

For mail order reporting, this action exempts from the reporting requirements a number of transactions that currently must be reported, thus reducing the overall reporting burden on many small businesses.

#### *Executive Order 12866*

The Deputy Assistant Administrator further certifies that this rulemaking has been drafted in accordance with the principles of Executive Order 12866 Section 1(b). DEA has determined that this is not a significant regulatory action. Therefore, this action has not been reviewed by the Office of Management and Budget.

#### *Executive Order 12988*

This rulemaking meets the applicable standards set forth in Sections 3(a) and 3(b)(2) of Executive Order 12988.

#### *Executive Order 13132*

This action has been analyzed in accordance with the principles and criteria in Executive Order 13132, and it has been determined that this rule does not have federalism implications and, therefore, does not warrant the preparation of a Federalism Assessment.

#### *Paperwork Reduction Act*

For those required to report under 21 U.S.C. 830(b)(3), MAPA adds the requirement of submitting a monthly report for certain export transactions with nonregulated persons involving ephedrine, pseudoephedrine, phenylpropanolamine, and drug products containing them. However, to reduce the burden on those affected, MAPA exempts monthly reporting of exports of the above list I chemicals and drug products containing them when they are reported to DEA pursuant to 21 U.S.C. 954 and 971.

MAPA further reduces the reporting burden on the regulated industry required to submit reports under 21 U.S.C. 830(b)(3) by exempting certain other transactions involving ephedrine, pseudoephedrine, phenylpropanolamine and drug products containing them from the requirement to submit reports as discussed in this rulemaking.

At this time it is not feasible for DEA to determine the extent of the impact of this rulemaking on the regulated industry. Once DEA has determined the impact, it will make the necessary filing with the Office of Management and Budget to adjust the burden of this information collection for the affected industry.

#### *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 1300*

Chemicals, Definitions, Drug traffic control.

##### *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, Exports, Imports, List I and List II chemicals, Reporting and recordkeeping requirements.

■ For the reasons set out above, 21 CFR parts 1300, 1309 and 1310 are amended as follows:

#### **PART 1300—DEFINITIONS [AMENDED]**

■ 1. The authority citation for Part 1300 continues to read as follows:

**Authority:** 21 U.S.C. 802, 871(b), 951, 958(f).

■ 2. Section 1300.02 is amended by revising paragraph (b)(28)(i)(D)(2) and by adding paragraphs (b)(33) and (b)(34) to read as follows:

##### **§ 1300.02 Definitions relating to listed chemicals.**

\* \* \* \* \*

(b) \* \* \*

(28) \* \* \*

(i) \* \* \*

(D) \* \* \*

(2) The quantity of ephedrine, pseudoephedrine,

phenylpropanolamine, or other listed chemical contained in the drug included in the transaction or multiple transactions equals or exceeds the threshold established for that chemical, except that the threshold for any sale of products containing pseudoephedrine or phenylpropanolamine by retail distributors or by distributors required to submit reports by § 1310.03(c) shall be 9 grams of pseudoephedrine or 9 grams of phenylpropanolamine in a single transaction and sold in package sizes of not more than 3 grams of pseudoephedrine base or 3 grams of phenylpropanolamine base. For combination ephedrine products the threshold for any sale by retail distributors or by distributors required to submit reports by § 1310.03(c) shall be 24 grams of ephedrine in a single transaction.

\* \* \* \* \*

(33) The term *drug product* means an active ingredient in dosage form that has been approved or otherwise may be lawfully marketed under the Food, Drug, and Cosmetic Act for distribution in the United States.

(34) The term *valid prescription* means a prescription that is issued for a legitimate medical purpose by an individual practitioner licensed by law to administer and prescribe the drugs concerned and acting in the usual course of the practitioner's professional practice.

#### **PART 1309—REGISTRATION OF MANUFACTURERS, DISTRIBUTORS, IMPORTERS AND EXPORTERS OF LIST I CHEMICALS [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 1309.24 is amended by revising paragraph (e) to read as follows:

##### **§ 1309.24 Waiver of registration requirement for certain activities.**

\* \* \* \* \*

(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 a pseudoephedrine, phenylpropanolamine, or combination ephedrine product that is regulated pursuant to § 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