

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 superseded 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