for a DEA registrant, the registrant's Coordinator must verify the applicant's identity, review the application package, and submit the completed package to the Certification Authority.

§ 1311.25 Requirements for obtaining a CSOS digital certificate.

(a) To obtain a certificate to use for signing electronic orders for controlled substances, a registrant or person with power of attorney for a registrant must complete the application that the DEA Certification Authority provides and submit the following:

(1) Two copies of identification, one of which must be a government-issued photographic identification.

(2) A current listing of DEA registrations for which the individual has authority to sign controlled substances orders.

(3) A copy of the power of attorney from the registrant, if applicable.

(4) An acknowledgment that the applicant has read and understands the Subscriber Agreement and agrees to the statement of subscriber obligations that DEA provides.

(b) The applicant must provide the completed application to the registrant's coordinator for CSOS digital certificate holders who will review the application and submit the completed application and accompanying documentation to the DEA Certification Authority.

(c) When the Certification Authority approves the application, it will send the applicant a one-time use reference number and access code, via separate channels, and information on how to use them. Using this information, the applicant must then electronically submit a request for certification of the public digital signature key. After the request is approved, the Certification Authority will provide the applicant with the signed public key certificate.

(d) Once the applicant has generated the key pair, the Certification Authority must prove that the user has possession of the key. For public keys, the corresponding private key must be used to sign the certificate request. Verification of the signature using the public key in the request will serve as proof of possession of the private key.

§ 1311.30 Requirements for storing and using a private key for digitally signing orders.

(a) Only the certificate holder may access or use his or her digital certificate and private key.

(b) The certificate holder must provide FIPS-approved secure storage for the private key, as discussed by FIPS 140–2, 180–2, 186–2, and accompanying change notices and annexes, as incorporated by reference in § 1311.08.

(c) A certificate holder must ensure that no one else uses the private key. While the private key is activated, the certificate holder must prevent unauthorized use of that private key.

(d) A certificate holder must not make back-up copies of the private key.

(e) The certificate holder must report the loss, theft, or compromise of the private key or the password, via a revocation request, to the Certification Authority within 24 hours of substantiation of the loss, theft, or compromise. Upon receipt and verification of a signed revocation request, the Certification Authority will revoke the certificate. The certificate holder must apply for a new certificate under the requirements of § 1311.25.

§ 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

additional independent third-party audit whenever the signing or verifying functionality is changed to determine whether it correctly performs the functions listed under paragraphs (b) and (c) of this section. The system developer must retain the most recent audit results and retain the results of any other audits of the software completed within the previous two years.

§ 1311.60 Recordkeeping.

(a) A supplier and purchaser must maintain records of CSOS electronic orders and any linked records for two years. Records may be maintained electronically. Records regarding controlled substances that are maintained electronically must be readily retrievable from all other records.

(b) Electronic records must be easily readable or easily rendered into a format that a person can read. They must be made available to the Administration upon request.

(c) CSOS certificate holders must maintain a copy of the subscriber agreement that the Certification Authority provides for the life of the certificate.

Dated: March 28, 2005.

Michele M. Leonhart,

Deputy Administrator.

[FR Doc. 05–6504 Filed 3–31–05; 8:45 am]

BILLING CODE 4410–09–P

Public Law 109–60
109th Congress

An Act

To provide for the establishment of a controlled substance monitoring program in each State.

Aug. 11, 2005
[H.R. 1132]

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

National All Schedules Prescription Electronic Reporting Act of 2005.
Health and health care.
42 USC 201 note.
42 USC 280g–3 note.

SECTION 1. SHORT TITLE.

This Act may be cited as the "National All Schedules Prescription Electronic Reporting Act of 2005".

SEC. 2. PURPOSE.

It is the purpose of this Act to—

(1) foster the establishment of State-administered controlled substance monitoring systems in order to ensure that health care providers have access to the accurate, timely prescription history information that they may use as a tool for the early identification of patients at risk for addiction in order to initiate appropriate medical interventions and avert the tragic personal, family, and community consequences of untreated addiction; and

(2) establish, based on the experiences of existing State controlled substance monitoring programs, a set of best practices to guide the establishment of new State programs and the improvement of existing programs.

SEC. 3. CONTROLLED SUBSTANCE MONITORING PROGRAM.

Part P of title III of the Public Health Service Act (42 U.S.C. 280g et seq.) is amended by adding after section 399N the following:

"SEC. 399O. CONTROLLED SUBSTANCE MONITORING PROGRAM.

42 USC 280g–3.

"(a) GRANTS.—

"(1) IN GENERAL.—Each fiscal year, the Secretary shall award a grant to each State with an application approved under this section to enable the State—

"(A) to establish and implement a State controlled substance monitoring program; or

"(B) to make improvements to an existing State controlled substance monitoring program.

"(2) DETERMINATION OF AMOUNT.—

"(A) MINIMUM AMOUNT.—In making payments under a grant under paragraph (1) for a fiscal year, the Secretary shall allocate to each State with an application approved under this section an amount that equals 1.0 percent of the amount appropriated to carry out this section for that fiscal year.

"(B) ADDITIONAL AMOUNTS.—In making payments under a grant under paragraph (1) for a fiscal year, the Secretary shall allocate to each State with an application approved under this section an additional amount which bears the same ratio to the amount appropriated to carry out this section for that fiscal year and remaining after amounts are made available under subparagraph (A) as the number of pharmacies of the State bears to the number of pharmacies of all States with applications approved under this section (as determined by the Secretary), except that the Secretary may adjust the amount allocated to a State under this subparagraph after taking into consideration the budget cost estimate for the State's controlled substance monitoring program.

"(3) TERM OF GRANTS.—Grants awarded under this section shall be obligated in the year in which funds are allotted.

Deadline. Federal Register, publication.

"(b) DEVELOPMENT OF MINIMUM REQUIREMENTS.—Prior to awarding a grant under this section, and not later than 6 months after the date on which funds are first appropriated to carry out this section, after seeking consultation with States and other interested parties, the Secretary shall, after publishing in the Federal Register proposed minimum requirements and receiving public comments, establish minimum requirements for criteria to be used by States for purposes of clauses (ii), (v), (vi), and (vii) of subsection (c)(1)(A).

"(c) APPLICATION APPROVAL PROCESS.—

"(1) IN GENERAL.—To be eligible to receive a grant under this section, a State shall submit an application to the Secretary at such time, in such manner, and containing such assurances and information as the Secretary may reasonably require. Each such application shall include—

"(A) with respect to a State that intends to use funds under the grant as provided for in subsection (a)(1)(A)—

"(i) a budget cost estimate for the controlled substance monitoring program to be implemented under the grant;

"(ii) criteria for security for information handling and for the database maintained by the State under subsection (e) generally including efforts to use appropriate encryption technology or other appropriate technology to protect the security of such information;

"(iii) an agreement to adopt health information interoperability standards, including health vocabulary and messaging standards, that are consistent with any such standards generated or identified by the Secretary or his or her designee;

"(iv) criteria for meeting the uniform electronic format requirement of subsection (h);

"(v) criteria for availability of information and limitation on access to program personnel;

"(vi) criteria for access to the database, and procedures to ensure that information in the database is accurate;

"(vii) criteria for the use and disclosure of information, including a description of the certification process to be applied to requests for information under subsection (f);

"(viii) penalties for the unauthorized use and disclosure of information maintained in the State controlled substance monitoring program in violation of applicable State law or regulation;

"(ix) information on the relevant State laws, policies, and procedures, if any, regarding purging of information from the database; and

"(x) assurances of compliance with all other requirements of this section; or

"(B) with respect to a State that intends to use funds under the grant as provided for in subsection (a)(1)(B)—

"(i) a budget cost estimate for the controlled substance monitoring program to be improved under the grant;

"(ii) a plan for ensuring that the State controlled substance monitoring program is in compliance with the criteria and penalty requirements described in clauses (ii) through (viii) of subparagraph (A);

"(iii) a plan to enable the State controlled substance monitoring program to achieve interoperability with at least one other State controlled substance monitoring program; and

"(iv) assurances of compliance with all other requirements of this section or a statement describing why such compliance is not feasible or is contrary to the best interests of public health in such State.

"(2) STATE LEGISLATION.—As part of an application under paragraph (1), the Secretary shall require a State to demonstrate that the State has enacted legislation or regulations to permit the implementation of the State controlled substance monitoring program and the imposition of appropriate penalties for the unauthorized use and disclosure of information maintained in such program.

"(3) INTEROPERABILITY.—If a State that submits an application under this subsection geographically borders another State that is operating a controlled substance monitoring program under subsection (a)(1) on the date of submission of such application, and such applicant State has not achieved interoperability for purposes of information sharing between its monitoring program and the monitoring program of such border State, such applicant State shall, as part of the plan under paragraph (1)(B)(iii), describe the manner in which the applicant State will achieve interoperability between the monitoring programs of such States.

"(4) APPROVAL.—If a State submits an application in accordance with this subsection, the Secretary shall approve such application.

"(5) RETURN OF FUNDS.—If the Secretary withdraws approval of a State's application under this section, or the State chooses to cease to implement or improve a controlled substance monitoring program under this section, a funding agreement for the receipt of a grant under this section is that the State will return to the Secretary an amount which bears the same ratio to the overall grant as the remaining time period for expending the grant funds bears to the overall time period for expending the grant (as specified by the Secretary at the time of the grant).

"(d) REPORTING REQUIREMENTS.—In implementing or improving a controlled substance monitoring program under this section, a State shall comply, or with respect to a State that applies for a grant under subsection (a)(1)(B) submit to the Secretary for approval a statement of why such compliance is not feasible or is contrary to the best interests of public health in such State, with the following:

Deadline.

"(1) The State shall require dispensers to report to such State each dispensing in the State of a controlled substance to an ultimate user not later than 1 week after the date of such dispensing.

"(2) The State may exclude from the reporting requirement of this subsection—

"(A) the direct administration of a controlled substance to the body of an ultimate user;

"(B) the dispensing of a controlled substance in a quantity limited to an amount adequate to treat the ultimate user involved for 48 hours or less; or

"(C) the administration or dispensing of a controlled substance in accordance with any other exclusion identified by the Secretary for purposes of this paragraph.

"(3) The information to be reported under this subsection with respect to the dispensing of a controlled substance shall include the following:

"(A) Drug Enforcement Administration Registration Number (or other identifying number used in lieu of such Registration Number) of the dispenser.

"(B) Drug Enforcement Administration Registration Number (or other identifying number used in lieu of such Registration Number) and name of the practitioner who prescribed the drug.

"(C) Name, address, and telephone number of the ultimate user or such contact information of the ultimate user as the Secretary determines appropriate.

"(D) Identification of the drug by a national drug code number.

"(E) Quantity dispensed.

"(F) Number of refills ordered.

"(G) Whether the drug was dispensed as a refill of a prescription or as a first-time request.

"(H) Date of the dispensing.

"(I) Date of origin of the prescription.

"(J) Such other information as may be required by State law to be reported under this subsection.

"(4) The State shall require dispensers to report information under this section in accordance with the electronic format specified by the Secretary under subsection (h), except that the State may waive the requirement of such format with respect to an individual dispenser that is unable to submit such information by electronic means.

"(e) DATABASE.—In implementing or improving a controlled substance monitoring program under this section, a State shall comply with the following:

"(1) The State shall establish and maintain an electronic database containing the information reported to the State under subsection (d).

"(2) The database must be searchable by any field or combination of fields.

"(3) The State shall include reported information in the database in a manner consistent with criteria established by the Secretary, with appropriate safeguards for ensuring the accuracy and completeness of the database.

"(4) The State shall take appropriate security measures to protect the integrity of, and access to, the database.

"(f) USE AND DISCLOSURE OF INFORMATION.—

"(1) IN GENERAL.—Subject to subsection (g), in implementing or improving a controlled substance monitoring program under this section, a State may disclose information from the database established under subsection (e) and, in the case of a request under subparagraph (D), summary statistics of such information, only in response to a request by—

Certification.

"(A) a practitioner (or the agent thereof) who certifies, under the procedures determined by the State, that the requested information is for the purpose of providing medical or pharmaceutical treatment or evaluating the need for such treatment to a bona fide current patient;

"(B) any local, State, or Federal law enforcement, narcotics control, licensure, disciplinary, or program authority, who certifies, under the procedures determined by the State, that the requested information is related to an individual investigation or proceeding involving the unlawful diversion or misuse of a schedule II, III, or IV substance, and such information will further the purpose of the investigation or assist in the proceeding;

"(C) the controlled substance monitoring program of another State or group of States with whom the State has established an interoperability agreement;

"(D) any agent of the Department of Health and Human Services, a State medicaid program, a State health department, or the Drug Enforcement Administration who certifies that the requested information is necessary for research to be conducted by such department, program, or administration, respectively, and the intended purpose of the research is related to a function committed to such department, program, or administration by law that is not investigative in nature; or

"(E) an agent of the State agency or entity of another State that is responsible for the establishment and maintenance of that State's controlled substance monitoring program, who certifies that—

"(i) the State has an application approved under this section; and

"(ii) the requested information is for the purpose of implementing the State's controlled substance monitoring program under this section.

"(2) DRUG DIVERSION.—In consultation with practitioners, dispensers, and other relevant and interested stakeholders, a State receiving a grant under subsection (a)—

"(A) shall establish a program to notify practitioners and dispensers of information that will help identify and prevent the unlawful diversion or misuse of controlled substances; and

"(B) may, to the extent permitted under State law, notify the appropriate authorities responsible for carrying out drug diversion investigations if the State determines that information in the database maintained by the State under subsection (e) indicates an unlawful diversion or abuse of a controlled substance.

"(g) LIMITATIONS.—In implementing or improving a controlled substance monitoring program under this section, a State—

"(1) shall limit the information provided pursuant to a valid request under subsection (f)(1) to the minimum necessary to accomplish the intended purpose of the request; and

"(2) shall limit information provided in response to a request under subsection (f)(1)(D) to nonidentifiable information.

Records.

"(h) ELECTRONIC FORMAT.—The Secretary shall specify a uniform electronic format for the reporting, sharing, and disclosure of information under this section.

"(i) RULES OF CONSTRUCTION.—

"(1) FUNCTIONS OTHERWISE AUTHORIZED BY LAW.—Nothing in this section shall be construed to restrict the ability of any authority, including any local, State, or Federal law enforcement, narcotics control, licensure, disciplinary, or program authority, to perform functions otherwise authorized by law.

"(2) NO PREEMPTION.—Nothing in this section shall be construed as preempting any State law, except that no such law may relieve any person of a requirement otherwise applicable under this Act.

"(3) ADDITIONAL PRIVACY PROTECTIONS.—Nothing in this section shall be construed as preempting any State from imposing any additional privacy protections.

"(4) FEDERAL PRIVACY REQUIREMENTS.—Nothing in this section shall be construed to supersede any Federal privacy or confidentiality requirement, including the regulations promulgated under section 264(c) of the Health Insurance Portability and Accountability Act of 1996 (Public Law 104–191; 110 Stat. 2033) and section 543 of the Public Health Service Act.

"(5) NO FEDERAL PRIVATE CAUSE OF ACTION.—Nothing in this section shall be construed to create a Federal private cause of action.

"(j) STUDIES AND REPORTS.—

"(1) IMPLEMENTATION REPORT.—

"(A) IN GENERAL.—Not later than 180 days after the date of enactment of this section, the Secretary, based on a review of existing State controlled substance monitoring programs and other relevant information, shall determine whether the implementation of such programs has had a substantial negative impact on—

"(i) patient access to treatment, including therapy for pain or controlled substance abuse;

"(ii) pediatric patient access to treatment; or

"(iii) patient enrollment in research or clinical trials in which, following the protocol that has been approved by the relevant institutional review board for the research or clinical trial, the patient has obtained a controlled substance from either the scientific investigator conducting such research or clinical trial or the agent thereof.

"(B) ADDITIONAL CATEGORIES OF EXCLUSION.—If the Secretary determines under subparagraph (A) that a substantial negative impact has been demonstrated with regard to one or more of the categories of patients described in such subparagraph, the Secretary shall identify additional appropriate categories of exclusion from reporting as authorized under subsection (d)(2)(C).

"(2) PROGRESS REPORT.—Not later than 3 years after the date on which funds are first appropriated under this section, the Secretary shall—

"(A) complete a study that—

"(i) determines the progress of States in establishing and implementing controlled substance monitoring programs under this section;

"(ii) provides an analysis of the extent to which the operation of controlled substance monitoring programs have reduced inappropriate use, abuse, or diversion of controlled substances or affected patient access to appropriate pain care in States operating such programs;

"(iii) determines the progress of States in achieving interoperability between controlled substance monitoring programs, including an assessment of technical and legal barriers to such activities and recommendations for addressing these barriers;

"(iv) determines the feasibility of implementing a real-time electronic controlled substance monitoring program, including the costs associated with establishing such a program;

"(v) provides an analysis of the privacy protections in place for the information reported to the controlled substance monitoring program in each State receiving a grant for the establishment or operation of such program, and any recommendations for additional requirements for protection of this information;

"(vi) determines the feasibility of implementing technological alternatives to centralized data storage, such as peer-to-peer file sharing or data pointer systems, in controlled substance monitoring programs and the potential for such alternatives to enhance the privacy and security of individually identifiable data; and

"(vii) evaluates the penalties that States have enacted for the unauthorized use and disclosure of information maintained in the controlled substance monitoring program, and reports on the criteria used by the Secretary to determine whether such penalties qualify as appropriate pursuant to this section; and

"(B) submit a report to the Congress on the results of the study.

"(k) PREFERENCE.—Beginning 3 years after the date on which funds are first appropriated to carry out this section, the Secretary, in awarding any competitive grant that is related to drug abuse (as determined by the Secretary) and for which only States are eligible to apply, shall give preference to any State with an application approved under this section. The Secretary shall have the discretion to apply such preference to States with existing controlled substance monitoring programs that meet minimum requirements

Effective date.

under this section or to States that put forth a good faith effort to meet those requirements (as determined by the Secretary).

"(l) ADVISORY COUNCIL.—

"(1) ESTABLISHMENT.—A State may establish an advisory council to assist in the establishment, implementation, or improvement of a controlled substance monitoring program under this section.

"(2) LIMITATION.—A State may not use amounts received under a grant under this section for the operations of an advisory council established under paragraph (1).

"(3) SENSE OF CONGRESS.—It is the sense of the Congress that, in establishing an advisory council under this subsection, a State should consult with appropriate professional boards and other interested parties.

"(m) DEFINITIONS.—For purposes of this section:

"(1) The term 'bona fide patient' means an individual who is a patient of the practitioner involved.

"(2) The term 'controlled substance' means a drug that is included in schedule II, III, or IV of section 202(c) of the Controlled Substance Act.

"(3) The term 'dispense' means to deliver a controlled substance to an ultimate user by, or pursuant to the lawful order of, a practitioner, irrespective of whether the dispenser uses the Internet or other means to effect such delivery.

"(4) The term 'dispenser' means a physician, pharmacist, or other person that dispenses a controlled substance to an ultimate user.

"(5) The term 'interoperability' with respect to a State controlled substance monitoring program means the ability of the program to electronically share reported information, including each of the required report components described in subsection (d), with another State if the information concerns either the dispensing of a controlled substance to an ultimate user who resides in such other State, or the dispensing of a controlled substance prescribed by a practitioner whose principal place of business is located in such other State.

"(6) The term 'nonidentifiable information' means information that does not identify a practitioner, dispenser, or an ultimate user and with respect to which there is no reasonable basis to believe that the information can be used to identify a practitioner, dispenser, or an ultimate user.

"(7) The term 'practitioner' means a physician, dentist, veterinarian, scientific investigator, pharmacy, hospital, or other person licensed, registered, or otherwise permitted, by the United States or the jurisdiction in which he or she practices or does research, to distribute, dispense, conduct research with respect to, administer, or use in teaching or chemical analysis, a controlled substance in the course of professional practice or research.

"(8) The term 'State' means each of the 50 States and the District of Columbia.

"(9) The term 'ultimate user' means a person who has obtained from a dispenser, and who possesses, a controlled substance for his or her own use, for the use of a member of his or her household, or for the use of an animal owned by him or her or by a member of his or her household.

"(n) AUTHORIZATION OF APPROPRIATIONS.—To carry out this section, there are authorized to be appropriated—

"(1) $15,000,000 for each of fiscal years 2006 and 2007; and

"(2) $10,000,000 for each of fiscal years 2008, 2009, and 2010.".

Approved August 11, 2005.

LEGISLATIVE HISTORY—H.R. 1132 (S. 518):

HOUSE REPORTS: No. 109–191 (Comm. on Energy and Commerce).
SENATE REPORTS: No. 109–117 accompanying S. 518 (Comm. on Health, Education, Labor, and Pensions).
CONGRESSIONAL RECORD, Vol. 151 (2005):
July 27, considered and passed House.
July 29, considered and passed Senate.

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office when the Associate Commissioner for OHA determines that appearances at hearings conducted in the areas can be conducted more efficiently by VTC than in person. However, while the Associate Commissioner makes the decision about the general efficiency of using VTC in an area, the ALJ is responsible for determining if using VTC for any appearance in a particular case will be efficient.

Comment: The same organization also commented that our rules should require the hearing notice to include a statement that a ME and/or a VE will appear by VTC and provide an opportunity to object.

Response: Sections 404.938(b) and 416.1438(b) of the final rules with request for comment specify that the claimant ''will also be told if [his/her] appearance or that of any other party or witness is scheduled to be made by [VTC] rather than in person.'' We reflect these requirements in HALLEX guidance that modifies our standardized notices of hearing to notify claimants that a witness will appear by VTC and to advise them explicitly of their right to object to any aspect of the hearing (see Footnote 7 above).

Regulatory Procedures

Executive Order 12866, As Amended by Executive Order 13258

We have consulted with the Office of Management and Budget (OMB) and determined that this final rules document meets the criteria for a significant regulatory action under Executive Order 12866, as amended by Executive Order 13258. Thus, it was reviewed by OMB.

Regulatory Flexibility Act

We certify that these rules will not have a significant economic impact on a substantial number of small entities as they affect individuals only. Therefore, a regulatory flexibility analysis as provided in the Regulatory Flexibility Act, as amended, is not required.

Paperwork Reduction Act

The Paperwork Reduction Act (PRA) of 1995 says that no persons are required to respond to a collection of information unless it displays a valid OMB control number. In accordance with the PRA, SSA is providing notice that the Office of Management and Budget has approved the information collection requirements contained in §§ 404.929, 404.936(d), (e) & (f), 404.938(c) (HA–504), 404.950(a), 416.1429, 416.1436(d), (e) and (f), 416.1438(c) (HA–504), and 416.1450(a) of these final rules. The OMB control number for this collection is 0960–0671, expiring November 30, 2004.

(Catalog of Federal Domestic Assistance Program Nos. 96.001, Social Security-Disability Insurance; 96.002, Social Security-Retirement Insurance; 96.003, Social Security-Special Benefits for Persons Aged 72 and Over; 96.004, Social Security-Survivors Insurance; 96.006, Supplemental Security Income.)

List of Subjects

20 CFR Part 404

Administrative practice and procedure, Aged, Blind, Disability benefits, Old-age, Survivors and Disability Insurance, Reporting and recordkeeping requirements, Social Security.

20 CFR Part 416

Administrative practice and procedure, Aged, Blind, Disability benefits, Public assistance programs, Reporting and recordkeeping requirements, Supplemental Security Income (SSI).

Dated: October 3, 2003.

Jo Anne B. Barnhart,

Commissioner of Social Security.

■ Accordingly, the final rules with request for comment amending 20 CFR parts 404 and 416 that were published at 68 FR 5210 on February 3, 2003, are adopted as final rules without change.

[FR Doc. 03–30691 Filed 12–10–03; 8:45 am]

BILLING CODE 4191–02–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 314 and 601

[Docket No. 2000N–1652]

RIN 0910–AB91

Requirements for Submission of Labeling for Human Prescription Drugs and Biologics in Electronic Format

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending its regulations governing the format in which certain labeling is required to be submitted for review with new drug applications (NDAs), certain biological license applications (BLAs), abbreviated new drug applications (ANDAs), supplements, and annual reports. The final rule requires that certain labeling content be submitted electronically in a form that FDA can process, review, and archive. Submitting the content of labeling in electronic format will simplify the drug labeling review process and speed up the approval of labeling changes.

DATES: The rule is effective June 8, 2004.

FOR FURTHER INFORMATION CONTACT:

Randy Levin, Center for Drug Evaluation and Research (CDER) (HFD–001), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–7756, or

Robert A. Yetter, Center for Biologics Evaluation and Research (HFM–10), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852, 301–827–0373.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of May 3, 2002 (67 FR 22367), FDA published a proposed rule to require the submission of the content of labeling for human prescription drugs and certain biologics in electronic format in a form that FDA can process, review, and archive. This electronic submission requirement would necessitate the amendment of FDA's regulations under §§ 314.50(l) (21 CFR 314.50(l)), 314.81(b)(2)(iii) (21 CFR 314.81(b)(2)(iii)), 314.94(d)(1) (21 CFR 314.94(d)(1)), and the addition of § 601.14 (21 CFR 601.14).

Under current regulations, as noted in the preamble to the proposed rule, labeling for the archival copy of an NDA must be submitted to the agency on paper, labeling for the archival copy of an ANDA may be submitted in any form that FDA and the applicant agree upon, and the current regulations for BLA labeling do not specify a format for submission to the agency. The term ''labeling'' used in §§ 314.50, 314.94, 314.81, and § 601.12 is defined in section 201(m) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 321(m)) to mean both labels[1] and other written, printed, or graphic matter upon any article or any of its containers or wrappers, or accompanying such article. Thus, requiring the submission of ''labeling'' entails submission of the label (i.e., the label on the immediate container) and labeling. Labeling consists of the comprehensive prescription drug labeling directed to health care practitioners (i.e., the labeling required under § 201.100(d)(3) (21 CFR 201.100(d)(3)), commonly referred to as the ''package insert'' or

[1] Under section 201(k) of the act, the term ''label'' means a display of written, printed, or graphic matter upon the immediate container of any article.

''professional labeling'')[2] and other labeling. This final rule applies to the electronic submission of the content of labeling, defined as the contents of the package insert or professional labeling, including all text, tables, and figures.

Each year FDA conducts a word-for-word comparison of the labeling as part of the review process for more than 1,000 proposed labeling changes for approved NDAs and BLAs, and more than 2,600 proposed original and supplemental labeling changes for ANDAs.[3] Because reviewers currently conduct these comparisons manually using two paper copies of the labeling, the process is slow and subject to error. Requiring the electronic submission of labeling for NDAs, certain BLAs, ANDAs, supplements, and annual reports will greatly enhance the accuracy and speed of labeling review. This will result in increased protection of the public health because electronic review and comparison of labeling files will provide a higher degree of certainty that all sections of prescription drug labeling are correct.

Although FDA has not previously required regulatory submissions in electronic format, we have issued several guidances describing how to make voluntary electronic submissions to the agency. In the **Federal Register** of January 28, 1999 (64 FR 4433), we (FDA) issued a guidance on general considerations for electronic submissions entitled ''Providing Regulatory Submissions in Electronic Format—General Considerations'' (general considerations guidance). In the general considerations guidance, we included a description of the types of electronic file formats that we are able to accept for processing, reviewing, and archiving electronic documents. In the **Federal Register** of January 28, 1999 (64 FR 4432), we announced the availability of a guidance entitled ''Providing Regulatory Submissions in Electronic Format—NDAs,'' which provided information on how to submit a complete archival copy of an NDA in electronic format. In November 1999, we published a guidance to assist applicants in submitting documents in electronic format for review and archive purposes as part of a BLA, product license application (PLA), or establishment license application (ELA) (64 FR 61647, November 12, 1999). Most recently, we published a guidance for ANDAs entitled ''Providing Regulatory Submission in Electronic Format—ANDAs'' (67 FR 43331, June 27, 2002). In addition, part 11 (21 CFR part 11), concerning electronic records and electronic signatures, describes certain controls for electronic regulatory submissions and states that we are prepared to accept those regulatory submissions that have been identified in the public docket (62 FR 13430, March 20, 1997).

FDA received 13 comments (which raised 21 issues) on the proposed rule and addresses each of those comments in section III of this document. The majority of the comments supported the proposed amendments to FDA's regulations. After careful consideration of the comments, the agency is adopting this final rule without any changes from the proposed rule. The final rule is described in section II of this document.

II. Description of the Final Rule

We are revising our regulations to require the electronic submission of the content of labeling (i.e., the content of the package insert or professional labeling, including all text, tables, and figures) for NDAs, certain BLAs, ANDAs, supplements, and annual reports. This requirement is in addition to existing requirements, found elsewhere in our regulations, that copies of the label and labeling and specimens of enclosures be submitted.

Under the amended regulations that we are adopting in this final rule, §§ 314.50(l), 314.81(b)(2)(iii), and 314.94(d)(1) are revised to require applicants to submit the content of labeling in NDAs, ANDAs, supplements, and annual reports electronically in a form that we can process, review, and archive.[4] Under new § 314.94(d)(1), ANDA applicants are required to submit in electronic format the content of labeling for the proposed drug product (i.e., the content of the generic drug product labeling). As previously stated in the preamble to the proposed rule, ANDA applicants are not required to submit in electronic format the content of labeling for the reference listed drug product. Section 601.14 is added to require applicants for biological products subject to the requirements of § 201.100(d)(3) to submit the content of labeling in BLAs, supplements, and annual reports electronically in a form that we can process, review, and archive.[5]

At this time, portable document format (PDF) is the only type of electronic file format that we have the ability to accept for processing, reviewing, and archiving. PDF is commonly used, easily obtainable, and affordable. Software to convert electronic files to PDF is commercially available at a cost of approximately $100 to $300. The technology necessary to create PDF documents is also publicly available. Because PDF is the only acceptable file type, references to specific media (microfiche, microform, optical disc, and magnetic tape) under §§ 314.50(l)(1) and 314.94.(d)(1) will be deleted.

To be responsive to technological advances, we may recommend in the future that new file formats and software applications be used to submit labeling electronically. As mentioned in the preamble to the proposed rule, we will provide advance notice, in accordance with FDA's good guidance practice regulations under § 10.115 (21 CFR 10.115), so that affected parties will have adequate time to convert to any new format or software. In addition, we expect that such format or software will be widely available before we switch to a new technology. Changes in format and/or software will be identified in public docket number 92S–0251. During any such transition, we will accept submissions using either file format or software.

Finally, these new regulations also make minor changes to reformat and modernize certain regulatory provisions. This final rule is amending § 314.50(l) by adding headings to paragraphs (l)(1) through (l)(4) and by removing the word ''shall'' and adding in its place the word ''must.''

[2] Section 201.100(d) requires that any labeling distributed by or on behalf of the manufacturer, packer, or distributor of the drug, that furnishes or purports to furnish information for use of the drug, or which prescribes, recommends, or suggests a dosage for the use of the drug, must meet the content and format requirements in 21 CFR 201.56 and 201.57.

[3] We also conduct a word-for-word comparison of the labeling for the proposed generic drug product and the reference listed drug to verify that any differences in labeling have been correctly annotated and explained by the ANDA applicant under § 314.94(a)(8)(iv).

[4] The submission of labeling for the archival copy of an NDA is required under § 314.50(e)(2)(ii). Section 314.71(b) (21 CFR 314.71(b)) requires that supplements to approved applications submitted to the agency under § 314.70 (21 CFR 314.70) follow the procedures described in § 314.50. Section 314.81(b)(2)(iii) (21 CFR 314.81(b)(2)(iii)) requires that annual reports include ''currently used professional labeling, patient brochures, or package inserts.'' With respect to the archival copy of an ANDA, § 314.94(a)(8)(ii) requires copies of the label and all labeling for the drug product. Under § 314.97 (21 CFR 314.97), supplements and other changes to approved ANDAs must be submitted to the agency under the requirements of §§ 314.70 and 314.71. Under § 314.98(c) (21 CFR 314.98(c)), annual reports for ANDAs must be submitted as required in § 314.81(b)(2)(iii).

[5] Section 601.2 (21 CFR 601.2) describes the requirements for submission of a BLA, which include the requirement that specimens of enclosures and Medication Guides for a product, if any, be submitted. Section 601.12 (21 CFR 601.12) describes the requirements to make changes to an approved BLA, including labeling changes.

III. Comments on the Proposed Rule

FDA received 13 sets of written comments on the proposed rule from manufacturers, trade associations, advocacy groups, consulting firms, and individuals. The majority of the comments supported FDA's proposal to require that the content of certain labeling be submitted electronically in a form that FDA can process, review, and archive. A few comments requested clarification on various aspects of the rule and one comment opposed the exemptions from specific controls under part 11. A summary of the comments received and the agency's responses follows:

A. General Comments

(Comment 1) One comment identified as a typographical error the citation of § 314.50(l). The comment suggested that § 314.50(l)(1)(i) was being referenced as (1)(1)(i).

(Response) This is not a typographical error; we are citing to § 314.50(l)(1)(i) in the proposed rule, but the lower case letter L (''l'') looks similar to the number 1.

(Comment 2) One comment recommended adding changes to § 314.70 and § 601.12 to address labeling supplements.

(Response) FDA believes that § 314.70 and § 601.12 do not need any changes because the recommended requirements already exist.

Under § 314.71, all procedures that apply to an application under § 314.50 also apply to supplement submissions. Thus, by amending the provisions in § 314.50, the final rule also covers the requirements for labeling supplements. Similarly, § 601.14 requires applicants for biological products subject to the requirements of § 201.100(d)(3) to submit the content of labeling in BLAs, supplements, and annual reports electronically in a form that FDA can process, review, and archive.

(Comment 3) One comment stated that it supported the adoption of regulations to require bar coding for all pharmaceuticals.

(Response) The agency is pursuing bar coding initiatives separately from this rulemaking. A proposed rule to require bar codes on certain human drug product labels and biological product labels was published in the **Federal Register** of March 14, 2003 (68 FR 12500). This final rule deals solely with the content of labeling for human prescription drugs and biologics submitted to FDA in electronic format that FDA can process, review, and archive.

(Comment 4) Although supportive of the proposed rule, one comment was concerned about industry initiatives to use this rule to advocate for electronic versions as a substitute for printed patient inserts (PPIs).[6] The comment expressed concern that this rule could serve as a basis for the elimination of printed PPIs.

(Response) FDA understands the comment's concern, but the agency's regulation of PPIs is unrelated to the requirement to submit the content of labeling electronically. This rule requires that the content of labeling (i.e., the content of the package insert or professional labeling, including all text, tables, and figures) be submitted electronically. It does not alter the current regulatory treatment of PPIs. The PPIs can be submitted in paper or electronic format under part 11. If the PPI is submitted electronically, it must appear in the electronic format as it would in printed form.

(Comment 5) One comment mentioned that this rule will enable the agency to move forward with other initiatives to make labeling more rapidly available. The comment asks the agency to consider providing certain recommendations on a standard database for labeling and standard display formats for viewing labels.

(Response) FDA welcomes the comment, and we are working on several initiatives to make labeling more readily available to the public. This rule is a necessary step to provide FDA with the information needed to improve the readability, organization, and access to labeling information, including the possibility of using the information in a standard database.

B. Applicability/Scope of the Proposed Rule

(Comment 6) One comment requested that FDA clarify whether the Circular of Information for the Use of Human Blood Components (the Circular) is exempt from this rule. The comment stated that the Circular is prepared on a biannual basis by a committee representing all blood organizations and a single submission is made to FDA. The same version of the Circular is used by the majority of licensed blood establishments.

(Response) It is true that FDA reviews a version of the Circular that a consortium of blood establishments submits periodically. Although individual blood establishments may use different versions of the Circular and must submit those versions in supplemental applications to FDA, the amount of variation from the FDA-recognized Circular is so minimal that electronic submission is not necessary at this time. Therefore, the final rule does not require the submission of the Circular to the agency in electronic format.

(Comment 7) Several comments asked for clarification of the following statement in the proposed rule: ''This proposed requirement would be in addition to existing requirements, described in section I.A of this document, that copies of the label and labeling and specimens of enclosures be submitted.'' The comments requested that the agency explicitly state that no paper copies of labeling are to be submitted.

(Response) The content of labeling is a new labeling type not previously required in the regulations to be submitted. The content of labeling, defined as the contents of the package insert or professional labeling, including all text, tables, and figures for prescription products approved under an ANDA, BLA, or NDA, does not replace any previously required labeling type, including the package insert. In other words, the regulations require the package insert to be submitted in addition to the content of labeling. However, no paper copies of any labeling are required. As discussed in our response to comment 4, the applicant has the option of providing the package insert in paper or electronic format under part 11. The package insert, if submitted electronically, must appear as it would in printed form. Submission in this form allows us to evaluate the format of the package insert, such as font size and positioning of the text.

(Comment 8) A few comments asked for clarification of whether the rule requires the submission in electronic format of all types of labeling, such as carton and container labels, labels submitted with advertising material, and labeling that might be submitted with periodic adverse drug experience reports.

(Response) The agency did not intend that the final rule require the electronic submission of the previously mentioned types of labeling. The rule requires only that the content of labeling (i.e. the content of the package insert or professional labeling, including all text, tables, and figures) be submitted in electronic format.

(Comment 9) Some comments requested clarification of whether the rule restricts the submission of labeling in electronic format to the content of labeling.

[6] The comment refers to patient package inserts as ''PIs.'' FDA, though, refers to such inserts as ''PPIs.''.

(Response) The agency did not intend to restrict the voluntary submission of labeling in electronic format. Under part 11, an applicant may submit labeling in electronic format as long as the controls in part 11 are met and the labeling is listed in public docket number 92S–0251.[7] Because the agency has listed labeling in conjunction with NDAs, BLAs, and ANDAs in public docket number 92S–0251, applicants may submit all labeling for an NDA, BLA, or ANDA in electronic format.

(Comment 10) Two comments suggested that the electronic submission of labeling submitted with annual reports under § 314.81 should be optional if the product's labeling has not been revised beyond editorial changes. The comments noted that the labeling revisions to older products are infrequent and often insubstantial in nature; therefore, the submission of annual report labeling is not justified by the objectives of this rule.

(Response) FDA disagrees that the electronic submission of labeling in the annual report is not justified by the objectives of the final rule. The labeling submitted with the annual report, aside from editorial corrections, can also include other changes related to the manufacturing of the product. As with other labeling changes, these changes must be reviewed and require the same degree of comparison with previous versions of labeling. In addition, the labeling changes described in the annual report must be included in FDA's database. Finally, it is important to note that in our economic analysis, we found that the one-time costs to convert the labeling in annual reports to electronic format would not be overly burdensome (see section VIII of this document). Accordingly, the electronic submission of labeling submitted with annual reports under § 314.81 is not optional.

C. Reviewer Support and Training

(Comment 11) Some comments expressed concern that reviewers will accept ''special requests'' to receive the labeling in paper format or other formats to bypass existing agency guidance on electronic submissions. These same comments emphasized the importance of training and support of reviewers and staff in the use of electronic review and version comparison utilities.

(Response) FDA agrees that reviewers should not ''bypass'' our guidance documents. We train reviewers and managers on the details and provisions of guidance documents. When there are differences in opinion concerning the meaning of such provisions, it is best for the applicant and agency personnel to discuss those differences to ensure that everyone understands the relevant issues and the parties' respective positions. In addition, we will update our specific policy and procedure documents for reviewers to help enforce the common practice of reviewing documents electronically. The reviewers and staff will have sufficient training and support to fulfill their duties in reviewing the electronic version of the content of labeling.

(Comment 12) One comment pointed out that the Office of Generic Drugs (OGD) has limited experience with electronic labeling because it has only recently published guidance on providing an ANDA in electronic format.[8] The comment recommended that OGD pilot a program with industry to accept and process electronic labeling before the effective date of this rule.

(Response) FDA does not believe a pilot program is necessary to prepare OGD reviewers for the implementation of this rule. OGD reviewers used the electronic label review technology for many years before the issuance of the guidance on electronic submissions of ANDAs[9] and; therefore, have adequate experience in this area.

D. Requiring Electronic Submission

(Comment 13) The comments were overwhelmingly supportive of requiring the electronic submission of the content of labeling. The comments commend FDA's goal of using electronic labeling to facilitate labeling reviews. However, a few comments suggested that the agency use appropriate metrics for tracking the gains associated with the electronic submission of labeling.

(Response) The agency agrees with the comment, and notes that, as explained in section II.A of the proposed rule, there will be numerous benefits from the regulation, particularly through enhancing the accuracy and speed of the labeling review process. Nevertheless, it may be difficult to quantify precisely the improvements derived solely from receiving labeling in electronic format because we also plan to improve our current business practice for processing and reviewing such labeling changes. To the extent possible, we plan to evaluate the success of all these changes and hope to make the results of our evaluations available to the public.

(Comment 14) A few comments suggested that the implementation of the rule would improve the availability of labeling to the public.

(Response) We believe that a number of changes are needed to improve the public's access to medication information. This rule is an important and necessary step toward that goal, because it will greatly enhance the accuracy and speed of labeling reviews. We are actively working with the pharmaceutical industry, other government agencies, and health care information suppliers to achieve success in this area. For example, we are currently working with several agencies, including the National Library of Medicine, on an initiative to promote patient safety through accessible medication information (DailyMed Initiative). The electronic submission of the content of labeling will allow the agency to provide the DailyMed system with labeling in a comprehensive, reliable, and structured format. The DailyMed can then use this information to make information on medications available to the public. Consumers, health professionals, and others may use this information in several ways, including to identify drug interactions, contraindications, and possible adverse reactions.

(Comment 15) Some comments suggested that the use of electronic labeling may lead to improvement in the communication between the agency and industry when the review division requests modifications for proposed labeling changes. Specifically, the comments referred to word processing software available for tracking changes and editing documents. In addition, the comments suggested that the use of a secure electronic mail exchange system between applicants and the agency during labeling negotiations could be beneficial.

(Response) We appreciate the suggestion and our guidance document entitled ''Providing Regulatory Submissions in Electronic Format—NDAs,'' currently describes submission of the content of labeling in a word processing format in addition to PDF to support editing changes. As mentioned in the proposed rule, PDF is the only type of electronic file format that we have the ability to process, review, and archive because it is currently the most cost effective and best meets our needs

[7] A recent draft guidance issued by the agency provides for the exercise of enforcement discretion with respect to the following part 11 requirements: Validation (§ 11.10(a) (21 CFR 11.10(a))); copies of records § 11.10(b)); record retention (§ 11.10(c)); audit trails (§ 11.10(e) and (k)(2)); and any corresponding requirements in § 11.30. See FDA guidance for industry entitled ''Part 11, Electronic Records; Electronic Signatures—Scope and Application,'' available at *www.fda.gov/cder/guidance*.

[8] See ''Providing Regulatory Submission in Electronic Format—ANDAs'' guidance (67 FR 43331, June 27, 2002).

[9] Id.

for word-for-word comparisons of files. As for any direct communication between applicants and FDA requiring the editing of specific content of labeling, the guidance notes the utility of also submitting labeling in word processing format to facilitate this editing process. In addition, we are looking into new technologies to improve the methods for exchanging and reviewing labeling changes.

E. Providing Labeling to FDA in Electronic Format

(Comment 16) Two comments requested clarification on how to provide labeling with annual reports. They state that some of the confusion with the annual report labeling is because of the lack of a published guidance document on the submission of annual reports in electronic format. The comments also asked if the hard copy information submitted with annual reports containing electronic labeling (distribution, chemistry, manufacturing and controls, preclinical/clinical) should be submitted to the respective reviewing divisions, the central document room, or both.

(Response) As explained previously, the agency has issued guidance for the electronic submission of NDAs, ANDAs, and BLAs. Although there is no published guidance specifically on providing labeling with annual reports, submission of that labeling is covered by these other agency guidance documents on electronic submissions. Therefore, the content of labeling submitted with annual reports would be prepared and submitted electronically as described in the following FDA guidance documents: (1) ''Providing Regulatory Submissions in Electronic Format—General Considerations,'' (2) ''Providing Regulatory Submissions in Electronic Format—NDAs,'' and (3) ''Providing Regulatory Submission in Electronic Format—ANDAs'' (see section I for a description of these guidance documents).

It should be noted that this final rule only applies to the electronic submission of the content of labeling. It does not address the electronic submission of annual reports generally or any other part of an application. To the extent that the commentors asked for more detailed information about annual report submissions, applicants should continue following the regulations and guidance documents pertaining to those submissions.

(Comment 17) One comment requested harmonization of all elements of annual reports for NDAs, ANDAs, and BLAs.

(Response) As noted previously, the content of the annual report, other than labeling, is not affected by this regulation. However, the labeling submitted with an annual report will be prepared and submitted electronically in the same fashion as described for other electronic labeling submissions in an application (i.e., original labeling submissions in an NDA, ANDA, or BLA).

(Comment 18) One comment requested that Form FDA 2567 not be required with each labeling component submitted to a BLA because CDER does not require that such a form accompany labeling.

(Response) The agency agrees that Form FDA 2567 is not required when submitting BLA labeling electronically using form 356h (Application to Market a New Drug, Biologic, or an Antibiotic Drug for Human Use). The form should only be used for human blood and blood components (The human blood and blood components circular is not covered by this rule. See comment 6 in section III of this document.)

(Comment 19) Generally, the comments supported our flexible approach regarding the acceptable content of labeling file format. The comments recognized that a flexible approach would enable the industry and FDA to take advantage of future improvements in computer technology and software design. They also agreed with the proposal to describe the method for submitting the content of labeling in guidance, but requested that FDA guidance accompany the final rule. Some comments, however, made suggestions for the use of specific technologies. In addition, we were requested to limit changes to the file format or software specifications.

(Response) Currently, guidance on the submission of labeling is included in the guidance for industry series ''Providing Regulatory Submissions in Electronic Format'' (see section I of this document). We understand that changes to the file format or software can lead to costly changes in the information technology systems used by industry. For this reason, we plan to limit future changes to those that can lead to increased benefits for both the agency and industry. As mentioned in section II of this final rule, the agency will not switch to new format or software until it is widely available.

(Comment 20) One comment asked that we identify the software used for working on an applicant's labeling (e.g., to compare texts) and whether the software is commercially available or proprietary.

(Response) Currently, the reviewers use Adobe Acrobat and Microsoft Word for reviewing labeling. Both are commercially available. As new technology is developed and we change the software used in reviews, we will make this information available to the public.

F. Part 11 Requirements for Electronic Submissions

(Comment 21) We received a number of comments related to the proposed exemption of the submission of electronic labeling from specific controls under §§ 11.10 and 11.30. Most of the comments were positive and supported the rationale for the exemptions. One comment, however, raised concerns about the effect of the proposed exemptions from part 11 requirements on the integrity of part 11 generally.

(Response) We have recently articulated our current thinking on part 11 in the draft guidance document entitled ''Part 11, Electronic Records; Electronic Signatures—Scope and Application'' (part 11 draft guidance) issued in the **Federal Register** of February 25, 2003 (68 FR 8775). Among other things, this part 11 draft guidance announces the agency's intent to exercise enforcement discretion in the manner specified in the draft guidance with respect to the specific part 11 requirements of validation (§ 11.10 (a)), copies of records (§ 11.10(b)), record retention, audit trails (§ 11.10(e) and (k)(2)), and any corresponding requirements in § 11.30. This final rule exempts the electronic submission of labeling content from the requirements of § 11.10(a), (c) through (h), and (k), and the corresponding requirements of § 11.30.

We recognize that there are some differences with respect to the exemptions from part 11 requirements provided in this final rule (i.e., § 11.10(a), (c) through (h), and (k), and the corresponding requirements of § 11.30), and the part 11 requirements set forth in the part 11 draft guidance for which the agency intends to exercise enforcement discretion (i.e., § 11.10(a) through (c), (e), and (k)(2), and any other corresponding requirements in 11.30)). Although the final rule does not provide an exemption from § 11.10(b), the part 11 draft guidance announces that we intend to exercise enforcement discretion with respect to that section in the manner described in the draft guidance.

The exemptions in the final rule and the part 11 requirements for which we intend to exercise enforcement discretion, as described in the part 11

draft guidance, differ because the final rule is specific to the electronic submission of labeling content for human prescription drugs and certain biologics, and the part 11 draft guidance applies to the maintenance of all electronic records and to all electronic submissions subject to part 11.

We exempted the submission of electronic labeling content from certain part 11 requirements because we believe these part 11 requirements are not critical to ensure the quality of the content of labeling submitted under this rule and we want to ensure that industry resources are not being spent on unnecessary controls. For example, validation for the system used to generate the labeling record is not necessary because the applicant's verification that the information in the labeling record is accurate serves the same objective. Our review of the content of labeling is based on the version of the labeling record submitted to us. Earlier versions of the record, as well as changes made to the earlier versions, are not relevant to our analysis. Thus, other controls related to the creation, modification, and maintenance of the labeling records are also not needed.

IV. Legal Authority

Our legal authority to amend our regulations governing the format of labeling for human prescription drugs and biologics derives from sections 201, 301, 501, 502, 503, 505, 506, 506A, 506B, 506C, 510, 513–516, 518–520, 701, 704, 721, and 801 of the act (21 U.S.C. 321, 331, 351, 352, 353, 355, 356, 356a, 356b, 356c, 360, 360c–360f, 360h–360j, 371, 374, 379e, and 381); 15 U.S.C. 1451–1561; the Public Health Service Act (42 U.S.C. 216, 241, 262, 263, 264); and section 122, Public Law 105–115, 111 Stat. 2322 (21 U.S.C. 355 note).

V. Paperwork Reduction Act of 1995

This final rule contains information collection provisions that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). A description of these provisions is given below with an estimate of the annual reporting burden. Included in this estimate is the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing each collection of information.

Title: Requirements for Submission of Labeling for Human Prescription Drugs and Biologics in Electronic Format.

Description: FDA is amending its regulations governing the format in which certain labeling is required to be submitted for review with NDAs, certain BLAs, ANDAs, supplements, and annual reports. The final rule requires that the content of labeling for prescription drug and biological products required under § 201.100(d)(3) be submitted to FDA electronically in a form that we can process, review, and archive. Copies of product labeling are currently required to be submitted to FDA for review in NDAs, certain BLAs, ANDAs, certain supplements, and annual reports under §§ 314.50, 314.70, 314.81, 314.94, 314.97, 314.98, §§ 601.2, and 601.12. Copies of labeling may be submitted electronically or on paper. The agency is adding the new requirements because submitting the content of labeling in electronic format will simplify the drug labeling review process and speed up the approval of labeling changes.

As required under section 3506(c)(2)(B) of the Paperwork Reduction Act, FDA provided an opportunity for public comments on May 3, 2002 (67 FR 22367), on the information collection provisions of the proposed rule. FDA received two comments stating that the agency underestimated the time and costs to prepare the content of labeling in electronic format for submission to FDA. Specifically, the comments stated that the 15 minutes to convert the labeling into PDF was underestimated because it did not take into account the time needed to proofread the content of labeling document.

FDA believes that proofreading is not an additional cost for submitting labeling in electronic format for new submissions of NDAs, BLAs, and ANDAs. Labeling is proofread prior to submission regardless of the format. If the labeling is in a word processing file, it is irrelevant whether the document is printed or converted to a PDF file. This is because the finished product, the labeling, is proofread for quality assurance in either case. We also note that someone may need even less time to proofread an electronic file than a printed document because the computer could assist in finding errors. As such, we are not changing the burden estimate for these applications in the final rule.

However, we agree that we should allow for proofreading of labeling under certain circumstances. Applicants that have previously submitted labeling in paper format in annual reports or supplements, but also maintained the labeling document in electronic format, should be provided time for proofreading the converted file. This category of labeling would not require any changes to the labeling since it was last submitted to the agency. It only requires additional time for proofreading to ensure that the electronic document being submitted is the same as the labeling previously submitted in paper format. We estimate that the hours per response (i.e., the time it will take an applicant to submit the labeling content electronically for these annual reports and supplements) will be approximately 5 hours. We discuss this new category of reporting in more detail in this section V when we calculate the burdens associated with submission of electronic labeling in supplements and annual reports. We also add sections to the estimated annual reporting burden chart to report the burdens.

As we noted in the proposed rule, we recognize that some older annual reports may require additional steps, such as accessing the labeling in the archives, putting the content of labeling into an electronic format, and converting it to a PDF file. In response to the proofreading comments mentioned previously, we are allowing an additional 2 hours for proofreading this type of labeling (the proposed rule allowed for 8 hours and the final rule is allowing for 10 hours).

The reporting burdens for submitting labeling as currently required under §§ 314.50, 314.70, 314.81, 314.94, 314.97, and 314.98 have previously been estimated by FDA, and this collection of information was approved by OMB until March 31, 2005, under OMB control number 0910–0001. The reporting burdens associated with current §§ 601.2 and 601.12 have also previously been estimated and this collection of information was approved by OMB until August 31, 2005, under OMB control number 0910–0338 (this includes the collection of information previously approved by OMB under control number 0910–0315). We are not reestimating these approved burdens in this rulemaking. Only the additional reporting burdens associated with the electronic submission of the content of labeling are estimated.

New NDAs (§ 314.50), ANDAs (§ 314.94), and BLAs (§ 601.2): Based on data in the approved collections of information for §§ 314.50, 314.94, and § 601.2, we estimate that approximately 83 NDA applicants, 117 ANDA applicants, and 17 BLA applicants (respondents) submit applications to us annually. We estimate that these applicants (respondents) will submit approximately 85 NDAs, 323 ANDAs, and 17 BLAs each year that will be

subject to this rule.[10] Based on our experience with voluntary electronic submissions and our knowledge of the drug and biologic industries, we assume that applicants for new NDAs, ANDAs, and BLAs will already have the necessary labeling in an electronic format that can be easily accessed and converted to a PDF file. Thus, we have estimated that the hours per response, i.e., the additional time necessary for submission of the content of labeling in electronic format for these applications, will be less than 15 minutes. Therefore, we estimate that respondents will spend approximately 106 hours per year submitting the content of labeling to us in accordance with the final rule.

Supplements to NDAs (§ 314.70) and ANDAs (§ 314.97) and BLAs (§ 601.12(f)(1) and (f)(2)): Based on data in the approved collections of information for §§ 314.70, 314.97, and § 601.12(f)(1) and (f)(2), we estimate that approximately 418 NDA applicants, 152 ANDA applicants, and 20 BLA applicants (respondents) submit supplements to approved applications to us annually. We estimate that these applicants (respondents) will submit approximately 630 NDA supplements, 1,000 ANDA supplements, and 20 BLA supplements each year that will be subject to this rule.

Based on our experience with voluntary electronic submissions and our knowledge of the drug and biologic industries, we assume that approximately 254 NDA supplements, 396 ANDA supplements, and 10 BLA supplements will be submitted by applicants who already have the necessary labeling in an electronic format that can be easily accessed and converted to a PDF file. Thus, we have estimated that the hours per response, i.e., the additional time necessary for submission of the content of labeling in electronic format for these supplements, will be less than 15 minutes. Therefore, we estimate that respondents would spend approximately 165 hours per year submitting the content of labeling to us in these supplements under the final rule.

As mentioned previously, we are adding a new category to the paperwork section to allow for proofreading the converted file of labeling that was previously submitted in supplements in paper form (and not requiring any changes since it was last submitted), but is also maintained by the applicant in an electronic format. We estimate that approximately 376 NDA supplements, 604 ANDA supplements, and 10 BLA supplements will be submitted by applicants who previously submitted labeling in paper, but have such labeling available in electronic format. We estimate that the hours per response, i.e., the time it will take an applicant to submit the labeling content electronically for these supplements, will be approximately 5 hours. Therefore, we estimate that in the first year, respondents will spend approximately 4,950 hours submitting the content of labeling that was previously submitted in supplements in paper form. For all supplements combined, we estimate that in the first year, respondents will spend approximately 5,115 hours submitting the content of labeling to us in supplements under the final rule. This expenditure of time will only be necessary the first time that a supplement is submitted with the content of labeling in electronic format. Once the content of labeling has been converted to an electronic format, the time necessary to submit the content of labeling in subsequent supplements will be the same as that for the other types of submissions or less than 15 minutes. Therefore, we estimate that, in subsequent years, respondents will spend approximately 413 hours per year submitting the content of labeling in supplements.

Annual Reports for NDAs (§ 314.81), ANDAs (§ 314.98), and BLAs (§ 601.12(f)(3)): Based on data in the approved collections of information for §§ 314.81, 314.98, and § 601.12(f)(3), we estimate that approximately 275 NDA applicants, 275 ANDA applicants, and 75 BLA applicants (respondents) submit annual reports to us annually. We also estimate that each NDA applicant submits to us approximately 9.45 annual reports, each ANDA applicant submits approximately 16.18 annual reports, and each BLA applicant submits approximately 1 annual report each year. Further, we estimate that the total annual responses, i.e., the total number of annual reports submitted to us per year, will remain approximately 2,600 NDA annual reports, 4,450 ANDA annual reports, and 75 BLA annual reports.

Based on our experience with voluntary electronic submissions and our knowledge of the drug and biologic industries, we estimate that approximately 24 percent of NDA annual reports (624 NDA annual reports), 20 percent of ANDA annual reports (890 ANDA annual reports), and 24 percent of BLA annual reports (18 BLA annual reports), will already have the necessary labeling in an electronic format that can be easily accessed and converted to a PDF file. As discussed above, we estimate that each NDA applicant submits to us approximately 9.45 annual reports, each ANDA applicant submits approximately 16.18 annual reports, and each BLA applicant submits approximately 1 annual report each year. Therefore, approximately 66 NDA applicants, 55 ANDA applicants, and 18 BLA applicants can easily access labeling in electronic form and convert it to a PDF file. For the applicants submitting these annual reports, we estimate that the hours per response, i.e., the additional time necessary for submission of the content of labeling in electronic format in the annual report, will be less than 15 minutes. Therefore, we estimate that respondents would spend approximately 383 hours per year submitting the content of labeling to us in these annual reports under the final rule.

As mentioned previously, we are adding a new category to the paperwork section to allow for proofreading the converted file of labeling that was previously submitted in annual reports in paper form (and not requiring any changes since it was last submitted), but is also maintained by the applicant in an electronic format. For applicants to include labeling content in their annual reports in electronic format, we estimate that approximately 36 percent of NDA annual reports (936 NDA annual reports), 30 percent of ANDA annual reports (1,335 ANDA annual reports), and 36 percent of BLA annual reports (27 BLA annual reports) will be submitted by applicants who previously submitted labeling in paper, but have such labeling available in electronic format. As discussed above, we estimate that each NDA applicant submits to us approximately 9.45 annual reports, each ANDA applicant submits approximately 16.18 annual reports, and each BLA applicant submits approximately 1 annual report each year. Therefore, under the final rule, approximately 99 NDA applicants, 83 ANDA applicants, and 27 BLA applicants would need additional time to proofread these annual reports. We estimate that the hours per response, i.e., the time it will take an applicant to submit the labeling content electronically for these annual reports, will be approximately 5 hours. Therefore, we estimate that respondents would spend approximately 11,490 hours per year submitting the content of labeling to us in these annual reports under the final rule.

We recognize that annual reports for some drug and biological products, particularly older products for which labeling changes have not been made in

[10] The numbers in this final rule have changed from the proposed rule because we have updated the numbers to be more current.

several years, may require additional steps. For applicants to include labeling content in their annual reports in electronic format, we estimate that approximately 40 percent of NDA annual reports (1,040 NDA annual reports), 50 percent of ANDA annual reports (2,225 ANDA annual reports), and 40 percent of BLA annual reports (30 BLA annual reports) will be submitted by applicants who may need to access the labeling in their archives, put the content of labeling into an electronic format, and convert it to a PDF file. As discussed previously, we estimate that each NDA applicant submits to us approximately 9.45 annual reports, each ANDA applicant submits approximately 16.18 annual reports, and each BLA applicant submits approximately 1 annual report each year. Therefore, under the final rule, approximately 110 NDA applicants, 137 ANDA applicants, and 30 BLA applicants would need to put labeling content in an electronic format and convert it to a PDF file. We estimate that the hours per response, i.e., the time it will take an applicant to submit the labeling content electronically for these annual reports, will be approximately 10 hours.[11] Therefore, we estimate that respondents would spend approximately 32,950 hours per year submitting the content of labeling to us in these annual reports under the final rule.

We estimate that in the first year, respondents will spend approximately 44,823 hours submitting the content of labeling to us in annual reports under the final rule. This expenditure of time will only be necessary the first time that an annual report is submitted with the content of labeling in electronic format. Once the content of labeling has been converted to an electronic format, the time necessary to submit the content of labeling in subsequent annual reports will be the same as that for the other types of submissions or less than 15 minutes. Therefore, we estimate that, in subsequent years, respondents will spend approximately 1,781 hours per year submitting the content of labeling in annual reports.

Description of Respondents: An applicant submitting an NDA, ANDA, BLA, supplement, or annual report to us for a drug or biological product.

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

21 CFR Section	No. of Respondents	No. of Responses per Respondent	Total Responses	Hours per Response	Total Hours
Applications: 314.50	83	1.02	85	.25	21
314.94	117	2.76	323	.25	81
601.14 (Applications submitted under § 601.2)	17	1	17	.25	4
Subtotal, applications					106
Supplements: 314.70 (Products not requiring additional steps for electronic submission)	167	1.52	254	.25	63
314.70 (Products requiring additional proofreading)	251	1.50	376	5	1,880
314.97 (Products not requiring additional steps for electronic submission)	61	6.50	396	.25	99
314.97(Products requiring additional proofreading)	91	6.50	604	5	3,020
601.14 (Supplements submitted under § 601.12(f)(1) and (f)(2))(Products not requiring additional steps for electronic submission)	8	1.25	10	.25	3
601.14 (Supplements submitted under § 601.12(f)(1) and (f)(2)) (Products requiring additional proofreading)	12	.83	10	5	50
Subtotal, supplements, year one					5,115
Subtotal, supplements, subsequent years[2]					413
Annual Reports: 314.81 (Products not requiring additional steps for electronic submission)	66	9.45	624	.25	156
314.81 (Products requiring additional proofreading)	99	9.45	936	5	4,680

[11] The number increased from 8 hours to 10 hours to allow for additional time to proofread.

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]—Continued

21 CFR Section	No. of Respondents	No. of Responses per Respondent	Total Responses	Hours per Response	Total Hours
314.81 (Products requiring additional steps for electronic submission)	110	9.45	1,040	10	10,400
314.98 (Products not requiring additional steps for electronic submission)	55	16.18	890	.25	222
314.98 (Products requiring additional proofreading)	83	16.18	1,335	5	6,675
314.98 (Products requiring additional steps for electronic submission)	137	16.18	2,225	10	22,250
601.14 (Annual reports submitted under § 601.12(f)(3) not requiring additional steps for electronic submission)	18	1	18	.25	5
601.14 Annual reports submitted under § 601.12(f)(3) (Products requiring additional proofreading)	27	1	27	5	135
601.14 (Annual reports submitted under § 601.12(f)(3) requiring additional steps for electronic submission)	30	1	30	10	300
Subtotal, annual reports, year one					44,823
Subtotal, annual reports, subsequent years[3]					1,781
Total, year one					50,044
Total, subsequent years[3]					2,300

[1] There are one-time capital costs to: (1) Acquire computer software; (2) train employees to use the software; and (3) convert certain labeling to an electronic format. These costs are estimated to be about $2.3 million (see section VIII of this document). There are no operating or maintenance costs associated with this collection of information.

[2] We estimate that for certain annual reports, respondents will spend 5 hours per response in the first year. We estimate that in subsequent years respondents will spend less than 15 minutes per response for all supplements.

[3] We estimate that for certain annual reports, respondents will spend either 5 or 10 hours per response in the first year. We estimate that in subsequent years respondents will spend less than 15 minutes per response for all annual reports.

In compliance with section 3507(d) of the Paperwork Reduction Act of 1995 (44 U.S.C. 3507(d)), the agency has submitted a copy of this rule to OMB for its review and approval of these information collections.

The information collection provisions in this final rule have been approved under OMB control number 0910–0530. This approval expires on November 30, 2006. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless the information collection displays a currently valid OMB control number.

VI. Environmental Impact

The agency has determined under 21 CFR 25.30(h) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

VII. Federalism

FDA has analyzed this final rule in accordance with the principles set forth in Executive Order 13132. FDA has determined that the rule does not contain policies that have substantial direct effects on the States, on the relationship between the National Government and the States, or on the distribution of power and responsibilities among the various levels of government. Accordingly, the agency has concluded that the rule does not contain policies that have federalism implications as defined in the Executive order and, consequently, a federalism summary impact statement is not required.

VIII. Analysis of Economic Impacts

We have examined the impacts of this final rule under Executive Order 12866 and the Regulatory Flexibility Act (5 U.S.C. 601–612), and the Unfunded Mandates Reform Act of 1995 (Public Law 104–4). Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). Under the Regulatory Flexibility Act, if a rule may have a significant economic impact on a substantial number of small entities, an agency must consider alternatives that would minimize the economic impact of the rule on small entities. Section 202(a) of the Unfunded

Mandates Reform Act of 1995 requires that agencies prepare a written assessment of anticipated costs and benefits before proposing any rule that may result in an expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of $100 million in any one year (adjusted annually for inflation).

We believe that this final rule is consistent with the regulatory philosophy and principles identified in Executive Order 12866 and in these two statutes. The final rule is a significant regulatory action as defined in section 3 paragraph (f)(4) of the Executive order. However, as shown in this section VIII, the final rule will not be an economically significant regulatory action as defined by the Executive order and will not require further analysis under the Regulatory Flexibility Act.

The Unfunded Mandates Reform Act of 1995 does not require FDA to prepare a statement of costs and benefits for the final rule because the final rule would not result in an expenditure of $100 million in any one year, adjusted for inflation. The current inflation-adjusted statutory threshold is approximately $110 million.

The purpose of this final rule is to require applicants to submit in electronic format the content of labeling required under § 201.100(d)(3) in NDAs, ANDAs, BLAs, annual reports, and applicable supplements. Submissions in electronic format will help simplify and speed up our review of these documents. Currently, applicants may voluntarily submit such data in electronic form, but they are not required to do so. The rule will require all applicants of approved and new NDAs, BLAs, and ANDAs to convert the content of labeling to an electronic format for submission. At this time, PDF is the type of electronic file format that we have the ability to accept for processing, reviewing, and archiving. Applicants that do not already have the capabilities to create PDF files will have to acquire the software and expertise to do so or make contractual arrangements to have documents converted.

The economic burden on industry will include a one-time cost to acquire the appropriate computer software and train employees on its use. Applicants may also incur additional one-time costs to revise applications that have not had any labeling changes within the last few years to a format that can be converted to a PDF file. We do not know the number of applicants that currently have the capability to submit electronic files, nor do we have firsthand information on how labeling files are currently maintained or on how much time will be required to train employees on the software and new procedures.

Three comments were received regarding the economic impact analysis. Two of these comments suggested that the cost to convert the content of labeling to a PDF format was underestimated because it did not include the cost to proofread the labeling after it is converted to a PDF file. The time required for proofreading ranged from 4 to 6 hours depending on the complexity/length of the labeling. One of these comments also suggested that the cost for converting older labeling that is only available on paper was underestimated, suggesting that the costs should include costs for equipment, training, and time to scan paper documents.

The agency agrees that we should allow for proofreading of labeling under certain circumstances. Applicants that have previously submitted annual reports or supplements in paper form, but also maintained the documents in electronic format, should be provided time for proofreading the converted file. This category of labeling would not require any changes to the labeling since it was last submitted to the agency. It only requires additional time for proofreading to ensure that it is the same as the labeling submitted in paper format. Five hours was used in this analysis to reflect the cost under these circumstances.

However, we do not agree that proofreading is an incremental cost for labeling that has been changed and is in a word processing file. Proofreading of the finished product for submission (in this case, the PDF file) is done now as part of current industry quality assurance practice. We also do not agree with the comment that costs for scanning labeling should be included in the impact analysis. While scanning paper labeling and using optical character recognition software is an option some firms may choose, it is not required. The labeling can be transcribed into a word processing format and then converted. However, we did increase the time estimate for such conversions by an additional 2 hours and we also increased our estimate of the percent of labeling that is included in this category because we now believe that number was underestimated.

Annually, we receive approximately 425 applications, 7,125 annual reports, and 1,650 supplements that contain labeling from approximately 625 applicants. Based on our experience working with voluntary electronic submissions, we estimate that overall approximately 70 percent of the applicants (440) already have the necessary software and trained personnel to comply with this rule. The remaining 30 percent of applicants (190) would need to purchase software, which costs about $250. Based on agency review, approximately 78 percent of these 190 applicants 148 would be considered small (fewer than 750 employees for drug product manufacturers and fewer than 500 employees for biological product manufacturers). We estimate that each small applicant would need to purchase only one copy of the software, for a total of 148 copies. The remaining 22 percent of applicants (42) that would need to purchase software are large entities. The agency estimates that each of these firms would need to purchase about 3 copies of the software or 126 copies (42 x 3). Thus, the total one-time cost for software is $68,500 ((148 + 126) x $250). Training costs include the cost of the software training course (estimated at $150 for a 6-hour course) and the wages of the employees attending the course (assuming an average weighted wage rate of $40 per hour). We estimate that applicants would train two employees per software purchase (548 employees), for a total one-time cost of $213,720 (($150 + (6 hours x $40)) x 548). The total one-time cost for software and training combined is estimated to be $282,220 ($68,500 + $213,720).

The cost to convert the applicable labeling to an electronic format is a one-time cost. The cost of conversions for new NDAs, BLAs, and ANDAs will be nominal because the file would be in a format easily convertible to PDF. The PDF file, being the finished product, would be proofread for quality assurance. Annually, we receive approximately 1,650 supplements that would be subject to the final rule. Because the majority of products for which supplements are submitted would have had labeling changes within the last few years, most labeling files would be easily accessible. Currently, the labeling in about 40 percent (660) of the supplements received is submitted in a PDF format and would require an estimated additional 15 minutes to comply with this final rule. The labeling in the remaining 60 percent (990) will require an estimated 5 hours to process and proofread. Thus, the total number of hours needed to convert applicable labeling in supplements to a PDF file format is 5,115 ((0.25 x 660) + (5 x 990)).

Labeling in most of the annual reports will also need to be converted. The conversion of this labeling to a PDF file for about 40 percent of NDA annual reports (975), 50 percent of ANDA annual reports (2,295), and 40 percent of

BLA annual reports (40), would require additional time to complete because they are not in a format easily convertible to PDF. We estimate that these annual reports would require 10 hours to complete, for a total of 33,100 hours ((975 + 2,295 + 40) x 10). For the content of labeling in the remaining annual reports (3,815), an estimated 40 percent (1,526) would require 15 minutes to process because they are currently in PDF format, and the remaining 2,289 annual reports will require approximately 5 hours to process and proofread, for a total of 11,827 hours ((1,526 x 0.25) + (2,289 x 5)). Thus, the total number of hours needed to convert all applicable labeling to a PDF file format in supplements and annual reports is 50,042 (5,115 + 33,100 + 11,827). Using the weighted average wage rate ($40 per hour), the total one-time costs to convert applicable labeling in supplements and annual reports would be about $2.0 million (50,042 x $40). The cost for the entire rule is estimated to be about $2.3 million ($0.3 million (software and training + $2.0 million labeling)).

Approximately 300 domestic entities would be affected by this final rule, about 240 of which meet the Small Business Administration's definition of a small entity (fewer than 750 employees for drug product manufacturers and fewer than 500 employees for biological product manufacturers). The economic impact of this final rule would vary by firm depending on the number of applications they hold and whether or not the company has PDF capabilities. The number of applications per firm ranges from 1 to 124, with a median of 4 applications per small entity. The average small entity has about 7 applications, and, assuming a worst case scenario—the firm did not have the content of labeling in an electronic format and needed to purchase software and train employees—this rule would cost the average small firm about $4,000 ($1,030 software and training + (7 x 10 hours x $40)), which is about $550 per application. Because these costs would almost certainly be less than 1 percent of product revenues, the agency certifies that this final rule will not have a significant economic impact on a substantial number of small entities.

List of Subjects

21 CFR Part 314

Administrative practice and procedure, Confidential business information, Drugs, Reporting and recordkeeping requirements.

21 CFR Part 601

Administrative practice and procedure, Biologics, Confidential business information.

■ Therefore, under the Federal Food, Drug, and Cosmetic Act, the Public Health Service Act, and under authority delegated to the Commissioner of Food and Drugs, 21 CFR parts 314 and 601 are amended as follows:

PART 314—APPLICATIONS FOR FDA APPROVAL TO MARKET A NEW DRUG

■ 1. The authority citation for 21 CFR part 314 continues to read as follows:

Authority: 21 U.S.C. 321, 331, 351, 352, 353, 355, 355a, 356, 356a, 356b, 356c, 371, 374, 379e.

■ 2. Section 314.50 is amended by revising paragraph (l)(1); by adding headings for paragraphs (l)(2), (l)(3), and (l)(4); by removing from paragraphs (l)(2) and (l)(3) the word ''shall'' and adding in its place the word ''must''; and by adding paragraph (l)(5) to read as follows:

§ 314.50 Content and format of an application.

* * * * *

(l) *Format of an original application.* (1) *Archival copy.* The applicant must submit a complete archival copy of the application that contains the information required under paragraphs (a) through (f) of this section. FDA will maintain the archival copy during the review of the application to permit individual reviewers to refer to information that is not contained in their particular technical sections of the application, to give other agency personnel access to the application for official business, and to maintain in one place a complete copy of the application. Except as required by paragraph (l)(1)(i) of this section, applicants may submit the archival copy on paper or in electronic format provided that electronic submissions are made in accordance with part 11 of this chapter.

(i) *Labeling.* The content of labeling required under § 201.100(d)(3) of this chapter (commonly referred to as the package insert or professional labeling), including all text, tables, and figures, must be submitted to the agency in electronic format as described in paragraph (l)(5) of this section. This requirement is in addition to the requirements of paragraph (e)(2)(ii) of this section that copies of the formatted label and all labeling be submitted. Submissions under this paragraph must be made in accordance with part 11 of this chapter, except for the requirements of § 11.10(a), (c) through (h), and (k), and the corresponding requirements of § 11.30.

(ii) [Reserved]

(2) *Review copy.* * * *

(3) *Field copy.* * * *

(4) *Binding folders.* * * *

(5) *Electronic format submissions.* Electronic format submissions must be in a form that FDA can process, review, and archive. FDA will periodically issue guidance on how to provide the electronic submission (e.g., method of transmission, media, file formats, preparation and organization of files).

■ 3. Section 314.81 is amended by revising paragraph (b)(2)(iii) to read as follows:

§ 314.81 Other postmarketing reports.

* * * * *

(b) * * *

(2) * * *

(iii) *Labeling.* (*a*) Currently used professional labeling, patient brochures or package inserts (if any), and a representative sample of the package labels.

(*b*) The content of labeling required under § 201.100(d)(3) of this chapter (i.e., the package insert or professional labeling), including all text, tables, and figures, must be submitted in electronic format. Electronic format submissions must be in a form that FDA can process, review, and archive. FDA will periodically issue guidance on how to provide the electronic submission (e.g., method of transmission, media, file formats, preparation and organization of files). Submissions under this paragraph must be made in accordance with part 11 of this chapter, except for the requirements of § 11.10(a), (c) through (h), and (k), and the corresponding requirements of § 11.30.

(*c*) A summary of any changes in labeling that have been made since the last report listed by date in the order in which they were implemented, or if no changes, a statement of that fact.

* * * * *

■ 4. Section 314.94 is amended by revising paragraph (d)(1) to read as follows:

§ 314.94 Content and format of an abbreviated application.

* * * * *

(d) * * * (1) The applicant must submit a complete archival copy of the abbreviated application as required under paragraphs (a) and (c) of this section. FDA will maintain the archival copy during the review of the application to permit individual reviewers to refer to information that is not contained in their particular technical sections of the application, to give other agency personnel access to

the application for official business, and to maintain in one place a complete copy of the application.

(i) *Format of submission.* An applicant may submit portions of the archival copy of the abbreviated application in any form that the applicant and FDA agree is acceptable, except as provided in paragraph (d)(1)(ii) of this section.

(ii) *Labeling.* The content of labeling required under § 201.100(d)(3) of this chapter (commonly referred to as the package insert or professional labeling), including all text, tables, and figures, must be submitted to the agency in electronic format as described in paragraph (d)(1)(iii) of this section. This requirement applies to the content of labeling for the proposed drug product only and is in addition to the requirements of paragraph (a)(8)(ii) of this section that copies of the formatted label and all proposed labeling be submitted. Submissions under this paragraph must be made in accordance with part 11 of this chapter, except for the requirements of § 11.10(a), (c) through (h), and (k), and the corresponding requirements of § 11.30.

(iii) *Electronic format submissions.* Electronic format submissions must be in a form that FDA can process, review, and archive. FDA will periodically issue guidance on how to provide the electronic submission (e.g., method of transmission, media, file formats, preparation and organization of files).

* * * * *

PART 601—LICENSING

■ 5. The authority citation for 21 CFR part 601 continues to read as follows:

Authority: 15 U.S.C. 1451–1561; 21 U.S.C. 321, 351, 352, 353, 355, 356b, 360, 360c–360f, 360h–360j, 371, 374, 379e, 381; 42 U.S.C. 216, 241, 262, 263, 264; sec. 122, Pub. L. 105–115, 111 Stat. 2322 (21 U.S.C. 355 note).

■ 6. Add 601.14 to subpart C to read as follows:

§ 601.14 Regulatory submissions in electronic format.

(a) *General.* Electronic format submissions must be in a form that FDA can process, review, and archive. FDA will periodically issue guidance on how to provide the electronic submission (e.g., method of transmission, media, file formats, preparation and organization of files.)

(b) *Labeling.* The content of labeling required under § 201.100(d)(3) of this chapter (commonly referred to as the package insert or professional labeling), including all text, tables, and figures, must be submitted to the agency in electronic format as described in paragraph (a) of this section. This requirement is in addition to the provisions of §§ 601.2(a) and 601.12(f) that require applicants to submit specimens of the labels, enclosures, and containers, or to submit other final printed labeling. Submissions under this paragraph must be made in accordance with part 11 of this chapter except for the requirements of § 11.10(a), (c) through (h), and (k), and the corresponding requirements of § 11.30.

Dated: July 31, 2003.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 03–30641 Filed 12–9–03; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Part 1

[TD 9097]

RIN 1545–AX22

Arbitrage Restrictions Applicable to Tax-Exempt Bonds Issued by State and Local Governments

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Final regulations.

SUMMARY: This document contains final regulations on the arbitrage restrictions applicable to tax-exempt bonds issued by state and local governments. The regulations affect issuers of tax-exempt bonds and provide a safe harbor for qualified administrative costs for broker's commissions and similar fees incurred in connection with the acquisition of guaranteed investment contracts or investments purchased for a yield restricted defeasance escrow.

DATES: *Effective Date:* These regulations are effective February 9, 2004.

Applicability Date: For dates of applicability, *see* § 1.148–11(i) of these regulations.

FOR FURTHER INFORMATION CONTACT: Rose M. Weber, (202) 622–3980 (not a toll-free number).

SUPPLEMENTARY INFORMATION:

Background

This document amends 26 CFR part 1 under section 148 of the Internal Revenue Code by providing rules for determining when certain brokers' commissions or similar fees are qualified administrative costs (the final regulations). On August 27, 1999, the IRS published in the **Federal Register** a notice of proposed rulemaking (REG–105565–99)(64 FR 46876) (the proposed regulations). The proposed regulations modify § 1.148–5(e)(2) to provide a safe harbor for determining whether brokers' commissions and similar fees incurred in connection with the acquisition of guaranteed investment contracts or investments purchased for a yield restricted defeasance escrow are treated as qualified administrative costs. Comments on the proposed regulations were received and a hearing was held on December 14, 1999. After consideration of all the comments, the proposed regulations are adopted as revised by this Treasury decision. The revisions are discussed below.

Explanation of Provisions

I. Existing Regulations

A. Investment Yield and Administrative Costs

Section 148 limits the yield on investments purchased with proceeds of tax-exempt bonds. In general, under § 1.148–5(b)(1) of the existing regulations, the yield on an investment is computed by comparing receipts from the investment to payments for the investment. Section 1.148–5(e)(1) provides that the yield on an investment generally is not adjusted to take into account any costs or expenses paid, directly or indirectly, to purchase, carry, sell, or retire the investment (administrative costs). However, § 1.148–5(e)(2)(i) provides that the yield on nonpurpose investments (as defined in § 1.148–1(b)) is adjusted to take into account qualified administrative costs. Qualified administrative costs are reasonable, direct administrative costs, other than carrying costs, such as separately stated brokerage or selling commissions, but not legal and accounting fees, recordkeeping, custody, and similar costs. In general, under § 1.148–5(e)(2)(i), administrative costs are not reasonable unless they are comparable to administrative costs that would be charged for the same investment or a reasonably comparable investment if acquired with a source of funds other than gross proceeds of tax-exempt bonds (the comparability standard).

B. Special Rule for Guaranteed Investment Contracts

Section 1.148–5(e)(2)(iii) of the existing regulations provides that, for a guaranteed investment contract, a broker's commission or similar fee paid on behalf of either an issuer or the guaranteed investment contract provider generally is a qualified administrative

From: Margo Burnette, Director
Office of Information Technology
CDER, HFD-070

MB

3432 S 05 21 P2:35

Subject: Docket 92S-0251 – Transmittal

To: Chief, Dockets Management Branch, HFA-305

Pursuant to 21 CFR part 112(b)(2), and on behalf of the Center for Drug Evaluation and Research (CDER), please find the attached notification of CDER's readiness to accept electronic regulatory submissions for content of labeling.

Regulatory citation: 21 CFR 314,50(l), 314.94(d), 601.14(b), and 314.81(b)

Effective date: October 31, 2005

Please add the attached notification to the official docket 92S-0251

Memorandum 31 to docket 92S-0251 (dated September 21, 2004) announced the Center's readiness to accept content of labeling in either PDF or XML format

This notification updates Memorandum 31 by eliminating the use of PDF as an acceptable format for the submission of content of labeling beginning October 31, 2005. Health Level Seven (HL7) Structured Product Labeling (SPL) in XML format is the only acceptable format for the submission of the content of labeling in electronic format. This applies to the content of labeling provided with original submissions, supplements, and annual reports.

The Agency has developed an automated system to process, review and archive the contents of labeling in electronic format using the HL7/SPL standard and implementation begins on October 31, 2005.

Applicants should provide the SPL content of labeling file as described in the document *SPL Implementation Guide for FDA Content of Labeling Submissions* available from HL7. Additional details on content of labeling submissions may be found in guidance to industry: *Providing Regulatory Submissions in Electronic Format - Content of Labeling.*

Documentation for creating and viewing SPL files may be found through the FDA web site at http://www.fda.gov/oc/datacouncil/spl.html . This site provides the following:

- Directions for obtaining the SPL standard and schema from HL7

1992S-0251 / M32

- Links to the document *SPL Implementation Guide for FDA Content of Labeling Submissions*, the companion document to the HL7 SPL standard providing additional details on creating SPL files
- Link to the guidance to industry: *Providing Regulatory Submissions in Electronic Format - Content of Labeling*
- Stylesheet files for viewing SPL content of labeling files
- Sample SPL content of labeling files

Electronic Labeling Information Processing System (ELIPS) Validation and Conformance Rules[1]

October, 2005

[1] This document is not an HL7 informative document. It is used with the *SPL Implementation Guide for FDA Content of Labeling Submissions* posted on the FDA website at http://www.fda.gov/oc/datacouncil/spl.html). Questions or comments regarding this document should be directed to Binh Ta at binh.ta@fda.gov

1. Purpose and Scope

The purpose of this document is to provide the Electronic Labeling Information Processing System (ELIPS) validation and conformance rules for the submission of Structured Product Labeling (SPL). The concept of 'validation' is well-defined in XML to mean the successful parsing of an instance against a DTD or Schema, in this case the SPL Schema. In addition, an SPL instance must also conform to the business rules as documented in the *SPL Implementation Guide for FDA Content of Labeling Submissions*.

2. SPL Validation

SPL validation includes three tiers. The detailed business rules for the first two tiers are presented in the following sub-sections. Final tier involves a manual review of data elements in SPL.

2.1 First Tier Validations

The first tier validation includes file validation, XML validation, and header and section data element validation on the SPL submission files. **Failure of first tier validation prevents SPL from loading into ELIPS**. The validation results will be reported to the review division.

2.1.1 File Validation

Table 1, *File Validation Business Rules for Incoming SPL Submissions* lists the rules used to check the SPL submission files. SPL will fail to load into ELIPS if any of the rules are violated.

Table 1. File Validation Business Rules for Incoming SPL Submissions

No.	Business Rule
1.	• SPL submission files must be accessible (opened and copied) from the electronic submission media (e.g., CD-ROM)
2.	• SPL submission files (SPL and all associated image files) must be present in the SPL folder/directory
3.	• SPL submission files must have valid extensions (XML, JPG, GIF)

2.1.2 XML Validation

Table 2, *XML Validation Business Rules for Incoming SPL Submissions* lists the rules used to check the SPL xml file. SPL will fail to load into ELIPS if any of the rules are violated.

Table 2. XML Validation Business Rules for Incoming SPL Submissions

No.	Business Rule
1.	• The SPL document must validate successfully against the SPL schema

Table 2. XML Validation Business Rules for Incoming SPL Submissions

No.	Business Rule
2.	• The references to the image files in the SPL XML must have a valid path relative to the SPL folder.

2.1.3 Data Element Validation

Table 3, *Data Elements Validation Business Rules for Incoming SPL Submissions* lists the rules used to check the SPL data elements. SPL will fail to load into ELIPS if any of the rules are violated.

Table 3. Data Elements Validation Business Rules for Incoming SPL Submissions

No.	Data Element	Business Rule
SPL Header Data Elements		
1.	setId	• Data element must be present
2.	id	• Data element must have an unique value for each SPL file submitted • This value must be a properly formatted GUID
3.	code	• Data element must have a value representing the LOINC code (34391-3) for Human Prescription Drug Label
4.	title	• Data element must be present
SPL Elements Within <section> Element		
5.	id	• Data element must be present • Data element must have a unique value for the particular logical instance. • Value for data element must be a properly formatted GUID
6.	code	• Value for data element must be a valid LOINC code if specified. May be omitted for sections having no LOINC code assigned.
7.	component	• Data element must be present for nested <section>s

2.2 Second Tier Validations

The second tier validation includes an automated data element validation. Failure of second tier validations causes the SPL data elements to be flagged for manual review during the labeling review process. Problems found during tier 2 must be corrected prior to transmission to NLM.

Table 4, *Data Elements Validation Business Rules during Labeling Review* lists business rules that will result in the flagging of data elements.

Table 4. Data Elements Validation Business Rules during Labeling Review

No.	Conceptual Data Element	Business Rule
SPL Data Elements		
1.	Proprietary Name	• Name element must be present and have a value
2.	Nonproprietary Name	• Data element must be present • Data element must have a value
3.	Active Ingredients	• Data element must be present • Data element must have a value • Value must be from the Substance Registration System /Ingredient Dictionary (SRS/ID), which is populated by FDA in the original submission. • Package type, quantity, and unit must be present and must have values. Values for package type and unit must be from NCI Thesaurus.
4.	Inactive Ingredients	• Data element must have a value if data element tag is present • Value must be from the SRS/ID, which is populated by FDA after original submission. • If inactive ingredient is specified, the package type, quantity, and unit must also be present and have values. Values for package type and unit must be from NCI Thesaurus.
5.	Dosage Form	• Data element must be present • Data element must have a value • Value must be from NCI Thesaurus
6.	Labeled Route of Administration	• Data element must be present • Data element must have a value • Value must be from NCI Thesaurus
7.	NDC	• Data element must be present • Data element must have a value
8.	DEA Schedule	• Data element must have a value if present • Value must be from NCI Thesaurus
9.	Color	• If the data element tag is present, then the data element must have a value • Value must be from NCI Thesaurus
10.	Score	• If the data element tag is present, then the data element must have a value
11.	Shape	• If the data element tag is present, then the data element must have a value • Value must be from NCI Thesaurus
12.	Size	• If the data element tag is present, then the data element must have a value

Table 4. Data Elements Validation Business Rules during Labeling Review

No.	Conceptual Data Element	Business Rule
13.	Coating	• If the data element tag is present, then the data element must have a value • Value must be true or false
14.	Symbol	• If the data element tag is present, then the data element must have a value • Value must be true or false
15.	Imprint	• If the data element tag is present, then the data element must have a value

106TH CONGRESS } HOUSE OF REPRESENTATIVES { REPORT
2d Session } { 106–661

ELECTRONIC SIGNATURES IN GLOBAL AND NATIONAL COMMERCE ACT

JUNE 8, 2000.—Ordered to be printed

Mr. BLILEY, from the committee of conference, submitted the following

CONFERENCE REPORT

[To accompany S. 761]

The committee of conference on the disagreeing votes of the two Houses on the amendments of the House to the bill (S. 761), to regulate interstate commerce by electronic means by permitting and encouraging the continued expansion of electronic commerce through the operation of free market forces, and other purposes, having met, after full and free conference, have agreed to recommend and do recommend to their respective Houses as follows:

That the Senate recede from its disagreement to the amendment of the House to the text of the bill and agree to the same with an amendment as follows:

In lieu of the matter proposed to be inserted by the House amendment, insert the following:

SECTION 1. SHORT TITLE.

This Act may be cited as the "Electronic Signatures in Global and National Commerce Act".

TITLE I—ELECTRONIC RECORDS AND SIGNATURES IN COMMERCE

SEC. 101. GENERAL RULE OF VALIDITY.

(a) IN GENERAL.—Notwithstanding any statute, regulation, or other rule of law (other than this title and title II), with respect to any transaction in or affecting interstate or foreign commerce—

(1) a signature, contract, or other record relating to such transaction may not be denied legal effect, validity, or enforceability solely because it is in electronic form; and

(2) a contract relating to such transaction may not be denied legal effect, validity, or enforceability solely because an

electronic signature or electronic record was used in its formation.

(b) PRESERVATION OF RIGHTS AND OBLIGATIONS.—This title does not—

(1) limit, alter, or otherwise affect any requirement imposed by a statute, regulation, or rule of law relating to the rights and obligations of persons under such statute, regulation, or rule of law other than a requirement that contracts or other records be written, signed, or in nonelectronic form; or

(2) require any person to agree to use or accept electronic records or electronic signatures, other than a governmental agency with respect to a record other than a contract to which it is a party.

(c) CONSUMER DISCLOSURES.—

(1) CONSENT TO ELECTRONIC RECORDS.—Notwithstanding subsection (a), if a statute, regulation, or other rule of law requires that information relating to a transaction or transactions in or affecting interstate or foreign commerce be provided or made available to a consumer in writing, the use of an electronic record to provide or make available (whichever is required) such information satisfies the requirement that such information be in writing if—

(A) the consumer has affirmatively consented to such use and has not withdrawn such consent;

(B) the consumer, prior to consenting, is provided with a clear and conspicuous statement—

(i) informing the consumer of (I) any right or option of the consumer to have the record provided or made available on paper or in nonelectronic form, and (II) the right of the consumer to withdraw the consent to have the record provided or made available in an electronic form and of any conditions, consequences (which may include termination of the parties' relationship), or fees in the event of such withdrawal;

(ii) informing the consumer of whether the consent applies (I) only to the particular transaction which gave rise to the obligation to provide the record, or (II) to identified categories of records that may be provided or made available during the course of the parties' relationship;

(iii) describing the procedures the consumer must use to withdraw consent as provided in clause (i) and to update information needed to contact the consumer electronically; and

(iv) informing the consumer (I) how, after the consent, the consumer may, upon request, obtain a paper copy of an electronic record, and (II) whether any fee will be charged for such copy;

(C) the consumer—

(i) prior to consenting, is provided with a statement of the hardware and software requirements for access to and retention of the electronic records; and

(ii) consents electronically, or confirms his or her consent electronically, in a manner that reasonably demonstrates that the consumer can access information

in the electronic form that will be used to provide the information that is the subject of the consent; and

(D) after the consent of a consumer in accordance with subparagraph (A), if a change in the hardware or software requirements needed to access or retain electronic records creates a material risk that the consumer will not be able to access or retain a subsequent electronic record that was the subject of the consent, the person providing the electronic record—

(i) provides the consumer with a statement of (I) the revised hardware and software requirements for access to and retention of the electronic records, and (II) the right to withdraw consent without the imposition of any fees for such withdrawal and without the imposition of any condition or consequence that was not disclosed under subparagraph (B)(i); and

(ii) again complies with subparagraph (C).

(2) OTHER RIGHTS.—

(A) PRESERVATION OF CONSUMER PROTECTIONS.—Nothing in this title affects the content or timing of any disclosure or other record required to be provided or made available to any consumer under any statute, regulation, or other rule of law.

(B) VERIFICATION OR ACKNOWLEDGEMENT.—If a law that was enacted prior to this Act expressly requires a record to be provided or made available by a specified method that requires verification or acknowledgment of receipt, the record may be provided or made available electronically only if the method used provides verification or acknowledgment of receipt (whichever is required).

(3) EFFECT OF FAILURE TO OBTAIN ELECTRONIC CONSENT OR CONFIRMATION OF CONSENT.—The legal effectiveness, validity, or enforceability of any contract executed by a consumer shall not be denied solely because of the failure to obtain electronic consent or confirmation of consent by that consumer in accordance with paragraph (1)(C)(ii).

(4) PROSPECTIVE EFFECT.—Withdrawal of consent by a consumer shall not affect the legal effectiveness, validity, or enforceability of electronic records provided or made available to that consumer in accordance with paragraph (1) prior to implementation of the consumer's withdrawal of consent. A consumer's withdrawal of consent shall be effective within a reasonable period of time after receipt of the withdrawal by the provider of the record. Failure to comply with paragraph (1)(D) may, at the election of the consumer, be treated as a withdrawal of consent for purposes of this paragraph.

(5) PRIOR CONSENT.—This subsection does not apply to any records that are provided or made available to a consumer who has consented prior to the effective date of this title to receive such records in electronic form as permitted by any statute, regulation, or other rule of law.

(6) ORAL COMMUNICATIONS.—An oral communication or a recording of an oral communication shall not qualify as an electronic record for purposes of this subsection except as otherwise provided under applicable law.

(d) RETENTION OF CONTRACTS AND RECORDS.—

(1) ACCURACY AND ACCESSIBILITY.—If a statute, regulation, or other rule of law requires that a contract or other record relating to a transaction in or affecting interstate or foreign commerce be retained, that requirement is met by retaining an electronic record of the information in the contract or other record that—

(A) accurately reflects the information set forth in the contract or other record; and

(B) remains accessible to all persons who are entitled to access by statute, regulation, or rule of law, for the period required by such statute, regulation, or rule of law, in a form that is capable of being accurately reproduced for later reference, whether by transmission, printing, or otherwise.

(2) EXCEPTION.—A requirement to retain a contract or other record in accordance with paragraph (1) does not apply to any information whose sole purpose is to enable the contract or other record to be sent, communicated, or received.

(3) ORIGINALS.—If a statute, regulation, or other rule of law requires a contract or other record relating to a transaction in or affecting interstate or foreign commerce to be provided, available, or retained in its original form, or provides consequences if the contract or other record is not provided, available, or retained in its original form, that statute, regulation, or rule of law is satisfied by an electronic record that complies with paragraph (1).

(4) CHECKS.—If a statute, regulation, or other rule of law requires the retention of a check, that requirement is satisfied by retention of an electronic record of the information on the front and back of the check in accordance with paragraph (1).

(e) ACCURACY AND ABILITY TO RETAIN CONTRACTS AND OTHER RECORDS.—Notwithstanding subsection (a), if a statute, regulation, or other rule of law requires that a contract or other record relating to a transaction in or affecting interstate or foreign commerce be in writing, the legal effect, validity, or enforceability of an electronic record of such contract or other record may be denied if such electronic record is not in a form that is capable of being retained and accurately reproduced for later reference by all parties or persons who are entitled to retain the contract or other record.

(f) PROXIMITY.—Nothing in this title affects the proximity required by any statute, regulation, or other rule of law with respect to any warning, notice, disclosure, or other record required to be posted, displayed, or publicly affixed.

(g) NOTARIZATION AND ACKNOWLEDGMENT.—If a statute, regulation, or other rule of law requires a signature or record relating to a transaction in or affecting interstate or foreign commerce to be notarized, acknowledged, verified, or made under oath, that requirement is satisfied if the electronic signature of the person authorized to perform those acts, together with all other information required to be included by other applicable statute, regulation, or rule of law, is attached to or logically associated with the signature or record.

(h) ELECTRONIC AGENTS.—A contract or other record relating to a transaction in or affecting interstate or foreign commerce may not be denied legal effect, validity, or enforceability solely because its

formation, creation, or delivery involved the action of one or more electronic agents so long as the action of any such electronic agent is legally attributable to the person to be bound.

(i) INSURANCE.—It is the specific intent of the Congress that this title and title II apply to the business of insurance.

(j) INSURANCE AGENTS AND BROKERS.—An insurance agent or broker acting under the direction of a party that enters into a contract by means of an electronic record or electronic signature may not be held liable for any deficiency in the electronic procedures agreed to by the parties under that contract if—

(1) the agent or broker has not engaged in negligent, reckless, or intentional tortious conduct;

(2) the agent or broker was not involved in the development or establishment of such electronic procedures; and

(3) the agent or broker did not deviate from such procedures.

SEC. 102. EXEMPTION TO PREEMPTION.

(a) IN GENERAL.—A State statute, regulation, or other rule of law may modify, limit, or supersede the provisions of section 101 with respect to State law only if such statute, regulation, or rule of law—

(1) constitutes an enactment or adoption of the Uniform Electronic Transactions Act as approved and recommended for enactment in all the States by the National Conference of Commissioners on Uniform State Laws in 1999, except that any exception to the scope of such Act enacted by a State under section 3(b)(4) of such Act shall be preempted to the extent such exception is inconsistent with this title or title II, or would not be permitted under paragraph (2)(A)(ii) of this subsection; or

(2)(A) specifies the alternative procedures or requirements for the use or acceptance (or both) of electronic records or electronic signatures to establish the legal effect, validity, or enforceability of contracts or other records, if—

(i) such alternative procedures or requirements are consistent with this title and title II; and

(ii) such alternative procedures or requirements do not require, or accord greater legal status or effect to, the implementation or application of a specific technology or technical specification for performing the functions of creating, storing, generating, receiving, communicating, or authenticating electronic records or electronic signatures; and

(B) if enacted or adopted after the date of the enactment of this Act, makes specific reference to this Act.

(b) EXCEPTIONS FOR ACTIONS BY STATES AS MARKET PARTICIPANTS.—Subsection (a)(2)(A)(ii) shall not apply to the statutes, regulations, or other rules of law governing procurement by any State, or any agency or instrumentality thereof.

(c) PREVENTION OF CIRCUMVENTION.—Subsection (a) does not permit a State to circumvent this title or title II through the imposition of nonelectronic delivery methods under section 8(b)(2) of the Uniform Electronic Transactions Act.

SEC. 103. SPECIFIC EXCEPTIONS.

(a) EXCEPTED REQUIREMENTS.—The provisions of section 101 shall not apply to a contract or other record to the extent it is governed by—

(1) a statute, regulation, or other rule of law governing the creation and execution of wills, codicils, or testamentary trusts;

(2) a State statute, regulation, or other rule of law governing adoption, divorce, or other matters of family law; or

(3) the Uniform Commercial Code, as in effect in any State, other than sections 1–107 and 1–206 and Articles 2 and 2A.

(b) ADDITIONAL EXCEPTIONS.—The provisions of section 101 shall not apply to—

(1) court orders or notices, or official court documents (including briefs, pleadings, and other writings) required to be executed in connection with court proceedings;

(2) any notice of—

(A) the cancellation or termination of utility services (including water, heat, and power);

(B) default, acceleration, repossession, foreclosure, or eviction, or the right to cure, under a credit agreement secured by, or a rental agreement for, a primary residence of an individual;

(C) the cancellation or termination of health insurance or benefits or life insurance benefits (excluding annuities); or

(D) recall of a product, or material failure of a product, that risks endangering health or safety; or

(3) any document required to accompany any transportation or handling of hazardous materials, pesticides, or other toxic or dangerous materials.

(c) REVIEW OF EXCEPTIONS.—

(1) EVALUATION REQUIRED.—The Secretary of Commerce, acting through the Assistant Secretary for Communications and Information, shall review the operation of the exceptions in subsections (a) and (b) to evaluate, over a period of 3 years, whether such exceptions continue to be necessary for the protection of consumers. Within 3 years after the date of enactment of this Act, the Assistant Secretary shall submit a report to the Congress on the results of such evaluation.

(2) DETERMINATIONS.—If a Federal regulatory agency, with respect to matter within its jurisdiction, determines after notice and an opportunity for public comment, and publishes a finding, that one or more such exceptions are no longer necessary for the protection of consumers and eliminating such exceptions will not increase the material risk of harm to consumers, such agency may extend the application of section 101 to the exceptions identified in such finding.

SEC. 104. APPLICABILITY TO FEDERAL AND STATE GOVERNMENTS.

(a) FILING AND ACCESS REQUIREMENTS.—Subject to subsection (c)(2), nothing in this title limits or supersedes any requirement by a Federal regulatory agency, self-regulatory organization, or State regulatory agency that records be filed with such agency or organization in accordance with specified standards or formats.

(b) PRESERVATION OF EXISTING RULEMAKING AUTHORITY.—

(1) USE OF AUTHORITY TO INTERPRET.—Subject to paragraph (2) and subsection (c), a Federal regulatory agency or State regulatory agency that is responsible for rulemaking under any other statute may interpret section 101 with respect to such statute through—

(A) the issuance of regulations pursuant to a statute; or

(B) to the extent such agency is authorized by statute to issue orders or guidance, the issuance of orders or guidance of general applicability that are publicly available and published (in the Federal Register in the case of an order or guidance issued by a Federal regulatory agency).

This paragraph does not grant any Federal regulatory agency or State regulatory agency authority to issue regulations, orders, or guidance pursuant to any statute that does not authorize such issuance.

(2) LIMITATIONS ON INTERPRETATION AUTHORITY.—Notwithstanding paragraph (1), a Federal regulatory agency shall not adopt any regulation, order, or guidance described in paragraph (1), and a State regulatory agency is preempted by section 101 from adopting any regulation, order, or guidance described in paragraph (1), unless—

(A) such regulation, order, or guidance is consistent with section 101;

(B) such regulation, order, or guidance does not add to the requirements of such section; and

(C) such agency finds, in connection with the issuance of such regulation, order, or guidance, that—

(i) there is a substantial justification for the regulation, order, or guidance;

(ii) the methods selected to carry out that purpose—

(I) are substantially equivalent to the requirements imposed on records that are not electronic records; and

(II) will not impose unreasonable costs on the acceptance and use of electronic records; and

(iii) the methods selected to carry out that purpose do not require, or accord greater legal status or effect to, the implementation or application of a specific technology or technical specification for performing the functions of creating, storing, generating, receiving, communicating, or authenticating electronic records or electronic signatures.

(3) PERFORMANCE STANDARDS.—

(A) ACCURACY, RECORD INTEGRITY, ACCESSIBILITY.—Notwithstanding paragraph (2)(C)(iii), a Federal regulatory agency or State regulatory agency may interpret section 101(d) to specify performance standards to assure accuracy, record integrity, and accessibility of records that are required to be retained. Such performance standards may be specified in a manner that imposes a requirement in violation of paragraph (2)(C)(iii) if the requirement (i) serves an important governmental objective; and (ii) is substantially related to the achievement of that objective. Nothing in this paragraph shall be construed to grant any Federal regu-

latory agency or State regulatory agency authority to require use of a particular type of software or hardware in order to comply with section 101(d).

(B) PAPER OR PRINTED FORM.—Notwithstanding subsection (c)(1), a Federal regulatory agency or State regulatory agency may interpret section 101(d) to require retention of a record in a tangible printed or paper form if—

(i) there is a compelling governmental interest relating to law enforcement or national security for imposing such requirement; and

(ii) imposing such requirement is essential to attaining such interest.

(4) EXCEPTIONS FOR ACTIONS BY GOVERNMENT AS MARKET PARTICIPANT.—Paragraph (2)(C)(iii) shall not apply to the statutes, regulations, or other rules of law governing procurement by the Federal or any State government, or any agency or instrumentality thereof.

(c) ADDITIONAL LIMITATIONS.—

(1) REIMPOSING PAPER PROHIBITED.—Nothing in subsection (b) (other than paragraph (3)(B) thereof) shall be construed to grant any Federal regulatory agency or State regulatory agency authority to impose or reimpose any requirement that a record be in a tangible printed or paper form.

(2) CONTINUING OBLIGATION UNDER GOVERNMENT PAPERWORK ELIMINATION ACT.—Nothing in subsection (a) or (b) relieves any Federal regulatory agency of its obligations under the Government Paperwork Elimination Act (title XVII of Public Law 105–277).

(d) AUTHORITY TO EXEMPT FROM CONSENT PROVISION.—

(1) IN GENERAL.—A Federal regulatory agency may, with respect to matter within its jurisdiction, by regulation or order issued after notice and an opportunity for public comment, exempt without condition a specified category or type of record from the requirements relating to consent in section 101(c) if such exemption is necessary to eliminate a substantial burden on electronic commerce and will not increase the material risk of harm to consumers.

(2) PROSPECTUSES.—Within 30 days after the date of enactment of this Act, the Securities and Exchange Commission shall issue a regulation or order pursuant to paragraph (1) exempting from section 101(c) any records that are required to be provided in order to allow advertising, sales literature, or other information concerning a security issued by an investment company that is registered under the Investment Company Act of 1940, or concerning the issuer thereof, to be excluded from the definition of a prospectus under section 2(a)(10)(A) of the Securities Act of 1933.

(e) ELECTRONIC LETTERS OF AGENCY.—The Federal Communications Commission shall not hold any contract for telecommunications service or letter of agency for a preferred carrier change, that otherwise complies with the Commission's rules, to be legally ineffective, invalid, or unenforceable solely because an electronic record or electronic signature was used in its formation or authorization.

SEC. 105. STUDIES.

(a) DELIVERY.—Within 12 months after the date of the enactment of this Act, the Secretary of Commerce shall conduct an inquiry regarding the effectiveness of the delivery of electronic records to consumers using electronic mail as compared with delivery of written records via the United States Postal Service and private express mail services. The Secretary shall submit a report to the Congress regarding the results of such inquiry by the conclusion of such 12-month period.

(b) STUDY OF ELECTRONIC CONSENT.—Within 12 months after the date of the enactment of this Act, the Secretary of Commerce and the Federal Trade Commission shall submit a report to the Congress evaluating any benefits provided to consumers by the procedure required by section 101(c)(1)(C)(ii); any burdens imposed on electronic commerce by that provision; whether the benefits outweigh the burdens; whether the absence of the procedure required by section 101(c)(1)(C)(ii) would increase the incidence of fraud directed against consumers; and suggesting any revisions to the provision deemed appropriate by the Secretary and the Commission. In conducting this evaluation, the Secretary and the Commission shall solicit comment from the general public, consumer representatives, and electronic commerce businesses.

SEC. 106. DEFINITIONS.

For purposes of this title:

(1) CONSUMER.—The term "consumer" means an individual who obtains, through a transaction, products or services which are used primarily for personal, family, or household purposes, and also means the legal representative of such an individual.

(2) ELECTRONIC.—The term "electronic" means relating to technology having electrical, digital, magnetic, wireless, optical, electromagnetic, or similar capabilities.

(3) ELECTRONIC AGENT.—The term "electronic agent" means a computer program or an electronic or other automated means used independently to initiate an action or respond to electronic records or performances in whole or in part without review or action by an individual at the time of the action or response.

(4) ELECTRONIC RECORD.—The term "electronic record" means a contract or other record created, generated, sent, communicated, received, or stored by electronic means.

(5) ELECTRONIC SIGNATURE.—The term "electronic signature" means an electronic sound, symbol, or process, attached to or logically associated with a contract or other record and executed or adopted by a person with the intent to sign the record.

(6) FEDERAL REGULATORY AGENCY.—The term "Federal regulatory agency" means an agency, as that term is defined in section 552(f) of title 5, United States Code.

(7) INFORMATION.—The term "information" means data, text, images, sounds, codes, computer programs, software, databases, or the like.

(8) PERSON.—The term "person" means an individual, corporation, business trust, estate, trust, partnership, limited liability company, association, joint venture, governmental agency, public corporation, or any other legal or commercial entity.

(9) RECORD.—The term "record" means information that is inscribed on a tangible medium or that is stored in an electronic or other medium and is retrievable in perceivable form.

(10) REQUIREMENT.—The term "requirement" includes a prohibition.

(11) SELF-REGULATORY ORGANIZATION.—The term "self-regulatory organization" means an organization or entity that is not a Federal regulatory agency or a State, but that is under the supervision of a Federal regulatory agency and is authorized under Federal law to adopt and administer rules applicable to its members that are enforced by such organization or entity, by a Federal regulatory agency, or by another self-regulatory organization.

(12) STATE.—The term "State" includes the District of Columbia and the territories and possessions of the United States.

(13) TRANSACTION.—The term "transaction" means an action or set of actions relating to the conduct of business, consumer, or commercial affairs between two or more persons, including any of the following types of conduct:

(A) the sale, lease, exchange, licensing, or other disposition of (i) personal property, including goods and intangibles, (ii) services, and (iii) any combination thereof; and

(B) the sale, lease, exchange, or other disposition of any interest in real property, or any combination thereof.

SEC. 107. EFFECTIVE DATE.

(a) IN GENERAL.—Except as provided in subsection (b), this title shall be effective on October 1, 2000.

(b) EXCEPTIONS.—

(1) RECORD RETENTION.—

(A) IN GENERAL.—Subject to subparagraph (B), this title shall be effective on March 1, 2001, with respect to a requirement that a record be retained imposed by—

(i) a Federal statute, regulation, or other rule of law, or

(ii) a State statute, regulation, or other rule of law administered or promulgated by a State regulatory agency.

(B) DELAYED EFFECT FOR PENDING RULEMAKINGS.—If on March 1, 2001, a Federal regulatory agency or State regulatory agency has announced, proposed, or initiated, but not completed, a rulemaking proceeding to prescribe a regulation under section 104(b)(3) with respect to a requirement described in subparagraph (A), this title shall be effective on June 1, 2001, with respect to such requirement.

(2) CERTAIN GUARANTEED AND INSURED LOANS.—With regard to any transaction involving a loan guarantee or loan guarantee commitment (as those terms are defined in section 502 of the Federal Credit Reform Act of 1990), or involving a program listed in the Federal Credit Supplement, Budget of the United States, FY 2001, this title applies only to such transactions entered into, and to any loan or mortgage made, insured, or guaranteed by the United States Government thereunder, on and after one year after the date of enactment of this Act.

(3) STUDENT LOANS.—With respect to any records that are provided or made available to a consumer pursuant to an application for a loan, or a loan made, pursuant to title IV of the Higher Education Act of 1965, section 101(c) of this Act shall not apply until the earlier of—

(A) such time as the Secretary of Education publishes revised promissory notes under section 432(m) of the Higher Education Act of 1965; or

(B) one year after the date of enactment of this Act.

TITLE II—TRANSFERABLE RECORDS

SEC. 201. TRANSFERABLE RECORDS.

(a) DEFINITIONS.—For purposes of this section:

(1) TRANSFERABLE RECORD.—The term "transferable record" means an electronic record that—

(A) would be a note under Article 3 of the Uniform Commercial Code if the electronic record were in writing;

(B) the issuer of the electronic record expressly has agreed is a transferable record; and

(C) relates to a loan secured by real property.

A transferable record may be executed using an electronic signature.

(2) OTHER DEFINITIONS.—The terms "electronic record", "electronic signature", and "person" have the same meanings provided in section 106 of this Act.

(b) CONTROL.—A person has control of a transferable record if a system employed for evidencing the transfer of interests in the transferable record reliably establishes that person as the person to which the transferable record was issued or transferred.

(c) CONDITIONS.—A system satisfies subsection (b), and a person is deemed to have control of a transferable record, if the transferable record is created, stored, and assigned in such a manner that—

(1) a single authoritative copy of the transferable record exists which is unique, identifiable, and, except as otherwise provided in paragraphs (4), (5), and (6), unalterable;

(2) the authoritative copy identifies the person asserting control as—

(A) the person to which the transferable record was issued; or

(B) if the authoritative copy indicates that the transferable record has been transferred, the person to which the transferable record was most recently transferred;

(3) the authoritative copy is communicated to and maintained by the person asserting control or its designated custodian;

(4) copies or revisions that add or change an identified assignee of the authoritative copy can be made only with the consent of the person asserting control;

(5) each copy of the authoritative copy and any copy of a copy is readily identifiable as a copy that is not the authoritative copy; and

(6) any revision of the authoritative copy is readily identifiable as authorized or unauthorized.

(d) STATUS AS HOLDER.—Except as otherwise agreed, a person having control of a transferable record is the holder, as defined in section 1–201(20) of the Uniform Commercial Code, of the transferable record and has the same rights and defenses as a holder of an equivalent record or writing under the Uniform Commercial Code, including, if the applicable statutory requirements under section 3–302(a), 9–308, or revised section 9–330 of the Uniform Commercial Code are satisfied, the rights and defenses of a holder in due course or a purchaser, respectively. Delivery, possession, and endorsement are not required to obtain or exercise any of the rights under this subsection.

(e) OBLIGOR RIGHTS.—Except as otherwise agreed, an obligor under a transferable record has the same rights and defenses as an equivalent obligor under equivalent records or writings under the Uniform Commercial Code.

(f) PROOF OF CONTROL.—If requested by a person against which enforcement is sought, the person seeking to enforce the transferable record shall provide reasonable proof that the person is in control of the transferable record. Proof may include access to the authoritative copy of the transferable record and related business records sufficient to review the terms of the transferable record and to establish the identity of the person having control of the transferable record.

(g) UCC REFERENCES.—For purposes of this subsection, all references to the Uniform Commercial Code are to the Uniform Commercial Code as in effect in the jurisdiction the law of which governs the transferable record.

SEC. 202. EFFECTIVE DATE.

This title shall be effective 90 days after the date of enactment of this Act.

TITLE III—PROMOTION OF INTERNATIONAL ELECTRONIC COMMERCE

SEC. 301. PRINCIPLES GOVERNING THE USE OF ELECTRONIC SIGNATURES IN INTERNATIONAL TRANSACTIONS.

(a) PROMOTION OF ELECTRONIC SIGNATURES.—

(1) REQUIRED ACTIONS.—The Secretary of Commerce shall promote the acceptance and use, on an international basis, of electronic signatures in accordance with the principles specified in paragraph (2) and in a manner consistent with section 101 of this Act. The Secretary of Commerce shall take all actions necessary in a manner consistent with such principles to eliminate or reduce, to the maximum extent possible, the impediments to commerce in electronic signatures, for the purpose of facilitating the development of interstate and foreign commerce.

(2) PRINCIPLES.—The principles specified in this paragraph are the following:

(A) Remove paper-based obstacles to electronic transactions by adopting relevant principles from the Model Law on Electronic Commerce adopted in 1996 by the United Nations Commission on International Trade Law.

(B) Permit parties to a transaction to determine the appropriate authentication technologies and implementation

models for their transactions, with assurance that those technologies and implementation models will be recognized and enforced.

(C) Permit parties to a transaction to have the opportunity to prove in court or other proceedings that their authentication approaches and their transactions are valid.

(D) Take a nondiscriminatory approach to electronic signatures and authentication methods from other jurisdictions.

(b) CONSULTATION.—In conducting the activities required by this section, the Secretary shall consult with users and providers of electronic signature products and services and other interested persons.

(c) DEFINITIONS.—As used in this section, the terms "electronic record" and "electronic signature" have the same meanings provided in section 106 of this Act.

TITLE IV—COMMISSION ON ONLINE CHILD PROTECTION

SECTION 401. AUTHORITY TO ACCEPT GIFTS.

Section 1405 of the Child Online Protection Act (47 U.S.C. 231 note) is amended by inserting after subsection (g) the following new subsection:

"(h) GIFTS, BEQUESTS, AND DEVISES.—The Commission may accept, use, and dispose of gifts, bequests, or devises of services or property, both real (including the use of office space) and personal, for the purpose of aiding or facilitating the work of the Commission. Gifts or grants not used at the termination of the Commission shall be returned to the donor or grantee.".

And the House agree to the same.

That the Senate recede from its disagreement to the amendment of the House to the title of the bill and agree to the same.

TOM BLILEY,
BILLY TAUZIN,
MICHAEL G. OXLEY,
JOHN D. DINGELL,
EDWARD J. MARKEY,
Managers on the Part of the House.

From the Committee on Commerce, Science, and Transportation:

JOHN MCCAIN,
CONRAD BURNS,
TED STEVENS,
SLADE GORTON,
SPENCER ABRAHAM,
ERNEST F. HOLLINGS,
DANIEL K. INOUYE,
JAY ROCKEFELLER,
JOHN F. KERRY,
RON WYDEN,

From the Committee on Banking, Housing, and Urban Affairs, for items within their jurisdiction:

PAUL S. SARBANES,

From the Committee on the Judiciary, for items within their jurisdiction:

ORRIN HATCH,
PATRICK LEAHY,
Managers on the Part of the Senate.

JOINT EXPLANATORY STATEMENT OF THE COMMITTEE OF CONFERENCE

The managers on the part of the House and Senate at the conference on the disagreeing votes of the two Houses on the amendments of the House to the bill (S. 761) to regulate interstate commerce by electronic means by permitting and encouraging the continued expansion of electronic commerce through the operation of free market forces, and for other purposes, submit the following joint statement to the House and the Senate in explanation of the effect of the action agreed upon by the managers and recommended in the accompanying conference report:

The House amendment to the text of the bill struck all of the Senate bill after the enacting clause, and inserted a substitute text.

The Senate recedes from its disagreement to the amendment of the House with an amendment that is a substitute for the Senate bill and House amendment.

The managers on the part of the House and Senate met on May 18, 2000, and reconciled the differences between the two bills.

TOM BLILEY,
BILLY TAUZIN,
MICHAEL G. OXLEY,
JOHN D. DINGELL,
EDWARD J. MARKEY,
Managers on the Part of the House.

From the Committee on Commerce, Science, and Transportation:

JOHN MCCAIN,
CONRAD BURNS,
TED STEVENS,
SLADE GORTON,
SPENCER ABRAHAM,
ERNEST F. HOLLINGS,
DANIEL K. INOUYE,
JAY ROCKEFELLER,
JOHN F. KERRY,
RON WYDEN,

From the Committee on Banking, Housing, and Urban Affairs, for items within their jurisdiction:

PAUL S. SARBANES,

From the Committee on the Judiciary, for items within their jurisdiction:

ORRIN HATCH,
PATRICK LEAHY,
Managers on the Part of the Senate.

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