DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. 97–CE–61–AD]

RIN 2120–AA64

Airworthiness Directives; The New Piper Aircraft, Inc. PA–23, PA–30, PA–31, PA–34, and PA–42 Series Airplanes

AGENCY: Federal Aviation Administration, DOT.

ACTION: Notice of proposed rulemaking; correction.

SUMMARY: This document makes a correction to a proposed Airworthiness Directive (AD); notice of proposed rulemaking (NPRM); Docket No. 97–CE–61–AD, which was published in the **Federal Register** on September 16, 1997 (62 FR 48546), and is applicable to The New Piper Aircraft, Inc. (Piper) PA–23, PA–30, PA–31, PA–34, and PA–42 series airplanes. This NPRM incorrectly shows the proposed applicability in Section 39.13 of the proposed AD as Raytheon Aircraft Company (Raytheon) Models E55, E55A, 58, 58A, 58P, 58PA, 58TC, 58TCA airplanes and 60, 65–B80, 65–B90, 90, F90, 100, 300, and B300 series airplanes. The NPRM currently proposes airplane flight manual (AFM) limitations for recognizing and exiting severe icing conditions. This action corrects the applicability in Section 39.13 of Docket No. 97–CE–61–AD.

DATES: Comments must be received on or before October 14, 1997.

ADDRESSES: Submit comments in triplicate to the Federal Aviation Administration (FAA), Central Region, Office of the Regional Counsel, *Attention:* Rules Docket No. 97–CE–61–AD, Room 1558, 601 E. 12th Street, Kansas City, Missouri 64106. Comments may be inspected at this location between 8 a.m. and 4 p.m., Monday through Friday, holidays excepted.

This information also may be examined at the Rules Docket at the address above.

FOR FURTHER INFORMATION CONTACT: Mr. John P. Dow, Sr., Aerospace Engineer, Small Airplane Directorate, Aircraft Certification Service, 1201 Walnut, suite 900, Kansas City, Missouri 64106, telephone (816) 426–6932, facsimile (816) 426–2169.

SUPPLEMENTARY INFORMATION:

Discussion

On September 9, 1997, the FAA issued NPRM, Docket 97–CE–61–AD, (62 FR 48546, September 16, 1997), which applies to Piper Models PA–23, PA–23–160, PA–23–235, PA–23–250, PA–E23–250, PA–30, PA–39, PA–40, PA–31, PA–31–300, PA–31–325, PA–31–350, PA–34–200, PA–34–200T, PA–34–220T, PA–42, PA–42–720, and PA–42–1000 airplanes. This NPRM incorrectly references the applicability in Section 39.13 of the proposed AD as Raytheon Models E55, E55A, 58, 58A, 58P, 58PA, 58TC, 58TCA airplanes and 60, 65–B80, 65–B90, 90, F90, 100, 300, and B300 series airplanes.

Need for the Correction

This NPRM Docket No. 97–CE–61–AD, currently has the wrong applicability in Section 39.13 of the proposed AD. If the applicability is not changed, owners/operators of Piper and Raytheon model airplanes will not know which airplanes are effected by the NPRM.

Correction of Publication

Accordingly, the publication of September 16, 1997 (62 FR 48546), which was the subject of FR Doc. 97–24493, is corrected as follows: On page 48548, in the third column, starting on the 30th line in Section 39.13, correct:

''**Raytheon Aircraft Company:** Docket No. 97–CE–61–AD.

Applicability: Models E55, E55A, 58, 58A, 58P, 58PA, 58TC, 58TCA Airplanes and 60, 65–B80, 65–B90, 90, F90, 100, 300, and B300 Series Airplanes, certificated in any category.'' to read:

''**The New Piper Aircraft, Inc.:** Docket No. 97–CE–61–AD.

Applicability: Models PA–23, PA–23–160, PA–23–235, PA–23–250, PA–E23–250, PA–30, PA–39, PA–40, PA–31, PA–31–300, PA–31–325, PA–31–350, PA–34–200, PA–34–200T, PA–34–220T, PA–42, PA–42–720, and PA–42–1000 airplanes, certificated in any category.

Issued in Kansas City, Missouri on October 1, 1997.

Michael Gallagher,

Manager, Small Airplane Directorate, Aircraft Certification Service.

[FR Doc. 97–26526 Filed 10–6–97; 8:45 am]

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DEPARTMENT OF JUSTICE

Drug Enforcement Administration

21 CFR Parts 1300, 1309, 1310

[DEA Number 163P]

RIN 1117–AA44

Implementation of the Comprehensive Methamphetamine Control Act of 1996; Regulation of Pseudoephedrine, Phenylpropanolamine, and Combination Ephedrine Drug Products and Reports of Certain Transactions to Nonregulated Persons

AGENCY: Drug Enforcement Administration (DEA), Justice.

ACTION: Proposed rule.

SUMMARY: DEA is proposing amending its regulations to implement the requirements of the Comprehensive Methamphetamine Control Act of 1996 (MCA) with respect to the regulation of pseudoephedrine, phenylpropanolamine, and combination ephedrine drug products as List I chemicals and the reporting of certain transactions involving pseudoephedrine, phenylpropanolamine, and ephedrine.

The MCA removed the previous exemption from regulation as List I chemicals which had applied to pseudoephedrine, phenylpropanolamine, and combination ephedrine drug products.

This action makes persons who distribute the products subject to the registration requirement. Also, distributions, importations, and exportations of the products became subject to the existing chemical controls relating to regulated transactions, except in certain circumstances specified in the MCA. The MCA also requires that reports be submitted for certain distributions involving ephedrine, pseudoephedrine, and phenylpropanolamine (including drug products containing those chemicals) by Postal Service or private or commercial carrier to nonregulated persons. This proposed rule amends the regulations to make them consistent with the language of the MCA and to establish the specific procedures to be followed to satisfy the new reporting requirement.

DATES: Written comments or objections should be submitted by no later than December 8, 1997.

ADDRESSES: Comments and objections should be submitted in quintuplicate to the Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration, Washington, D.C. 20537, Attention: DEA Federal Register Representative/CCR.

FOR FURTHER INFORMATION CONTACT: G. Thomas Gitchel, Chief, Liaison and Policy Section, Office of Diversion Control, Drug Enforcement Administration, Washington, D.C. 20537, Telephone (202) 307–7297.

SUPPLEMENTARY INFORMATION:

Introduction

The Chemical Diversion and Trafficking Act of 1988 (CDTA) provided the framework for DEA's programs to control the diversion of the chemicals that are used in the illegal manufacture of controlled substances. The chemical control activities under the CDTA focused primarily on two areas: (1) the export of certain chemicals, mainly solvents, that are used in the illegal manufacture of cocaine and heroin, and (2) the domestic distribution of certain chemicals, principally precursors, that are used in the illegal manufacture of other dangerous drugs, such as methamphetamine, LSD, PCP, etc.

While the controls under the CDTA were successful in denying the cocaine traffickers access to U.S. sources of chemicals, a loophole was exploited by the methamphetamine traffickers. The CDTA contained a provision that ''. . .any transaction in a listed chemical that is contained in a drug that may be marketed or distributed lawfully in the United States under the Federal Food, Drug, and Cosmetic Act. . .'' was not subject to the controls of the CDTA. Thus, while the traffickers found their access to supplies of bulk ephedrine, pseudoephedrine, and other chemicals restricted by the new chemical controls, they were able to circumvent the controls and obtain the necessary source material for manufacturing methamphetamine through the purchase of ephedrine in drug product form, which remained exempt from the chemical controls.

Since passage of the CDTA, the principal focus of Federal and State legislative/regulatory activities with respect to domestic chemical control has been on closing the ''drug product'' loophole that clandestine methamphetamine manufacturers and traffickers have exploited.

As noted earlier, with the establishment of controls over transactions involving bulk pseudoephedrine, ephedrine, and other chemicals, the methamphetamine traffickers turned to single-entity ephedrine drug products for their source material. In the years following the implementation of the CDTA, ephedrine, in drug product form, became the principal source of methamphetamine precursor material. By 1993, domestic clandestine laboratory seizure data showed that 79 percent of the laboratories seized were using ephedrine. During the same period, the use of phenyl-2-propanone (P2P), also a popular source material in early laboratories, declined from a high of 31 percent in 1990 to 16 percent in 1993, and the use of pseudoephedrine as a precursor was virtually non-existent.

The primary source of supply of ephedrine for the traffickers was from mail order and wholesale distributions of single-entity ephedrine tablets. One manufacturer of a popular brand of single-entity ephedrine drug products indicated in interviews with DEA personnel that from January 1991 through September 1992, the company purchased 35 metric tons of ephedrine for the manufacture of its drug products. The company reported that it was producing 40 million 25mg ephedrine tablets per ton of ephedrine. Based on that figure, the company could manufacture 1.4 billion 25mg ephedrine tablets from the 35 tons of ephedrine purchased between the beginning of 1991 and September 1992. During the same period, a rival company purchased 27.5 metric tons of ephedrine, also for the manufacture of ephedrine tablets. The enormous volume of product and the lack of controls over its distribution provided the traffickers with a convenient source of supply.

DEA's initial domestic chemical control efforts focused on stemming the flow of material from the wholesale/mail order industry to the traffickers. While some investigations ultimately resulted in conviction of some of the more eregious violators of the law, DEA and State efforts were hampered by the exemption from regulation granted to the drug products, the lack of other controls under the CDTA, such as registration, and the increasing knowledge of the traffickers and their suppliers in how to shelter themselves from the criminal sanctions of the CDTA.

The Domestic Chemical Diversion Control Act of 1993 (DCDCA) was enacted, in part, to address these shortcomings in the CDTA. Two major elements in the DCDCA were the removal of the exemption from List I controls for single-entity ephedrine drug products and establishment of the registration requirement for distributors, importers, and exporters of List I chemicals. The DCDCA did establish control of the diversion of single-entity ephedrine drug products to clandestine laboratories (combination ephedrine products remained exempt); however, the traffickers switched to pseudoephedrine drug products, which remained exempt from chemical controls and are directly interchangeable with ephedrine drug products in the manufacture of methamphetamine. Companies that had previously been identified as distributors of large volumes of single-entity ephedrine drug products became distributors of large volumes of pseudoephedrine drug products, which has become the primary source material of choice in clandestine laboratories.

In 1993, the year the DCDCA was passed, ephedrine was identified as the source material in 79 percent of the methamphetamine laboratories seized and pseudoephedrine was identified as the source material in less than 2 percent of the seized laboratories. As is shown in the following chart, both the number of clandestine laboratories seized and number of laboratories using pseudoephedrine increased significantly between 1993 and 1996. In 1996, DEA seized 879 methamphetamine laboratories, of which 422 were positively identified as using pseudoephedrine. Of the remainder, there are 246 laboratories for which analysis of the source material has not yet been received, however it is anticipated that most, if not all, were using pseudoephedrine. In all of the identified cases, pseudoephedrine drug products were the source material.

For 1997, 392 clandestine methamphetamine laboratories have been seized as of April 30th, as compared to the 327 laboratories that were seized in all of 1995. At that rate, the total seizures for 1997 could exceed 1300 methamphetamine laboratories. The dramatic increase in seizures is due, in part, to the expansion of the methamphetamine laboratories into the Midwest.

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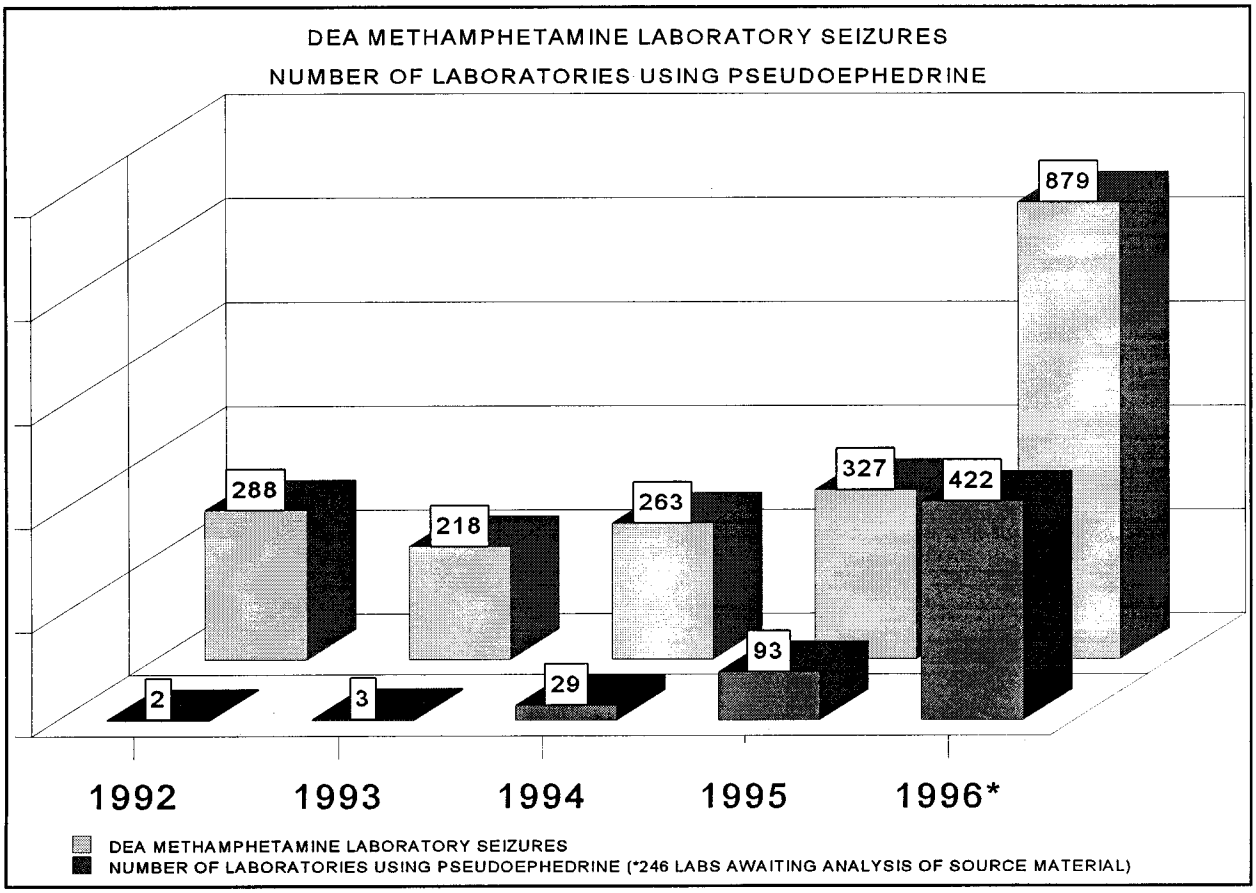

METHAMPHETAMINE LABORATORY SEIZURES IN WHICH DEA PARTICIPATED
(DOES NOT INCLUDE STATE/LOCAL SEIZURES IN WHICH DEA DID NOT PARTICIPATE)

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Pseudoephedrine Regulations

By 1995, it had become clear that action would have to be taken to stem the flow of pseudoephedrine drug products to the clandestine laboratories. DEA proposed regulations to control certain types of pseudoephedrine drug products on October 31, 1995 (60 FR 55348), including reduction of the threshold for pseudoephedrine from 1 kilogram to 24 grams and removal of the exemption from the chemical controls for certain drug products containing pseudoephedrine. DEA's proposal limited the controls to those products which could be readily used for the clandestine manufacture of methamphetamine. The exemption remained in place for gel capsules, liquids, and solid dosage form products containing pseudoephedrine in combination with acetaminophen, aspirin, or ibuprofen in therapeutically significant quantities. Further, DEA proposed to exempt retail distributors from the registration requirement if their activities were restricted to sub-threshold (24 grams) sales of pseudoephedrine drug products. Following comment, DEA published a Final Rule in the **Federal Register** on August 7, 1996 (61 FR 40981). In response to comments, the threshold for pseudoephedrine was raised from the proposed 24 grams to 48 grams and, for retail distributors, application of the cumulative transaction provision was lifted.

The Final Rule was scheduled to become effective on October 7, 1996, however, as discussed below, the rule did not go into effect and was superseded by the provisions of the MCA.

Comprehensive Methamphetamine Control Act of 1996

Paralleling DEA's rulemaking process, the United States Congress, also concerned with the illicit traffic in methamphetamine, introduced legislation to control the diversion of chemicals to clandestine laboratories. The result was the Comprehensive Methamphetamine Control Act of 1996 (Pub. L. 104–237) (MCA), which was enacted on October 3, 1996. The MCA superseded DEA's Final Rule, discussed above, declaring that the regulations were ''* * * null and void, and of no force and effect.'' (MCA, Section 210.)

The MCA legislatively replaced DEA's proposed rulemaking action with a more comprehensive system of controls relating to the distribution, importation, and exportation of pseudoephedrine, phenylpropanolamine, and combination ephedrine drug products, along with other strong tools to attack the illicit traffic. The MCA retained the existing Controlled Substances Act (CSA) requirements for distributors of List I chemicals and added the following changes to the CSA with respect to regulation of drug products containing these three chemicals:

Removal of Certain Drug Product Exemptions

The definition of ''regulated transaction'' (21 U.S.C. 802(39)) is amended in paragraph (A)(iv)(I)(aa) to provide that the exemption for drug products that contain ephedrine, pseudoephedrine, or phenylporpanolamine is removed. The new definition also provides that the sale of ''ordinary over-the-counter

pseudoephedrine or phenylproanolamine'' products by ''retail distributors'' shall not be a regulated transaction. The definition is also amended in paragraph (A)(iv)(II) to provide that the threshold for the sale of pseudoephedrine or phenylpropanolamine products by a retail distributor or a distributor required to submit reports by section 310(b)(3) of the CSA (21 U.S.C. 830(b)(3)) shall be 24 grams of pseudoephedrine base or 24 grams of phenylporpanolamine base in a single transaction. This threshold does not affect the reports required to be filed under 21 U.S.C. 830(b)(3) and 21 CFR 1310.03(c), 1310.05(e), and 1310.06(i), as amended herein.

Creation of a New Category of Distributor and Category of Product To Which Certain Exceptions Apply

Two new definitions are added under section 102 of the CSA (21 U.S.C. 802), as follows:

The term *ordinary over-the-counter pseudoephedrine* or *phenylpropanolamine product* is defined in section 102(45) of the Act (21 U.S.C. 802(45)) as a product containing pseudoephedrine or phenylpropanolamine that is regulated pursuant to the CSA and, except for liquids, packaged with not more than 3 grams of pseudoephedirne or phenylpropanolamine base per package, contained in blister packs, with not more than two dosage units per blister, or where the use of blister packs is not technically feasible, packaged in unit dose packets or pouches. For liquids, the product is sold in package sizes of not more than 3 grams of pseudoephedrine or phenylpropanolamine base. In the context of sales by retail distributors, this has been referred to as the ''safe harbor'' provision, because of the exemption from the definition of ''regulated transaction'' in section 102(39) of the Act (21 U.S.C. 802(39)).

The term *retail distributor* is defined in section 102(46) of the Act (21 U.S.C. 802(46)) as a grocery store, general merchandise store, drug store, or other entity or person whose activities as a distributor relating to pseudoephefrine or phenylpropanolamine products 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. *Sale for personal use* is defined by the MCA as the sale of below-threshold quantities in a single transaction to an individual for legitimate medical use. Further, certain entities are defined by reference to the following Standard Industrial Classification (SIC) codes: a grocery store is an entity within 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.

It is worth noting at this point that while the definition of ''retail distributor'' specifically references general merchandise stores, grocery stores, and drug stores and their respective SIC codes, it also refers to ''* * * or other entity or person * * *'' who engages in the described activities. As a result, a retail distributor is any person (not just a general merchandise store, grocery store, or drug store) whose activities as a distributor relating to pseudoephedrine or phenylpropanolamine products 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.

Expands the Opportunities for Product Specific Exemptions

The MCA amends the CSA to provide that the exemption with respect to a particular ephedrine, pseudoephedrine or phenylpropanolamine drug product shall be reinstated if it is determined that the drug product is manufactured and distributed in a manner that prevents diversion.

Defines Specific Controls for ''Combination Ephedrine Products''

The MCA defines *combination ephedrine product* as a drug product containing ephedrine or its salts, optical isomers, or salts of optical isomers and therapeutically significant quantities of another active medicinal ingredient; and establishes a 24-gram single transaction limit, notwithstanding the form in which the product is packaged, for sales by retail distributors and by distributors required to submit a report under section 310(b)(3) of the CSA (21 U.S.C. 830(b)(3)), and a 1-kilogram threshold for transactions by other distributors, importers and exporters.

Requires Reporting of Certain Distributions by Mail or Carrier

The MCA amends section 310 of the CSA (21 U.S.C. 830) to add a new paragraph (b)(3), which requires that each regulated person who engages in a transaction with a nonregulated person (that is, someone who does not further distribute the product) which involves ephedrine, pseudoephedrine or phenylpropanolamine, including drug products, and uses or attempts to use the Postal Service or any private or commercial carrier shall submit a report of all such transactions each month. The reports shall reflect the name of the purchaser, the quantity and form of the ephedrine, pseudoephedrine or phenylpropanolamine purchased, the address to which the chemicals were shipped, and such other information as is established by regulation.

Effective Dates

The MCA provides that the requirements with respect to the regulation of combination ephedrine products and the reporting requirement became effective on October 3, 1996. The requirements with respect to pseudoephedrine and phenylpropanolamine products become effective on October 3, 1997.

Regulatory Changes To Implement the MCA

Many of the legislative details of the MCA are provided in sufficient detail to be self-implementing without additional regulation. Thus, many of the regulatory amendments to implement the MCA are conforming amendments by which the definitions of ''regulated transaction'' and ''retail distributor'' are updated to parallel the new language in the MCA and the definitions of 1 ''ordinary over-the-counter pseudoephedrine or phenylpropanolamine product'' and ''combination ephedrine product'' are inserted in the regulations; 21 CFR 1310.04 is updated to reflect the new record retention period of two years for List I chemical transactions and the thresholds for transactions involving regulated drug products; and 21 CFR 1310.04–06 are updated to reflect the new reporting requirement. Finally, 21 CFR 1309.71 is being amended to reflect that in retail settings open to the public only ephedrine drug products, in both single-entity and combination form, just be stored behind a counter where only employees will have access; pseudoephedrine and phenylpropanolamine products are not required to be kept behind the counter.

In addition to the above amendments, DEA is proposing to amend 21 CFR Part 1309 to consolidate the various exemptions from the registration requirement into one section, expand the current exemption for retail distributors of combination ephedrine products to include retail distributors of pseudoephedrine and phenylpropanolamine products, and to add a temporary exemption from the registration requirement for persons who distribute, import, or export pseudoephedrine or phenylpropanolamine drug products, provided that they submit an

application for registration on or before December 3, 1997. Any person who engages in such activities and is not subject to an existing or proposed exemption from the registration requirement should submit an application for registration at the earliest possible time, to ensure that they may continue to distribute these products pending issuance of their registration.

Effect of the MCA

While the regulatory changes necessary to implement the MCA are primarily conforming regulations, the scope of the effect of the MCA's requirements is quite broad. The removal of the exemption for pseudoephedrine, phenylpropanolamine, and combination ephedrine drug products makes any person who distributes, imports, or exports them subject to the established chemical registration, recordkeeping, and reporting requirements already in effect for List I chemical handlers, as set out in 21 CFR parts 1309, 1310, and 1313. The MCA, however, created an exemption from the existing chemical controls for sales of ordinary over-the-counter pseudoephedrine and phenylpropanolamine products by retail distributors. Additionally, following the MCA's creation within the law of the category of ''retail distributor'', DEA has provided an exemption from registration for retail distributors whose activities are limited to the activities provided for by the MCA.

With respect to no-retail distributors, various segments of the affected distribution industry have offered varying interpretations of the law, proposing that distributors that only engage in sub-threshold transactions, or distributors that only supply corporately owned retail outlets are not subject to registration and concomitant controls. The CSA requires a registration for activities as a distributor. These two issues are addressed in the final rulemaking entitled ''Comprehensive Methamphetamine Control Act of 1996; Possession of List I Chemicals, Definitions, Record Retention, and Temporary Exemption From Chemical Registration for Distributors of Combination Ephedrine Products'', which will by published in the **Federal Register** on or about October 3, 1997. Interest persons are encouraged to obtain a copy of the final rule, which contains a detailed discussion of the issues.

Within this framework, importers, exporters, and distributors (other than retail distributors) of pseudoephedrine and phenylpropanolamine drug products (including ordinary over-the-counter pseudoephedrine and phenylpropanolamine products) become subject to the registration requirement of the MCA on October 3, 1997, and also the recordkeeping requirements for those transactions that either singly or cumulatively meet the threshold requirements in a calendar month. However, the allow for implementation of these regulations and issuance of the registrations, DEA is providing a temporary exemption from the registration requirement for persons who submit their applications on or before December 3, 1997. For combination ephedrine products, the requirements became effective on October 3, 1996.

Retail distributors of ordinary over-the-counter products are not subject to the registration, recordkeeping and reporting requirements.

For retail distributors whose sales of other pseudoephedrine and phenylpropanolamine products, or combination ephedrine products remain exclusively below the single transaction limit, DEA has established an exemption from the registration requirement in 21 CFR 1309.29. However, retail distributors are subject to the registration, recordkeeping, and reporting requirements to the extent that their transactions equal or exceed the single transaction limit of 24 grams. Additionally, the existing provision that any person who is registered with DEA to distribute or dispense controlled substances is not required to obtain a separate chemical registration applies to distributions of pseudoephedrine, phenylpropanolamine, or combination ephedrine products, as set forth in 21 CFR 1309.25.

They are, however, still subject to the recordkeeping requirements.

Reports of 'Mail Order' Transactions

The MCA requires that a regulated person must report, on a monthly basis, all transactions with non-regulated persons (those persons who do not redistribute the product) that involve ephedrine, pseudoephedrine, or phenylpropanolamine (including drug products that contain these chemicals), and who use or attempt to use the Postal Service or any private or commercial carrier. Each report must contain the name of the purchaser, the quantity and form of the material purchased, and the address to which the material was sent, as well as such other data as may be established by regulation. MCA, Section 401, 21 U.S.C. 830(b)(3). The language of the requirement clearly establishes that all persons engaging in any such transactions must report them. There is no statutory provision for exclusion of any class of person or transaction from the requirement.

DEA is proposing to amend 21 CFR 1310.03, 1310.05, and 1310.06 to incorporate the new reporting requirement. Section 1310.03 reflects who must file, Section 1310.05 reflects when and where the reports shall be filed, and Section 1310.06 reflects the information the report must contain.

The MCA requires monthly reports. DEA is proposing that the reports shall be submitted on or before the 15th day of the month following the month in which the reportable transaction took place; shall be submitted to the Drug Enforcement Administration, Office of Diversion Control, Chemical Operations Section, Washington, D.C. 20537; and shall contain the following information.

1. Supplier's Name and Registration Number
2. Purchaser's Name and Address
3. Name/Address Shipped To (if different from purchaser's name/address)
4. Name of the Chemical Shipped
5. Product Name
6. Dosage Form (if any)
7. Dosage Strength (if any)
8. Number of Dosage Units (if applicable)
9. Package Type
10. Package Quantity
11. Lot Number (for drug products)
12. Date of Shipment

As noted earlier, the MCA requires the name of the purchaser (item 2), the quantity and form of the material (items 4–10), and the address to which the material was shipped (item 3). In addition to the required information, DEA is proposing to include the supplier name and registration number (item 1), to identify the person making the report and their authority to distribute the material; the address of the purchaser (item 2), to assist in identifying the party; the name of the person to which the material is shipped (item 3), if different from the purchaser, to identify the actual recipient of the material in instances where drop-shipment is requested; the lot number of the product (item 11), if a drug product, to assist DEA in tracking products that are diverted; and, the date of the shipment (item 12) to identify when the specific transaction occurred.

While submission of a hard copy report will be adequate to satisfy the requirement, DEA is proposing that electronic reporting, initially via computer disk, also be allowed. Electronic reporting would minimize the burden by eliminating the time and expense necessary to print, package, and mail hard copy reports and would allow for more efficient processing of the data reported. DEA is proposing that persons interested in submitting reports by

electronic means contact the Chemical Operations Section, Office of Diversion Control, DEA at (202) 307–7204 to arrange for submission of electronic reports.

It is important to keep in mind that the reporting requirement applies only to distributions of ephedrine, pseudoephedrine, and phenylpropanolamine via the postal service or private or commercial carrier to nonregulated persons. A distributor does not have to report distributions to regulated persons. In this regard, it is critical that distributors take the appropriate steps to ascertain whether their customers are regulated or nonregulated persons. The failure of a distributor to report a transaction based on a customer's mere representation that they are a regulated person, without further inquiry to confirm that status, may be grounds for administrative, civil, or criminal action. Therefore, the distributor should take appropriate steps to confirm the customer's status as a regulated person. Steps may include verification of the customer's DEA registration status or, if they are not a registrant, inquiry as to whether the products are being obtained solely for use by the customer or whether they will be distributed to others.

Clarification of MCA and CSA Chemical Control Requirements

The MCA's removal of the exemption for pseudoephedrine, phenylpropanolamine, and combination ephedrine products makes a new segment of industry, which is not familiar with DEA's programs and requirements, subject to the chemical controls under the CSA. DEA has received numerous contacts from, and engaged in substantial discussions with, both individual companies and associations regarding the requirements of the MCA and of the chemical controls under the CSA with respect to combination ephedrine products. The upcoming control of pseudoephedrine and phenylpropanolamine products on October 3, 1997, will probably result in further questions and need for clarification of the requirements. DEA remains, as always, available to affected persons to clarify the requirements of the MCA and of the existing chemical controls. Inquiries should be addressed to DEA in writing to the attention of: G. Thomas Gitchel, Chief, Liaison and Policy Section, Office of Diversion Control, Drug Enforcement Administration, Washington, D.C. 20537.

Small Business Impact and Regulatory Flexibility Concerns

The MCA mandates a system of controls (including registration, recordkeeping, and reporting) over the distribution, importation, and exportation of pseudoephedrine, phenylpropanolamine, and combination ephedrine products. Within this system of controls, the MCA does provide an exemption for retail sales of ordinary over-the-counter pseudoephedrine and phenylpropanolamine products; however, wholesale distributions, importations, and exportations of these products are subject to the controls.

The specific mandates of the MCA, if applied as written, would have a far-reaching and significant impact. Pseudoephedrine and phenylpropanolamine over-the-counter products are a common part of every-day life, available in most supermarkets, drug stores, convenience stores, and other retail outlets. Combination ephedrine products are somewhat less common, due to their limited use as a bronchodilator for the treatment of asthma.

DEA consulted with industry organizations associated with over-the-counter drug manufacture and marketing in an effort to determine the potential size of the impacted industry. According to industry sources there are approximately 750,000 retail distributors of pseudoephedrine, phenylpropanolamine, and combination ephedrine products. Accurate identification of the number of wholesale distributors has been somewhat more difficult; however, following consultations with representatives of the food marketing, drug wholesale, and retail supplier industries, DEA estimates that there are approximately 3,000 to 3,500 wholesale locations distributing the products.

In considering the implementation of the MCA, DEA considered the impact of applying various levels of controls, from no application through full application of the requirements of the law, from the perspective of their impact on the industry, on the public health and safety,and on the ability of both industry and the government to administer the controls.

Of the available options, it is readily apparent that imposition of either no controls or the full level of controls would be unrealistic. With respect to no controls, the simple fact that the legislation was deemed necessary is recognition enough of the threat to the public health and safety that the diversion of pseudoephedrine, phenylpropanolamine, and combination ephedrine products to the illicit manufacture of methamphetamine represents and the intent to impose restrictions and monitoring controls on the distribution. At the same time, full application of the controls of the MCA would result in monetary and administrative burdens on the industry and DEA that would be out of proportion with the benefits to be derived and may unnecessarily interfere with legitimate public access to the products. Therefore, alternatives that avoided unnecessary burdens while still accomplishing the mandate of the MCA were explored.

Exploring the alternatives and exceptions required consideration of the scope of commerce, business practices, and capabilities of the different segments of the industry; the scope of diversion from each segment of industry; the activities of the traffickers; and the relative impact of different controls, both on the industry and DEA.

The MCA recognizes two distinct segments within industry: retail distributors, who, by definition, sell small amounts of product in face-to-face transactions to individuals for their personal use; and manufacturers/wholesalers (including importers/exporters), who introduce generally larger quantities of the products into commerce and distribute to other commercial concerns for further distribution, and some of whom also distribute larger quantities to non-commercial concerns without regard or consideration of the intended use.

Collectively, retail distributors are responsible for as great a scope of distribution as manufacturers/wholesalers, serving as they do as the principal source of supply for the individual consumers of the products. Individually, however, their scope of commerce, by definition, is very small, due to the fact that their activities are restricted to sales to individuals of small, personal use quantities of the products. Despite the collective volume of commerce at the retail level, the new controls of the MCA should, as a practical matter, significantly reduce the potential for major diversion from this level (provided retailers comply with the law and are alert to attempts to circumvent the controls). Because to the limited amount of product permitted to be distributed in an individual transaction, attempts to divert the products by the retail distributors should be noticeable, given that the volume of material required is out of proportion with any reasonable amount that might be purchased for personal use. However, traffickers have, on occasion, succeeded in obtaining tens of

thousands of dosage units of products by preying upon unsophisticated or negligent owners or employees of retail establishments who are not aware of, or are unconcerned with, the illicit use to which the products can be put. In addition, there are those unscrupulous individuals who will always be eager to profit from a transaction, capitalizing on the fact that, even with a 24 gram threshold for retail distributors, many of the smaller clandestine laboratories which DEA and state and local authorities are encountering could adequately satisfy their needs for precursor material be obtaining legal drug products at the retail level. This is a situation in which voluntary industry programs to prevent diversion at the retail level will be an important factor in achieving the goals of the MCA.

While far fewer in number (est. 3,000–3,500) and engaging in a lesser number of transactions, manufacturer/wholesalers account for as great a part of the distributions as retail distributors through the volume of products moved in each transaction. The significantly larger transaction sizes, which would be cause for concern at the retail level but are commonplace at the wholesale level, coupled with the relative anonymity of the transaction, have resulted in this segment of industry becoming the source of choice for the traffickers. Through conspiracy and deception, as well as carelessness on the part of some wholesalers, traffickers have been able to obtain large volumes of product without having their transactions stand out against the normal commerce.

Against this backdrop, and in recognition of the effectiveness of the new controls provided by the MCA, chemical controls for the consumer drug products should be focused on the wholesale level, and the retail level should be granted additional exemption as long as they operate within the new limits of the MCA. However, given the opportunistic nature of the traffickers and their preference for an unregulated source of supply, there exists the potential that, with the control of the wholesale distributors, traffickers may intensely focus on the retail level as a source of supply. Therefore, the exemption from the registration requirement applies to retail distributors that limit their activities exclusively to sales below the 24 gram threshold established by the MCA for those products. Retail distributors that engage in the distribution of ordinary over-the-counter pseudoephedrine and phenylpropanolamine products are also exempt from the registration requirement. Thus, it is likely that most, if not all, of the estimated 750,000 retail distributor will qualify and be exempt from registration.

The final element to be addressed was the impact that the controls would have on the industry and DEA. The determining factor in this assessment proved to be the types of transactions conducted and the business practices in the different segments of the industry.

The principal controls required under the MCA are recordkeeping and registration. The recordkeeping requirement applies to any person who engages in a regulated transaction involving a pseudoephedrine, phenylpropanolamine, or combination ephedrine product, other than a retail distribution of an ordinary over-the-counter pseudoephedrine or phenylpropanolamine product. The registration requirement applies to any person who distributes imports, or exports a pseudophedrine, phenylpropanolamine, or combination ephedrine product, except for the exemptions previously discussed.

The recordkeeping requirement would represent a minimal burden for both segments of industry. While retail distributors do not keep records of their sales to individuals as a matter of business practice, their sales are almost exclusively sub-threshold; therefore, the recordkeeping requirement would not apply for their distributions. Wholesale distributors, on the other hand, often engage in transactions that would be subject to the recordkeeping requirement. However, such distributors generally do keep detailed records of their transactions as a matter of good business practice. Such records can be made readily retrievable through the marking of the transactions involving regulated products with an asterisk or other unique code. Further, under the MCA, the record retention period for List I records has been reduced from four years to two years, thus reducing the regulatory burden of List I chemical controls. Additionally, recordkeeping at the wholesale level is further mitigated by a threshold of one kilogram for ephedrine combination and pseudoephedrine products, and 2.5 kilograms for phenylpropanolamine products. Transactions below these thresholds do not require records.

The registration requirement, on the other hand, would have a significant financial impact if applied across the board. The cost of initial registration (at $255.00 each) for 750,000 retail distributors would be over $190 million; annual reregistration (at $116.00 each) would cost approximately $87 million. For the estimated 3,500 manufacturers/wholesalers the cost for initial registration (at $595.00 each) would be slightly more than $2 million; annual reregistration (at $477.00 each) would cost approximately $1.7 million. The respective annual paperwork burdens associated with filing the applications for registration would be 150,000 hours for all retail distributors and 700 hours for all manufacturers/wholesalers. Further, the administrative burden for DEA of having to receive and process over 750,000 applications per year would be enormous.

The cost and administrative burden of requiring registration at the retail level, which is predominantly small business, would be significant, while the potential of large scale diversion at the retail level following implementation of the MCA is greatly reduced given the limited amounts of products being distributed in face-to-face sales to individuals.

Therefore, to best achieve the intended results of the MCA, while minimizing the burden on industry, DEA has determined to propose that: (a) the registration and recordkeeping provisions will apply at the manufacturer/wholesale level, and (b) the exemptions will apply to retail distributors who operate exclusively within the retail quantity limits established by the MCA, irrespective of whether the form of packaging meets the definition of ''ordinary over-the-counter pseudoephedrine or phenylpropanolamine product'' under Section 102(45) of the Act (21 U.S.C. 802(45)). The large volumes of products per transaction at wholesale, the opportunity for relatively anonymous transactions, and the existing history of diversion point to the need for adequate registration and recordkeeping at this level of industry. As noted earlier, the cost of imposing the full controls of the MCA on this segment of the industry will consist of slightly more than $2 million for initial registration, approximately $1.7 million for annual reregistration, and an estimated 700 burden hours per year. The recordkeeping requirement will not result in substantial additional burden due to the fact that the information required can be found in the normal business records (provided they are marked in such a way as to make them readily retrievable) that would be maintained as part of good business practice.

With respect to retail distributors, the determination was made to provide a waiver from the registration, and, thus, recordkeeping, requirement due to the small size and face-to-face nature of the transactions and the limited future potential of diversion from this segment of the industry. The waiver of the registration applies, regardless of the

form of packaging of the drug product, only to those retail distributors whose activities are restricted to below threshold transactions, to ensure that this segment of industry does not become the source of supply for the traffickers. If a retail distributor intends to engage in above-threshold transactions in the course of business, then a registration should be obtained. However, it is understood that unintentional sales which exceed the threshold are possible. In that regard, DEA wishes to note that the chemical control program is focused on preventing the diversion of chemicals to clandestine laboratories and not on identification of an action against the rare, inadvertent, non-egregious above-threshold sale of drug products by a checkout clerk or similar employee of an unregistered retail distributor in the normal course of legitimate business. Firms should, however, to protect their registration exemption, maintain programs to guard against such inadvertent sales.

In total, the proposed regulations, coupled with the existing exemption from chemical registration for controlled substances registrants and the exception from the regulations provided for distributors of prescription drug products that contain List I chemicals, provide a system of controls that minimize the financial and administrative burden on the industry while still allowing effective enforcement of the requirements of the MCA.

The Acting Deputy Administrator hereby certifies that this proposed rulemaking has been drafted in a manner consistent with the principles of the Regulatory Flexibility Act (5 U.S.C. 601 et seq.). As discussed in the preceding section regarding Small Business Impact And Regulatory Flexibility Concerns, consideration was given to the potential impact of varying levels of regulation, the population that would be impacted, and the nature of the problem to be addressed by the regulations. These proposed regulations will provide a system of controls to prevent the diversion of the drug products to clandestine laboratories that is consistent with the intent of the MCA, while providing regulatory relief for the approximately 750,000 retail distributors, most of whom are small businesses. For the remaining 3,000 to 4,000 wholesale distributors, importers, and exporters that will be subject to regulation, the primary impact will be the requirement that they obtain an annual registration from DEA and make occasional reports. A copy of this proposed rulemaking has been provided to the Chief Counsel for Advocacy at the Small Business Administration.

This proposed rulemaking has been drafted and reviewed in accordance with Executive Order 12866. This proposed rulemaking has been determined to be a significant action because the requirements of the MCA affect a broad spectrum of businesses distributing widely used products to the public. This proposed rule would establish specific exemptions to significantly reduce that impact. Therefore, this proposed rulemaking has been reviewed and approved by the Office of Management and Budget.

This action has been analyzed in accordance with the principles and criteria in Executive Order 12612, and it has been determined that this rule does not have sufficient federalism implications to warrant the preparation of a Federalism Assessment.

This rule will not result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of $100,000,000 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.

This rule is not a major rule as defined by Section 804 of the Small Business Regulatory Enforcement Fairness Act of 1996. This rule will not result in an annual effect on the economy of $100,000,000 or more; 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.

List of Subjects

21 CFR Part 1300

Definitions, Drug traffic control.

21 CFR Part 1309

Administrative practice and procedure, Drug traffic control, List I and II chemicals, Security measures. 21 CFR Part 1310

Drug traffic control, List I and II chemicals, Reporting and recordkeeping requirements.

For the reasons set out above, 21 CFR Parts 1300, 1309, and 1310 are proposed to be amended as follows:

PART 1300—[AMENDED]

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 proposed to be amended by revising paragraphs 1300.2(b)(28)(i)(D)(*1*) and (*2*) and by adding new paragraphs 1300.02(b) (31) and (32) to read as follows:

§ 1300.02 Definitions relating to listed chemicals.

* * * * *

(b) * * *

(28) * * *

(i) * * *

(D) * * *

(1)(i) The drug contains ephedrine or its salts, optical isomers, or salts of optical isomers, pseudoephedrine or its salts, optical isomers, or salts of optical isomers, or phenylpropanolamine or its salts, optical isomers, or salts of optical isomers unless otherwise exempted under § 1310.11 of this chapter, except that any sale of ordinary over-the-counter pseudoephedrine or phenylpropanolamine products by retail distributors shall not be a regulated transaction; or

(ii) 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 ephedrine, pseudoephedrine, phenylpropanolamine, or other listed chemical contained in the drug included in the transaction or multiple transactions equals or exceeds the threshold established for that chemical, except that the threshold for any sale of products containing pseudoephedrine or phenylpropanolamine by retail distributors or by distributors required to submit reports by § 1310.03(c) shall be 24 grams of pseudoephedrine or 24 grams of phenylpropanolamine in a single transaction.

* * * * *

(31) The term *ordinary over-the-counter pseudoephedrine or phenylpropanolamine product* means any product containing pseudoephedrine or phenylpropanolamine that is—

(i) Regulated pursuant to the Act; and

(ii)(A) Except for liquids, sold in package sizes of not more than 3.0 grams of pseudoephedrine base or 3.0 grams of phenylpropanolamine base, and that is packaged in blister packs, each blister containing no more than two dosage units, or where the use of blister packs is technically infeasible, that is packaged in unit dose packets or pouches, and

(B) For liquids, sold in package sizes of not more than 3.0 grams of pseudoephedrine base or 3.0 grams of phenylpropanolamine base.

(32) The term *combinaiton ephedrine product* means a drug product containing ephedrine or its salts, optical isomers, or salts of optical isomers, and therapeutically significant quantities of another active medicinal ingredient.

PART 1309—[AMENDED]

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

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

2. Section 1309.22 is proposed to be amended by revising paragraph (b) to read as follows:

§ 1309.22 Separate registration for independent activities.

* * * * *

(b) Every person who engages in more than one group of independent activities shall obtain a separate registration for each group of activities, unless otherwise exempted by the Act or §§ 1309.24 through 1309.26, except that a person registered to import any List I chemical shall be authorized to distribute that List I chemical after importation, but no other chemical that the person is not registered to import.

3. Section 1309.24 is proposed to be revised to read as follows:

§ 1309.24 Waiver of registration requirement for certain activities.

(a) The requirement of registration is waived for any agent or employee of a person who is registered to engage in any group of independent activities, if such agent or employee is acting in the usual course of his or her business or employment.

(b) The requirement of registration is waived for any person who distributes a product containing a List I chemical that is regulated pursuant to § 1300.02(b)(28)(i)(D), if that person is registered with the Administration to manufacture, distribute or dispense a controlled substance.

(c) The requirement of registration is waived for any person who imports or exports a product containing a List I chemical that is regulated pursuant to § 1300.02(b)(28)(i)(D), if that person is registered with the Administration to engage in the same activity with a controlled substance.

(d) The requirement of registration is waived for any person who distributes a prescription drug product containing a List I chemical that is regulated pursuant to § 1300.02(b)(28)(i)(D) of this chapter.

(e) The requirement of registration is waived for any retail distributor whose activities with respect to List I chemicals are limited to the distribution of below-threshold quantities of a pseudoephedrine, phenylpropanolamine, or combination ephedrine product that is regulated pursuant to § 1300.02(b)(28)(i)(D) of this chapter, in a single transaction to an individual for legitimate medical use, irrespective of whether the form of packaging of the product meets the definition of ''ordinary over-the-counter pseudoephedrine or phenylpropanolamine product'' under § 1300.02(b)(31) of this chapter. The threshold for a distribution of a product in a single transaction to an individual for legitimate medical use is 24 grams of pseudoephedrine, phenylpropanolamine, or ephedrine base.

(f) The requirement of registration is waived for any manufacturer of a List I chemical, if that chemical is produced solely for internal consumption by the manufacturer and there is no subsequent distribution or exportation of the List I chemical.

(g) If any person exempted under paragraph (b), (c), (d), or (e) of this section also engages in the distribution, importation or exportation of a List I chemical, other than as described in such paragraph, the person shall obtain a registration for such activities, as required by § 1309.21.

(h) The Administrator may, upon finding that continuation of the waiver would not be in the public interest, suspend or revoke a waiver granted under paragraph (b), (c), (d), or (e) of this section pursuant to the procedures set forth in §§ 1309.43 through 1309.46 and 1309.51 through 1309.57. In considering the revocation or suspension of a person's waiver granted pursuant to paragraph (b) or (c) of this section, the Administrator shall also consider whether action to revoke or suspend the person's controlled substance registration pursuant to 21 U.S.C. 824 is warranted.

(i) Any person exempted from the registration requirement under this section shall comply with the security requirements set forth in §§ 1309.71 through 1309.73 and the recordkeeping and reporting requirements set forth under parts 1310 and 1313 of this chapter.

4. Section 1309.25 is proposed to be revised to read as follows:

§ 1309. Temporary exemption from registration for chemical registration applicants.

(a) Each person required by section 302 of the Act (21 U.S.C. 822) to obtain a registration to distribute, import, or export a combination ephedrine product is temporarily exempted from the registration requirement, provided that the person submits a proper application for registration on or before July 12, 1997. The exemption will remain in effect for each person who has made such application until the Administration has approved or denied that application. This exemption applies only to registration; all other chemical control requirements set forth in parts 1309, 1310, and 1313 of this chapter remain in full force and effect.

(b) Each person required by section 302 of the Act (21 U.S.C. 822) to obtain a registration to distribute, import, or export a pseudoephedrine or phenylpropanolamine drug product is temporarily exempted from the registration requirement, provided that the person submits a proper application for registration on or before December 3, 1997. The exemption will remain in effect for each person who has made such application until the Administration has approved or denied that application. This exemption applies only to registration; all other chemical control requirements set forth in parts 1309, 1310, and 1313 of this chapter remain in full force and effect.

5. Sections 1309.27, 1309.28 and 1309.29 are proposed to be removed.

6. Section 1309.71 is proposed to be amended by revising paragraph (a)(2) to read as follows:

§ 1309.71 General security requirements.

(a)* * *

(2) In retail settings open to the public where drug products containing ephedrine or its salts, optical isomers, or salts of optical isomers are distributed, such drugs will be stocked behind the counter where only employees have access.

* * * * *

PART 1310—[AMENDED]

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

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

2. Section 1310.03 is proposed to be amended by adding a new paragraph (c) to read as follows:

§ 1310.03 Persons required to keep records and file reports.

* * * * *

(c) Each regulated person who engages in a transaction with a

nonregulated person which 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 file monthly reports of each such transaction as specified in § 1310.05.

3. Section 1310.04 is proposed to be amended by removing paragraph (g) and revising paragraph (f)(1) to read as follows:

§ 1310.04 Maintenance of records.

* * * * *

(f) * * *

(1) List I chemicals:

(i) Except as provided in paragraph (f)(1)(ii) of this section, the following thresholds have been established for List I chemicals:

Chemical	Threshold by base weight
(A) Anthranilic acid, its esters, and its salts	30 kilograms.
(B) Benzyl cyanide	1 kilogram.
(C) Ephedrine, its salts, optical insomers, and salts of optical isomers	No threshold-All transactions Regulated.
(D) Ergonovine and its salts	10 grams.
(E) Ergotamine and its salts	20 grams.
(F) N-Acetylanthranilic acid, its esters, and its salts	40 kilograms.
(G) Norpseudoephedrine, its salts, optical isomers, and salts of optical isomers	2.5 kilograms.
(H) Phenylacetic acid, its esters, and its salts	1 kilogram.
(I) Phenlpropanolamine, its salts, optical isomers, and salts of optical isomers	2.5 kilograms.
(J) Piperidine and its salts	500 grams.
(K) Pseudoephedrine, its salts, optical isomers, and salts of optical isomers	1 kilogram.
(L) 3, 4-Methylenedioxyphenyl-2-propanone	4 kilograms.
(M) Methylamine and its salts	1 kilogram.
(N) Ethylamine and its salts	1 kilogram.
(O) Propionic anhydride	1 gram.
(P) Isosafrole	4 kilograms.
(Q) Safrole	4 kilograms.
(R) Piperonal	4 kilograms.
(S) N-Methylephedrine, its salts, optical isomers, and salts of optical isomers (N-Methylephedrine	1 kilogram.
(T) N-Methylpseudoephedrine, its salts, optical isomers, and salts of optical isomers	1 kilogram.
(U) Hydriodic Acid	1.7 kilogrmas (or 1 liter by volume.
(V) Benzaldehyde	4 kilograms.
(W) Nitroethane	2.5 kilograms.

(ii) Notwithstanding the thresholds established in paragraph (f)(1)(i), the following thresholds will apply for the following List I chemicals that are contained in drug products that are regulated pursuant to § 1300.02(b)(28)(i)(D) (Retail distribution thresholds are for a single transaction; the cumulative threshold provision does not apply. All other distributions are subject to the cumulative threshold provision.):

Chemical	Threshold by base weight
(A) Ephedrine, its salts, optical isomers, and salts of optical isomers as the sole therapeutically significant medicinal ingredient.	No threshold-All transactions Regulated.
(B) Ephedrine, its salts, optical isomers, and salts of optical isomers in combination with therapeutically significant amounts of another medicinal ingredient:	
(1) Distributions by retail distributors	24 grams.
(2) Distributions by person required to report under § 1310.03(c)	24 grams.
(3) All other domestic distributions (other than (B) (1) and (2))	1 kilogram.
(4) Imports and Exports	1 kilogram.
(C) Pseudoephedrine, its salts, optical isomers, and salts of optical isomers (other than ordinary over-the-counter products):	
(1) Distributions by retail distributors	24 grams.
(2) Distributions by person required to report under § 1310.03(c)	24 grams.
(3) All other domestic distributions (other than (C) (1) and (2))	1 kilogram.
(4) Imports and Exports	1 kilogram.
(D) Pseudoephedrine, its salts, optical isomers, and salts of optical isomers (Ordinary over-the-counter products):	
(1) Distributions by retail distributors	Exempt.
(2) Distributions by person required to report under § 1310.03(c)	24 grams.
(3) All other domestic distributions (other than (D) (1) and (2))	1 kilogram.
(4) Imports and Exports	1 kilogram.
(E) Phenylpropanolamine, its salts, optical isomers, and salts of optical isomers (other than ordinary over-the-counter products):	
(1) Distributions by retail distributors	24 grams.
(2) Distributions by person required to report under § 1310.03(c)	24 grams.
(3) All other domestic distributions (other than (E) (1) and (2))	2.5 kilograms.
(4) Imports and Exports	2.5 kilograms.
(F) Phenylpropanolamine, its salts, optical isomers, and salts of optical isomers (Ordinary over-the-counter products):	
(1) Distributions by retail distributors	Exempt.

Chemical	Threshold by base weight
(2) Distributions by person required to report under § 1310.03(c)	24 grams.
(3) All other domestic distributions (other than (F) (1) and (2))	2.5 kilograms.
(4) Imports and Exports	2.5 kilograms.

4. Section 1310.05 is proposed to be amended by adding a new paragraph (e) to read as follows:

§ 1310.05 Reports.

* * * * *

(e) Each regulated person required to report pursuant to § 1310.03(c) shall either:

(1) Submit a written report, containing the information set forth in § 1310.06(i), on or before the 15th day of each month following the month in which the distributions took place. The report shall be submitted under company letterhead, signed by the person authorized to sign the registration application forms on behalf of the registrant, to the Chemical Operations Section, Office of Diversion Control, Drug Enforcement Administration, Washington, D.C. 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 Chemical Operations Section, Office of Diversion Control, Drug Enforcement Administration, Washington, D.C. 20537, ATTN: Electronic Reporting.

5. Section 1310.06 is proposed to be amended by adding a new paragraph (i) to read as follows:

§ 13.10.06 Content of records and reports.

* * * * *

(i) Each monthly report required by § 1310.05(e) shall provide the following information for each distribution:

(1) Supplier's name and registration number;

(2) Purchaser's name and address;

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

(4) Name of the Chemical and total amount shipped;

(5) Date of shipment;

(6) Product name (if drug product);

(7) Dosage form (if drug product);

(8) Dosage strength (if drug product);

(9) Number of dosage units (if drug product);

(10) Package type (if drug product);

(11) Package quantity (if drug product);

(12) Lot number (if drug product).

6. Section 1310.10 is proposed to be amended by revising paragraph (d) introductory text to read as follows:

§ 1310.10 Removal of the exemption of drugs distributed under the Food, Drug, and Cosmetic Act.

* * * * *

(d) Any manufacturer seeking reinstatement of a particular drug product that has been removed from an exemption may apply to the Administrator for reinstatement of the exemption for that particular drug product on the grounds that the particular drug product is manufactured and distributed in a manner that prevents diversion. In determining whether the exemption should be reinstated the Administrator shall consider:

* * * * *

Dated: September 26, 1997.

James S. Milford,

Acting Deputy Administrator.

[FR Doc. 97–26150 Filed 10–6–97; 8:45 am]

BILLING CODE 4410–09–M

FEDERAL EMERGENCY MANAGEMENT AGENCY

44 CFR Part 61

RIN 3067–AC73

National Flood Insurance Program (NFIP); Standard Flood Insurance Policy

AGENCY: Federal Emergency Management Agency (FEMA).

ACTION: Proposed rule.

SUMMARY: This proposed rule would increase the amount of the deductible under the Standard Flood Insurance Policy—from $750 to $1,000—for structures with subsidized coverage.

DATES: All comments received on or before November 7, 1997 will be considered before final action is taken on the proposed rule.

ADDRESSES: Please submit any written comments to the Rules Docket Clerk, Office of General Counsel, Federal Emergency Management Agency, 500 C Street, S.W., room 840, Washington, DC 20472, (facsimile) 202–646–4536.

FOR FURTHER INFORMATION CONTACT: Charles M. Plaxico, Jr., Federal Emergency Management Agency, Federal Insurance Administration, (202) 646–3422, (facsimile) (202) 646–4327.

SUPPLEMENTARY INFORMATION: This proposal is the result of an ongoing review and reappraisal of the National Flood Insurance Program (NFIP) to achieve greater administrative and fiscal effectiveness in the NFIP's operations. The proposed amendment is also intended to help the NFIP increase its capability to build reserves for catastrophic loss years. This can be handled either by rate increases, or by other means such as imposing coverage limitations or increasing deductibles, or by both.

Section 1308(b)(2) of the National Flood Insurance Act of 1968, as amended, charges the Director of FEMA with the responsibility of establishing ''chargeable premium rates'' which are ''* * * adequate, on the basis of accepted actuarial principles, to provide reserves for anticipated losses, or if less than such amount, consistent with the objective of making flood insurance available where necessary at reasonable rates so as to encourage prospective insureds to purchase such insurance * * *''.

Since there have been three premium increases in the last three years—two in the subsidized premium rates and a premium surcharge mandated by § 555 of the National Flood Insurance Reform Act of 1994, for the addition of increased cost of compliance coverage, FEMA believes that the better approach to enhancing fiscal soundness would be by adjustment to the deductible provisions for policies which are issued using subsidized rates. Therefore, this proposed rule would increase the standard deductible for structures covered by insurance at subsidized premium rates from $750 to $1,000. Concurrent with this proposed change, insureds would be provided the option to pay a higher premium at full-risk rates to ''buy back'' a reduced deductible under their Standard Flood Insurance Policy (SFIP).