

Dated: November 14, 2003.

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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