

products, and; (3) the lack of any evidence that the products are being diverted for the illicit manufacture of controlled substances.

In response to industry's concerns and in the interest of limiting regulatory burdens to those necessary for the enforcement of the law, DEA has reviewed the need for applying the chemical registration requirement on persons who distribute regulated prescription drug products and determined that such application is not necessary for the enforcement of the CSA at this time. Further, DEA has determined that distribution records required to be maintained pursuant to the FDA guidelines set forth in title 21, Code of Federal Regulations (21 CFR), Part 205 are adequate for satisfying DEA's recordkeeping requirements for distributions. This determination is based on DEA's finding that there is presently a lack of evidence that prescription drug products that contain List I chemicals are being diverted for the illicit manufacture of controlled substances, the products are already subject to an extensive system of regulatory controls, and the DEA access to the distribution records kept under the FDA guidelines should provide sufficient information to satisfy the intent of the regulations.

With respect to diversion, it has been DEA's experience that persons seeking to divert List I chemicals for the illicit manufacture of controlled substances have relied primarily on either non-regulated sources or smuggled chemicals. Initially, bulk ephedrine was the chemical of choice; following implementation of DEA's chemical control program in 1989, over-the-counter (OTC) ephedrine drug products which were exempt from the regulatory provisions of the CSA became the products of choice. With implementation of the DCDCA and regulation of the OTC ephedrine drug products, OTC pseudoephedrine drug products became a significant source for diversion. DEA is unaware of the diversion of prescription drug products containing List I chemicals to clandestine drug laboratories.

With respect to controls, prescription drugs are already subject to stringent requirements governing their distribution and dispensing. A prescription drug can only be dispensed to the public pursuant to the order of a licensed health care professional. Further, distributors of prescription drug products are subject to extensive licensing, security, recordkeeping and inventory requirements. These requirements, the guidelines for which are set forth in 21 CFR, Part 205,

establish a "closed system" for the distribution of prescription products.

In light of the existing controls and the lack of evidence of diversion of regulated prescription products, application of the registration requirement is unnecessary at this time for the enforcement of the CSA. In addition, the information maintained in the distribution records required under the FDA guidelines is sufficient to satisfy DEA's needs, should an inspection of the records be necessary. Therefore, DEA is proposing to amend 21 CFR Part 1309 to add a new Section 1309.28, waiving the requirement of registration for any person who distributes a regulated prescription drug product. Further, DEA is proposing to amend Section 1310.06 of the regulations, which currently allows that prescription and hospital records maintained in the course of medical practice are adequate for satisfying DEA's requirements, to also allow that records required to be maintained pursuant to the guidelines set forth in 21 CFR, Part 205 shall be adequate for wholesale distributions of regulated prescription drug products. If, however, evidence of diversion of prescription products is seen in the future, DEA will take action to make the products subject to the specific regulatory requirements of the CSA.

In addition to the proposed changes described above, Sections 1309.21 and 1309.22 are proposed to be amended to make reference to the addition of the new waiver of the registration requirement.

Under the CSA, the Attorney General may waive the requirement of registration for certain manufacturers, distributors or dispensers if it is consistent with the public interest (21 U.S.C. 822(d)). The Attorney General has delegated authority under the CSA and all subsequent amendments to the CSA to the Administrator of the DEA (28 CFR 0.100). The Administrator, in turn, has delegated this authority to the Deputy Administrator pursuant to 28 CFR 0.104 (59 FR 23637 (May 6, 1994)).

The Deputy Administrator of the Drug Enforcement Administration hereby certifies that this proposed rulemaking will not have a significant impact on a large number of entities whose interests must be considered under the Regulatory Flexibility Act, 5 U.S.C. 601 et seq. This rulemaking proposes to grant those persons who distribute regulated prescription drug products relief from DEA's chemical registration requirement and allow for the use of records already maintained pursuant to FDA guidelines in lieu of requiring that separate records be maintained. These

proposed amendments could potentially ease the regulatory burden for 1,200 or more distributors and manufacturers of regulated prescription drug products.

This proposed rule has been drafted and reviewed in accordance with Executive Order 12866. DEA has determined that this is not a significant regulatory action under the provisions of Executive Order 12866, section 3(f) and accordingly this rule has not been reviewed by the Office of Management and Budget. This rule will eliminate unnecessary regulatory requirements for distributors of regulated prescription drug products.

This action has been analyzed in accordance with the principles and criteria in Executive Order 12612, and it has been determined that the proposed rule does not have sufficient federalism implications to warrant the preparation of a Federalism Assessment.

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 and recordkeeping requirements.

For reasons set out above, it is proposed that 21 CFR part 1309 be amended as follows:

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 proposed to be 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 § 1310.01(f)(1)(iv), 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 §§ 1301.24 through 1309.28. 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.)