

ACTION: Final rule.

SUMMARY: The Tennessee Valley Authority is amending its Freedom of Information Act (FOIA) regulations to reflect an organizational reassignment of the FOIA function within TVA. It also provides a new address for filing FOIA appeals.

EFFECTIVE DATE: March 28, 2002.

FOR FURTHER INFORMATION CONTACT:

Denise Smith, FOIA Officer, Tennessee Valley Authority, 400 W. Summit Hill Drive (ET 5D), Knoxville, Tennessee 37902-1499, telephone number (865) 632-6945.

SUPPLEMENTARY INFORMATION: This rule was not published in proposed form since it relates to internal agency organization and administration. Since this rule is nonsubstantive, it is being made effective March 28, 2002.

List of Subjects in 18 CFR Part 1301

Freedom of Information, Government in the Sunshine, Privacy.

For the reasons stated in the preamble, TVA amends 18 CFR Part 1301 as follows:

PART 1301—PROCEDURES

1. The authority citation for part 1301, Subpart A, continues to read as follows:

Authority: 16 U.S.C. 831-831ee, 5 U.S.C. 552.

2. In § 1301.9, revise paragraph (a) to read as follows:

§ 1301.9 Appeals.

(a) *Appeals of adverse determinations.* If you are dissatisfied with TVA's response to your request, you may appeal an adverse determination denying your request, in any respect, to TVA's FOIA Appeal Official, the Vice President, External Communications, Tennessee Valley Authority, 400 Summit Hill Drive (ET 6A), Knoxville, TN 37902-1499. You must make your appeal in writing and it must be received by the Vice President, External Communications within 30 days of the date of the letter denying your request. Your appeal letter may include as much or as little related information as you wish, as long as it clearly identifies the TVA determination (including the assigned request number, if known) that you are appealing. An adverse determination by the TVA

Appeal Official will be the final action of TVA.

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Tracy S. Williams,

Vice President, External Communications, Tennessee Valley Authority.

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DEPARTMENT OF JUSTICE

Drug Enforcement Administration

21 CFR Parts 1300, 1309, 1310

[DEA Number 163F]

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: Final rule.

SUMMARY: DEA is 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 combination ephedrine drug products.

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 pseudoephedrine, phenylpropanolamine, and ephedrine (including drug products containing those chemicals) by Postal Service or private or commercial carrier to nonregulated persons.

This final rule amends the regulations to make them consistent with the

language of the MCA and to establish specific procedures to be followed to satisfy the new reporting requirement. DEA has, where possible, taken action to limit the public impact of these new requirements while remaining consistent with the intent of the MCA to attack the diversion of regulated drug products to the clandestine manufacture of methamphetamine.

EFFECTIVE DATE: April 29, 2002.

FOR FURTHER INFORMATION CONTACT:

Patricia M. Good, Chief, Liaison and Policy Section, Office of Diversion Control, Drug Enforcement Administration, Washington, DC 20537, Telephone (202) 307-7297.

SUPPLEMENTARY INFORMATION:

Special Notice Regarding Phenylpropanolamine

On November 6, 2000, the Food and Drug Administration (FDA) issued a public advisory announcing that it is taking steps to remove phenylpropanolamine from all drug products and has requested that all drug companies discontinue marketing products containing phenylpropanolamine.

What Is the Basis for This Action?

The Comprehensive Methamphetamine Control Act of 1996 was enacted on October 3, 1996, to provide a 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 in regulated chemicals. The MCA retained the existing Controlled Substances Act (CSA) requirements for distributors of List I chemicals and made certain changes with respect to the regulation of drug products containing pseudoephedrine, phenylpropanolamine, and ephedrine.

What Are the Requirements of the MCA?

Principal among the changes made by the MCA was amendment of the definition of regulated transaction (21 U.S.C. 802(39)) to remove the exemption for drug products that contain pseudoephedrine, phenylpropanolamine, or ephedrine and to establish a 24 gram threshold for the sale of pseudoephedrine or phenylpropanolamine products by a retail distributor or a distributor required to make reports by section 310(b)(3) of the CSA (21 U.S.C. 830(b)(3)). The definition was also amended to provide that the sale of ordinary over-the-counter

pseudoephedrine or phenylpropanolamine products by retail distributors shall not be a regulated transaction.

The MCA also added two new definitions:

The term ordinary over-the-counter pseudoephedrine or phenylpropanolamine product is defined in section 102(45) of the CSA (21 U.S.C. 802(45)) as a product containing pseudoephedrine or phenylpropanolamine that is regulated pursuant to the CSA and, except for liquids, is packaged with not more than 3 grams of pseudoephedrine 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 per package.

The term retail distributor is defined in section 102(46) of the CSA (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 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. 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.

The MCA also defined combination ephedrine product and established a 24 gram single transaction limit, notwithstanding the form of product packaging, for sales by retail distributors and 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.

Additionally, the MCA amended section 310(b)(3) of the CSA (21 U.S.C. 830(b)(3)) to require that regulated persons who engage in transactions with pseudoephedrine, phenylpropanolamine, or ephedrine (including drug products containing those chemicals) to non-regulated persons (i.e., someone who does not further distribute the product) and use or attempt to use the Postal Service or any private or commercial carrier shall submit a report of all such transactions each month.

The MCA also provided expanded opportunity for reinstatement of a

product exemption, through amendment of section 204 of the CSA (21 U.S.C. 814(e)), if it is determined that the product is manufactured and distributed in a manner that prevents diversion, and changed the record retention period for List I chemical transactions to 2 years from 4 years.

The requirements with respect to the regulation of combination ephedrine drug products and reports of sales to nonregulated individuals went into effect on October 3, 1996. In order to allow uninterrupted availability of the products while companies applied for and received their registrations, DEA published interim and final rules in the **Federal Register** on February 10, 1997 and October 7, 1997 (62 FR 5914 and 62 FR 52253) respectively, establishing a temporary waiver of the registration requirement for any person who submitted an application for registration prior to December 3, 1997. DEA also published a notice regarding the reporting requirement on February 7, 1997 (62 FR 5851), which provided affected persons guidance regarding submission of the required reports to DEA and requested certain additional information be submitted with the reports.

The requirements with respect to pseudoephedrine and phenylpropanolamine became effective on October 3, 1997.

What Regulatory Amendments Is DEA Making?

This rule makes final the notice of proposed rulemaking (NPRM) that DEA published in the **Federal Register** on October 7, 1997 (62 FR 52294), which proposed to implement certain regulatory changes mandated by the MCA. The changes included conforming regulatory definitions to the language of the MCA; new record retention, threshold and reporting requirements; and expanding waivers of the registration requirement. These changes are discussed in greater detail in the following paragraphs.

Because many of the requirements of the MCA were set out in such detail as to be self-implementing, many of the proposed regulatory changes are conforming amendments to make the language of the regulations consistent with that of the new law. The definitions of regulated transaction and retail distributor are updated and the definitions of ordinary over-the-counter pseudoephedrine or phenylpropanolamine product and combination ephedrine product are inserted. Additionally, 21 CFR 1310.04 was proposed to be amended to reflect the new List I chemical record retention

period and new threshold requirements; 21 CFR 1310.04–06 were proposed to be updated to reflect the new reporting requirement; and 21 CFR 1309.71 was proposed to be amended to reflect that in retail settings open to the public ephedrine drug products, in both single-entity and combination form, must be stored behind a counter where only employees have access. Finally, 21 CFR part 1309 was proposed to be amended to consolidate the various waivers of the registration requirement into one section, expand the current waiver of registration for retail distributors of combination ephedrine products to include retail distributors of pseudoephedrine and phenylpropanolamine products, and to provide a temporary waiver of the registration requirement for persons who distribute, import, or export pseudoephedrine or phenylpropanolamine drug products provided they submitted an application on or before December 3, 1997.

What Comments Were Received?

The comment period for the NPRM closed on December 8, 1997. Twenty comments were submitted which, while supportive of the efforts of the law and regulations to control the diversion of drug products and the illicit manufacture of methamphetamine, raised the following issues and concerns:

Registration Requirement

A number of comments focused on the registration requirement, expressing concerns that the paperwork burden and cost of registration are not commensurate with the volume of business being conducted in the products or that the manner in which the products are packaged or distributed is not conducive to diversion. The commenters recommended that DEA adopt alternative registration requirements, allowing for:

1. Exempting below threshold sales from the registration requirement;
2. A related general recommendation was also made that the retail distribution exemption for ordinary over-the-counter products be extended to the wholesale level;
3. Exempting distributors that purchase '2 pill packs' (presumably products that meet the definition of ordinary over-the-counter pseudoephedrine and phenylpropanolamine products) to manufacture retail displays and refills that contain 24 to 30 packs, for sale to distributors who, in turn, sell to retailers. This segment of the industry should not be subject to registration on

the grounds that clandestine laboratory operators are not interested in '2 pill packs' and the \$595.00 cost of registration would be more than many of the distributors of these products would be willing to pay.

4. Exempting any distributor that purchases less than the threshold amount in a calendar month; and

5. Exempting vending machine sales from the registration requirement.

The first two recommendations, exemption of below threshold sales and extension of the retail exemption for ordinary over-the-counter pseudoephedrine and phenylpropanolamine products to wholesale distributions of the products were discussed at length in DEA's final rule, published in the **Federal Register** on October 7, 1997 (62 FR 52253) (DEA-154F, RIN 1117-AA42), entitled Implementation of the Comprehensive Methamphetamine Control Act of 1996; Possession of Listed Chemicals Definitions, Record Retention, and Temporary Exemption From Chemical Registration for Distributors of Combination Ephedrine Products. In summary, DEA noted with respect to below threshold sales that the chemical registration requirement was patterned after the system of registration required for controlled substances handlers. The controlled substances registration system, while providing exemptions for certain products that contain controlled substances, does not take into consideration the quantity of controlled substance involved when determining whether registration is required; either a product is exempt from registration or it is not, the amount of the product involved in the transaction is immaterial. To clarify the fact that it is product exemption, rather than transaction exemption, that applies, §1309.21 is being amended to clarify that the exemption in §1300.02(b)(28)(i)(D) is determined irrespective of the threshold provisions in §1300.02(b)(28)(i)(D)(2).

With respect to the issue of extension of the retail distributor exemption for ordinary over-the-counter products to wholesale activities within the retail distribution chain, DEA noted that the MCA does not exempt retail distributors, it exempts sales by retail distributors, which sales are defined in section 401(b)(4) of the MCA as " * * either directly to walk-in customers or in face-to-face transactions by direct sales." The sales are further qualified in section 401(b)(4) of the MCA as involving " * * below threshold quantities in a single transaction to an individual for legitimate medical use." The specific language of the MCA in

defining the type of transactions that are exempted from the requirements of the law makes it clear that only qualifying retail transactions are to be exempted; the language does not contemplate the exemption of a major class of wholesale distributions.

In connection with the first two recommendations, certain commenters also raised the concern that, based on their sales, the initial registration fee of \$595.00 was too high. It should be noted that on October 17, 1997, DEA published a notice in the **Federal Register** (62 FR 53958) waiving a substantial portion of the registration fee, reducing it from \$595.00 to \$116.00. The reduction of the fee should address those concerns.

With respect to the issue of '2 packs', the assertion of the commenter that such products would not be of interest to clandestine laboratory operators at the retail level given their pricing and the 24 gram transaction limit may be true. However, at the wholesale level, with its much higher thresholds and size of transactions, 2 packs, while not the most convenient, would still represent a worthwhile source of material. The reduction of the fee should address the principal concern of this industry with respect to registration.

The fourth recommendation, exempting distributors from registration if they purchase less than a threshold amount in a calendar month, while appearing to be reasonable on the surface, would pose a potentially fatal flaw in the chemical control system. The basic premise of the registration system is to require identification of the participants in the system to DEA and give DEA the opportunity to review their credentials and background. Allowing an entire class of distributors to engage in general distribution outside of this system would provide an opportunity for illicit manufacturers to obtain the supplies they need. The current thresholds for pseudoephedrine and phenylpropanolamine at the wholesale level are 1 kilogram (2.2 pounds) and 2.5 kilograms (5.5 pounds) respectively. Under the proposed scenario, anyone could obtain drug products containing 2 pounds of pseudoephedrine and 5 pounds of phenylpropanolamine per month without being identified to DEA or subject to any background checks to confirm their legitimacy. This volume of product would allow, at the currently estimated conversion ratio of 50% to 70% in clandestine laboratories, the manufacture of between 1 and 1.4 pounds of methamphetamine and 2.5 to 3.5 pounds of amphetamine per month. In light of the opportunistic nature of

the clandestine laboratory operators, providing such an unregulated source of supply would be a golden opportunity. Further, the reduction of the new application fee minimizes the economic burden associated with registration for this class of distributor.

The fifth issue, vending machine sales, is apparently based on the mistaken assumption that vending machine sales and the supplying of vending machines is a form of wholesale distribution. DEA considers the sale of regulated drug products via vending machines to be retail sales. The sales are made in 'face-to-face' transactions to individual users for their personal medical use in amounts less than the 24 gram threshold. In a related issue, an individual owner of vending machines may receive and distribute regulated drug products to his/her machines without obtaining a registration as a distributor. DEA recognizes that, as a rule, vending machines are placed in locations that are not under the control of the machine owner and to which the owner cannot usually have supplies delivered. Under such circumstances, the owner of the machines may receive regulated drug products at another location for the purpose of resupplying the machines, without having to be registered as a distributor.

After careful review of the comments, DEA has concluded that its current waivers of the registration requirement constitute an appropriate balance between minimizing regulatory burden and preventing diversion. DEA believes that expanding the registration waivers as suggested in the above comments could result in an appreciable increase in the potential for diversion.

Security Requirements

Three commenters expressed concerns regarding the proposed requirement that combination ephedrine drug products be maintained behind the counter, noting that such a requirement appears to be inconsistent with the waiver of registration for retail distributors of these products. The diversion of ephedrine products at the retail level has been a significant problem in the past and remains an issue today. DEA is aware that there is some level of retail diversion and is concerned that, as controls at higher levels in the distribution system become more effective, the pressure to divert from retail sources will increase. However, in lieu of requiring that combination ephedrine products be maintained behind the counter, DEA will continue to monitor diversion from this level and, if circumstances require,

will consider additional controls, including removing the exemption from registration for retail distributors of non-ordinary over-the-counter drug products as well as imposition of additional security requirements. The existing requirement that single-entity ephedrine drug products be stocked behind the counter, where only employees have access, remains in effect.

Mail Order Reporting Requirement

A number of comments were received regarding the mail order reporting requirement. The comments focused on the following issues:

1. In addition to requiring that all distributions (regardless of amount) of ephedrine, pseudoephedrine, or phenylpropanolamine to non-regulated persons be reported under the mail order reporting requirement, the MCA also establishes a general distribution threshold of 24 grams in a single transaction, rather than the existing thresholds set forth in §1310.04, for persons required to submit mail order reports. Some commenters expressed the position that the 24 gram threshold applies only to those transactions that must be reported and not to all transactions of the distributor;

2. The reporting requirement should be amended to exclude pharmacies that deliver or mail prescriptions to patients and to exclude mail order transactions that are below established thresholds;

3. The reporting requirement is in conflict with patient confidentiality requirements; and

4. The additional information required by DEA adds to an already burdensome requirement, especially the requirement for the date of transaction and the lot number, which should be stricken from the requirement.

The first of the commenters' concerns relates to specific requirements of the MCA with respect to reporting mail order transactions over which DEA has no discretion. The MCA requires, at Section 402 (codified at 21 U.S.C. 830(b)(3)), that all distributions (regardless of quantity) of ephedrine, pseudoephedrine, or phenylpropanolamine to non-regulated persons be reported to DEA monthly in a format determined by the Attorney General (delegated to DEA). In section 401 (codified at 21 U.S.C. 802(39)(A)(iv)(II)), the MCA also defines a "regulated transaction," which is subject to various other regulatory requirements of Section 830 and elsewhere, to be any single transaction of 24 grams or more by a mail order distributor (the statute refers to "distributors required to submit reports by section 830(b)(3) of this title"). For

this business sector, the higher distribution thresholds set forth in §1310.04 (e.g., 1 kilogram for pseudoephedrine and 2.5 kilograms for phenylpropanolamine) are not applicable. Therefore, the position expressed by the commenters that the 24 gram threshold applies only to those transactions that must be reported under the mail order reporting requirement, and not to all transactions of a mail order distributor, runs contrary to the law as interpreted by the agency.

One commenter noted that the proposed amendment to §1310.04(f)(ii) should be amended to reflect that the single transaction threshold also applies to distributions by persons required to report mail order transactions. This correction has been made to the final regulations.

As to the issue of waiving the reporting requirement for pharmacies for delivering or mailing regulated drug products to patients, the law provides no discretion to waive the reporting requirement for any categories of transactions; all described transactions must be reported. A legislative amendment is being considered to address this issue.

Amending the mail order requirement to exclude the delivery or mailing of prescriptions would also address the issue of patient confidentiality. Pending such an amendment, it must be noted that DEA often reviews prescription information, including the names and addresses of patients, in the course of investigations and audits. Disclosure of such information from DEA's files is made only to other law enforcement and regulatory agencies engaged in the enforcement of controlled substances or chemical control laws; when relevant in any investigation or proceeding for the enforcement of controlled substances or chemical control laws; and when necessary for compliance by the United States under treaty or other international agreement. Other requests for disclosure of such information must be made under the Freedom of Information Act and are subject to the full requirements and protections of the Privacy Act. Further, section 310 of the CSA (21 U.S.C. 830), which requires chemical records and reports, including the mail order reports, also contains protections against the disclosure of confidential business information collected by DEA pursuant to the section. DEA is amending §1310.06 to add a paragraph clarifying that the protections set forth in 21 U.S.C. 830(c) for confidential business information will also apply to information collected in the mail order reports.

With respect to the additional information (name of recipient, if different from the purchaser; address of purchaser, if different from address delivered to; shipping date; and lot number, if drug products) that DEA is requesting in the reports, such information is important in helping to identify efforts to divert the chemicals, especially where orders are being placed with a number of different mail order providers. It is not unusual for traffickers to attempt to circumvent the chemical controls by ordering small, apparently innocuous amounts of product from a variety of different sources or having a number of individuals place orders for delivery to the same location. The availability of the additional information is critical for identification of such efforts. The lot numbers for drug products are important in allowing DEA to track and identify the source of products that are found at clandestine laboratory sites. Finally, to reflect organizational changes within DEA, references to "Chemical Operations Section" have been changed to "Chemical Control Section".

One commenter requested clarification of the shipment date, package type, and package quantity. Shipment date refers to the date the product is shipped by the regulated person to the non-regulated person. Package type refers to the specific form of packaging of the product, i.e., bottle, blister pack, etc., and package quantity refers to the number of packages shipped. Section 1310.06 has been amended to include examples for items, where appropriate, for clarification.

One commenter expressed concern that with the mail order reporting requirement " * * * DEA is unfairly creating an 'uneven' playing field between retail distributors and mail order distributors."

The statutory language enacting the mail order reporting requirement is clear and unequivocal and allows DEA no discretion to limit the requirement or exclude any categories of mail order transactions; all mail order transactions by a regulated person with a non-regulated person must be reported. As noted earlier, DEA is considering a legislative amendment to allow some discretion in the enforcement of this requirement of the MCA. However, until such an amendment is passed by Congress and signed into law, DEA must enforce the requirement as written.

In a related issue, two commenters that distribute ephedrine and pseudoephedrine products to Occupational Health Clinics requested that proposed §1310.04(f)(1)(i)(B)(2) and (D)(2) be amended to increase the

threshold from 24 grams to 160 grams for products packaged in unit dose form. DEA has responded directly to each of the commenters clarifying the fact that distributions to Occupational Health Clinics would not be subject to the mail order reporting requirement. If the commenters' activities are restricted to such sales they would be subject to the appropriate wholesale thresholds for ephedrine and pseudoephedrine and not to the threshold that applies to persons required to submit mail order reports.

Waiver of the Registration Requirement for Retail Distributors

One commenter objected to DEA's waiver of registration, contained in §1309.24(e), for retail distributors of regulated drug products " * * * irrespective of the form of packaging * * *". The commenter argued that Congress intended that the exemption apply only to 'ordinary over-the-counter products' and that the commenter was unaware of * * * any authority that DEA has to determine that 'minimizing the burden on industry' is more important than implementing public law."

The implementation of any law that has an impact on legitimate commerce is a balancing act between the specific requirements of the law and the impact that the law will have on the industry engaged in such commerce. The Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*), Executive Order 12866, and the Small Business Regulatory Enforcement Fairness Act of 1996 all require that implementation of regulatory requirements be accomplished in such a manner as to minimize the burden on the public to the greatest possible extent while remaining consistent with the requirements of the law. DEA has, in implementing the requirements of the MCA, acted consistently with those principles.

The definition of 'retail distributor' established by Congress is sufficiently restrictive that, as noted in the proposed rule, * * * 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 of 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." This fact, coupled with the widespread concern

that these regulations have the smallest necessary impact on public access to the products at the retail level led DEA to exercise its authority under section 302(d) of the CSA (21 U.S.C. 822(d)) to exempt retail distributors from the registration requirement.

It should be noted that waiver of registration for retail distributors does not confer 'ordinary over-the-counter' status on products not meeting the definition of that category. Retail distributors whose transactions in listed chemicals consist solely of 'ordinary over-the-counter' products are exempt from the registration, recordkeeping, and reporting requirements of §1310.05, but not the reporting requirements of §1310.03(c). Retail distributions of products not meeting the definition of that category that exceed the retail threshold of 24 grams in a single transaction are subject to the registration, recordkeeping, and reporting requirements.

In granting the waiver of registration for retail distributors of regulated drug products irrespective of the form of packaging, DEA has acted within the bounds of responsible rulemaking without jeopardizing the requirements or intent of the MCA. Two commenters, representing elements of the manufacturing and retail distribution industry, recognized the waiver as * * * a rational interpretation of the MCA" and commended DEA for the action.

Miscellaneous

One commenter, while acknowledging the analysis of regulatory alternatives in the proposed rule, expressed concern that DEA has overlooked a class of affected entities that deserves additional consideration: wholesalers that distribute their products to small independent retailers. The commenter suggested that DEA consider less frequent reporting or waive the registration requirement for such small wholesalers.

DEA is familiar with the independent wholesale industry, having worked with the national trade associations representing this segment of the industry on a number of occasions since the passage of the MCA regarding its requirements and impact on the industry. As a result of requests from this part of the industry, DEA waived a substantial portion of the registration fee in order to reduce the economic impact of registration on the wholesalers. However, as noted earlier, waiving the registration requirement altogether is not an acceptable alternative; to do so would establish an unregulated portion of the industry that could become a

source of supply for clandestine laboratory operators. This segment of the industry has been the subject of a substantial portion of DEA's enforcement efforts. Since October, 1997, there have been at least 33 criminal convictions and 23 civil fines obtained against wholesalers, all for violations of the CSA involving sales of regulated drug products. Additionally, at least 4 wholesalers have surrendered their registrations for violations involving regulated drug products, 6 have had their registrations suspended, and 13 companies are the subject of administrative actions to deny an application or revoke a registration. A recent national enforcement action directed at this segment of the industry resulted in over 170 arrests and seizure of sufficient product to provide over 12 tons of pseudoephedrine to the methamphetamine traffickers. Thus, it is clear that some level of regulation and oversight of this sector of the industry is necessary.

With respect to the issue of reporting, the only reports that must be made periodically are mail order reports, which are mandated by Congress. DEA has no discretion to modify the required reporting period. All other reports are to be submitted on an as-needed basis using the guidance of §1310.05. In total, DEA has taken action where possible to limit the burden on industry without compromising the legislative efforts to attack the problem of diversion of regulated drug products to clandestine laboratories.

In a related issue, two commenters objected to the characterization of the wholesale industry as the source of choice for the clandestine laboratory operators. It has never been the intent of DEA to cast the wholesale industry in a negative light. The majority of the industry is honest and reputable and has worked with DEA and Congress in an effort to address the diversion problem. However, there are the few proverbial 'bad apples' whose activities reflect poorly on the industry as a whole. These individuals, who are the focus of DEA's enforcement efforts, have taken advantage of their position within the wholesale industry to sell their products to clandestine laboratory operators or those who supply them, in order to gain illicit profits. DEA recognizes that while the clandestine laboratory operators have been able to obtain their supplies through this route, the actions of the few corrupt wholesalers are in no way a reflection of the industry as a whole. DEA looks forward to working with the legitimate industry in dealing with the problem of

diversion of regulated drug products to clandestine laboratories.

One commenter requested clarification regarding the status of a variety of activities, such as contract processors, vending machine sales, and samples and donations. The commenter also proposed that DEA should more clearly define the evidentiary standards for reinstatement of the drug product exemption.

DEA recognizes that there are within the chemical and drug product industry certain activities of which regulation is not necessary for effective enforcement of the law. In that regard, DEA is preparing a separate proposed rule regarding the waiver for certain activities, including those listed in the previous paragraph, from either the registration requirement or the fee requirement. Until such waivers are finalized, however, the full requirements of the law and regulations apply.

With respect to the exemption criteria, DEA understands the desire on the part of industry for concrete, objective evidentiary guidelines to be satisfied in requesting reinstatement of the exemptions for certain drug products. However, the variety of circumstances that could affect a decision to grant such a reinstatement for any product is so great that the establishment of a concise and exclusive standard is not possible. As an alternative, DEA maintains a policy of open discussion with applicants for reinstatement. If there are any questions regarding an application or is a need for additional information, DEA will work with the applicant in an effort to address the issues.

One commenter objected that during the course of pre-registration investigations, DEA investigators were requesting information to which DEA is not entitled. This concern was also brought directly to DEA's attention by the commenter and has been resolved through a modification of the pre-registration investigation information collection procedures.

One commenter noted that the difficulties and burdens experienced by small distributors in complying with the recordkeeping requirement reinforce the need to establish waivers from the regulations where possible. DEA is committed to ensuring that the requirements of the chemical control program are applied with the least possible public burden while remaining consistent with the intent of the law. As noted earlier, DEA is preparing a proposal to exempt certain activities from the registration or fee requirement. DEA will continue to review the

chemical control requirements to try and identify further waivers that might be possible.

Note Regarding Amendments to the Regulations

On October 17, 2001, DEA published a final rule in the **Federal Register** entitled "Control of Red Phosphorus, White Phosphorus, and Hypophosphorous Acid (and its salts) as List I Chemicals". That final rule added new text to 21 CFR 1309.29. This final rule removes 21 CFR 1309.29 and incorporates its text into 21 CFR 1309.24. The amendments made in the October 17, 2001, final rule have been incorporated into new 21 CFR 1309.24, where appropriate.

Regulatory Flexibility Act

The Administrator in accordance with the Regulatory Flexibility Act (5 U.S.C. 605(b)), has reviewed this regulation and by approving it hereby certifies that this rulemaking will not have a significant economic impact upon a substantial number of small entities for the following reasons. As discussed in the NPRM, in the section regarding SMALL BUSINESS IMPACT AND REGULATORY FLEXIBILITY CONCERNS, consideration was given to the population that would be impacted, the potential impact of varying levels of regulation, and the nature of the problem to be addressed by the regulations.

As noted in the NPRM, there are two distinct, but related, groups within the industry: retail distributors and wholesalers. There are an estimated 750,000 retail distributors who distribute the regulated drug products directly to the public. Their activities are, by law, limited almost exclusively to sales of 24 grams or less directly to walk-in customers or in face-to-face sales for personal medical use. Wholesalers, while far fewer in number (approximately 3,500) and engaging in fewer transactions, account for as great a level of commerce as retail distributors through significantly larger transaction sizes.

There were three basic enforcement options available to DEA in applying the requirements of the MCA:

1. Apply the requirements to both the retail and wholesale distributor industries;
2. Regulate only the retail distributors;
- or
3. Regulate only the wholesale distributors.

In reviewing the options, it became clear that the burdens associated with regulation of retail distributors would potentially be enormous. As detailed in

the NPRM, the initial registration cost for 750,000 retail distributors at \$255.00 each would be over \$190 million, with a subsequent annual reregistration cost, at \$116.00 each, of approximately \$87 million. Additionally, there would be a 150,000 hour annual paperwork burden associated with the registration requirement. For DEA, the administrative burden of handling 750,000 applications per year would be enormous. Further, the new requirements of the MCA with respect to retail distributors should reduce the potential for significant diversion, provided that retailers comply with the requirements of the law and are alert to attempts to circumvent the controls. Because of the limited amount of product permitted to be distributed in a single transaction, attempts to divert the products at the retail level 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. Under the circumstances, the monetary and administrative burdens associated with registration and regulation of the retail industry would be out of proportion with the benefits to be derived and might unnecessarily interfere with legitimate public access to the products.

Registration and regulation of the wholesale industry would have a much lesser impact. With respect to registration, the cost for initial registration would be slightly more than \$2 million (3,500 registrations at \$595.00 each) and annual reregistration costs would be approximately \$1.7 million (3,500 at \$477.00 each). The annual paperwork burden associated with registration would be 700 hours per year. With respect to regulation, the recordkeeping requirement would be minimal, since the transaction information DEA requires would generally be maintained by a business as a matter of good business practice, and the reporting requirements (except for the mail order reporting requirement which is non-discretionary) are limited to an "as-needed" basis using the guidance of §1310.05. Weighing these much lower economic and administrative costs against the larger 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 regulatory controls at this level of the industry.

Therefore, to best achieve the intended results of the MCA, while minimizing the burden on the industry, DEA has determined that the registration and regulatory controls will

apply to the manufacturer/wholesale level, while retail distributors will be exempt from the registration and recordkeeping requirements provided that the requirements of the law and regulations with respect to retail distributions are met.

These regulations 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 3000 to 4000 wholesale distributors, importers, and exporters that became subject to registration and regulation, DEA reduced the initial registration fee from \$595.00 to \$116.00, thus minimizing the financial impact. With respect to the other requirements, DEA has traditionally based the recordkeeping requirement on standard business practices, thus minimizing the impact. Further, the MCA reduced the record retention period from 4 years to 2 years. As for reports, the MCA is absolute in the requirement that mail order reports be submitted monthly; DEA has no discretion to modify that requirement. For other reports, the requirement is limited to reporting only those transactions that are suspicious or unusual; it is not necessary for the regulated persons to report all their transactions.

DEA has not restricted its consideration of the impact of the MCA to this rulemaking only. DEA continues to work with the industry in identifying areas in which regulation is not necessary for effective enforcement of the chemical controls. As noted earlier, DEA is drafting a separate proposed rule to exempt certain other activities from either registration or registration fees. As the chemical program matures, DEA will continue to work to focus the controls where they are necessary. A copy of this rulemaking has been provided to the Chief Counsel for Advocacy at the Small Business Administration.

Executive Order 12866

This rulemaking has been drafted and reviewed in accordance with Executive Order 12866. This rulemaking has been determined to be a significant action and, therefore, this rulemaking has been reviewed and approved by the Office of Management and Budget.

Executive Order 12988

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

Executive Order 13132

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

Unfunded Mandates Reform Act of 1995

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

Small Business Regulatory Enforcement Fairness Act of 1996

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.

Paperwork Reduction Act

This rule contains a new reporting requirement, Report of Mail Order Transactions, that has been reviewed and approved by the Office of Management and Budget and issued OMB approval number 1117-0033.

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 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 amended by revising paragraph (b)(28)(i)(D) and by adding new paragraphs (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. For combination ephedrine products the threshold for any sale by retail distributors or by distributors required to submit reports by § 1310.03(c) shall be 24 grams of ephedrine 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 not 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 combination 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 1309.21 is revised to read as follows:

§ 1309.21 Persons required to register.

(a) Every person who distributes, imports, or exports any List I chemical, other than those List I chemicals contained in a product exempted under § 1300.02(b)(28)(i)(D) of this chapter (irrespective of the threshold provisions under § 1300.02(b)(28)(i)(D)(2) of this chapter), or who proposes to engage in the distribution, importation, or exportation of any List I chemical, shall obtain annually a registration specific to the List I chemicals to be handled, unless exempted by law or pursuant to §§ 1309.24 through 1309.26 of this part. Only persons actually engaged in such activities are required to obtain a registration; related or affiliated persons who are not engaged in such activities are not required to be registered. (For example, a stockholder or parent corporation of a corporation distributing List I chemicals is not required to obtain a registration.)

(b) Every person who distributes or exports a List I chemical they have manufactured, other than a List I chemical contained in a product exempted under § 1300.02(b)(28)(i)(D) of this chapter, or proposes to distribute or export a List I chemical they have manufactured, shall obtain annually a registration specific to the List I chemicals to be handled, unless exempted by law or pursuant to §§ 1309.24 through 1309.26 of this part.

3. Section 1309.22 is 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.

4. Section 1309.24 is 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 person whose activities with respect to List I chemicals are limited to the distribution of red phosphorus, white phosphorus, or

hypophosphorous acid (and its salts) to: another location operated by the same firm solely for internal end-use; or an EPA or State licensed waste treatment or disposal firm for the purpose of waste disposal.

(g) The requirement of registration is waived for any person whose distribution of red phosphorus or white phosphorus is limited solely to residual quantities of chemical returned to the producer, in reusable rail cars and isotainers (with capacities greater than or equal to 2500 gallons in a single container).

(h) 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.

(i) If any person exempted under paragraph (b), (c), (d), (e), (f) or (g) 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 of this part.

(j) 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), (e), (f) or (g) of this section pursuant to the procedures set forth in §§ 1309.43 through 1309.46 and 1309.51 through 1309.55 of this part. 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.

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

5. Section 1309.25 is revised to read as follows:

§ 1309.25 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 this part 1309 and parts 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 October 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 this

part 1309 and parts 1310 and 1313 of this chapter remain in full force and effect.

6. Sections 1309.27, 1309.28 and 1309.29 are removed.

7. Section 1309.71 is 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 drugs containing ephedrine as the sole active medicinal ingredient are distributed, such drugs will be stocked behind a 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 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 of this part.

3. Section 1310.04 is 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 isomers, 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) Phenylpropanolamine, 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 kilograms (or 1 liter by volume).
(V) Benzaldehyde	4 kilograms.
(W) Nitroethane	2.5 kilograms.

(ii) Notwithstanding the thresholds established in paragraph (f)(1)(i) of this section, 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) of this chapter (thresholds for retail distributors and distributors required to report under § 1310.03(c) of this part 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 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.

Chemical	Threshold by weight
(2) Distributions by persons required to report under § 1310.03(c) of this part	24 grams.
(3) All other domestic distributions (other than paragraphs (f)(1)(ii)(B) (1) and (2) of this section)	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 persons required to report under §1310.03(c) of this part	24 grams.
(3) All other domestic distributions, (other than paragraphs (f)(1)(ii)(C) (1) and (2) of this section)	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 persons required to report under §1310.03(c) of this part	24 grams.
(3) All other domestic distributions (other than paragraphs (f)(1)(ii)(D) (1) and (2) of this section)	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 persons required to report under § 1310.03(c) of this part	24 grams.
(3) All other domestic distributions (other than paragraphs (f)(1)(ii)(E) (1) and (2) of this section)	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.
(2) Distributions by persons required to report under §1310.03(c) of this part	24 grams.
(3) All other domestic distributions (other than paragraphs (f)(1)(ii)(F) (1) and (2) of this section)	2.5 kilograms.
(4) Imports and Exports	2.5 kilograms.

4. Section 1310.05 is 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) of this part shall either:

(1) Submit a written report, containing the information set forth in § 1310.06(i) of this part, 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 Control 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 Chemical Control Section, Office of Diversion Control, Drug Enforcement Administration, Washington, DC 20537, ATTN: Electronic Reporting.

5. Section 1310.06 is amended by adding new paragraphs (i) and (j) to read as follows:

§ 1310.06 Content of records and reports.

* * * * *

(i) Each monthly report required by § 1310.05(e) of this part shall 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) Name of the chemical and total amount shipped (i.e. Pseudoephedrine, 250 grams).
- (5) Date of shipment.
- (6) Product name (if drug product).
- (7) Dosage form (if drug product) (i.e., pill, tablet, liquid).
- (8) Dosage strength (if drug product) (i.e., 30mg, 60mg, per dose etc.).
- (9) Number of dosage units (if drug product) (100 doses per package).
- (10) Package type (if drug product) (bottle, blister pack, etc.).
- (11) Number of packages (if drug product) (10 bottles).
- (12) Lot number (if drug product).

(j) Information provided in reports required by § 1310.05(e) of this part which is exempt from disclosure under section 552(a) of Title 5, by reason of section 552(b)(6) of Title 5, will be provided the same protections from disclosure as are provided in section 310(c) of the Act (21 U.S.C. 830(c)) for confidential business information.

6. Section 1310.10 is amended by revising the introductory text of paragraph (d) 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: March 18, 2002.

Asa Hutchinson,
Administrator.

[FR Doc. 02-7258 Filed 3-27-02; 8:45 am]

BILLING CODE 4410-09-U

DEPARTMENT OF TRANSPORTATION

Coast Guard

33 CFR Part 117

[CGD08-02-006]

RIN 2115-AE47

Drawbridge Operation Regulation; Mississippi River, Iowa and Illinois

AGENCY: Coast Guard, DOT.

ACTION: Temporary rule; request for comments.

SUMMARY: The Commander, Eighth Coast Guard District is temporarily changing the regulation governing the Rock Island Railroad and Highway