Dated: November 14, 2003.

Laura M. Nagel,

Deputy Assistant Administrator, Office of Diversion Control.

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DEPARTMENT OF JUSTICE

Drug Enforcement Administration

21 CFR Parts 1309, 1310

[Docket No. DEA–189P]

RIN 1117–AA67

Chemical Registration Waivers; Exemption From Chemical Registration Fees for Certain Persons

AGENCY: Drug Enforcement Administration (DEA), Justice.

ACTION: Notice of proposed rulemaking.

SUMMARY: DEA is proposing amending its regulations to waive the requirement of registration for contract processors, medical/first aid kit providers, distributors of sample packages of drug products, and distributors of research/reference standards pursuant to 21 U.S.C. 822(d). These actions are being taken in response to industry comments and suggestions. DEA has determined that requiring registration for these activities is not necessary for effective enforcement under the Controlled Substances Act (CSA), and waiving the requirement of registration will ease regulatory burdens for the affected industries. DEA is also proposing exempting charitable organizations and governmental entities from initial and renewal registration fees. These fee exemptions will bring the chemical regulations into conformance with the controlled substances regulations (21 CFR 1301.21).

DATES: Written comments must be postmarked on or before January 26, 2004.

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

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

Due to concerns regarding possible harmful side effects, the Food and Drug Administration (FDA) initiated action in November, 2000, to remove phenylpropanolamine from the market. As a result, many firms voluntarily discontinued marketing products containing phenylpropanolamine and removed them from the shelves for disposal. However, since some products containing phenylpropanolamine are still available, DEA has written these proposed regulations to include drug products containing phenylpropanolamine, where appropriate, as well as drug products containing pseudoephedrine.

I. Background

What Legislation Permits DEA to Regulate the Chemicals Industry, and What Laws Allow DEA To Waive Registration Requirements?

The Domestic Chemical Diversion Control Act of 1993 (DCDCA) established that persons distributing, importing, or exporting List I chemicals must register with DEA. In addition, it removed the exemption of single-entity ephedrine drug products from the chemical regulations. The Comprehensive Methamphetamine Control Act of 1996 (MCA) expanded on the registration requirement of the DCDCA by removing the exemption for pseudoephedrine, phenylpropanolamine and combination ephedrine drug products. Persons distributing, importing or exporting these drug products must register with DEA (21 U.S.C. 822, 957).

The registration requirement is not absolute. Section 302(c) of the CSA (21 U.S.C. 822(c)) provides that certain persons, including common or contract carriers and warehousemen, are not subject to the registration requirement. Further, section 302(d) of the CSA (21 U.S.C. 822(d)) provides that the Attorney General may waive the registration requirement for certain persons if it is consistent with the public health and safety.

As DEA has worked to implement the DCDCA and MCA, a number of issues have been raised regarding waiving the requirement of registration for persons engaged in certain activities under the regulations. In some cases there are parallels between identified activities and activities previously exempted from the registration requirement. DEA has reviewed the requests received from industry and has determined that the requirement of registration is not necessary for contract processors, medical/first aid kit providers, distributors of sample packages, and distributors of research/reference standards as discussed below. Further, DEA has determined that charitable organizations and governmental entities should be exempted from payment of the application fee for registration and reregistration, but that the requirement of registration itself must remain in effect for effective diversion control. These proposed fee exemptions are also discussed below.

How Will These Proposed Waivers and Exemptions Benefit the Regulated Industry?

Current DEA regulations require that any person who manufactures, distributes, imports, or exports a List I chemical must first register with DEA annually as a List I chemicals handler and pay a registration fee. DEA has recognized that, for certain industries, registration is unnecessary for effective enforcement of the law, and has accommodated the waiver of registration through Memoranda of Understanding (MOUs) between DEA and affected persons. In this rulemaking, DEA is proposing to waive the requirement of registration for contract processors, medical/first aid kit providers, distributors of sample packages, and distributors of research/reference standards. Were DEA not to propose these regulations, thereby codifying present Administration policy, each affected person would be required to register with DEA annually and pay an initial registration fee of $595 and annual reregistration fees of $477. If finalized, these proposed regulations will require exempt persons to notify DEA only once of their activities, at a cost of mailing one letter, as opposed to an annual registration fee. Industry would benefit from a significant cost savings as no fee would be charged for the one-time notification. Further, in this rulemaking DEA is proposing to exempt charitable organizations and governmental entities from payment of the application fee for registration and reregistration as List I chemical handlers. These exemptions will reduce regulatory requirements for the applicable industry, creating a cost savings for affected persons.

What Chemicals Would Be Affected by These Proposed Regulations?

The proposed waiver of the requirement of registration or reregistration for contract processors will affect all List I chemicals. List I chemicals have legitimate uses within commercial industry, being used for research and manufacturing purposes. List I chemicals include, but are not

limited to, ephedrine, pseudoephedrine and phenylpropanolamine (used in the manufacture of pharmaceutical products), benzaldehyde (used in the manufacture of perfumes and dyes), hydriodic acid (a disinfectant and chemical reagent), nitroethane (a solvent), and white phosphorus (used in the production of other phosphoric compounds). As a rule, with the exception of pseudoephedrine, phenylpropanolamine, and ephedrine, which are distributed to the public in regulated form as over-the-counter medications, List I chemicals in regulated form are usually distributed in commercial transactions between businesses and only rarely to the public in retail transactions. It is within this commercial arena that contract processors operate; they do not distribute at retail to the public.

The proposed waiver of the requirement of registration or reregistration for distributors of research/reference standards would affect the List I chemicals ephedrine, pseudoephedrine and phenylpropanolamine. The proposed waiver of the requirement of registration or reregistration for medical/first aid kit providers and distributors of sample packages would affect the List I chemical pseudoephedrine. Pseudoephedrine, a chemical widely used in over-the-counter medications, is a decongestant used for the temporary relief of nasal congestion due to the common cold, hay fever or other upper respiratory allergies. Products containing pseudoephedrine are widely available in a variety of dosage forms as a single entity or in combination with antihistamines, antitussives, analgesics, expectorants, and/or vitamins. Ephedrine is used for the temporary relief of shortness of breath, tightness of chest, and wheezing due to bronchial asthma.

The majority of the products purchased by the public containing pseudoephedrine are commonly used medications and are easily accessible at pharmacies, grocery stores, discounted department stores, and a variety of other retail stores. These products are available to the public without a prescription. A few products containing pseudoephedrine or ephedrine are prescription products and require a prescription issued by a practitioner prior to being dispensed to a patient. This proposed regulation will not adversely impact the public's ability to easily access these products.

II. Waivers of the Requirement of Registration

A. Contract Processors

What Are Contract Processors?

Contract processors, sometimes referred to within the industry as ''tollers'', are those persons who, through a legally binding agreement with a registrant, take physical possession of a listed chemical for the purpose of providing a processing service to the registrant. Such processes may include, but are not limited to, packaging a product and adding chemicals to a mixture. The contract processor never has legal ownership or control of the chemicals; legal title remains with the registrant. Following processing, the contract processor either returns all of the chemicals received to the registrant, or distributes them as required by the registrant.

Why Is DEA Waiving the Requirement of Registration for Contract Processors?

In reviewing this situation, DEA has noted that activities of certain contract processors parallel those of a warehouse at which chemicals are stored, for which an exemption from registration has been provided under 21 U.S.C. 822(c) (21 CFR 1309.23(b)(1)). As with the warehouseman, the contract processor merely carries out the processing requirements of the registrant; the contract processor does not have, at any time, legal title to or legal control of the chemicals. The registrant provides the material to the contract processor for a specific function, after which the material is returned to the registrant, thus maintaining a closed-loop system. DEA has determined that, under such circumstances, the requirement of registration is not necessary for effective chemical control. Therefore, DEA is proposing to amend the regulations to waive the requirement of registration for contract processors provided that chemicals are distributed only back to the registrant. As with warehousemen, a registrant utilizing a contract processor's services would be responsible for exercising due care in selection of the processor (21 CFR 1309.71, 21 CFR 1309.72). The registrant would have to ensure that the contract processor has in place appropriate procedures and safeguards to protect chemicals from diversion.

What Circumstances Are Not Permitted Under This Waiver?

Contract processors do not always operate within a closed-loop system. In some cases, a contract processor may receive chemicals from an outside source, process them, and distribute the chemicals to the registrant. In other cases, a registrant may provide the chemicals to the contract processor which processes them and, per the registrant's instructions, distributes the chemicals to other persons. These activities deviate from the closed-loop system between the registrant and contract processor and involve distributions to or from other registrants. Therefore, these types of activities will remain subject to the registration requirements under the law. DEA is proposing that, as with the existing provisions for warehouses, the waiver will apply only to those circumstances in which a registrant distributes directly to a contract processor which, in turn, will distribute only back to the registrant from which it received the chemicals.

B. Medical/First Aid Kit Providers

What Are Medical/First Aid Kit Providers?

Medical/first aid kit providers distribute small amounts of pseudoephedrine drug products, in individual transactions, to medical/first aid kits maintained by businesses for the personal medical use of employees in the workplace. The distributions are usually conducted in face-to-face transactions (an agent or employee of the distributor delivers the products directly to the customer), the products are distributed for the personal medical use of the employees of the customer, and are less than the retail threshold per transaction. [As used in this document and referenced in the Methamphetamine Anti-Proliferation Act of 2000 (Section XXXVI of Pub.L. 106–310), the term ''transaction'' is defined to mean the provision of regulated drug products to a specific location, *not* the provision of regulated drug products to a specific medical/first aid kit within a location. Thus, under the terms of this proposed waiver, if a location had multiple medical/first aid kits, the medical/first aid kit provider would be permitted to supply the location with a quantity of product below the retail per-transaction limit during each visit to that specific location. Product may be allocated to multiple medical/first aid kits throughout a specific location, without the medical/first aid kit provider being required to register with DEA, so long as the amount of product distributed does not exceed the retail per-transaction threshold.]

Why is DEA Waiving the Requirement of Registration for Medical/First Aid Kit Providers?

Medical/first aid kit provider activities closely parallel those of retail distributors; sales involve retail below-threshold amounts of the products, are made in face-to-face transactions, and are intended for the personal medical use of the employees of the business. DEA has determined that, where a medical/first aid provider's activities are restricted to retail below-threshold, face-to-face transactions to supply/replenish medical or first aid kits maintained for the personal medical use of employees in the workplace, application of the registration requirement is not necessary for effective enforcement of the chemical control program. Instead, the providers must submit written notice to DEA certifying that their activities will be limited to distribution of retail below-threshold quantities of a drug product containing pseudoephedrine that is regulated pursuant to § 1300.02(b)(28)(i)(D) for purposes of supplying/replenishing medical or first aid kits maintained by businesses for the use of their employees. (A model of the notice to be used may be found in proposed 1309.24(i).) Notice must be provided on official company letterhead to the Drug Enforcement Administration, Chemical Control Section, Washington, D.C. 20537.

Those medical/first aid kit providers currently operating pursuant to Memoranda of Understanding (MOU) with DEA will be required to request a waiver of the requirement of registration once the Final Rule implementing these regulations is published in the **Federal Register**.

Although medical/first aid kit providers conduct individual transactions in retail below-threshold quantities, they may store large quantities of drug products containing list I chemicals that are regulated pursuant to § 1300.02(b)(28)(i)(D) at any one time. Because of this, the issue of theft or loss of these drug products is of concern to DEA. It is extremely important that persons supplying/replenishing medical or first aid kits maintained by businesses for the use of their employees take adequate and appropriate measures to ensure the security of these drug products in their possession (21 CFR 1309.71–1309.73). Persons receiving a waiver of the requirement of registration should pay special attention to the storage and security of the regulated drug products. Further, waiver of the registration requirement does not obviate the need for complete and accurate recordkeeping and reporting to DEA (21 CFR 1310, 1313). The waiver of the requirement of registration may be revoked or suspended under the terms discussed in Section II.E. of this preamble and the proposed regulations.

C. Distributors of Sample Packages of Drug Products

What Are Sample Packages, and When May the Requirement of Registration Be Waived for Distributions of Sample Packages?

It is not unusual for manufacturers of drug products containing retail below-threshold amounts of pseudoephedrine that are regulated pursuant to § 1300.02(b)(28)(i)(D) to distribute free samples of their products directly to the public as part of marketing campaigns. The samples may be distributed through mass distributions in newspapers, magazines, or through the mail. A sample package contains not more than two solid dosage units of the product, or the equivalent of two dosage units in liquid form, not to exceed 10 milliliters of liquid per package. DEA has determined that application of the specific registration requirement is not necessary for effective enforcement of chemical controls, provided that the sampler does not distribute more than one sample package of a drug product containing retail below-threshold amounts of pseudoephedrine that is regulated pursuant to § 1300.02(b)(28)(i)(D) to an individual or residential address in any 30-day time period. Instead, DEA will require that the sampler must submit written notice to DEA certifying that their activities will be limited to individual distributions of sample packages containing not more than two solid dosage units of the product, or the equivalent of two dosage units in liquid form, not to exceed 10 milliliters of liquid per package, and that distributions will not exceed one per individual or residential address per 30-day time period. Notice must be provided on official company letterhead to the local field office of the Drug Enforcement Administration. Contact information for local DEA field offices may be obtained from the Drug Enforcement Administration Web site at *http://www.dea.gov*. Once notification has been received, the local field office will provide instruction on handling the product.

Those persons distributing sample packages currently operating pursuant to Memoranda of Understanding (MOU) with DEA will be required to request a waiver of the requirement of registration once the final rule implementing these regulations is published in the **Federal Register**.

Although distributors of sample packages may distribute only one sample package to an individual or residential address in a 30-day time period, they may store very large quantities of regulated drug products. The issue of theft or loss of these drug products is of concern to DEA. It is extremely important that persons making distributions of these sample packages take adequate and appropriate measures to ensure the security of these drug products in their possession (21 CFR 1309.71–1309.73). Persons receiving a waiver of the requirement of registration should pay special attention to the storage and security of the sample packages. Further, waiver of the requirement of registration does not obviate the need for accurate recordkeeping and reporting to DEA (21 CFR 1310, 1313). The waiver of the requirement of registration may be revoked or suspended under the terms discussed in Section II.E. of this preamble and the proposed regulations.

D. Distribution of Research/Reference Standards

What Are Distributions of Research/Reference Standards, and When May the Requirement of Registration Be Waived for These Distributions?

DEA registered manufacturers of regulated drug products sometimes maintain separate locations at which ephedrine, pseudoephedrine, and phenylpropanolamine research/reference standards are manufactured and distributed to other locations operated by the registrant for use in manufacturing processes. DEA has determined that requiring registration for such distributions is not necessary for effective enforcement of the chemical control program provided that the distributions are less than five (5) grams per transaction, not to exceed fifty (50) grams cumulatively per calendar month, and are made solely between locations operated by the same regulated person. The small amounts of material involved and the closed system within which the material is distributed do not present significant potential for diversion. Further, because these samples are used for research purposes, the controls surrounding these chemicals, as well as their chain of custody, are very strict. These added safeguards lessen the potential for diversion. Therefore, DEA is proposing the amendment of 21 CFR 1309.24 to waive the requirement of registration for the distribution of research/reference standards. The waiver of the

requirement of registration may be revoked or suspended under the terms discussed in Section II.E. of this preamble and the proposed regulations.

E. Waiver Revocations and Suspensions

Any waiver granted to any medical/first aid kit provider, distributor of sample packages, or distributor of research/reference standards under the provisions of this Notice of Proposed Rulemaking may be revoked or suspended. If the Administrator of DEA finds that continuation of the waiver of the requirement of registration for any person granted a waiver pursuant to these regulations would not be in the public interest, or would be subject to suspension or revocation pursuant to any other ground under Section 304 of the Act (21 U.S.C. 824), the Administrator shall serve upon the person an order to show cause why the waiver of registration should not be revoked or suspended as set forth in 21 CFR 1309.46(b), and, if applicable, why any pending applications for List I chemical registration should not be denied as set forth in 21 CFR 1309.46(a).

III. Fee Exemptions

A. Charitable Organizations

It is not unusual for charitable organizations to receive donations of drug products containing a List I chemical that are regulated pursuant to § 1300.02(b)(28)(i)(D) as part of their normal course of business. These donations may be received from a variety of sources including retail distributors, wholesale distributors and manufacturers. The charitable organizations distribute the products either directly to the ultimate users or to other foreign or domestic charitable organizations.

For purposes of these proposed regulations, DEA is defining a charitable organization as one meeting the requirements of the Internal Revenue Service Code (26 U.S.C. 501(c)(3)). When seeking an exemption from payment of application fees for registration or reregistration, such charitable organizations must present to DEA, along with their application for registration or reregistration, a copy of their advance determination letter or determination letter issued by the Internal Revenue Service as proof of their tax-exempt status under the provisions of 26 U.S.C. 508 and its implementing regulations.

Distributions made by charitable organizations directly to ultimate users are retail distributions; products are distributed in face-to-face transactions for personal medical use, and involve below-threshold amounts of listed chemicals. As retail transactions, they are not subject to the registration requirement.

However, distributions to other charitable organizations, whether domestic distribution or exportation, are subject to the registration requirement. Because the volume of drug products containing a List I chemical that are regulated pursuant to § 1300.02(b)(28)(i)(D) being distributed by these organizations can be significant, registration with DEA remains necessary, as well as the recordkeeping and reporting requirements. However, it is not DEA's intent that these organizations be financially penalized for their activities. Therefore, DEA is proposing amendments to the regulations exempting charitable organizations from registration fees.

B. Federal, State, and Local Agencies

It has been general practice and tradition that DEA does not assess other governmental entities—Federal, state or local—the fees required for registration or reregistration. This provision, which does exist for controlled substances registrants, was inadvertently not included in the chemical regulations. Therefore, to provide consistent registration fee requirements, DEA is proposing the amendment of the chemical regulations to exempt governmental entities from fees.

IV. Clarification of the Waiver of the Requirement of Registration for Certain Controlled Substances Registrants

Title 21 CFR 1309.24 provides that persons registered with DEA to distribute or dispense controlled substances are not required to obtain a separate chemical registration to distribute drug products containing a List I chemical that are regulated pursuant to § 1300.02(b)(28)(i)(D).

This provision is intended to allow controlled substances manufacturers, distributors, and dispensers to engage in activities with regulated drug products that are similar or equivalent to their activities with controlled substances, *i.e.*, manufacturers and distributors may engage in wholesale transactions and dispensers, such as retail pharmacies, may engage in retail transactions.

However, DEA has become aware of instances in which controlled substances dispensers, in particular retail pharmacies, have been engaging in listed chemical activities inconsistent with their controlled substances activities. DEA intended that the waiver for dispensers would apply to retail type transactions, *i.e.*, distributions of below-threshold amounts to individual customers for personal medical use, and not to distributions of above-threshold quantities or distributions not intended for the personal medical use of the customer. For example, a retail pharmacy may distribute retail quantities of drug products containing a List I chemical that are regulated pursuant to 21 CFR 1300.02(b)(28) under the chemical registration waiver, but must obtain a separate chemical registration for distributions above the retail threshold or distributions not intended for the personal medical use of the customer. Similarly, a controlled substances distributor would be exempt from obtaining a registration for distributing, but not manufacturing, regulated drug products. It was not DEA's intent to permit controlled substances registrants to use the waiver of the requirement of chemical registration to conduct activities inconsistent with their controlled substances activities. Therefore, DEA proposes to amend its regulations to clarify that controlled substances manufacturers, distributors, and dispensers may conduct similar or equivalent activities involving drug products containing a List I chemical that are regulated pursuant to § 1300.02(b)(28)(i)(D) without having to obtain a chemical registration.

V. Technical Corrections

What Technical Corrections Are Proposed in This Rulemaking?

While preparing this notice, DEA noted inaccurate citations for the definition of ''regulated transaction'' in 21 CFR Part 1310. Therefore, DEA is proposing the correction of these inaccurate citations.

Further, it was noted that Sections 1310.14 and 1310.15 have been superceded by the Comprehensive Methamphetamine Control Act of 1996 (MCA) which regulates all products containing ephedrine, whether single entity or combination ephedrine. Therefore, DEA is proposing the removal of Sections 1310.14 and 1310.15.

VI. Office of Management and Budget Information Collection Requirements

DEA is proposing two new collections of information: *Report of Medical/First Aid Kit Provider Business Activities* and *Report of Distribution of Sample Packages* under the Paperwork Reduction Act of 1995. This process is conducted in accordance with 5 CFR 1320.11.

These proposed information collections are published to obtain

comments from the public and affected agencies. Comments are encouraged and will be accepted until January 26, 2004. Written comments and suggestions are requested from the public and affected agencies concerning the proposed collections of information.

Comments should address one or more of the following four points:

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

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

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

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

If you have comments, especially on the estimated public burden or associated response time, suggestions, or need a copy of the proposed information collection instrument(s) with instructions, if applicable, or additional information, please contact Patricia M. Good, Chief, Liaison and Policy Section, Office of Diversion Control, Drug Enforcement Administration, Washington, DC 20537, Telephone (202) 307–7297.

Overview of *Report of Medical/First Aid Kit Provider Business Activities* Information Collection:

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

(2) *The title of the form/collection:* Report of Medical/First Aid Kit Provider Business Activities.

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

Form No.: None.

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

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

Primary: Business or other for-profit.

Other: None.

Abstract: The collection of this information is necessary to maintain appropriate oversight of the distribution of regulated drug products containing List I chemicals by requiring notification from businesses of their intent to distribute retail subthreshold quantities of pseudoephedrine drug products for the purpose of supplying/replenishing medical/first aid kits.

(5) *An estimate of the total number of respondents and the amount of time estimated for an average respondent to respond/reply:* 600 Respondents. 600 responses per year × 1 hour per response = 600 hrs.

(6) An estimate of the total public burden (in hours) associated with the collection: 600 annual burden hours. 600 respondents × 1 hour per respondent per year.

Overview of *Report of Distribution of Sample Packages* Information Collection:

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

(2) *The title of the form/collection:* Report of Distribution of Sample Packages.

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

Form No.: None.

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

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

Primary: Business or other for-profit.

Other: None.

Abstract: The collection of this information is necessary to maintain appropriate oversight of the distribution of regulated drug products containing retail below-threshold amounts of pseudoephedrine. By requiring notification from businesses of their intent to distribute sample packages containing not more than two solid dosage units, or the equivalent of two dosage units in liquid form, not to exceed 10 milliliters of liquid per package, to the general public. Distributions are limited to not more than one package distributed to an individual or residential address in any 30-day time period. Notice provides the business name and address and acknowledges distribution restrictions, compliance with the requirements of Title 21, Code of Federal Regulations (CFR), part 1310, the reporting and recordkeeping requirements, and the fact that exemption from the registration requirement applies to this activity only.

(5) An estimate of the total number of respondents and the amount of time estimated for an average respondent to respond/reply: 1,000 respondents. 1,000 responses per year × 1 hour per response = 1,000 hours.

(6) An estimate of the total public burden (in hours) associated with the collection: 1,000 annual burden hours. 1,000 respondents × 1 hour per respondent per year.

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

Regulatory Certifications

Regulatory Flexibility Act

The Deputy Assistant Administrator hereby certifies that this rulemaking has been drafted in accordance with the Regulatory Flexibility Act (5 U.S.C. 605(b)), and by approving it certifies that this regulation will not have a significant economic impact on a substantial number of small business entities. These proposed regulations would ease registrants', primarily small businesses, regulatory burdens including waiving the requirement of registration and exempting certain regulated persons from the imposition of registration fees.

Executive Order 12866

The Deputy Assistant Administrator further certifies that this rulemaking has been drafted in accordance with the principles in Executive Order 12866, Section 1(b). DEA has determined that this is a significant regulatory action. Therefore, this action has been reviewed by the Office of Management and Budget. Further, the proposed information collections, ''Report of Medical/First Aid Kit Provider Business Activities'' and ''Report of Distributions of Sample Packages'', have been submitted for review. This rulemaking eases the regulatory burden for registrants by waiving the requirement of registration for certain activities, as well as exempting certain regulated persons from the registration fees. Were DEA not to propose these regulations, thereby codifying present Administration policy, each affected person would be required to register with DEA annually and pay an initial registration fee of $595 and annual reregistration fees of $477. If finalized, these proposed regulations will require exempt persons to notify DEA only once of their activities, at a cost of mailing one letter, as opposed to an annual registration fee. Industry would benefit

from a significant cost savings as no fee would be charged for the one-time notification.

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.

List of Subjects

21 CFR Part 1309

Administrative practice and procedure, Drug traffic control, List I and List II chemicals, Security measures.

21 CFR Part 1310

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

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

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

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 1309.13 is proposed to be added to read as follows:

§ 1309.13 Exemptions from fees.

(a) The Administrator shall exempt from payment of an application fee for registration or reregistration any hospital or other institution which is operated by an agency of the United States (including the U.S. Army, Navy, Marine Corps, Air Force, and Coast Guard), of any State, or any political subdivision or agency thereof.

(b) The Administrator shall exempt from payment of an application fee for registration or reregistration any charitable organization as specified under Internal Revenue Service Code Title XXVI, United States Code, section 501(c)(3) which obtains a drug product containing a List I chemical that is regulated pursuant to § 1300.02(b)(28)(i)(D), and which distributes or exports the drug product to other charitable organizations as specified under Title XXVI, United States Code, section 501(c)(3) for ultimate distribution to the end user. Charitable organizations seeking an exemption from the payment of application fees for registration or reregistration must present to the Administration, along with their application for registration or reregistration, a copy of their advance determination letter or determination letter issued by the Internal Revenue Service as proof of tax-exempt status under the provisions of Title XXVI, United States Code, section 508 and its implementing regulations.

(c) Exemption from payment of an application fee for registration or reregistration does not relieve the registrant of any other requirements or duties prescribed by law.

3. Section 1309.23 is proposed to be amended by revising paragraph (b) to read as follows:

§ 1309.23 Separate registration for separate locations.

* * * * *

(b) The following locations shall be deemed to be places not subject to the registration requirement:

(1) A warehouse where List I chemicals are stored by or on behalf of a registered person, unless such chemicals are distributed directly from such warehouse to locations other than the registered location from which the chemicals were originally delivered;

(2) An office used by agents of a registrant where sales of List I chemicals are solicited, made, or supervised but which neither contains such chemicals (other than chemicals for display purposes) nor serves as a distribution point for filling sales orders; and

(3) A contract processor where List I chemicals are processed by or on behalf of a registered person, unless such chemicals are distributed directly from such contract processor to locations other than the registered location from which the chemicals were originally delivered.

4. 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 21 CFR 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 registered with the Administration to manufacture, distribute, or dispense controlled substances who is conducting similar or equivalent activities with a drug product containing a List I chemical that is regulated pursuant to 21 CFR 1300.02(b)(28)(i)(D). However, a separate chemical registration must be obtained for dissimilar activities. (For example, a retail pharmacy may distribute below-threshold retail quantities of drug products containing List I chemicals that are regulated pursuant to 21 CFR 1300.02(b)(28) to an individual for personal medical use under its retail distribution exemption, but must obtain a separate chemical registration for distributions of above-threshold quantities or distributions not intended for the personal medical use of an individual customer. Further, a controlled substances distributor may distribute drug products containing List I chemicals that are regulated pursuant to 21 CFR 1300.02(b)(28) under its controlled substances distribution registration, but must obtain a separate chemical registration to manufacture drug products containing List I

chemicals that are regulated pursuant to 21 CFR 1300.02(b)(28).)

(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 21 CFR 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 pseudoephedrine, phenylpropanolamine, or combination ephedrine product that is regulated pursuant to 21 CFR 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 21 CFR 1300.02(b)(31) of this chapter.

(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 intermodal tank containers which conform to International Standards Organization specifications (with capacities greater than or equal to 2,500 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) The requirement of registration under this part is waived for any medical/first aid kit provider whose activities consist of distributing, in face-to-face transactions, a drug product containing retail below-threshold amounts of pseudoephedrine that is regulated pursuant to 21 CFR 1300.02(b)(28)(i)(D) to businesses for the sole purpose of supplying/replenishing a medical/first aid kit maintained for the personal use of employees in the workplace. For purposes of this paragraph, the term transaction is defined to mean the provision of regulated drug products to a specific location, not the provision of regulated drug products to a specific medical/first aid kit within a location.

(1) Persons requesting a waiver of the requirement of registration must submit a notification of this business activity on official company letterhead to the Drug Enforcement Administration, Office of Diversion Control, Chemical Control Section, Washington, DC 20537.

(2) Notification of this business activity should be in the following form:

I, _____ the _____ (title) of _____ (name of company) located at _____ (street address) _____ (city) _____ (state)_____ (ZIP code) am writing to request a waiver of the Drug Enforcement Administration (DEA) chemical registration requirement for _____ (name of company)'s activities involving the distribution of drug products containing pseudoephedrine that are regulated pursuant to Title 21, Code of Federal Regulations, § 1300.02(b)(28)(i)(D) to businesses for the purpose of supplying/replenishing medical or first aid kits maintained by those businesses for the personal medical use of their employees.

This is to certify that _____ (name of company) will comply with the provisions of Title 21, Code of Federal Regulations, Part 1309, namely:

1. The distribution of retail below-threshold amounts of drug products containing pseudoephedrine that are regulated pursuant to § 1300.02(b)(28)(i)(D) are to individual customers;

2. The distributions are made only in face-to-face transactions; and

3. The distributions are only for the purpose of supplying/replenishing medical or first aid kits maintained by businesses for the personal medical use of their employees.

_____ (name of company) distributes an average of _____ dosage units of pseudoephedrine products per year.

I understand that the waiver of the registration requirement applies only to those activities; any distribution of the products other than as described above is subject to the registration requirement.

Further, I understand that the waiver applies only to the registration requirement. The recordkeeping and reporting requirements set forth in Title 21, Code of Federal Regulations, Part 1310, still apply to both receipts and distributions of products containing a List I chemical that are regulated pursuant to Title 21, Code of Federal regulations, § 1300.02(b)(28)(i)(D). I understand that if I receive more than a non-retail threshold amount of pseudoephedrine, either singly or cumulatively, in a calendar month from a supplier, then I must keep a record of such receipt(s).

I understand that I will receive a written decision regarding my request for a waiver of the requirement of registration. I further understand that to engage in the distribution of drug products containing pseudoephedrine that are regulated pursuant to Title 21, Code of Federal Regulations, § 1300.02(b)(28)(i)(D) to medical/first aid kits I must either be registered with the Drug Enforcement Administration as a List I chemical handler or have received a written waiver of the requirement of registration. A copy of this letter will be kept in my records.

_____

(signature)

_____

(title)

_____

(date)

(3) The request for a waiver of the requirement of registration will be evaluated based on compliance with the above criteria and on public interest criteria as defined in 21 U.S.C. 823(h). Once a determination has been made regarding the request for waiver, DEA will notify the requestor in writing of the decision.

(4) Public reporting burden for collection of this information is estimated to average 1 hour per response, including the time to review instructions, write the request, and send it to the appropriate location. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to the Drug Enforcement Administration, Records Management Section, Washington, DC 20537; and to the Office of Management and Budget, Paperwork Reduction Project No. 1117–00xx, Washington, DC 20503.

(j) The requirement of registration under this part is waived for persons distributing sample packages of a product containing retail below-threshold amounts of pseudoephedrine that is regulated pursuant to 21 CFR 1300.02(b)(28)(i)(D) containing not more than two solid dosage units, or the equivalent of two dosage units in liquid form, not to exceed 10 milliliters of liquid per package. Distributions are limited to not more than one package distributed to an individual or residential address in any 30-day period.

(1) Persons requesting a waiver of the requirement of registration must submit a notification of this business activity on official company letterhead to the Special Agent in Charge of the Administration in the area in which the person is located.

(2) The Special Agent in Charge shall authorize and instruct the person distributing the sample packages on handling and security of the product.

(3) Public reporting burden for collection of this information is estimated to average 1 hour per response, including the time to review instructions, write the notification, and send it to the appropriate location. Send comments regarding this burden

estimate or any other aspect of this collection of information, including suggestions for reducing this burden to the Drug Enforcement Administration, Records Management Section, Washington, DC 20537; and to the Office of Management and Budget, Paperwork Reduction Project No. 1117–00??, Washington, DC 20503.

(k) For any person who manufactures ephedrine, pseudoephedrine or phenylpropanolamine at a registered location and also manufactures research/reference standards containing ephedrine, pseudoephedrine or phenylpropanolamine at a separate location, the requirement of registration under this part is waived for the location at which research/reference standards containing ephedrine, pseudoephedrine or phenylpropanolamine are manufactured and distributed, so long as the research/reference standards are distributed only to other locations operated by the same registered manufacturer. Distributions may not exceed five grams per transaction and fifty grams cumulatively per calendar month.

(l) If any person exempted under paragraph (b), (c), (d), (e), (f), (g) or (k) 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.

(m) 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), (g), (h), (i), (j) or (k) 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.

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

§ 1309.62 [Amended]

5. In Section 1309.62(a) remove the word ''cases'' and add the word ''ceases'' in its place.

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

6. The authority citation for 21 CFR Part 1310 continues to read as follows:

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

§ 1310.05 [Amended]

7. In § 1310.05(d), remove the reference to § 1310.01(f)(1)(iv) or § 1310.01(f)(1)(v) and add the reference § 1300.02(b)(28)(i)(D) or § 1300.02(b)(28)(i)(E)'' in its place.

§ 1310.06 [Amended]

8. In § 1310.06(h)(5), remove the reference to § 1310.01(f)(1)(iv) or § 1310.01(f)(1)(v) and add the reference ''§ 1300.02(b)(28)(i)(D) or § 1300.02(b)(28)(i)(E) in its place.

§ 1310.10 [Amended]

9. In § 1310.10(a), remove the reference to ''§ 1310.01(b)(28)(i)(D)'' and add the reference ''§ 1300.02(b)(28)(i)(D)'' in its place.

§ 1310.14 [Removed]

10. Remove § 1310.14.

§ 1310.15 [Removed]

11. Remove § 1310.15.

Dated: November 14, 2003.

Laura M. Nagel,

Deputy Assistant Administrator, Office of Diversion Control.

[FR Doc. 03–29236 Filed 11–24–03; 8:45 am]

BILLING CODE 4410–09–P

DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Part 1

[REG–138499–02]

RIN 1545–BB05

Changes in Use Under Section 168(i)(5)

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Cancellation of notice of public hearing on proposed rulemaking.

SUMMARY: This document provides notice of cancellation of a public hearing on proposed regulations relating to the depreciation of property subject to section 168 of the Internal Code (MACRS property).

DATES: The public hearing originally scheduled for Wednesday, December 3, 2003, at 10 a.m., is cancelled.

FOR FURTHER INFORMATION CONTACT: Treena Garrett of the Publications and Regulations Branch, Legal Processing Division, Associate Chief Counsel (Procedure and Administration), (202) 622–7180 (not a toll-free number).

SUPPLEMENTARY INFORMATION: A notice of proposed rulemaking and notice of public hearing that appeared in the **Federal Register** on Monday, July 21, 2003, (68 FR 43047), announced that a public hearing was scheduled for Wednesday, December 3, 2003, at 10 a.m., in room 4718, Internal Revenue Service Building, 1111 Constitution Avenue, NW., Washington, DC. The subject of the public hearing is proposed regulations under section 168 of the Internal Revenue Code. The public comment period for these proposed regulations expired on Monday, October 20, 2003. Outlines of oral comments were due on Wednesday, November 12, 2003.

The notice of proposed rulemaking and notice of public hearing, instructed those interested in testifying at the public hearing to submit an outline of the topics to be addressed. As of Wednesday, November 19, 2003, no one has requested to speak. Therefore, the public hearing scheduled for Wednesday, December 3, 2003, is cancelled.

LaNita Van Dyke,

Acting Chief, Publications and Regulations Branch, Legal Processing Division, Associate Chief Counsel (Procedure and Administration).

[FR Doc. 03–29441 Filed 11–24–03; 8:45 am]

BILLING CODE 4830–01–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 117

[CGD11–03–006]

RIN 1625–AA09

Drawbridge Operation Regulations; Mare Island Strait, Napa River, Vallejo, CA

AGENCY: Coast Guard, DHS.

ACTION: Notice of proposed rulemaking.

SUMMARY: The Coast Guard proposes to change the regulation governing the operation of the Mare Island Drawbridge, spanning the Napa River between the City of Vallejo and Mare Island, CA., by eliminating the rush-hour closure periods when the drawspan need not open for vessels and by increasing the hours when vessels provide advance notice for drawspan operation. The proposed action would