

chemical mixtures proposed by DEA on October 13, 1994 (59 FR 51888). That portion of the proposal was withdrawn on December 9, 1994 (59 FR 63738) in response to industry concerns. DEA met with representatives from associations (and affiliated members) representing chemical manufacturers, the paints and coating industry, flavor and fragrance manufacturers, chemical distributors, the dietary supplements industry and others. These different groups expressed unique concerns that the DEA attempted to address within the notice of proposed rulemaking (63 FR 49506).

How and at What Concentration Did the NPRM Propose to Regulate Dietary Supplements?

List I chemicals comprise 24 of the 35 chemicals regulated by DEA, but only a few have been identified to be routinely used in chemical mixtures. This contrasts with the situation for List II chemicals which exist in a multitude of chemical mixtures used in a vast variety of industries.

The few list I chemicals that are used in chemical mixtures are utilized by a small number of industries. The dietary supplement industry is the primary industry having chemical mixtures containing these six listed chemicals. Natural ephedrine is obtained from the ephedra plant. The ephedrine is extracted and sold as bulk ephedra extract and used to formulate dietary supplements.

Prior to proposing the concentration limit for ephedrine, DEA gathered information from representatives of several dietary supplement manufacturers and distributors within the nutritional supplement industry. Information from industry, law enforcement and other sources indicated that a two percent concentration limit for ephedrine/pseudoephedrine would be adequate to prevent diversion and not unduly burden industry. The NPRM therefore proposed a two percent concentration limit.

In the NPRM, the DEA specifically solicited information from the dietary supplement and other industries regarding this matter and subsequently obtained new information suggesting that a higher concentration limit may be warranted.

Who Is Affected by This Final Rule?

This Rulemaking will affect only persons who manufacture, distribute, import, or export chemical formulations containing the List I chemicals ephedrine, N-methylephedrine, N-methylpseudoephedrine, norpseudoephedrine,

phenylpropanolamine, and/or pseudoephedrine. End users, including those who manufacture a regulated mixture and convert it to a nonregulated form in an on-site manufacturing process, are not affected. Of those persons whose mixtures are regulated, only those distributions above the established threshold quantity for the listed chemical(s) are regarded as regulated transactions (as specified in 21 CFR 1310.04). Since no threshold has been established for ephedrine, all transactions in regulated chemical mixtures containing ephedrine will be regulated transactions. The threshold for regulated chemical mixtures containing N-methylephedrine, N-methylpseudoephedrine, norpseudoephedrine, phenylpropanolamine, and pseudoephedrine are found in 21 CFR 1310.04(f)(1). This Final Rule will not affect the regulatory status for chemical mixtures containing the remaining listed chemicals.

This is an appropriate decision at this time, for most dietary supplements are not formulated in such a way to be easily used in the illicit manufacture of a controlled substance and are therefore not likely to be diverted. This will exempt the majority of these chemical mixtures from regulatory controls. Taking this information into account, DEA is implementing a concentration limit of five percent (total ephedrine/pseudoephedrine). This should exempt those dietary supplements which are not likely to be sources of precursor material for clandestine laboratories. By taking this action, DEA is endeavoring to permit public access to these chemical mixtures while ensuring that they are not subject to diversion. Based on the comments DEA received, as well as discussions with members of the affected industry, DEA believes that dietary and nutritional supplements will not be adversely affected by this rulemaking, and that the public will continue to have full access to these products.

II. Comments Received in Response to the NPRM for These Six Chemicals

DEA proposed new regulations regarding the exemption of chemical mixtures by publishing an NPRM on September 16, 1998, entitled "Exemption of Chemical Mixtures" (63 FR 49506). The comment period, which was twice extended, closed on April 16, 1999. Comments discussed in this Final Rule will be limited to those related to the listed chemicals being addressed in this Final Rule. Two comments addressed ephedrine and pseudoephedrine only in relation to

dietary supplement products. There were no comments on N-methylephedrine, N-methylpseudoephedrine, norpseudoephedrine, or phenylpropanolamine.

Three comments addressed the application process as being limited and suggested a means to exempt a group or family of mixtures and allow for variation, without having to reapply for exemption. Two comments requested that once a mixture is granted exemption it should apply to all manufacturers of the same mixture. Three persons suggested a 21-day time limit to determine if a mixture is exempt by the application process. One person suggested a five-day period for approval of an application. Below is a discussion on the specific comments.

Comments Pertaining to Dietary Supplements

Request for Exemption of Multiple Ingredient Dietary Supplements or Products With Less Than Five Percent Total Ephedrine/Pseudoephedrine

One comment requested that DEA automatically exempt multiple ingredient dietary supplement products containing ephedrine alkaloids or, alternatively, increase the concentration limit for ephedrine from two to five percent. The comment also requested that the capsule weight be considered in determining automatic exemption.

DEA attempted to obtain information on pertinent formulations and was provided, by the interested parties requesting a five percent concentration limit, formulations representing the dietary supplements in question. Labeling information for six products containing ephedra extract were provided to DEA. Five of the six labels provided sufficient information to determine that they contain more than two percent but less than five percent ephedrine alkaloids.

The total weight was not included in the label information for one of the examples. Therefore, the exact concentration could not be calculated. DEA estimates that the concentration of ephedrine alkaloids for this product is also less than five percent from available label information. This label stated that the ephedra was standardized to supply 24 mg of ephedrine alkaloids. This quantity of ephedrine is approximately that found in over-the-counter (OTC) drug products.

Some formulators add additional ephedrine to standardize a product. This practice is used to assure uniformity between batches of raw