

Concentration Limits,” in 21 CFR 1310.12. This table lists the concentration limits for each listed chemical.

While the concentration limits will be sufficient for many chemical mixtures, there are certain categories of mixtures that fall outside the limits provided, but are not considered to be likely sources of diversion. Therefore the DEA also proposed the exemption of three categories of chemical mixtures. The NPRM proposed that (1) waste materials regulated by the Environmental Protection Agency (EPA); (2) completely formulated paints and coatings; and (3) harvested plant material containing listed chemicals, shall remain exempt regardless of concentration.

In recognition that not all mixtures that qualify for exemption can be identified by concentration or category, the DEA also proposed an application process to exempt additional mixtures which are not likely to be diverted for use in the illicit production of controlled substances.

How Will This Rulemaking Affect Access to the Products?

As noted previously, the only products affected by this rulemaking include dietary and nutritional supplements. These products are readily available to the general public through a variety of commercial outlets, including grocery and health stores, and direct marketing campaigns. These products are available to the public without a prescription.

To permit access to these products, while their diversion for the illicit manufacture of controlled substances is limited, DEA worked with members of the dietary and nutritional supplements manufacturing industry to determine an appropriate concentration level for each of these listed chemicals. DEA was assured by members of the affected industry, through discussions between the Administration and manufacturers, that the concentration levels discussed in this rulemaking would allow manufacturers to continue their manufacturing processes without harm to the product. Indeed, as discussed below, DEA received and incorporated comments from the affected industry suggesting these concentration levels rather than those originally proposed by DEA. At the same time, these levels are sufficient to prevent the diversion of these products for the illicit manufacture of controlled substances. This rulemaking will not affect the public's access to these products, nor, according to members of the industry, will these concentration levels have an

adverse impact on the manufacturers of dietary and nutritional supplements.

The U.S. Department of Health and Human Services (HHS) and Food and Drug Administration (FDA) Recently Expressed Concerns Regarding the Safety of Dietary Supplements Containing Ephedra (i.e. Ephedrine and Pseudoephedrine). Does This DEA Regulation Mean That DEA Has Determined That Dietary Supplements Containing Less Than 5 Percent Ephedrine and Pseudoephedrine Are Safe for Human Consumption?

No, this regulation does not attempt to address the issue of safety or human consumption of any products containing these listed chemicals. This regulation only deals with the issue of the potential illicit use of dietary supplements (and other chemical mixtures) containing ephedrine/pseudoephedrine as precursor material for the production of methamphetamine.

On February 28, 2003 the U.S. Department of Health and Human Services (HHS) and Food and Drug Administration (FDA) announced a series of actions designed to protect the public from potentially serious risks from the use of dietary supplement products containing ephedra. The announcement cites new evidence in the medical literature and in adverse event reports, of heightened concerns that dietary supplements containing ephedra may represent a “significant and unreasonable risk of illness and injury.” DEA recognizes that determinations regarding the safety of such dietary supplement products are the purview of HHS/FDA. This rule does not address the issue of safety or human consumption of such products.

DEA has met with HHS/FDA staff on numerous occasions to discuss DEA's chemical mixture rule. HHS/FDA staff have been extremely supportive of DEA efforts to implement regulations which will subject materials containing greater than 5 percent ephedrine/pseudoephedrine to CSA regulatory controls in order to prevent their use in the illicit production of methamphetamine. Any future action directed at dietary supplements by HHS/FDA will be separate from (and in addition to) the regulatory requirements implemented in this final rule.

What Action Is DEA Taking in This Final Rule?

1. Establishment of Chemical Mixture Regulations for Six Listed Chemicals

While the September 16, 1998 Notice of Proposed Rulemaking “Exemption of

Chemical Mixtures” (63 FR 49506) pertained to the regulation of chemical mixtures which contained any of 34 listed chemicals, this rulemaking finalizes only those portions of the NPRM pertaining to six specific chemicals: ephedrine, N-methylephedrine, N-methylpseudoephedrine, norpseudoephedrine, phenylpropanolamine, and pseudoephedrine. These chemicals are precursors to methamphetamine and related substances.

a. Establishment of Concentration Limits

This final rule establishes a concentration limit for each of these six listed chemicals. If the concentration of the listed chemical is at or below the limit, then the mixture will be automatically exempted and therefore treated as a nonregulated chemical mixture. These concentration limits are provided in the “Table of Concentration Limits,” in 21 CFR 1310.12. The weight of the free base will be used to determine the concentration of a listed chemical if it is a salt. A mixture is exempt if the concentration of the listed chemical or chemicals is less than or equal to the percentages and other conditions described in the “Table of Concentration Limits.”

Therefore (1) a chemical mixture having a total concentration of ephedrine and/or pseudoephedrine of less than or equal to five percent by weight will be automatically exempt; (2) a chemical mixture having a total concentration of N-methylephedrine and/or N-methylpseudoephedrine of less than or equal to 0.1 percent by weight will be automatically exempt; and (3) a chemical mixture having a total concentration of phenylpropanolamine and/or norpseudoephedrine of less than or equal to 0.6 percent by weight, will be automatically exempt.

b. Exemption of Harvested Plant Material Containing These Six Listed Chemicals

This final rulemaking also establishes an exemption for a category of chemical mixtures which contain ephedrine, N-methylephedrine, N-methylpseudoephedrine, norpseudoephedrine, phenylpropanolamine, and/or pseudoephedrine. While these mixtures may have higher concentration limits than provided above, the DEA believes they are not a likely source of diversion due to their inherent composition. Therefore, this rule also establishes an