

respect to a regulated mixture containing a List I chemical, shall obtain a registration pursuant to the CSA (21 U.S.C. 822). Regulations describing registration for list I handlers are set forth in 21 CFR part 1309.

Separate registration is required for retail distribution, non-retail distribution, importing, and exporting. A separate registration is required for each principal place of business at one general physical location where list I chemicals are distributed, imported, or exported by a person (21 CFR 1309.23). Effective June 30, 2003, any person distributing, importing, exporting or serving as a broker or trader in an international transaction involving any amount of a regulated mixture will become subject to the registration requirement under the CSA. DEA recognizes, however, that it is not possible for persons who are subject to the registration requirement to immediately complete and submit an application for registration and for DEA to immediately issue registrations for those activities. Therefore, in order to allow continued legitimate commerce in regulated mixtures, DEA is establishing in 21 CFR 1310.09 a temporary exemption from the registration requirement for persons desiring to engage in activities with regulated mixtures that are subject to registration requirements, provided that DEA receives a properly completed application for registration on or before June 30, 2003. The temporary exemption for such persons will remain in effect until DEA takes final action on their application for registration.

Any person 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 exemption has not been approved. The temporary exemption for such persons will remain in effect until DEA takes final action on their registration application.

The temporary exemption applies solely to the registration requirement; all other chemical control requirements, including recordkeeping and reporting, are effective on June 2, 2003. Therefore, all transactions of the chemical mixture will be regulated, if at or above threshold, while an application for registration or exemption is pending. This is necessary because not regulating these transactions could result in

increased diversion of chemicals desirable to drug traffickers.

Additionally, the temporary exemption does not suspend applicable federal criminal laws relating to the regulated mixture, nor does it supersede state or local laws or regulations. All handlers of a regulated mixture must comply with applicable state and local requirements in addition to the CSA regulatory controls.

Records and Reports. The CSA (21 U.S.C. 830) requires certain records to be kept and reports to be made involving listed chemicals. Regulations describing recordkeeping and reporting requirements are set forth in 21 CFR part 1310. A record must be made and maintained for two years after the date of a regulated transaction involving a list I chemical. Only a distribution, receipt, sale, importation, exportation, brokerage or trade of a regulated mixture above the established threshold is a regulated transaction (21 CFR 1300.02(b)(28)).

Each regulated bulk manufacturer of a regulated mixture shall submit manufacturing, inventory and use data on an annual basis (21 CFR 1310.05(d)). Bulk manufacturers producing the mixture solely for internal consumption, e.g. formulating a nonregulated mixture, are not required to submit this information. Existing standard industry reports containing the required information are acceptable, provided the information is readily retrievable from the report.

21 CFR 1310.05 requires that each regulated person shall report to DEA any regulated transaction involving an extraordinary quantity, an uncommon method of payment or delivery, or any other circumstance that causes the regulated person to believe that the listed chemical will be used in violation of the CSA.

Imports/Exports. All import/exports and brokered transactions of regulated mixtures shall comply with the CSA (21 U.S.C. 957 and 971). Regulations for importation and exportation of list I chemicals are described in 21 CFR part 1313. Separate registration is necessary for each activity (21 CFR part 1309.22).

Administrative Inspection. Places, including factories, warehouses, or other establishments and conveyances, where regulated persons may lawfully hold, manufacture, or distribute, dispense, administer, or otherwise dispose of a regulated mixture or where records relating to those activities are maintained, are controlled premises as defined in 21 CFR 1316.02(c). The CSA (21 U.S.C. 880) allows for administrative inspections of these controlled premises

as provided in 21 CFR part 1316 subpart A.

Regulatory Certifications

Regulatory Flexibility Act

DEA, pursuant to 21 U.S.C. 802(39)(A)(v), is defining criteria for the exemption of chemical mixtures containing one or more of the List I chemicals ephedrine, N-methylephedrine, N-methylpseudoephedrine, norpseudoephedrine, phenylpropanolamine, and pseudoephedrine from regulatory control. To implement an exemption, a concentration limit is placed on each chemical, or combination of chemicals, which defines its regulatory status. In addition, an application process is established to exempt chemical mixtures, not automatically exempt by these provisions, from the regulatory process.

DEA has determined that dietary supplements, including bulk material used to formulate these supplements, are the principle chemical mixtures that utilize ephedrine and pseudoephedrine. While DEA is aware that some dietary supplements are sources for methamphetamine precursors, DEA is also aware that most of these supplements are not viable sources for diversion of precursor chemicals.

DEA sought information from the affected industry prior to publishing the Proposed Rule to exempt chemical mixtures. Information gathered prior to drafting a proposed rule indicated that the majority of chemical mixtures most likely to be affected contain not more than 1.2 percent ephedrine. To ensure that most legitimately marketed dietary supplements are not regulated, DEA proposed a two percent concentration limit on ephedrine/pseudoephedrine. This amount was greater than the highest concentration of ephedrine/pseudoephedrine in the final product, as related to DEA by the industry.

However, a comment received in response to the NPRM suggested that the percent concentration of ephedrine and pseudoephedrine be raised from two percent to five percent. The commentor states that it represents individual member companies with hundreds of thousands of independent distributors. One member company alone is said to have over 100,000 distributors. The commentor suspects that its members will be regulated if a two percent concentration limit is finalized. Registration costs for this number of new registrants would result in a significant regulatory action.