

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.

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(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