The basis of approval is discussed in the freedom of information summary.

In addition, FDA is amending § 558.311 to remove redundant text in an entry for combination use of single-ingredient lasalocid and chlortetracycline in cattle feed which was published in error in the **Federal Register** of April 27, 2006 (71 FR 24816). This correction is being made to improve the accuracy of the regulations.

Approval of this supplemental NADA did not require review of additional safety or effectiveness data or information. Therefore, a freedom of information summary is not required.

The agency has determined under 21 CFR 25.33(a)(6) 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.

This rule does not meet the definition of ''rule'' in 5 U.S.C. 804(3)(A) because it is a rule of ''particular applicability.'' Therefore, it is not subject to the congressional review requirements in 5 U.S.C. 801–808.

List of Subjects in 21 CFR Part 558

Animal drugs, Animal feeds.

■ Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs and redelegated to the Center for Veterinary Medicine, 21 CFR part 558 is amended as follows:

PART 558—NEW ANIMAL DRUGS FOR USE IN ANIMAL FEEDS

■ 1. The authority citation for 21 CFR part 558 continues to read as follows:

Authority: 21 U.S.C. 360b, 371.

§ 558.311 [Amended]

■ 2. In § 558.311, in paragraph (b)(8), after the number ''15'' add the words ''and 20''; and in paragraph (e)(1)(xxvii) in the ''Indications for use'' column, remove ''control of control of'' and in its place add ''control of''.

Dated: September 15, 2006.

Steven D. Vaughn,

Director, Office of New Animal Drug Evaluation, Center for Veterinary Medicine.

[FR Doc. 06–8261 Filed 9–25–06; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

21 CFR Parts 1300, 1309, 1310, 1314

[Docket No. DEA–291I]

RIN 1117–AB05

Retail Sales of Scheduled Listed Chemical Products; Self-Certification of Regulated Sellers of Scheduled Listed Chemical Products

AGENCY: Drug Enforcement Administration (DEA), Justice.

ACTION: Interim final rule with request for comment.

SUMMARY: In March 2006, the President signed the Combat Methamphetamine Epidemic Act of 2005, which establishes new requirements for retail sales of over-the-counter (nonprescription) products containing the List I chemicals ephedrine, pseudoephedrine, and phenylpropanolamine. The three chemicals can be used to manufacture methamphetamine illegally. DEA is promulgating this rule to incorporate the statutory provisions and make its regulations consistent with the new requirements. This action establishes daily and 30-day limits on the sales of scheduled listed chemical products to individuals and requires recordkeeping on most sales.

DATES: *Effective Dates:* September 21, 2006, except that §§ 1314.20, 1314.25, and 1314.30 (with the exception of § 1314.30(a)(2)) are effective September 30, 2006. Section 1314.30(a)(2) is effective November 27, 2006.

Comment Date: Written comments must be postmarked on or before November 27, 2006.

ADDRESSES: To ensure proper handling of comments, please reference ''Docket No. DEA–291I'' on all written and electronic correspondence. Written comments being sent via regular mail should be sent to the Deputy Administrator, Drug Enforcement Administration, Washington, DC 20537, Attention: DEA Federal Register Representative/ODL. Written comments sent via express mail should be sent to DEA Headquarters, Attention: DEA Federal Register Representative/ODL, 2401 Jefferson-Davis Highway, Alexandria, VA 22301. Comments may be directly sent to DEA electronically by sending an electronic message to *dea.diversion.policy@usdoj.gov.* Comments may also be sent electronically through *http://www.regulations.gov* using the electronic comment form provided on that site. An electronic copy of this document is also available at the *http://www.regulations.gov* Web site. DEA will accept attachments to electronic comments in Microsoft word, WordPerfect, Adobe PDF, or Excel file formats only. DEA will not accept any file format other than those specifically listed here.

FOR FURTHER INFORMATION CONTACT: Mark W. Caverly, Chief, Liaison and Policy Section, Office of Diversion Control, Drug Enforcement Administration, Washington, DC 20537; telephone: (202) 307–7297.

SUPPLEMENTARY INFORMATION:

DEA's Legal Authority

DEA implements the Comprehensive Drug Abuse Prevention and Control Act of 1970, often referred to as the Controlled Substances Act (CSA) and the Controlled Substances Import and Export Act (21 U.S.C. 801–971), as amended. DEA publishes the implementing regulations for these statutes in Title 21 of the Code of Federal Regulations (CFR), Parts 1300 to 1399. These regulations are designed to ensure that there is a sufficient supply of controlled substances for legitimate medical, scientific, research, and industrial purposes and to deter the diversion of controlled substances to illegal purposes. The CSA mandates that DEA establish a closed system of control for manufacturing, distributing, and dispensing controlled substances. Any person who manufactures, distributes, dispenses, imports, exports, or conducts research or chemical analysis with controlled substances must register with DEA (unless exempt) and comply with the applicable requirements for the activity. The CSA as amended also requires DEA to regulate the manufacture and distribution of chemicals that may be used to manufacture controlled substances illegally. Listed chemicals that are classified as List I chemicals are important to the manufacture of controlled substances. Those classified as List II chemicals may be used to manufacture controlled substances.

On March 9, 2006, the President signed the Combat Methamphetamine Epidemic Act of 2005 (CMEA), which is Title VII of the USA PATRIOT Improvement and Reauthorization Act of 2005 (Pub. L. 109–177). DEA is promulgating this rule as an interim final rule rather than a proposed rule because the changes being made codify statutory provisions, some of which are already in effect. Parts of the statute are self-implementing; certain changes related to retail sales became effective upon signature (March 9, 2006), others

became effective on April 8, 2006, and still others will become effective September 30, 2006. An agency may find good cause to exempt a rule from certain provisions of the Administrative Procedure Act (APA) (5 U.S.C. 553), including notice of proposed rulemaking and the opportunity for public comment, if it is determined to be unnecessary, impracticable, or contrary to the public interest. Many of the requirements of the Combat Methamphetamine Epidemic Act of 2005 included in this rulemaking were set out in such detail as to be self-implementing. Therefore the changes in this rulemaking provide conforming amendments to make the language of the regulations consistent with that of the law. DEA is accepting comments on other aspects of this rulemaking, particularly those not specifically mandated by the Combat Methamphetamine Epidemic Act of 2005.

Combat Methamphetamine Epidemic Act of 2005

The Combat Methamphetamine Epidemic Act of 2005 (CMEA) amends the CSA to change the regulations for selling nonprescription products that contain ephedrine, pseudoephedrine, and phenylpropanolamine, their salts, optical isomers, and salts of optical isomers. CMEA creates a new category of products called ''scheduled listed chemical products.'' Ephedrine, pseudoephedrine, and phenylpropanolamine are List I chemicals because they are used in, and important to, the illegal manufacture of methamphetamine. Products containing these List I chemicals also have legitimate medical uses. Ephedrine is used in some products for treating asthma. Pseudoephedrine, a decongestant, is a common ingredient in cold and allergy medications. In November 2000, the Food and Drug Administration (FDA) issued a public health advisory concerning phenylpropanolamine and requested that all drug companies discontinue marketing products containing phenylpropanolamine due to risk of hemorrhagic stroke. In response, many companies voluntarily reformulated their products to exclude phenylpropanolamine. Subsequently, on December 22, 2005, FDA published a Notice of Proposed Rulemaking (70 FR 75988) proposing to categorize all over-the-counter nasal decongestants and weight control drug products containing phenylpropanolamine preparations as Category II, nonmonograph, *i.e.*, not generally recognized as being safe for human consumption. Most products containing phenylpropanolamine intended for humans have been withdrawn from the market, but phenylpropanolamine is still sold by prescription for veterinary uses.

Under previous CSA amendments (the Comprehensive Methamphetamine Control Act of 1996 (MCA) and the Methamphetamine Anti-Proliferation Act of 2000 (MAPA)), Congress limited the quantity of products containing ephedrine, pseudoephedrine, and phenylpropanolamine that could be sold as nonprescription drugs at retail (which were, along with certain liquid products, defined as ''ordinary over-the-counter pseudoephedrine or phenylpropanolamine products'') without recordkeeping, but generally exempted products sold in blister packs sold by ''retail distributors''. The MCA established thresholds for these drug products, including a threshold of 24 grams of combination ephedrine products; single-entity ephedrine products had been regulated by the Domestic Chemical Diversion Control Act of 1993 (Pub. L. 103–200). MAPA reduced existing thresholds for pseudoephedrine and phenylpropanolamine to 9 grams per transaction, with each package containing not more than 3 grams of pseudoephedrine base or phenylpropanolamine base, but retained the so-called ''blister pack'' exemption. Because most retail outlets did not want to create and maintain records of sales or register as a retail distributor, the threshold for recordkeeping functioned for practical purposes similarly to a sales limit. Much of the product was also sold in blister packs.

Congress determined that the existing limits were not sufficient to prevent people from buying these products and using them to illegally manufacture methamphetamine. In the Combat Methamphetamine Epidemic Act of 2005, Congress adopted provisions that do the following:

- Limit the quantity of each of the chemicals that may be sold to an individual in a day to 3.6 grams of the chemical, without regard to the number of transactions.
- For nonliquids, limit packaging to blister packs containing no more than 2 dosage units per blister. Where blister packs are not technically feasible, the product must be packaged in unit dose packets or pouches.
- Require regulated sellers to place the products behind the counter or in locked cabinets.
- Require regulated sellers to check the identity of purchasers and maintain a log of each sale that includes the purchaser's name and address, signature of the purchaser, product sold, quantity sold, date, and time.
- Require regulated sellers to maintain the logbook for at least two years.
- Require regulated sellers to train employees in the requirements of the law and certify to DEA that the training has occurred.
- For mobile retail vendors and mail order sales, require sellers to limit sales to an individual in a 30-day period to 7.5 grams.
- For individuals, limit purchases in a 30-day period to 9 grams, of which not more than 7.5 grams may be imported by means of a common or contract carrier or the U.S. Postal Service.

The numbers of dosage units and milliliters (mL) that may be purchased under the sales limits are shown in Table 1 below. As noted previously, the FDA issued a voluntary recall on phenylpropanolamine products as being unsafe for humans so no phenylpropanolamine over-the-counter (OTC) product should be available for human consumption. Veterinary use is by prescription only.

TABLE 1.—NUMBER OF TABLETS/MILLILITERS THAT EQUAL RETAIL TRANSACTION LIMITS (AS BASE) FOR SCHEDULED LISTED CHEMICAL PRODUCTS

Scheduled listed chemical product	Transaction limits		
	3.6 gm	7.5 gm	9.0 gm
	Tablets		
Ephedrine:			
25 mg Ephedrine HCl	175	366	439
25 mg Ephedrine Sulfate	186	389	466
Pseudoephedrine (as HCl):			

TABLE 1.—NUMBER OF TABLETS/MILLILITERS THAT EQUAL RETAIL TRANSACTION LIMITS (AS BASE) FOR SCHEDULED LISTED CHEMICAL PRODUCTS—Continued

Scheduled listed chemical product	Transaction limits		
	3.6 gm	7.5 gm	9.0 gm
30 mg Pseudoephedrine HCl	146	305	366
60 mg Pseudoephedrine HCl	73	152	183
120 mg Pseudoephedrine HCl	36	76	91
Pseudoephedrine (as Sulfate):			
30 mg Pseudoephedrine Sulfate	155	324	389
60 mg Pseudoephedrine Sulfate	77	162	194
120 mg Pseudoephedrine Sulfate	38	81	97
240 mg Pseudoephedrine Sulfate	19	40	48
	Number of mL		
Ephedrine:			
6.25 mg/5 ml Ephedrine HCl	3,515	7,323	8,788
Pseudoephedrine (as HCl):			
15 mg/1.6 mL Pseudoephedrine HCl	468	976	1,171
7.5 mg/5 mL Pseudoephedrine HCl	2,929	6,103	7,323
15 mg/5 mL Pseudoephedrine HCl	1,464	3,051	3,661
15 mg/2.5 mL Pseudoephedrine HCl	732	1,525	1,830
30 mg/5 mL Pseudoephedrine HCl	732	1,525	1,830
30 mg/2.5 mL Pseudoephedrine HCl	366	762	915
60 mg/5 mL Pseudoephedrine HCl	366	762	915

Provisions of CMEA

Overview. Before CMEA, requirements for sales of products containing ephedrine, pseudoephedrine, and phenylpropanolamine, which were then called regulated drug products or drug products regulated pursuant to 21 CFR 1300.02(b)(28)(i)(D), distinguished between in-person sales to a purchaser (retail distribution) and mail order sales, which covered any sale where the product is shipped using the Postal Service or any common or private carrier. Mail order sellers had to file monthly reports with DEA if they sold a purchaser drug products containing more than a threshold quantity (9 grams for pseudoephedrine and phenylpropanolamine (maximum per package of 3 grams), 24 grams for ephedrine combination products), regardless of how the products were packaged. Retailers conducting face-to-face transactions had to maintain records for sales above the same thresholds except that, as noted above, sales of products in blister packs generally were not covered. The status of such sales was discussed in detail in an interpretive rule (69 FR 2862, January 14, 2004; corrected at 69 FR 3198, January 22, 2004). Either type of seller had to register with DEA if they sold the products to individuals in amounts above the threshold quantity. Only two persons are registered as retail distributors.

The CMEA provisions on retail sales create differing requirements for the various types of retail sales. As discussed further below, Table 2 summarizes the applicability of the CMEA provisions as well as existing DEA provisions to the different types of sellers.

TABLE 2.—SUMMARY OF REQUIREMENTS BY TYPE OF SELLER

	Regulated sellers (store)	Mobile retail vendors	Mail order sellers
Daily sales limit	3.6 gm/chemical	3.6 gm/chemical	3.6 gm/chemical.
30-day sales limit		7.5 gm	7.5 gm.
Blister packs	Yes	Yes	Yes.
Storage	Behind the counter Locked cabinet.	Locked cabinet	NA.
Logbook	Yes	Yes	NA.
Customer ID	Examine photo ID	Examine photo ID	Verify ID.
Train employees	Yes	Yes	NA.
Self-Certify	Yes	Yes	NA.
Notice of misrepresentation	Yes	Yes	NA.
Monthly reports	No	No	Yes.
Theft and loss reports	Yes	Yes	Yes.

CMEA defines nonprescription drug products containing ephedrine, pseudoephedrine, or phenylpropanolamine as ''scheduled listed chemical products.'' Direct, in-person sales to a customer, whether at a permanent store or movable site (*e.g.*, kiosk, flea market), are subject to new requirements for training of employees who take part in the sale of scheduled listed chemical products and certification to DEA that the employees have been trained. These sellers, called ''regulated sellers'' in CMEA, must also check photo identifications of purchasers and maintain specific records of each sale of scheduled listed chemical products. Under CMEA, the

only sales exempt from recordkeeping are sales of single packages of pseudoephedrine where the package contains not more than 60 milligrams. DEA will issue future guidance to further clarify remaining questions about how regulated entities may meet this regulation's training requirements.

The recordkeeping and reporting requirements for mail order sales basically remain the same as under the previous regulations, except that a waiver in the prior law that covered non face-to-face distributions by retail distributors has been eliminated for scheduled listed chemical products. As a result, retail stores that deliver these products to customers by mail or delivery services will need to comply with the provisions for mail order sales reporting for these transactions. Mail order sellers must file monthly reports with DEA. CMEA adds the requirement that these sellers verify the purchaser's identity prior to shipping.

As noted above, CMEA changes the limits on retail sales. Daily sales are now limited to a maximum of 3.6 grams of each chemical in scheduled listed chemical products. Mobile retail vendors and mail order vendors must also limit sales to an individual purchaser to 7.5 grams of each chemical in scheduled listed chemical products in any 30-day period. CMEA limits purchases by an individual purchaser to 9 grams of each chemical in scheduled listed chemical products in any 30-day period, not more than 7.5 grams of which may be imported by means of a private or commercial carrier or the U.S. Postal Service. Any imports of scheduled listed chemical products subject to the 7.5 gram purchase limit under CMEA must also otherwise comply with all other applicable Federal and State laws regarding their importation, including the Federal, Food, Drug, and Cosmetic Act. This provision is not included in this rule, but will be addressed in other rulemakings DEA is promulgating to implement the various provisions of the Combat Methamphetamine Epidemic Act of 2005. Finally, CMEA exempts all retail sellers and mail order distributors selling the products at retail from registration. The following sections discuss each of the statutory provisions in more detail.

Definitions. CMEA revises the definition of ''*regulated transaction*,'' adds several new definitions, and removes the definition of ''*ordinary over-the-counter pseudoephedrine or phenylpropanolamine product.*'' CMEA adds a definition of ''*scheduled listed chemical product,*'' which means any nonprescription product that contains ephedrine, pseudoephedrine, or phenylpropanolamine and is marketed lawfully under the Federal Food, Drug, and Cosmetic Act. References to ephedrine, pseudoephedrine, or phenylpropanolamine include their salts, optical isomers, and salts of optical isomers. CMEA exempts scheduled listed chemical products sold at retail by a regulated seller or by persons that sell the product for personal use and ship the product by mail or private or common carriers (mail order sellers) from the definition of regulated transaction. It also removes other references to the sale of these chemicals in drug products from the definition of regulated transactions. DEA notes that further clarification regarding regulated transactions will be addressed in a separate rulemaking. These changes remove retail sellers and mail order sellers from the registration system; in practice, retail and mail order sellers have not registered because they limited sales to below threshold quantities and to products sold in blister packs. At present, only two persons are registered as retail distributors.

CMEA adds definitions of ''*regulated seller*,'' to mean a retail distributor (including a pharmacy and mobile retail vendors), and ''*at retail,*'' to mean sale or purchase for personal use. It also revises the definition of ''*retail distributor*'' to remove the sentence referring to below threshold quantities. This change subjects all sales, except for sales of single packages containing not more than 60 milligrams of pseudoephedrine, to recordkeeping requirements.

Sales limits. Effective April 8, 2006, CMEA limits sales to an individual to 3.6 grams per day of each chemical in scheduled listed chemical products regardless of the number of purchases. Mobile retail vendors and mail order sellers may not sell an individual more than 7.5 grams of each chemical in scheduled listed chemical products in a 30-day period. A seller who violates these provisions is subject to civil penalties and possible criminal penalties.

Purchase limits. CMEA imposes a 9 gram purchase limit in a 30-day period on individuals. Not more than 7.5 grams of the 9 grams may be imported by means of common/contract carrier or the U.S. Postal Service. Any imports of scheduled listed chemical products subject to the 7.5 gram purchase limit under CMEA must also otherwise comply with all other applicable Federal and State laws regarding their importation, including the Federal, Food, Drug, and Cosmetic Act. This provision is not included in this rule, but will be addressed in other rulemakings DEA is promulgating to implement the various provisions of the Combat Methamphetamine Epidemic Act of 2005. In other rulemakings based on new CMEA provisions, imports, other than this 30-day individual limit, are limited to DEA registrants that have been issued a quota to import. (These rulemakings will be separately published in the **Federal Register**.) A purchaser who violates these limits is subject to criminal penalties.

Thirty-day limit. CMEA creates a 30-day sales limit. DEA interprets this to mean a rolling calendar where the sales limit is based on sales to the purchaser in the previous 30 days. DEA interprets the per day limit to refer to midnight to midnight, not a rolling 24-hour clock.

Blister packs. Effective April 8, 2006, nonliquid forms of scheduled listed chemical products (including gel capsules) must be sold only in blister packs, with no more than two dosage units per blister unless blister packs are technically infeasible. In that case, the dosage units must be in unit dose packets or pouches.

Product placement: Behind counter or locked cabinet. CMEA requires that on and after September 30, 2006, scheduled listed chemical products must be stored behind the counter or, if in an area where the public has access, in a locked cabinet. Although DEA is not including cabinet specifications in the rule, a locked cabinet should be substantial enough that it cannot be easily picked up and removed. In a store setting, the cabinet should be similar to those used to store items, such as cigarettes, that can be accessed only by sales staff.

Logbooks. CMEA requires retail sellers to maintain logbooks on and after September 30, 2006. If a retailer maintains the logbook on paper, DEA is requiring that the logbook be bound, as is currently the case for records of sales of Schedule V controlled substances that are sold without a prescription. Bound blank logbooks and ledger books meeting DEA's regulatory requirements are readily available on the commercial market. If the logbook is maintained electronically, the records must be readily retrievable by the seller and any DEA or other authorized law enforcement official. Logs must be kept for two years from the date the entry was made. The logs must include the information entered by the purchaser (name, address, signature, date, and time of sale) and the quantity and form of the product sold.

Where the record is entered electronically, the computer system may enter the date and time automatically. An electronic signature system, such as

the ones many stores use for credit card purchases, may be employed to capture the signature for electronic logs. The information that the seller must enter may be accomplished through a point-of-sales system and bar code reader.

DEA is aware that in some cases, such as pharmacy counters where the computer is behind the pharmacy counter, it may be difficult for the purchaser to enter the information electronically. DEA is seeking comments on whether systems currently used to capture signatures for credit or debit card purchases can be reprogrammed to allow customers to enter name and address, as well as the signature. DEA also recognizes that some purchasers will find it difficult or impossible to enter the information themselves. In these cases, the seller should ask for the name and address and enter it, rather than simply copy it off the photo ID. Regardless of how the information is entered, however, there must be a mechanism to allow the customer to sign the logbook.

Verification of photo ID. CMEA requires on and after September 30, 2006, that an individual must present an identification card that includes a photograph and is issued by a State or the Federal government or a document considered acceptable under 8 CFR 274a.2(b)(1)(v)(A) and (B). Those documents currently include the following:

- United States passport (unexpired or expired).
- Alien Registration Receipt Card or Permanent Resident Card, Form I–551.
- An unexpired foreign passport that contains a temporary I–551 stamp.
- An unexpired Employment Authorization Document issued by the Immigration And Naturalization Service which contains a photograph, Form I–766; Form I–688, Form I–688A, or Form I–688B.
- In the case of a nonimmigrant alien authorized to work for a specific employer incident to status, an unexpired foreign passport with an Arrival-Departure Record, Form I–94, bearing the same name as the passport and containing an endorsement of the alien's nonimmigrant status, so long as the period of endorsement has not yet expired and the proposed employment is not in conflict with any restrictions or limitations identified on the Form I–94.

For individuals 16 years of age or older:

- A driver's license or identification card containing a photograph, issued by a State or an outlying possession of the United States. If the driver's license or identification card does not contain a photograph, identifying information shall be included such as: Name, date of birth, sex, height, color of eyes, and address.
- School identification card with a photograph.
- Voter's registration card.
- U.S. military card or draft record.
- Identification card issued by Federal, State, or local government agencies or entities. If the identification card does not contain a photograph, identifying information shall be included such as: Name, date of birth, sex, height, color of eyes, and address.
- Military dependent's identification card.
- Native American tribal documents.
- United States Coast Guard Merchant Mariner Card.
- Driver's license issued by a Canadian government authority.

For individuals under age 18 who are unable to produce a document from the list above of acceptable documents for persons age 16 years and older:

- School record or report card.
- Clinic doctor or hospital record.
- Daycare or nursery school record.

The list of acceptable forms of identification, as cited in CMEA, may change (''in effect on or after the date of enactment''). DEA has no discretion to alter the list.

Notice on misrepresentations. CMEA requires that on and after September 30, 2006, the logbooks include a notice to purchasers that entering false statements or misrepresentations may subject the purchaser to criminal penalties under section 1001 of title 18 of the U.S. Code. DEA is requiring the inclusion of the following language in all logbooks:

> **Warning:** Section 1001 of Title 18, United States Code, states that whoever, with respect to the logbook, knowingly and willfully falsifies, conceals, or covers up by any trick, scheme, or device a material fact, or makes any materially false, fictitious, or fraudulent statement or representation, or makes or uses any false writing or document knowing the same to contain any materially false, fictitious, or fraudulent statement or entry, shall be fined not more than $250,000 if an individual or $500,000 if an organization, imprisoned not more than five years, or both.

With both a bound logbook and electronic log, inclusion of this notice may present difficulties. If the purchaser is not able to enter the information electronically in a store, providing the notice electronically will not meet the requirements. If not feasible in these situations, one alternative is that the seller prominently display the notice where the purchaser will see it when entering or providing the information.

Verification of identity for mail order sales. The Controlled Substances Act (21 U.S.C. § 830(b)(3)) requires that each regulated person, as defined in the Act, who engages in a transaction that involves ephedrine, pseudoephedrine, or phenylpropanolamine (including drug products containing these chemicals) and uses or attempts to use the Postal Service or any private or commercial carrier shall, on a monthly basis, submit a report of each transaction conducted during the previous month to DEA. Data contained in the report includes, but is not limited to: Name of purchaser; quantity and form of ephedrine, pseudoephedrine, or phenylpropanolamine purchased; and the address to which such ephedrine, pseudoephedrine, or phenylpropanolamine was sent. DEA has specified further information regarding mail order reports by regulation (21 CFR 1310.05).

CMEA requires that effective April 8, 2006, the mail order seller confirm the identity of the purchaser prior to shipping the product. CMEA requires DEA to establish procedures for this identity verification by regulation. To parallel the identification requirements for regulated sellers, and to provide reasonable assurance that the person purchasing the product is who they claim to be, DEA is requiring that mail order sellers verify the identity of the purchaser by obtaining a copy of an identification card that includes a photograph and is issued by a State or the Federal government or a document considered acceptable under 8 CFR 274a.2(b)(1)(v)(A) and (B). Such a copy may be obtained through use of the Postal Service, facsimile transmission of a photocopy, or the scanning and transmission of the identification card, among other examples. The mail order seller must determine that the name and address on the identification card correspond to the name and address provided to the mail order seller as part of the sales transaction. If the information cannot be confirmed, the seller may not ship the items.

Selling at retail. CMEA requires that on and after September 30, 2006, a regulated seller must not sell scheduled listed chemical products unless it has self-certified to DEA, through DEA's Web site. The self-certification requires the regulated seller to confirm the following:

- Its employees who will be engaged in the sale of scheduled listed chemical products have undergone training regarding provisions of CMEA.
- Records of the training are maintained.
- Sales to individuals do not exceed 3.6 grams of ephedrine, pseudoephedrine, or phenylpropanolamine per day. (Mobile

retail vendors must also confirm that sales to an individual in a 30-day period do not exceed 7.5 grams.)

- Nonliquid forms are packaged as required.
- Scheduled listed chemical products are stored behind the counter or in a locked cabinet.
- A written or electronic logbook containing the required information on sales of these products is properly maintained.
- The logbook information will be disclosed only to Federal, State, or local law enforcement and only to ensure compliance with Title 21 of the United States Code or to facilitate a product recall.

The seller must train its employees and self-certify before either the seller or individual employees may sell scheduled listed chemical products. The self-certification is subject to the provisions of 18 U.S.C. 1001. A regulated seller who knowingly or willfully self-certifies to facts that are not true is subject to fines and imprisonment.

Training. DEA has developed training that it has made available on its Web site (*http://www.deadiversion.usdoj.gov*). Employers must use the content of this training in the training of their employees who sell scheduled listed chemical products. An employer may include additional content to DEA's, but DEA's content must be included in the training. For example, a regulated seller may elect to incorporate DEA's content into initial training for new employees.

Training records. On and after September 30, 2006, each employee of a regulated seller who is responsible for delivering scheduled listed chemical products to purchasers or who deals directly with purchasers by obtaining payment for the scheduled listed chemical products must undergo training and must sign an acknowledgement of training received prior to selling scheduled listed chemical products. This record must be kept in the employee's personnel file.

Self-certification. On and after September 30, 2006, the regulated seller must self-certify to DEA as described above. DEA has established a Web page that will allow regulated sellers to complete the self-certification on-line and submit it to DEA electronically. A self-certification certificate will be generated by DEA upon receipt of the application. The regulated seller will print this self-certification certificate, or if the regulated seller is unable to print it, DEA will print and mail the certificate to the self-certifier. The regulated sellers will be classified into three categories: Chain stores that are currently controlled substance registrants, chain stores that are not registrants, and individual outlets. Chain stores wishing to file self-certifications for more than 10 locations will have to print or copy the form electronically and submit the information to DEA by mail. DEA will work with these persons to facilitate this process. Persons interested in this self-certification option should contact DEA for assistance. For current DEA registrants, the system will pre-populate the form with basic information.

Because CMEA specifically states that a separate self-certification is required for each separate location at which scheduled listed chemical products are sold, mobile retail vendors must self-certify for each location at which sales transactions occur. This self-certification for locations is required even if the same person or persons sell at each of the different locations.

DEA requests comments on who should be authorized to sign the self-certification for the regulated seller. The person should be in a position to know that all employees who require training have been trained and that the retail outlet is complying with all other requirements and should be authorized to sign documents for the regulated seller.

Time for self-certification. CMEA requires that regulated sellers self-certify by September 30, 2006. Although CMEA appears to link self-certification to training of each individual who will deliver the products to customers, the high rate of employee turnover in the retail sector could require frequent submissions of self-certifications if the regulated seller needed to recertify each time a new employee is trained. DEA, therefore, will require regulated sellers to self-certify by September 30, 2006. When regulated sellers file the initial self-certification, DEA will assign them to groups. Each group will have an expiration date that will be the last day of a month from 12 to 23 months after the initial filing. After the second self-certification, regulated sellers will be required to self-certify annually. It is the responsibility of the regulated seller to ensure that all employees have been trained prior to self-certifying each time. It is also the responsibility of the regulated seller to ensure that they self-certify before the self-certification lapses. DEA requests comments on annual self-certifications versus certifications whenever new employees are trained or quarterly self-certification.

Fee for self-certification. In a separate Notice of Proposed Rulemaking, DEA is proposing that regulated sellers who are not DEA registrants pay a fee for self-certification. While DEA is not making this fee effective with this Interim Rule, DEA is providing background discussion and rationale for this decision here so that all persons will be aware of this issue.

Section 886a of the CSA defines the Diversion Control Program as ''the controlled substance and chemical diversion control activities of the Drug Enforcement Administration,'' which are further defined as the ''activities related to the registration and control of the manufacture, distribution and dispensing, importation and exportation of controlled substances and listed chemicals.'' The CSA also states that reimbursements from the Diversion Control Fee Account ''* * * shall be made without distinguishing between expenses related to controlled substances activities and expenses related to chemical activities.'' [Pub. L. 108–447 Consolidated Appropriations Act of 2005].

In addition, Section 111(b)(3) of the Departments of Commerce, Justice, and State, the Judiciary, and Related Agencies Appropriations Act of 1993 (Pub. L. 102–395), codified at 21 U.S.C. 886a(3), requires that ''fees charged by the Drug Enforcement Administration under its diversion control program shall be set at a level that ensures the recovery of the full costs of operating the various aspects of that program.''

CMEA implements new requirements governing the sale of scheduled listed chemical products, defined as nonprescription drug products containing ephedrine, pseudoephedrine, or phenylpropanolamine. CMEA requires self-certification for all regulated sellers of scheduled listed chemical products. CMEA also exempts retail distributors from registration requirements under the CSA; however, in practice, retail distributors have not previously registered with DEA because they limited their sales to below threshold quantities and to products sold in blister packs.

DEA considers the self-certification requirements of the CMEA to fall within the legal definition of control as governed by Section 886a of the CSA (see above). Accordingly, these activities fall under the general operation of the Diversion Control Program and are subject to the requirements of the Appropriations Act of 1993 that mandates that fees charged shall be set at a level that ensures the recovery of the full costs of operating the various aspects of the Diversion Control Program. The self-certification requirements of CMEA fall under these

''various aspects.'' Therefore, in its Notice of Proposed Rulemaking, DEA will propose to charge a fee for each self-certification to comply with these statutory requirements.

DEA is proposing, in its separate Notice of Proposed Rulemaking, that the fee for self-certification will cover all associated costs, including the initial one-time costs of setting up the self-certification program, Web site, and programmatic infrastructure, as well as ongoing costs associated with the provision of self-certifications, call center support, maintenance of the self-certification system, printing costs for certificates that regulated sellers cannot print, financial management, and other related costs. DEA must establish a program to train its employees to provide information regarding, and accept, self-certifications and must establish the infrastructure necessary for the program. Required systems include creation of history, renewal cycles, investigative tools, business validation rules, and development and maintenance of the self-certification Web site.

In its Notice of Proposed Rulemaking, DEA is proposing that when regulated sellers submit a self-certification online via the DEA self-certification Web site that they pay a fee by credit card at the time of self-certification. DEA calculated this fee based on estimated set-up costs in Fiscal Year 2006 ($117,198) and Fiscal Year 2007 operating costs ($1,624,443) totaling $1,741,641, as shown below in Table 3. The initial systems development and set-up costs will not be repeated in subsequent years. The operational and maintenance costs for Fiscal Year 2008 are estimated to be $1,099,782. Total annual costs associated with operating the self-certification process include staff costs, operational and administrative costs, Web hosting, monitoring and maintenance costs (including hardware and software maintenance), and annual inflation adjustments. Therefore, DEA will propose in its separate Notice of Proposed Rulemaking, that the 89,000 persons DEA estimates will self-certify with the Administration would pay a self-certification fee of $32 for the Fiscal Year 2006 through Fiscal Year 2008 period.

To calculate the fee, DEA divided the total costs for Fiscal Years 2006 through 2008 by the anticipated population of affected regulated sellers of 89,000. DEA estimates 89,000 current retail vendors of scheduled listed chemical products. All costs are shown in the table below for Fiscal Years 2006 through 2008. The self-certification costs reflect the cost per each self-certification per each facility as required by CMEA.

TABLE 3.—SELF-CERTIFICATION COSTS AND FEE CALCULATION

Project detail	2006 *	2007	2008	Total cost
Planning [1]	$3,029	$36,343	$37,002	$76,373
Design, Development, Deployment [2]	43,512	703,863	71,662	819,037
Call center, Finance, Mail room, Printing [3]	59,253	711,034	723,916	1,494,203
Maintenance [4]	11,405	173,203	176,341	360,949
Enhancements [5]	.....	90,861	90,861	
Total	117,198	1,624,443	1,099,782	2,841,423
Population	.....	89,000	89,000	.....
Cost per certification	.....	.....	.....	31.92

[1] Planning is the costs to the government to plan the development, design, and implementation of the self-certification online system. This item is the costs of three percent of the time used by five government employees to supervise and manage software development.

[2] Design, development and deployment of the online self-certification system represents the cost to pay contract programmers, web designers, system administrators and database administrators to design, develop, and deploy the new application. These costs include testing and quality assurance of the new software and establishment of new security controls. The self-certification system will be designed with business validation rules and provide investigative tools to ensure compliance with the new legislation.

[3] Call Center, finance, mail room and printing represent the following costs.

- DEA currently operates a registration Call Center. Based on current Call Center customer service representative costs, this item includes the cost of the additional time required to respond to inquiries regarding the CMEA self-certification program. DEA provides call center assistance to approximately 400,000 persons annually. DEA estimates that CMEA will increase that population by 89,000 persons, a 23% increase.
- DEA currently operates a registration Finance Center. Based on current Finance Center employee costs, this item includes the cost of the additional time required to process fees collected from CMEA self-certifications.
- DEA currently operates a registration Mail Room. Based on current Mail Room clerical costs, this item includes cost of employee time for handling and mailing out of CMEA self-certification certificates if the self-certifier is unable to print the certificate.
- DEA currently operates a Printing and Mailing Facility. Based on current Printing Costs, this item includes paper, toner, envelope, and post-age costs to mail out the CMEA self-certification certificates.

[4] Maintenance. This item includes all employee salaries, hardware maintenance, and software license costs associated with the daily operation of the self-certification system.

[5] Enhancements. This item is the enhancement of the system to add the ability to maintain a history of changes to records and to allow for yearly renewal of records.

* 2006 is for 1 month of operations.

To minimize administrative and collection burdens, it is DEA's policy to round to the nearest dollar when calculating fees. The annual self-certification fee will be clearly defined on the self-certification Web site. However, in setting this fee DEA notes that it is based on assumptions about the total number of regulated sellers who will be required to self-certify. Should the total number of regulated sellers be significantly more or less than 89,000, DEA may adjust the self-certification fee as appropriate through future rulemakings. In any case, DEA will not exceed its operating budget as authorized by Congress.

In implementing this fee, DEA also notes that many of the affected regulated sellers are already registered with DEA to dispense controlled substances and therefore already pay a registration/reregistration fee to DEA. While these existing registrants are required by the CMEA to self-certify with DEA if selling scheduled listed chemical products, in its Notice of Proposed Rulemaking, DEA is proposing that the self-certification fee be waived upon submission of an active DEA registration number.

Other DEA activities associated with self-certification and compliance with CMEA include enforcement and judicial proceedings. CMEA gives DEA the authority to prohibit a regulated seller

from selling scheduled listed chemical products for certain violations of CMEA. If DEA issues an order to a regulated seller prohibiting that regulated seller from selling scheduled listed chemical products, the regulated seller is entitled to an administrative hearing if the seller files a timely request for a hearing. The costs of these enforcement activities and the subsequent proceedings must be supported through fees pursuant to the above described statutory requirements. DEA notes that these costs are not recovered in these fee calculations as DEA is uncertain of their utilization. However, once DEA is able to determine the frequency of use of these tools, and their associated costs, these costs will be recovered through fees associated with self-certification as established in future rulemakings.

Relationship to State Laws

Many States have enacted laws and/or regulations that impose conditions on the sale of scheduled listed chemical products.

- Eight states have enacted and six others have proposed legislation that makes these products Schedule V controlled substances. Among other requirements, Schedule V substances may be sold only by a pharmacist to individuals who are at least 18. A logbook of the sales must be maintained.
- Sixteen states have passed laws limiting sales to a pharmacist or pharmacy technicians or requiring that the products be stored behind the counter.
- Twenty-seven states require a photo ID for such purchases.
- Twenty-six states require a signed logbook.
- Twenty-seven states impose single transaction limits.
- Nineteen states have monthly or weekly limits.
- Twenty-seven states have exemptions for prescription drugs and various forms of over-the-counter (OTC) drugs (liquids, pediatric forms, *etc.*).
- One state requires a prescription to purchase these products.

As the list indicates, the State laws vary considerably. Some parts of a State law may be less stringent than the CMEA requirements; other parts may be more stringent. CMEA does not preempt those requirements under State laws/regulations that are more stringent than the CMEA requirements. Simply put, all persons subject to CMEA must comply with the CMEA and the laws in the State(s) in which they sell scheduled listed chemical products at retail. Where the CMEA is less stringent than a State law (*e.g.*, the State limits sales to licensed pharmacists or pharmacy technicians where CMEA does not), the State requirements continue to be in force. If there are State requirements that are less stringent than the CMEA provisions (*e.g.*, higher daily limits, exemptions of some products), CMEA supersedes the provisions. DEA emphasizes that if State requirements for records cover the information CMEA mandates, the record created to meet the State law is sufficient to meet DEA's regulation.

Regarding quantity sold, units may be specified in terms of the weight of the product or in terms of the number of packages sold. Logbook systems that display the quantity of the product sold by UPC code are sufficient to meet DEA's requirements. These options do not exclude other methods of displaying the quantity sold.

DEA is accepting public comment on the interaction between state and federal logbook requirements. In addition, DEA is accepting public comment on the broader interplay and potential overlap between state regulations and CMEA requirements, and whether compliance with state regulations, if comparable to or more stringent than an associated CMEA requirement, should constitute compliance with such Federal requirement.

Discussion of the Rule

To make the rule easier to follow for regulated sellers and mail order/Internet sellers, DEA is creating a new part 1314 that will include all requirements related to the sale of scheduled listed chemical products to end users. Regulations for the retail sale of these products that currently exist in part 1310 will either be moved, if still applicable, or removed. The new statutory definitions of ''scheduled listed chemical product,'' ''regulated seller,'' ''mobile retail vendor,'' and ''at retail'' are being added to part 1300 (Definitions). The definition of ''retail distributor'' is also being revised. Most of the new provisions in this Interim Final Rule are drawn from section 711 of the USA PATRIOT Improvement and Reauthorization Act of 2005.

Part 1314 is divided into four subparts. Subpart A contains requirements that apply to any retail sale. Subpart B applies to sales by regulated sellers (*i.e.*, sales for personal use, both in number of sales and volume of sales, either directly to walk-in customers or in face-to-face transactions, by stores or mobile retail vendors). Subpart C applies to retail sales that are shipped by mail or common or private carriers, regardless of how those sales are ordered. Subpart D contains the procedural requirements for issuing and responding to an order to show cause why the regulated seller or distributor should not be prohibited from selling scheduled listed chemical products.

Sections 1314.01 and 1314.02 simply state the scope and applicability of the part. Section 1314.03 defines ''mail order sales'' using the language from § 1310.03(c) and further clarifies that mail order includes any retail sale for personal use where the product is shipped by U.S. mail or by private or common carriers whether the order is received by mail, phone, fax, the Internet, or any method other than a face-to-face transaction.

Section 1314.05 incorporates the statutory requirement for blister packs for nonliquids unless such packaging is not technically feasible.

Section 1314.10 states the regulations do not preempt State laws unless there is a positive conflict between the laws and the regulations such that the two cannot consistently stand together. This language is drawn from 21 U.S.C. 903.

Section 1314.15 copies the requirements for reporting losses, including thefts, that currently exist in § 1310.06. DEA emphasizes that thefts must be reported as well as unusual or excessive losses or disappearances.

In subpart B, § 1314.20 includes the statutory requirements limiting sales, the daily limit of 3.6 grams and the 30-day mobile retail vendor limit of 7.5 grams. The 30-day limit of 9 grams applies to purchasers who are not addressed by this regulation. As noted previously, this provision is not included in this rule, but will be addressed in other rulemakings DEA is promulgating to implement the various provisions of the Combat Methamphetamine Epidemic Act of 2005.

Section 1314.25 incorporates CMEA's provisions for storing the products behind the counter or in a locked cabinet. Mobile retail vendors are required to store the product in a locked cabinet.

Section 1314.30 covers recordkeeping (logbook) requirements from CMEA as well as requirements currently in § 1310.04. In addition to CMEA's requirements, DEA has copied the existing requirements from part 1310 relative to where the records must be kept (at the place of business or at a central location if DEA has been notified). DEA is including in this section language stating that if a regulated seller is already maintaining records of these sales under State law, those records may be used to meet this requirement if they include the information specified in CMEA.

The part 1310 requirements incorporated into the amended regulations do not include the provision that a regulated seller with multiple locations must have a system to detect a person purchasing from multiple locations owned or operated by the regulated seller. CMEA in section 711(f) provides for a civil penalty for a person who sells at retail a scheduled listed chemical product in violation of the daily 3.6 gram sales limit, ''knowing at the time of the transaction involved (independent of consulting the logbook * * *) that the transaction is a violation.'' While the availability of civil penalties is not necessarily co-extensive with the chemical control requirements of the new law, DEA is not mandating, by this rule, that regulated sellers, other than mail order and mobile retail vendors, track multiple sales to individuals on a single day within the same retail outlet or across outlets of the same company. CMEA explicitly requires mail order outlets and mobile retail vendors to limit sales to an individual to 7.5 grams in a 30-day period; it imposes no similar requirement on other retail sellers to limit 30-day sales to individuals. The 30-day limit of 9 grams is imposed on the purchaser, not the seller.

Section 1314.35 incorporates the statutory requirements for training of sales personnel. DEA has developed training material, which it has made available on its Web site (*http://www.deadiversion.usdoj.gov*).

Section 1314.40 covers CMEA's requirements on self-certification. As discussed above, DEA is setting an annual period for renewal of the certification.

DEA has developed a web site that will allow many regulated sellers to complete and submit the self-certification form on line and print out a self-certification certificate for their records. The information required will include the name and address of the location and a point of contact. The regulated sellers will be classified into three categories: Chain stores that are currently controlled substance registrants, chain stores that are not registrants, and individual outlets. Chain stores wishing to file self-certifications for more than 10 locations will have to print or copy the form electronically and submit the information to DEA by mail. DEA will work with these persons to facilitate this process. Persons interested in this self-certification option should contact DEA for assistance. For current DEA registrants, the system will pre-populate the form with basic information.

Section 1314.45 incorporates the privacy protection provisions of CMEA. These provisions define who may access the sales records and the use to which the data may be put. They also provide a good faith protection to regulated sellers that release the data to law enforcement authorities.

Section 1314.50 includes CMEA's provision that states that a seller may take reasonable measures to guard against employing people who may present a risk of diversion. The measures may include asking about convictions of any crimes involving controlled substances or scheduled listed chemical products.

In subpart C, § 1314.100 incorporates the daily and 30-day sales limits for mail order sales. Section 1314.105 provides the above described requirements for verifying identity of the purchaser prior to shipment of the product. Section 1314.110 covers reports on mail order sales and is copied from § 1310.06. Finally, § 1314.115 copies language from § 1310.05(f) on distributions not subject to reporting (sample packages, sales to long-term care facilities, prescription drugs).

CMEA added to 21 U.S.C. 842 a provision that authorizes DEA to prohibit a regulated seller or a mail order seller from selling scheduled listed chemical products if the seller is found to be knowingly or recklessly in violation of the provisions controlling retail sales. To take this step, DEA must issue an order to show cause, as it does to suspend or revoke registrations. DEA is including in subpart D in §§ 1314.150 and 1314.155 provisions on the process of issuing and responding to an order to show cause. These sections are taken from part 1309 and are the same as DEA uses to issue and reach a conclusion on orders to show cause under other DEA programs. If DEA issues an order to show cause, the regulated seller or mail order distributor must respond to the order to show cause within 30 days of service of the order to show cause. The regulated seller or mail order seller may request a hearing. The seller may continue to sell scheduled listed chemical products until DEA issues a final order. If DEA finds that a regulated seller or mail order distributor poses an imminent danger to public health or safety, DEA may suspend the seller's right to sell scheduled listed chemical products pending a final decision on the order to show cause.

Other Changes

As noted above, CMEA's new definitions will be added to § 1300.02. In addition, the definition of ''regulated transaction'' is revised as mandated by section 712 of CMEA.

In § 1309.71, paragraph (a)(2), which requires certain ephedrine products to be stored behind the counter, is being removed because the new CMEA requirements supersede it. CMEA imposes the same restrictions on all scheduled listed chemical products unless they are stored in a locked cabinet in areas where the public has access.

In § 1310.04, paragraph (f)(1)(ii) is revised to indicate that the thresholds presented in the previous paragraph and in paragraph (g) for ephedrine, pseudoephedrine, and phenylpropanolamine apply only to non-retail distribution, import, and export and references part 1314 for retail sales. The table of thresholds for retail distribution has been removed.

In § 1310.05, paragraph (f)(2) is revised to remove retail sales of scheduled listed chemical products.

Sections 1310.14 and 1310.15 are being removed because the CSA no longer treats certain ephedrine products differently from other scheduled listed chemical products. These sections are being replaced by new § 1310.16, which states that a manufacturer may apply to have a scheduled listed chemical product exempted from the requirements if DEA determines that the product cannot be used in the illicit manufacture of methamphetamine. DEA is adopting the application process that currently applies to ephedrine products that include other medically significant ingredients (§ 1310.14).

Regulatory Certifications

Administrative Procedure Act (5 U.S.C. 553)

The Administrative Procedure Act (APA) generally requires that agencies, prior to issuing a new rule, publish a Notice of Proposed Rulemaking in the **Federal Register**. The APA also provides, however, that agencies may be excepted from this requirement when ''the agency for good cause finds (and incorporates the finding and a brief statement of reasons therefore in the rules issued) that notice and public procedure thereon are impracticable, unnecessary, or contrary to the public interest.'' 5 U.S.C. 553(b)(B).

With publication of this interim rule, DEA is invoking this ''good cause'' exception to the APA's notice requirement based on the combination of several extraordinary factors. CMEA requires that on and after September 30, 2006, regulated sellers selling scheduled listed chemical products at retail shall self-certify with DEA in order to

continue to sell these products. CMEA imposes sales limits, purchase limits, product placement requirements, mail order customer identification requirements, and other requirements, some of which must be specified by regulation, all with an effective date of September 30, 2006. Based on the effective date of this law, it is impracticable for DEA to comply with the APA's notice and comment requirements due to the limited time involved. Were DEA not to publish this Interim Rule with Request for Comment, regulated sellers selling scheduled listed chemical products at retail would not be able to self-certify by the date specified in the law. Were this not to occur, these regulated sellers would be forced to stop selling scheduled listed chemical products, or violate the law by doing so. Mail order distributors would also have difficulty, as DEA is required by regulation to establish procedures for these persons to identify their customers prior to shipping product. Without these regulations, mail order distributors would not be able to sell scheduled listed chemical products. Therefore, DEA also finds that it is contrary to the public interest not to issue these regulations as an Interim Rule, thereby allowing regulated sellers and mail order distributors to fully comply with the requirements of CMEA. While the CMEA was signed into law in March of 2006, most of the law must be in effect by September 30, 2006. The broad scope of the new law, as well as the expedited effective dates, is a clear reflection of Congress's concern about the nation's growing methamphetamine epidemic and its desire to act quickly to prevent further illicit use of these chemicals.

In light of these factors, DEA finds that ''good cause'' exists to issue this interim rule without engaging in traditional notice and comment rulemaking. In so doing, DEA recognizes that exceptions to the APA's notice and comment procedures are to be ''narrowly construed and only reluctantly countenanced.'' Am. Fed'n of Gov't Employees v. Block, 655 F2d 1153, 1156 (D.C.Cir. 1981) (quoting New Jersey Dep't of Envtl. Prot. v. EPA, 626 F.2d 1038, 1045 (D.C.Cir. 1980)). Based on the totality of the circumstances associated with the CMEA, however, DEA finds that invocation of the ''good cause'' exception is justified.

As noted throughout this document, DEA is seeking comments on details of implementation, particularly related to self-certification, where it has discretion.

Under section 553(d) of the APA, DEA must generally provide a 30-day delayed effective date for final rules. DEA may dispense with the 30-day delayed effective date requirement ''for good cause found and published with the rule.'' Since it would be unnecessary to provide a delayed effective date for a change to the law that has already taken effect DEA has dispensed with the 30-day delayed effective date requirement. The sales limits and blister pack provisions became effective on April 8, 2006. The requirements for logbooks, training, and self-certification become effective September 30, 2006.

Regulatory Flexibility Act

The Deputy Administrator hereby certifies that this rulemaking has been drafted in accordance with the Regulatory Flexibility Act (5 U.S.C. 605(b)). The Regulatory Flexibility Act (RFA) applies to rules that are subject to notice and comment. Because this rule is simply codifying statutory provisions, DEA has determined, as explained above, that public notice and comment are not necessary. Consequently, the RFA does not apply. Where DEA has discretion in the way in which provisions of CMEA are implemented, however, DEA is seeking public comment and has sought, through the development of training materials and Web sites for self-certification, to reduce the cost to small entities.

Although the RFA does not apply to this final rule, DEA has reviewed the potential impacts. The rule will affect a substantial number of small entities, but DEA does not believe that it will have a significant economic impact on small entities. As shown in the next section, OTC medications as a whole represent less than two percent of sales except for drug stores and mail order houses. Even the highest estimate of the value of scheduled listed chemical products represents less than 10 percent of the OTC market. Consequently, the loss of sales, if that occurs, will reduce sales at most by a fraction of one percent, not a significant economic impact. DEA expects that regulated sellers will decide whether their sale of the products is great enough to justify the cost of compliance or whether they can retain sufficient sales revenues by shifting to non-regulated substitutes. The smallest stores, which DEA expects to be convenience stores, may limit their sales of the products to individual transactions involving packages containing not more than 60 milligrams of pseudoephedrine, which would allow them to avoid the recordkeeping requirements. In this case, their total cost of compliance could be about $50 for training and self-certification. DEA is specifically seeking public comments regarding the cost of this regulation to small entities, using a pre-statutory baseline of comparison (*i.e.*, the state of the market prior to the Combat Methamphetamine Epidemic Act of 2005).

Although not directly the subject of this rule, manufacturers and distributors will be affected by a reduction in sales of these products. The manufacturers of scheduled listed chemical products are also the manufacturers of the substitutes being marketed and the distributors handle both product lines; DEA has not been able to identify any manufacturer of these products that does not also market substitute products. DEA expects that the primary impact will be limited to reduction in sales that occurs because diversion is curbed. If the sales restrictions and quotas reduce the United States' demand for these chemical products, the world production of the chemicals is likely to drop, which will make less available to be diverted to superlabs operated by drug cartels. DEA seeks comments on impacts on manufacturers and distributors.

Executive Order 12866

The Deputy Administrator further certifies that this rulemaking has been drafted in accordance with the principles in Executive Order 12866 § 1(b). It has been determined that this is ''a significant regulatory action.'' Therefore, this action has been reviewed by the Office of Management and Budget. As discussed above, this action is codifying statutory provisions and involves no agency discretion. However, DEA has reviewed the potential benefits and costs following OMB Circular A–4.

The CMEA requirements impose the following costs on regulated sellers:

- Training of employees who sell scheduled listed chemical product sales (0.5 hours).
- Time to file the self-certification (0.5 hours).
- Costs for logbooks ($47.55) or creating an electronic record system.
- Additional time per sale to verify purchaser IDs and enter information into the logbook (1 to 2 minutes).
- Storage space behind the counter or in locked cabinets ($200-$600).

DEA is seeking comments regarding all of the above assumptions and estimates.

The requirements may also affect the sales at regulated sellers. If a seller decides to avoid the requirements by eliminating the product line or selling only the available substitutes, some customers may seek the products from sellers that continue to carry them. Regulated sellers, manufacturers, and distributors will also see some reduction

in sales as a result of diversion from regulated sellers becoming more difficult.

Although DEA has estimated the unit cost of training, certification, logbooks, logbook entries, and storage space, DEA cannot estimate the total cost of the rule because the following critical items are unknown:

- The value of the existing market in these products and the number of transactions that this market represents.
- The number of stores that currently sell these products.
- The number and type of stores that will continue to sell the products, the number that will elect to sell only the substitutes, and the number that will limit sales of the products to individual transactions involving not more than one 60-milligram or two 30-milligram pseudoephedrine dosage units, which would not require recordkeeping, the most expensive part of compliance.
- The number of customers who will seek out these products rather than purchase substitutes available on open shelves.
- The number of stores that will elect to use bound logbooks versus using electronic systems.
- The number of existing electronic signature capture systems that are capable of accepting or linking to name and address records.
- The percentage of existing sales (and theft of the product) that is being diverted to illicit use.

DEA is seeking comments and data from the industry that would help address these items and provide an estimate of the impact. DEA recognizes that the answers to some of these issues will evolve over time as regulated sellers and manufacturers adjust to consumer choices. For example, regulated sellers may see little impact beyond the initial costs of training and self-certification if most consumers elect to purchase the substitute products that are already available under the same brand names as scheduled listed chemical products, either because the consumers are unaware of the product change, because the substitutes meet the consumers' needs, or because they are unwilling to spend extra time to buy scheduled listed chemical products.

Regulated Sellers. The 2002 Economic Census data on product line sales indicate that about 92,000 retailers sell OTC medications. These include pharmacies, grocery stores, discount stores, warehouse clubs and superstores, convenience stores, variety stores, and mail order stores. In addition, up to 40,000 gas stations with convenience stores may sell OTC drug products. The number of retailers in each sector, the number with pharmacies, the number that sell nonprescription OTC drugs, and the percentage of their sales represented by OTC drugs are shown in Table 4 below. DEA solicits comments on the number of these entities that sell these products.

TABLE 4.—SECTORS SELLING SCHEDULED LISTED CHEMICAL PRODUCTS

NAICS	Total number	Number w pharmacy	Number w OTC	Percent without pharmacy	OTC as percent of total sales *
44511 Grocery stores	66,150	19,721	26,029	70.2	1.30
44611 Pharmacy and drug stores	40,234	39,121	36,493	2.8	5.70
452112 Discount department stores	5,650	4,887	2,079	13.5	1.80
45291 Warehouse clubs and superstores	2,912	2,553	2,758	12.3	1.20
Subtotal	114,946	66,282	67,359		
44512 Convenience stores	29,212	370	12,399	98.7	1.60
44711 Gas stations with convenience stores	93,691	0	** 40,068	100	** 1.10
45299 All other general merchandise stores ***	28,456	577	11,840	98	1.20
4541 Electronic shopping and mail order houses	15,910	453	250	97.2	13
Total	167,269	1,400	24,489–64,557		

* For those firms that handle the product line.
** Drugs, health aids, beauty aids including cosmetics.
*** Includes variety stores.

Even if all gas stations with convenience stores sold OTC drugs, there would be fewer of these establishments than exist in the main sectors selling OTC drugs. Most gas stations and convenience stores do not have pharmacies; OTC products represent a very small percentage of sales for them.

DEA cannot determine what percentage of those selling OTC drugs sell scheduled listed chemical products, although it is likely that outlets that have pharmacies sell these products. Because 16 States representing 27 percent of the U.S. population already limit sales of these products to pharmacies, DEA estimates that the number of potentially regulated entities is between 89,000 and 118,000.[1] This estimate does not specifically include mobile retail vendors, but DEA does not believe that they constitute a large segment of retail sellers. The actual number could be lower; many of the stores, particularly convenience stores, do not carry a full range of OTC drug products, and some may not sell this category of drugs. DEA seeks comment on this issue. Conversely, large mail order distributors may handle large quantities of scheduled listed chemical products. DEA also seeks comment on the number, size, and sales of mail order entities.

Substitutes. As discussed above, many States have imposed sales restrictions on scheduled listed chemical products prior to CMEA. In reaction to those restrictions and to concern about diversion of their products, manufacturers have reformulated many product lines to alternative decongestants that cannot be used to make methamphetamine. These substitutes are being sold under the same product names and in boxes that look the same as those used for scheduled listed chemical products. One major manufacturer expected to have converted half of its decongestant product line to substitutes by January 2006. Two of the largest drug store

[1] The 27 percent is a conservation estimate; the 16 states represents 28 percent of the convenience stores in the country and 35 percent of the gas stations with convenience stores.

chains do not list scheduled listed chemical products on their online stores, but offer more than 60 cold medications containing other ingredients.

At present, there is little information on how consumers will react to sales restrictions. On April 7, 2004, Oklahoma made pseudoephedrine products Schedule V controlled substances, but exempted gel caps and liquids. According to IRI InfoScan, in the 52 weeks after implementation, sales of all pseudoephedrine products fell 16.2 percent and sales of the substitutes rose by 24 percent. Sales of exempted gel caps rose 109.3 percent and liquids 14.5 percent, but tablets fell 35.5 percent. Overall, sales in the cold and allergy group in Oklahoma fell 3.9 percent. Illinois, which imposed less stringent rules, saw little change in purchases, according to IRI InfoScan. The Slone Epidemiology Center at Boston University took a broader look at drug purchases in 2004 and found that between 2003 and 2004, the number of adults reporting use of pseudoephedrine fell from 7 percent to 4.8 percent. This decline occurred prior to State restrictions and to the availability of many substitute products, but after limits on purchases were set by Federal law and by many large chain stores.

If national patterns reflect Oklahoma's experience, a 3.9 percent drop in cold/allergy medicine sales would imply a $117,000,000 loss in sales. However, if they reflect national trends reported by the Slone Epidemiology Center, a 2.2 percent drop in cold/allergy medicine sales would imply a $33,000,000 loss in sales. Since market effects will occur within the context of increased marketing and distribution of substitutes, the direct effects on revenues could be lower than either estimate.

It is not clear how consumers and retailers will react to a nationwide limit on all scheduled listed chemical product sales because the availability of substitute products may increase. If consumers continue to ask for scheduled listed chemical products, retailers will incur costs to store them behind the counter or in locked cabinets and to record every transaction. The purchaser will take extra time and possibly delay other customers who have to wait while the transaction is completed. DEA notes that in stores with pharmacies, the recordkeeping requirements established by this rule may direct a higher proportion of transactions to the pharmacy versus the standard checkout line. DEA is seeking public comment on the effect of these recordkeeping and product placement requirements on pharmacy wait times and any staffing costs these requirements generate. Alternatively, if few consumers seek the products, many retailers may decide not to carry them. This decision would eliminate their costs, but could impose a cost on the consumer who has to go to multiple stores or travel greater distances to find the product. Regulated sellers who continue to sell the products will have to decide how to log the sales, which will impose costs. DEA is seeking comment on the cost of logging sales, whether this log be paper or electronic. Part of each seller's calculation will be whether the value of the sales is sufficient to offset the costs. As discussed above, OTC medications as a whole represent between one and two percent of the sales of sellers except for pharmacies and mail order sellers; scheduled listed chemical products probably represent less than 10 percent of those sales. For many smaller stores a small decline in sales, if that occurs, may be less costly than compliance. DEA has estimated that small convenience stores sell between $20 and $40 a month of these products for legitimate purposes (69 FR 8691, February 25, 2004).

Size of the market; data issues. DEA has been unable to determine the size of the market for scheduled listed chemical products. The Food and Drug Administration reported that IMS Health data estimated the market is about $500 million; FDA further reported that IRI estimated the market was $1.5 billion. The IRI Oklahoma data implied that pseudoephedrine represented about 75 percent of the cold medication market, but the value other sources provide for the cold medication market in 2005 is about $4 billion.

IRI indicated that national sales for the category had dropped by 0.5 percent between May 2004 and May 2005. A Kline & Company study indicated that sales in the cold medication category rose 12 percent in 2005. Part of the problem is that different groups appear to define the market segment differently, including a different mix of products. DEA seeks information on the actual value of the market for scheduled listed chemical products and the number of transactions. Even with the total value of the market, DEA would need to understand the value of the average transactions. The products are available in a wide variety of strengths and number of dosage units; the sales limits allow purchases of multiple packages of most products. DEA also seeks comments on the effect of the restrictions on product prices. At present, the substitutes are selling for prices that are equivalent to those for scheduled listed chemical products (based on maximum daily dosage units). The additional costs of handling scheduled listed chemical products could, however, increase their prices if sellers pass on the costs to consumers.

Diversion. The limits and restrictions that CMEA imposes are intended to reduce the diversion of scheduled listed chemical products. Manufacturers and regulated sellers will see some reduction in sales as a result of retail purchases for diversion declining. DEA has no reliable information on the percentage of the market in these products that was diverted. DEA expects that as it implements other CMEA requirements it will have a better understanding of the size of the diversion market. Nonetheless, because sales of these products represent less than one percent of most retailer's total sales, the loss of sales for diversion is unlikely to impose a substantial cost on retailers selling to legitimate purchasers.

Implementation Costs. For most regulated sellers that continue to carry scheduled listed chemical products, the largest cost will be the added time to collect and record logbook information regarding the purchaser at each transaction. DEA estimates that it will take one to two minutes for the seller and purchaser to enter into the logbook the information required by CMEA—name and address of purchaser, name and quantity of product sold, date and time of transaction, and purchaser's signature—and seeks comment on this estimate.

Assuming market changes may reflect the Oklahoma experience to a degree, a 16 percent drop in sales of regulated products would change the number of transactions that would require recordkeeping to 56,490,000. Assuming the recordkeeping requirements add 2 minutes to each transaction, they would impose an annual cost between $73,000,000 and $80,000,000 in terms of time burden. These estimates assume, for the low end, the average hourly wage of retail sales clerks ($11.86 with fringe benefits) plus public time ($27/hour); for the high end, it assumes the average hourly wage of a pharmacy technician ($15.26 with fringe benefits) plus public time ($27/hour).

Assuming market changes reflect data reported by The Slone Epidemiology Center, a 2.2 percent drop in sales of regulated products would change the number of transactions that would require recordkeeping by 2,193,000. Using the same assumptions regarding increased transaction times, this would imply an annual cost in terms of time

burden between $85,000,000 and $93,000,000.

Another cost will be the costs of recordkeeping systems. CMEA allows either a logbook or an electronic record. DEA is seeking comments on whether regulated sellers will be able to use electronic signature capture systems to collect names and addresses as well as signatures, the cost of adapting systems to perform this function, and likelihood that sellers will do this versus using a bound logbook. DEA is seeking information from regulated sellers on whether they plan to limit sales to pharmacy or special counters or whether they will handle sales at regular checkout lines. Finally, DEA is seeking comments on how much behind-the-counter space regulated sellers will need to devote to these products, the cost of doing so, and the extent to which costs may be passed on to the consumer.

Blister Packs. For reasons of product safety and the previous blister-pack exemption, almost all scheduled listed chemical products are already sold in blister packs. DEA seeks comments on whether this requirement imposes a burden on any manufacturers.

Benefits. Congress passed CMEA to make it more difficult for individuals to purchase scheduled listed chemical products and use them to make methamphetamine. The retail restrictions are part of a series of steps that Congress adopted to address the sources of methamphetamine abuse; other steps include import and production quotas and tracking of international transactions.

Methamphetamine remains the primary drug produced in illicit laboratories within the United States. Data from the El Paso Intelligence Center's (EPIC) Clandestine Laboratory Database indicates that more than 17,170 methamphetamine laboratory incidents in calendar year 2004 and 12,139 incidents in calendar year 2005 (as reported to EPIC through June 29, 2006). According to EPIC, from January 2000 through June 2006, there were 7,125 laboratories reportedly using ephedrine and 44,380 reportedly using pseudoephedrine as precursor material for methamphetamine production. Additionally EPIC reports the seizure of 51 amphetamine laboratories (using phenylpropanolamine) during the same period. The vast majority of these laboratories used pharmaceutical products containing pseudoephedrine, ephedrine, and phenylpropanolamine as the source of precursor material.

According to the Substance Abuse and Mental Health Services Administration (SAMHSA), Drug Abuse Warning Network (DAWN), in 2004, the latest year for which data are available, amphetamine and methamphetamine was mentioned in almost 103,000 emergency department (ED) visits; methamphetamine accounted for 73,400 of these visits. These numbers represent a rapid increase in recent years. SAMHSA reported that drug abuse-related ED visits involving amphetamine/methamphetamine rose from 25,200 in 1995 to 38,960 in 2002 and 42,500 in 2003. If the cost of the visit is $500, which is probably low in many areas, the total cost would have been $50 million. The DAWN mortality data for 33 metropolitan areas in 2003, the most recent year available, report amphetamine or methamphetamine was involved in 524 deaths and was the only drug present in 93 of those deaths. A University of Arkansas Study on the economic impact of methamphetamine use in Benton County, Arkansas, estimated that the average methamphetamine user cost his or her employer $47,500 a year, with 50 percent of cost due to increased absenteeism and 32 percent due to lost productivity.

The surge in methamphetamine abuse and the manufacture of the drug in clandestine laboratories has caused serious law enforcement and environmental problems, particularly in rural communities. Rural areas are frequently the site of clandestine laboratories because the manufacturing process produces distinctive odors and can be identified if there are close neighbors. Besides causing crime as people steal ingredients to make methamphetamine and steal to support their addiction, the clandestine laboratories often leave serious pollution behind. A laboratory can produce 6 to 10 pounds of hazardous waste for every pound of methamphetamine produced. Table 5 shows the hazardous waste cleanup costs incurred by States and DEA by Fiscal Year (October 1 through September 30) for several previous fiscal years.

TABLE 5.—STATE AND FEDERAL CLANDESTINE LABORATORY CLEANUP COSTS

Fiscal year	DEA cost	State/local meth cost	Total cost
1998	$4,030,000	$1,420,000	$5,450,000
1999	3,020,000	8,420,000	11,440,000
2000	4,120,000	11,800,000	15,920,000
2001	2,800,000	19,240,000	22,040,000
2002	2,190,000	21,490,000	23,680,000
2003	1,150,000	15,040,000	16,190,000
2004	810,000	17,680,000	18,490,000
2005	650,000	17,020,000	17,670,000
2006*	470,000	12,180,000	12,650,000

* Data for fiscal year 2006 is through the third quarter (June 30, 2006).

The Federal and State cleanups are generally limited to removing chemicals that could be reused; they do not address water and soil pollution that remain. Owners of the property are responsible for completing the cleanup of contaminated water and soil, but if the owner cannot pay the cost, local governments bear the burden or the contamination remains.

The effectiveness of the control of retail sales can be seen in the decline in clandestine laboratory incidents in States such as Oklahoma. In 2003, before Oklahoma implemented retail sales controls, there were 1,068 clandestine laboratory incidents in the State. In 2005, the first full year of the sales controls, there were only 217 incidents. The CMEA provisions on retail sales will continue the trend of reducing the number of clandestine laboratories. This trend will reduce the cost to State and local governments as well as the hazard to law enforcement officers and others from exposure to the hazardous chemicals left behind.

Conclusion. Because of the many unknowns, DEA is unable to determine with any certainty whether the CMEA

requirements will impose an annual cost on the economy of $100 million or more, the standard for an economically significant rule under Executive Order 12866. If the value of the existing market is on the low end of the range ($500 million), the additional costs, including transaction costs, would be considerably lower than $100 million even if there is no reduction in sales. If the value of the market is $1.5 billion and there is no reduction in sales, the cost could exceed $100 million. DEA considers it likely that product switching and reduced sales will result in annual costs below $100 million, but until the statutory requirements are implemented and both retailers and consumers respond, DEA cannot estimate total costs with any certainty.

Public Comment

To assist DEA in finalizing its Regulatory Impact Analysis, DEA is seeking public comment on the following questions:

- What is the size of the market for products regulated under this rule? What proportion of the cold and allergy product market are pseudoephedrine-based products?
- Using a pre-CMEA baseline, will this regulation have any effect on the prices of regulated products? If so, what is the magnitude of the change?
- How many retailers may choose not to carry the regulated products rather than incur the regulatory costs? What is their annual sales volume with regard to regulated products? What is the cost associated with that effect?
- If stores choose not to carry the regulated products, what are consumers' travel costs associated with the decreased quantity of stores selling the product?
- Placing products behind the counter may increase competition for space behind the counter. Will it increase the cost of storage space behind the counter? What is the cost imposed on the consumption of other goods? What, if any, effect will this have on the prices of other goods?
- Among stores that opt to direct regulated transactions to their pharmacies, will this additional traffic have an effect on pharmacy wait times? Will the increase in pharmacy transactions require additional staffing?
- What equipment is required for retailers who wish to handle regulated sales at the regular checkout line? What is its cost?
- What are wait times for regulated transactions when two or more consumers arrive to purchase regulated products?
- What is the cost to manufacturers, given expected demand reductions for regulated products?
- To what extent, and under what circumstances, can substitutes for the regulated products reduce the expected cost of this regulation?
- What are the results of any recent studies on the effective doses of substitute products and their safety at different levels?
- To what extent are training and recordkeeping costs fixed versus variable?

Paperwork Reduction Act of 1995

CMEA mandates a number of new information collections and recordkeeping requirements. Regulated sellers are required to train any employee who will be involved in selling scheduled listed chemical products and to document the training. Regulated sellers must also self-certify to DEA that all affected employees have been trained and that the seller is in compliance with all CMEA provisions. Finally, CMEA mandates that each sale at retail be documented in a written or electronic logbook and that the logbooks be retained for two years.

The Department of Justice, Drug Enforcement Administration, has submitted the following information collection request to the Office of Management and Budget for review and clearance in accordance with review procedures of the Paperwork Reduction Act of 1995. The information collection is published to obtain comments from the public and affected agencies.

All comments and suggestions, or questions regarding additional information, to include obtaining a copy of the information collection instrument with instructions, should be directed to Mark W. Caverly, Chief, Liaison and Policy Section, Office of Diversion Control, Drug Enforcement Administration, Washington, DC 20537.

Written comments and suggestions from the public and affected agencies concerning the collection of information are encouraged. Your comments on the information collection-related aspects of this rule should address one or more of the following four points:

(1) Evaluate whether the collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

(2) Evaluate the accuracy of the agency's estimate of the burden of the collection of information, including the validity of the methodology and assumptions used;

(3) Enhance the quality, utility, and clarity of the information to be collected; and

(4) Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.*, permitting electronic submission of responses.

Overview of This Information Collection

(1) *Type of Information Collection:* New collection.

(2) *Title of the Form/Collection:* Self-certification, Training and Logbooks for Regulated Sellers of Scheduled Listed Chemical Products.

(3) *Agency form number, if any, and the applicable component of the Department of Justice sponsoring the collection:* Form Number: DEA Form 597, 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: None.

Abstract: CMEA mandates that retail sellers of scheduled listed chemical products maintain a written or electronic logbook of sales, retain a record of employee training, and complete a self-certification form verifying the training and compliance with CMEA provisions regarding retail sales of scheduled listed chemical products.

(5) *An estimate of the total number of respondents and the amount of time estimated for an average respondent to respond:* 89,000, 25.9 hours.

As discussed in the previous section, DEA estimates that the number of potential regulated sellers could range from 89,000 to 118,000. That number would include a substantial number of convenience stores, most of which may not find the burden of self-certification, storage, recordkeeping, and training worth the sales of items that represent a very small percentage of their overall sales. Thus, DEA expects that the number of regulated sellers that will seek to self-certify will be no higher than 89,000. Consequently, DEA has used the lower estimate for the information collection. The average annual burden hour per respondent is 25.9 hours, most of which is the additional time needed to record the statutorily mandated information on each sales transaction.

(6) *An estimate of the total public burden (in hours) associated with the*

collection: 4,548,500 hours. The estimate includes both the burden hours for regulated sellers and the time customers would take to provide information during the transaction.

Regulated sellers will need to maintain a record of employee training, self-certify, and maintain a logbook of transactions. DEA estimates that each regulated seller will spend 0.5 hours collecting the information and completing the online self-certification form. Completing a roster of employees trained is estimated to take 3 minutes per employee, assuming that the recordkeeping takes one tenth of the time spent on training. Finally, DEA estimates that having the customer enter information and sign the log while the sales person checks the photo ID will take two minutes per transaction. DEA assumes recordkeeping requirements will not lengthen checkout lines, and will not influence the transaction times of other customers. Further, this estimate does not account for scenarios in which two or more customers arrive to purchase scheduled listed chemical products. DEA assumes that all pharmacists and pharmacy technicians will be trained (about 300,000) plus 100,000 other sales clerks. DEA used an estimate of 133 million transactions to develop total burden hours for transactions, assuming that the total value of the market is the midpoint of the estimates ($1 billion) and that the average value of a transaction is $8. (Product prices range from $4 to $14 per package depending on the number of dosage units and strength.) The number of transactions was reduced to 67.25 million to account for the states that already have requirements for logbooks; this rule imposes no additional burden for the transactions on either purchasers or sellers in those states. Based on Bureau of Census state population numbers for 2005, these states represent 49 percent of the United States population. Table 6 presents the burden hour calculations.

TABLE 6.—ESTIMATE OF TOTAL BURDEN HOURS

Activity	Unit burden hour	Number of activities	Total burden hours
Training record	0.05 hour (3 minutes)	400,000	20,000
Self-certification	0.5 hour (30 minutes)	89,000	44,500
Transaction record	0.033 hour (2 minutes)	67,250,000	2,242,000
Customer time	0.033 hour (2 minutes)	67,250,000	2,242,000
Total			4,548,500

If additional information is required contact: Lynn Bryant, Department Clearance Officer, Information Management and Security Staff, Justice Management Division, 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 impose enforcement responsibilities on any State; nor does it diminish the power of any State to enforce its own laws. The rule does preempt State laws that are less stringent than the statutory requirements. These requirements, however, are mandated under CMEA and DEA has no authority to alter them or change the preemption. 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 $118,000,000 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.

Congressional Review Act

This rule is a major rule as defined by section 804 of the Small Business Regulatory Enforcement Fairness Act of 1996 (Congressional Review Act). This rule may result in an annual effect on the economy of $100,000,000 or more; it will not cause 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. Depending heavily on the assumptions used, the economic impact of this rule could be substantially higher or lower than $100,000,000.

CMEA requires that on and after September 30, 2006, regulated sellers selling scheduled listed chemical products at retail shall self-certify with DEA in order to continue to sell these products. CMEA imposes sales limits, purchase limits, product placement requirements, mail order customer identification requirements, and other requirements, some of which must be specified by regulation, all with an effective date of September 30, 2006. Based on the effective date of this law, it is impracticable for DEA to comply with the requirements of CRA section 801 pertaining to delayed effective dates of major rules due to the limited time involved. Were DEA not to publish this Interim Rule with Request for Comment, regulated sellers selling scheduled listed chemical products at retail would not be able to self-certify by the date specified in the law. Were this not to occur, these regulated sellers would be forced to stop selling scheduled listed chemical products, or violate the law by doing so. Mail order distributors would also have difficulty, as DEA is required by regulation to establish procedures for these persons to identify their customers prior to shipping product. Without these regulations, mail order distributors would not be able to sell scheduled listed chemical products. Therefore, DEA also finds that it is contrary to the public interest not to issue these regulations as an Interim Rule, thereby allowing regulated sellers and mail order distributors to fully comply with the requirements of CMEA. While the CMEA was signed into law in March of 2006, most of the law must be in effect by September 30, 2006. The broad scope of the new law, as well as the expedited effective dates, is a clear reflection of Congress's concern about the nation's growing methamphetamine epidemic and its desire to act quickly to prevent further illicit use of these chemicals. In light of these factors, DEA finds that ''good cause'' exists to make this Interim Rule with Request for Comment

effective September 21, 2006, except that §§ 1314.20, 1314.25, and 1314.30 (with the exception of § 1314.30(a)(2)) are effective September 30, 2006. Section 1314.30(a)(2) is effective November 27, 2006.

List of Subjects

21 CFR Part 1300

Chemicals, Drug traffic control.

21 CFR Part 1309

Administrative practice and procedure, Drug traffic control, Exports, Imports, Security measures.

21 CFR Part 1310

Drug traffic control, Exports, Imports, Reporting and recordkeeping requirements.

21 CFR Part 1314

Drug traffic control, Reporting and recordkeeping requirements.

■ For the reasons set out above, 21 CFR Chapter II is amended as follows:

PART 1300—DEFINITIONS

■ 1. The authority citation for part 1300 continues to read as follows:

Authority: 21 U.S.C. 802, 871(b), 951, 958(f).

■ 2. Section 1300.02 is amended by revising paragraphs (b)(28) and (29), removing paragraph (b)(31), redesignating paragraphs (b)(32) through (b)(34) as (b)(31) through (b)(33), and adding new paragraphs (b)(34) through (b)(37) to read as follows:

§ 1300.02 Definitions related to listed chemicals.

* * * * *

(b) * * *

(28) The term *regulated transaction* means:

(i) A distribution, receipt, sale, importation, or exportation of a listed chemical, or an international transaction involving shipment of a listed chemical, or if the Administrator establishes a threshold amount for a specific listed chemical, a threshold amount as determined by the Administrator, which includes a cumulative threshold amount for multiple transactions, of a listed chemical, except that such term does not include:

(A) A domestic lawful distribution in the usual course of business between agents or employees of a single regulated person; in this context, agents or employees means individuals under the direct management and control of the regulated person;

(B) A delivery of a listed chemical to or by a common or contract carrier for carriage in the lawful and usual course of the business of the common or contract carrier, or to or by a warehouseman for storage in the lawful and usual course of the business of the warehouseman, except that if the carriage or storage is in connection with the distribution, importation, or exportation of a listed chemical to a third person, this paragraph does not relieve a distributor, importer, or exporter from compliance with parts 1309, 1310, and 1313 of this chapter;

(C) Any category of transaction or any category of transaction for a specific listed chemical or chemicals specified by regulation of the Administrator as excluded from this definition as unnecessary for enforcement of the Act;

(D) Any transaction in a listed chemical that is contained in a drug other than a scheduled listed chemical product that may be marketed or distributed lawfully in the United States under the Federal Food, Drug, and Cosmetic Act, subject to paragraph (b)(28)(i)(E) of this section, unless—

(1) The Administrator has determined pursuant to the criteria in § 1310.10 of this chapter that the drug or group of drugs is being diverted to obtain the listed chemical for use in the illicit production of a controlled substance; and

(2) The quantity of the listed chemical contained in the drug included in the transaction or multiple transactions equals or exceeds the threshold established for that chemical;

(E) Any transaction in a scheduled listed chemical product that is a sale at retail by a regulated seller or a distributor required to submit reports under § 1310.03(c) of this chapter; or

(F) Any transaction in a chemical mixture designated in §§ 1310.12 and 1310.13 of this chapter that the Administrator has exempted from regulation.

(ii) A distribution, importation, or exportation of a tableting machine or encapsulating machine except that such term does not include a domestic lawful distribution in the usual course of business between agents and employees of a single regulated person; in this context, agents or employees means individuals under the direct management and control of the regulated person.

(29) The term *retail distributor* means a grocery store, general merchandise store, drug store, or other entity or person whose activities as a distributor relating to drug products containing pseudoephedrine or phenylpropanolamine are limited almost exclusively to sales for personal use, both in number of sales and volume of sales, either directly to walk-in customers or in face-to-face transactions by direct sales. Also for the purposes of this paragraph, a grocery store is an entity within Standard Industrial Classification (SIC) code 5411, a general merchandise store is an entity within SIC codes 5300 through 5399 and 5499, and a drug store is an entity within SIC code 5912.

* * * * *

(34)(i) The term *scheduled listed chemical product* means a product that contains ephedrine, pseudoephedrine, or phenylpropanolamine and may be marketed or distributed lawfully in the United States under the Federal, Food, Drug, and Cosmetic Act as a nonprescription drug. Ephedrine, pseudoephedrine, and phenylpropanolamine include their salts, optical isomers, and salts of optical isomers.

(ii) Scheduled listed chemical product does not include any product that is a controlled substance under part 1308 of this chapter. In the absence of such scheduling by the Attorney General, a chemical specified in paragraph (b)(34)(i) of this section may not be considered to be a controlled substance.

(35) The term *regulated seller* means a retail distributor (including a pharmacy or a mobile retail vendor), except that the term does not include an employee or agent of the distributor.

(36) The term *mobile retail vendor* means a person or entity that makes sales at retail from a stand that is intended to be temporary or is capable of being moved from one location to another, whether the stand is located within or on the premises of a fixed facility (such as a kiosk at a shopping center or an airport) or whether the stand is located on unimproved real estate (such as a lot or field leased for retail purposes).

(37) The term *at retail*, with respect to the sale or purchase of a scheduled listed chemical product, means a sale or purchase for personal use, respectively.

PART 1309—REGISTRATION OF MANUFACTURERS, DISTRIBUTORS, IMPORTERS, AND EXPORTERS OF LIST I CHEMICALS

■ 3. The authority citation for part 1309 continues to read as follows:

Authority: 21 U.S.C. 802, 821, 822, 823, 824, 830, 871(b), 875, 877, 958.

■ 4. Section 1309.71(a) is revised to read as follows:

§ 1309.71 General security requirements.

(a) All applicants and registrants must provide effective controls and

procedures to guard against theft and diversion of List I chemicals. Chemicals must be stored in containers sealed in such a manner as to indicate any attempts at tampering with the container. Where chemicals cannot be stored in sealed containers, access to the chemicals should be controlled through physical means or through human or electronic monitoring.

* * * * *

PART 1310—RECORDS AND REPORTS OF LISTED CHEMICALS AND CERTAIN MACHINES

■ 5. The authority citation for part 1310 continues to read as follows:

Authority: 21 U.S.C. 802, 827(h), 830, 871(b), 890.

■ 6. In § 1310.04, paragraph (f)(1)(ii) is revised to read as follows:

§ 1310.04 Maintenance of records.

* * * * *

(f) * * *

(1) * * *

(ii) For List I chemicals that are scheduled listed chemical products as defined in § 1300.02, the thresholds established in paragraphs (f)(1)(i) and (g) of this section apply only to non-retail distribution, import, and export. Sales of these products at retail are subject to the requirements of part 1314 of this chapter.

* * * * *

■ 7. Section 1310.05 is amended by revising paragraph (f)(2) to read as follows:

§ 1310.05 Reports.

* * * * *

(f) * * *

(2) Distributions of drug products by retail distributors that may not include face-to-face transactions to the extent that such distributions are consistent with the activities authorized for a retail distributor as specified in § 1300.02(b)(29) of this chapter, except that this paragraph does not apply to sales of scheduled listed chemical products at retail.

* * * * *

■ 8. Remove § 1310.14.

■ 9. Remove § 1310.15.

■ 10. Add § 1310.16 to read as follows:

§ 1310.16 Exemptions for certain scheduled listed chemical products.

(a) Upon the application of a manufacturer of a scheduled listed chemical product, the Administrator may by regulation provide that the product is exempt from part 1314 of this chapter if the Administrator determines that the product cannot be used in the illicit manufacture of a controlled substance.

(b) An application for an exemption under this section must contain all of the following information:

(1) The name and address of the applicant.

(2) The exact trade name of the scheduled listed chemical product for which exemption is sought.

(3) The complete quantitative and qualitative composition of the drug product.

(4) A brief statement of the facts that the applicant believes justify the granting of an exemption under this section.

(5) Certification by the applicant that the product may be lawfully marketed or distributed under the Federal, Food, Drug, and Cosmetic Act.

(6) The identification of any information on the application that is considered by the applicant to be a trade secret or confidential and entitled to protection under U.S. laws restricting the public disclosure of such information by government employees.

(c) The Administrator may require the applicant to submit additional documents or written statements of fact relevant to the application that he deems necessary for determining if the application should be granted.

(d) Within a reasonable period of time after the receipt of a completed application for an exemption under this section, the Administrator shall notify the applicant of acceptance or non-acceptance of the application. If the application is not accepted, an explanation will be provided. The Administrator is not required to accept an application if any of the information required in paragraph (b) of this section or requested under paragraph (c) of this section is lacking or not readily understood. The applicant may, however, amend the application to meet the requirements of paragraphs (b) and (c) of this section.

(e) If the application is accepted for filing, the Administrator shall issue and publish in the **Federal Register** an order on the application, which shall include a reference to the legal authority under which the order is based. This order shall specify the date on which it shall take effect.

(f) The Administrator shall permit any interested person to file written comments on or objections to the order. If any comments or objections raise significant issues regarding any findings of fact or conclusions of law upon which the order is based, the Administrator shall immediately suspend the effectiveness of the order until he may reconsider the application in light of the comments and objections filed. Thereafter, the Administrator shall reinstate, revoke, or amend the original order as deemed appropriate.

■ 11. Part 1314 is added to 21 CFR Chapter II to read as follows:

PART 1314—RETAIL SALE OF SCHEDULED LISTED CHEMICAL PRODUCTS

Authority: 21 U.S.C. 802, 830, 842, 871(b), 875, 877.

Subpart A—General

§ 1314.01 Scope.

This part specifies the requirements for retail sales of scheduled listed chemical products to individuals for personal use.

§ 1314.02 Applicability.

(a) This part applies to the following regulated persons who sell scheduled listed chemical products for personal use:

(1) Regulated sellers of scheduled listed chemical products sold at retail for personal use through face-to-face sales at stores or mobile retail vendors.

(2) Regulated persons who engage in a transaction with a non-regulated person and who ship the products to the non-regulated person by the U.S. Postal Service or by private or common carriers.

(b) The requirements in subpart A apply to all regulated persons subject to this part. The requirements in subpart B apply to regulated sellers as defined in

§ 1300.02 of this chapter. The requirements in subpart C apply to regulated persons who ship the products to the customer by the U.S. Postal Service or by private or common carriers.

§ 1314.03 Definitions.

As used in this part, the term ''mail-order sale'' means a retail sale of scheduled listed chemical products for personal use where a regulated person uses or attempts to use the U.S. Postal Service or any private or commercial carrier to deliver the product to the customer. Mail-order sale includes purchase orders submitted by phone, mail, fax, Internet, or any method other than face-to-face transaction.

§ 1314.05 Requirements regarding packaging of nonliquid forms.

A regulated seller or mail order distributor may not sell a scheduled listed chemical product in nonliquid form (including gel caps) unless the product is packaged either in blister packs, with each blister containing no more than two dosage units or, if blister packs are technically infeasible, in unit dose packets or pouches.

§ 1314.10 Effect on State laws.

Nothing in this part preempts State law on the same subject matter unless there is a positive conflict between this part and a State law so that the two cannot consistently stand together.

§ 1314.15 Loss reporting.

(a) Each regulated person must report to the Special Agent in Charge of the DEA Divisional Office for the area in which the regulated person making the report is located, any unusual or excessive loss or disappearance of a scheduled listed chemical product under the control of the regulated person. The regulated person responsible for reporting a loss in-transit is the supplier.

(b) Each report submitted under paragraph (a) of this section must, whenever possible, be made orally to the DEA Divisional Office for the area in which the regulated person making the report is located at the earliest practicable opportunity after the regulated person becomes aware of the circumstances involved.

(c) Written reports of losses must be filed within 15 days after the regulated person becomes aware of the circumstances of the event.

(d) A report submitted under this section must include a description of the circumstances of the loss (in-transit, theft from premises, *etc.*).

(e) A suggested format for the report is provided below:

Regulated Person

Registration number (if applicable) _____
Name _____
Business address _____
City _____
State _____
Zip _____
Business phone _____
Date of loss _____
Type of loss _____
Description of circumstances _____

Subpart B—Sales by Regulated Sellers

§ 1314.20 Restrictions on sales quantity.

(a) Without regard to the number of transactions, a regulated seller (including a mobile retail vendor) may not in a single calendar day sell any purchaser more than 3.6 grams of ephedrine base, 3.6 grams of pseudoephedrine base, or 3.6 grams of phenylpropanolamine base in scheduled listed chemical products.

(b) A mobile retail vendor may not in any 30-day period sell an individual purchaser more than 7.5 grams of ephedrine base, 7.5 grams of pseudoephedrine base, or 7.5 grams of phenylpropanolamine base in scheduled listed chemical products.

§ 1314.25 Requirements for retail transactions.

(a) Each regulated seller must ensure that sales of a scheduled listed chemical product at retail are made in accordance with this section and § 1314.20.

(b) The regulated seller must place the product so that customers do not have direct access to the product before the sale is made (in this paragraph referred to as ''behind-the-counter'' placement). For purposes of this paragraph, a behind-the-counter placement of a product includes circumstances in which the product is stored in a locked cabinet that is located in an area of the facility where customers do have direct access. Mobile retail vendors must place the product in a locked cabinet.

(c) The regulated seller must deliver the product directly into the custody of the purchaser.

§ 1314.30 Recordkeeping for retail transactions.

(a)(1) Except for purchase by an individual of a single sales package containing not more than 60 milligrams of pseudoephedrine, the regulated seller must maintain, in accordance with criteria issued by the Administrator, a written or electronic list of each scheduled listed chemical product sale that identifies the products by name, the quantity sold, the names and addresses of the purchasers, and the dates and times of the sales (referred to as the ''logbook''). The logbook may be maintained on paper or in electronic form.

(2) Effective November 27, 2006, if a logbook is maintained on paper, it must be created and maintained in a bound record book.

(b) The regulated seller must not sell a scheduled listed chemical product at retail unless the purchaser does the following:

(1) Presents an identification card that provides a photograph and is issued by a State or the Federal Government, or a document that, with respect to identification, is considered acceptable for purposes of 8 CFR 274a.2(b)(1)(v)(A) and 274a.2(b)(1)(v)(B).

(2) Signs the logbook and enters in the logbook his or her name, address, and the date and time of the sale.

(c) For records created electronically, the regulated seller may use an electronic signature system to capture the signature and may have the computer automatically enter the date and time of the sale. The regulated seller may ask the purchaser for their name and address and enter information if it is not feasible for the purchaser to enter the information electronically.

(d) The regulated seller must determine that the name entered in the logbook corresponds to the name provided on identification presented and that the date and time entered are correct.

(e) The regulated seller must enter in the logbook the name of the product and the quantity sold. Examples of methods of recording the quantity sold include the weight of the product per package and number of packages of each chemical, the cumulative weight of the product for each chemical, or quantity of product by Universal Product Code. These examples do not exclude other methods of displaying the quantity sold. For electronic records, the regulated seller may use a point-of-sale and bar code reader. Such electronic records must be provided pursuant to paragraph (i) of this section in a human readable form such that the requirements of paragraph (a)(1) of this section are satisfied.

(f) The regulated seller must include in the logbook or display by the logbook, the following notice:

Warning: Section 1001 of Title 18, United States Code, states that whoever, with respect to the logbook, knowingly and willfully falsifies, conceals, or covers up by any trick, scheme, or device a material fact, or makes any materially false, fictitious, or fraudulent statement or representation, or makes or uses any false writing or document knowing the same to contain any materially false, fictitious, or fraudulent statement or entry, shall be fined not more than $250,000 if an

individual or $500,000 if an organization, imprisoned not more than five years, or both.

(g) The regulated seller must maintain each entry in the logbook for not fewer than 2 years after the date on which the entry is made.

(h) A record under this section must be kept at the regulated seller's place of business where the transaction occurred, except that records may be kept at a single, central location of the regulated seller if the regulated seller has notified the Administration of the intention to do so. Written notification must be submitted by registered or certified mail, return receipt requested, to the Special Agent in Charge of the DEA Divisional Office for the area in which the records are required to be kept.

(i) The records required to be kept under this section must be readily retrievable and available for inspection and copying by authorized employees of the Administration under the provisions of 21 U.S.C. 880.

(j) A record developed and maintained to comply with a State law may be used to meet the requirements of this section if the record includes the information specified in this section.

§ 1314.35 Training of sales personnel.

Each regulated seller must ensure that its sales of a scheduled listed chemical product at retail are made in accordance with the following:

(a) In the case of individuals who are responsible for delivering the products into the custody of purchasers or who deal directly with purchasers by obtaining payments for the products, the regulated seller has submitted to the Administration a self-certification that all such individuals have, in accordance with criteria issued by the Administration, undergone training provided by the regulated seller to ensure that the individuals understand the requirements that apply under this part.

(b) The regulated seller maintains a copy of each self-certification and all records demonstrating that individuals referred to in paragraph (a) of this section have undergone the training.

§ 1314.40 Self-certification.

(a) A regulated seller must submit to the Administration the self-certification referred to in § 1314.35(a) in order to sell any scheduled listed chemical product. The certification is not effective for purposes of this section unless, in addition to provisions regarding the training of individuals referred to in § 1314.35(a), the certification includes a statement that the regulated seller understands each of the requirements that apply under this part and agrees to comply with the requirements.

(b) When a regulated seller files the initial self-certification, the Administration will assign the regulated seller to one of twelve groups. The expiration date of the self-certification for all regulated sellers in any group will be the last day of the month designated for that group. In assigning a regulated seller to a group, the Administration may select a group with an expiration date that is not less than 12 months or more than 23 months from the date of the self-certification. After the initial certification period, the regulated seller must update the self-certifications annually.

(c) The regulated seller must provide a separate certification for each place of business at which the regulated seller sells scheduled listed chemical products at retail.

§ 1314.45 Privacy protections.

To protect the privacy of individuals who purchase scheduled listed chemical products, the disclosure of information in logbooks under § 1314.15 is restricted as follows:

(a) The information shall be disclosed as appropriate to the Administration and to State and local law enforcement agencies.

(b) The information in the logbooks shall not be accessed, used, or shared for any purpose other than to ensure compliance with this title or to facilitate a product recall to protect public health and safety.

(c) A regulated seller who in good faith releases information in a logbook to Federal, State, or local law enforcement authorities is immune from civil liability for the release unless the release constitutes gross negligence or intentional, wanton, or willful misconduct.

§ 1314.50 Employment measures.

A regulated seller may take reasonable measures to guard against employing individuals who may present a risk with respect to the theft and diversion of scheduled listed chemical products, which may include, notwithstanding State law, asking applicants for employment whether they have been convicted of any crime involving or related to such products or controlled substances.

Subpart C—Mail-Order Sales

§ 1314.100 Sales limits for mail-order sales.

(a) Each regulated person who makes a sale at retail of a scheduled listed chemical product and is required under § 1310.03(c) of this chapter to submit a report of the sales transaction to the Administration may not in a single calendar day sell to any purchaser more than 3.6 grams of ephedrine base, 3.6 grams of pseudoephedrine base, or 3.6 grams of phenylpropanolamine base in scheduled listed chemical products.

(b) Each regulated person who makes a sale at retail of a scheduled listed chemical product and is required under § 1310.03(c) of this chapter to submit a report of the sales transaction to the Administration may not in any 30-day period sell to an individual purchaser more than 7.5 grams of ephedrine base, 7.5 grams of pseudoephedrine base, or 7.5 grams of phenylpropanolamine base in scheduled listed chemical products.

§ 1314.105 Verification of identity for mail-order sales.

(a) Each regulated person who makes a sale at retail of a scheduled listed chemical product and is required under § 1310.03(c) of this chapter to submit a report of the sales transaction to the Administration must, prior to shipping the product, receive from the purchaser a copy of an identification card that provides a photograph and is issued by a State or the Federal Government, or a document that, with respect to identification, is considered acceptable for purposes of 8 CFR 274a.2(b)(1)(v)(A) and 274a.2(b)(1)(v)(B). Prior to shipping the product, the regulated person must determine that the name and address on the identification correspond to the name and address provided by the purchaser as part of the sales transaction. If the regulated person cannot verify the identities of both the purchaser and the recipient, the person may not ship the scheduled listed chemical product.

(b) If the product is being shipped to a third party, the regulated person must comply with the requirements of paragraph (a) to verify that both the purchaser and the person to whom the product is being shipped live at the addresses provided. If the regulated person cannot verify the identities of both the purchaser and the recipient, the person may not ship the scheduled listed chemical product.

§ 1314.110 Reports for mail-order sales.

(a) Each regulated person required to report under § 1310.03(c) of this chapter must either:

(1) Submit a written report, containing the information set forth in paragraph (b) of this section, on or before the 15th day of each month following the month in which the distributions took place. The report must be submitted under company

letterhead, signed by the person authorized to sign on behalf of the regulated seller, to the Drug and Chemical Evaluation Section, Office of Diversion Control, Drug Enforcement Administration, Washington, DC 20537; or

(2) Upon request to and approval by the Administration, submit the report in electronic form, either via computer disk or direct electronic data transmission, in such form as the Administration shall direct. Requests to submit reports in electronic form should be submitted to the Drug and Chemical Evaluation Section, Office of Diversion Control, Drug Enforcement Administration, Washington, DC 20537, ATTN: Electronic Reporting.

(b) Each monthly report must provide the following information for each distribution:

(1) Supplier name and registration number;

(2) Purchaser's name and address;

(3) Name/address shipped to (if different from purchaser's name/address);

(4) Method used to verify the identity of the purchaser and, where applicable, person to whom product is shipped;

(5) Name of the chemical contained in the scheduled listed chemical product and total quantity shipped (*e.g.* pseudoephedrine, 3 grams);

(6) Date of shipment;

(7) Product name;

(8) Dosage form (*e.g.*, tablet, liquid);

(9) Dosage strength (*e.g.*, 30mg, 60mg, per dose etc.);

(10) Number of dosage units (*e.g.*, 100 doses per package);

(11) Package type (blister pack, etc.);

(12) Number of packages;

(13) Lot number.

§ 1314.115 Distributions not subject to reporting requirements.

(a) The following distributions to nonregulated persons are not subject to the reporting requirements in § 1314.110:

(1) Distributions of sample packages when those packages contain not more than two solid dosage units or the equivalent of two dosage units in liquid form, not to exceed 10 milliliters of liquid per package, and not more than one package is distributed to an individual or residential address in any 30-day period.

(2) Distributions by retail distributors that may not include face-to-face transactions to the extent that such distributions are consistent with the activities authorized for a retail distributor as specified in § 1300.02(b)(29) of this chapter, except that this paragraph (a)(2) does not apply to sales of scheduled listed chemical products at retail.

(3) Distributions to a resident of a long term care facility or distributions to a long term care facility for dispensing to or for use by a resident of that facility.

(4) Distributions in accordance with a valid prescription.

(b) The Administrator may revoke any or all of the exemptions listed in paragraph (a) of this section for an individual regulated person if the Administrator finds that drug products distributed by the regulated person are being used in violation of the regulations in this chapter or the Controlled Substances Act.

Subpart D—Order to Show Cause

§ 1314.150 Order To show cause.

(a) If, upon information gathered by the Administration regarding any regulated seller or a distributor required to submit reports under § 1310.03(c) of this chapter, the Administrator determines that a regulated seller or distributor required to submit reports under § 1310.03(c) of this chapter has sold a scheduled listed chemical product in violation of Section 402 of the Act (21 U.S.C. 842(a)(12) or (13)), the Administrator will serve upon the regulated seller or distributor an order to show cause why the regulated seller or distributor should not be prohibited from selling scheduled listed chemical products.

(b) The order to show cause shall call upon the regulated seller or distributor to appear before the Administrator at a time and place stated in the order, which shall not be less than 30 days after the date of receipt of the order. The order to show cause shall also contain a statement of the legal basis for such hearing and for the prohibition and a summary of the matters of fact and law asserted.

(c) Upon receipt of an order to show cause, the regulated seller or distributor must, if he desires a hearing, file a request for a hearing as specified in subpart D of part 1316 of this chapter. If a hearing is requested, the Administrator shall hold a hearing at the time and place stated in the order, as provided in part 1316 of this chapter.

(d) When authorized by the Administrator, any agent of the Administration may serve the order to show cause.

§ 1314.155 Suspension pending final order.

(a) The Administrator may suspend the right to sell scheduled listed chemical products simultaneously with, or at any time subsequent to, the service upon the seller or distributor required to file reports under § 1310.03(c) of this chapter of an order to show cause why the regulated seller or distributor should not be prohibited from selling scheduled listed chemical products, in any case where he finds that there is an imminent danger to the public health or safety. If the Administrator so suspends, he shall serve with the order to show cause under § 1314.150 an order of immediate suspension that shall contain a statement of his findings regarding the danger to public health or safety.

(b) Upon service of the order of immediate suspension, the regulated seller or distributor shall, as instructed by the Administrator:

(1) Deliver to the nearest office of the Administration or to authorized agents of the Administration all of the scheduled listed chemical products in his or her possession; or

(2) Place all of the scheduled listed chemical products under seal as described in Section 304 of the Act (21 U.S.C. 824(f)).

(c) Any suspension shall continue in effect until the conclusion of all proceedings upon the prohibition, including any judicial review, unless sooner withdrawn by the Administrator or dissolved by a court of competent jurisdiction. Any regulated seller or distributor whose right to sell scheduled listed chemical products is suspended under this section may request a hearing on the suspension at a time earlier than specified in the order to show cause under § 1314.150, which request shall be granted by the Administrator, who shall fix a date for such hearing as early as reasonably possible.

Dated: September 20, 2006.

Michele M. Leonhart,

Deputy Administrator.

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DEPARTMENT OF TRANSPORTATION

National Highway Traffic Safety Administration

49 CFR Part 593

[Docket No. NHTSA–2006–25686]

List of Nonconforming Vehicles Decided To Be Eligible for Importation

AGENCY: National Highway Traffic Safety Administration (NHTSA), DOT.

ACTION: Final rule.

SUMMARY: This document revises the list of vehicles not originally manufactured to conform to the Federal motor vehicle