

This industry is comprised mainly of small businesses, as defined by U.S. Small Business Administration (SBA) regulations (13 CFR 121.201). However, DEA is finalizing the concentration limit at a level suggested by the commentor, which will not require registration by these hundreds of thousands of businesses and distributors. In addition, other industry representatives have informed DEA that the alkaloid concentration of most dietary supplements is less than two percent. Therefore, DEA concludes that the majority of dietary supplements will be exempt from regulatory provisions of the CSA if a five percent concentration limit for ephedrine/pseudoephedrine is established.

The commentor informed DEA that there are approximately 12 importers and approximately six manufacturers of bulk ephedra. A bulk manufacturing process may involve taking the natural ephedra extract and spiking it with ephedrine hydrochloride. Therefore, DEA will assume that all six manufacturers will need to register, although some may qualify as end-users and not need to register.

DEA is also finalizing in this Rulemaking a process by which manufacturers may request exemption from DEA for specific products. This process will allow chemical mixtures not automatically exempt by the concentration limit to be considered for exempt status under the CSA. This will ensure that certain chemical mixtures, including dietary supplements having formulations useless to traffickers, but not automatically exempt by provision, can be granted exempt status.

Therefore, in accordance with the Regulatory Flexibility Act (5 U.S.C. 605(b)), the Acting Administrator has reviewed this Final Rule and by approving it certifies that this regulation will not have a significant economic impact upon a substantial number of small entities.

#### *Executive Order 12866*

This regulation has been drafted and reviewed in accordance with Executive Order 12866, section 1(b), Principles of Regulation. DEA has determined that this rule is a "significant regulatory action" under Executive Order 12866, section 3(f), Regulatory Planning and Review, and accordingly this rule has been reviewed by the Office of Management and Budget.

#### *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 1300*

Controlled substances, Definitions, Drug traffic control, List I and List II chemicals.

##### *21 CFR Part 1310*

Drug traffic control, List I and List II chemicals, Reporting and recordkeeping requirements.

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

#### **PART 1300—[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)(E) to read as follows:

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

\* \* \* \* \*

(b) \* \* \*

(28) \* \* \*

(i) \* \* \*

(E) Any transaction in a chemical mixture designated in § 1310.12 and § 1310.13 that the Administrator has exempted from regulation.

\* \* \* \* \*

#### **PART 1310—[AMENDED]**

■ 1. The authority citation for part 1310 continues to read as follows:

**Authority:** 21 U.S.C. 802, 830, 871(b).

■ 2. Section 1310.04 is amended by adding a new paragraph (h) to read as follows:

##### **§ 1310.04 Maintenance of records.**

\* \* \* \* \*

(h) The thresholds and conditions in paragraphs (f) and (g) of this section will apply to transactions involving regulated chemical mixtures. All regulated chemical mixtures containing List I chemicals will have the threshold determined by taking the weight of the listed chemical in the regulated mixture.

■ 3. Section 1310.09 is amended by adding a new paragraph (e) to read as follows:

##### **§ 1310.09 Temporary exemption from registration.**

\* \* \* \* \*

(e) Each person required by section 302 of the Act (21 U.S.C. 822) to obtain a registration to distribute, import, or export regulated chemical mixtures which contain ephedrine, N-methylephedrine, N-methylpseudoephedrine, norpseudoephedrine, phenylpropanolamine, and/or pseudoephedrine, pursuant to §§ 1310.12 and 1310.13, is temporarily exempted from the registration requirement, provided that DEA receives a proper application for registration or application for exemption on or before June 30, 2003. The exemption will remain in effect for each person who has made such application until the Administration has approved or denied that application. This exemption applies only to registration; all other chemical control requirements set forth in parts 1309, 1310, and 1313 of this chapter remain in full force and effect. Any person who distributes, imports or exports a chemical mixture whose application for exemption is subsequently denied by DEA must obtain a registration with DEA. A temporary exemption from the registration requirement will also be provided for these persons, provided that DEA receives a properly completed application for registration on or before 30 days following the date of official DEA notification that the application for