

material obtained from natural sources. However, this method may also be used to formulate supplements that have an unnaturally high level of ephedrine or other alkaloid. This is sometimes referred to as "spiking." Both standardization and spiking imply that the product is not "all natural" and contains pharmaceutical grade ephedrine, or ephedrine hydrochloride. Ephedrine hydrochloride is the most common form of ephedrine used by clandestine laboratory operators to make methamphetamine.

The comment requested that if the five percent limit is unacceptable to DEA then multiple component dietary supplements should be exempt as a category. DEA agrees that the multiple ingredient dietary supplements, represented by the labels submitted by this commentor, would not be likely sources for diversion due to the added difficulty in extracting the listed chemicals. However, DEA realizes that these formulations do not represent all possibilities for dietary supplements containing ephedrine/pseudoephedrine. Without a concentration limit, formulations could be sold that have a high percentage of ephedrine.

DEA had been informed that persons represented in this comment sell only products with a maximum amount of 25 mg of ephedrine alkaloids per dosage unit. That amount is common in OTC drug products containing ephedrine. Ephedrine products containing 25 mg are commonly seized at clandestine laboratories. Therefore, DEA concludes that a maximum amount of ephedrine that is based on weight is not a deterrent for using a product as a source of precursor material.

DEA carefully considered exempting these dietary supplements by category but decided against this for the following reasons. Manufacturers can formulate multiple component dietary supplements rich in ephedrine that are legally marketed as dietary supplements. DEA has experienced multiple component OTC products being diverted upon control of single entity ephedrine OTC products. Further, the manufacturer may include innocuous substances within an ephedrine-rich formulation. The overall result is a legitimately marketed dietary supplement useful to traffickers. Permitting unlimited trade in such chemical mixtures would defeat previous efforts by Congress and DEA to curtail the illicit production of methamphetamine.

As stated on one of the labels provided to DEA, the ephedra supplement may be standardized to obtain an amount of ephedrine at least

equal to that found in OTC drug products. As noted above, standardization is achieved by using a synthetic form of ephedrine, ephedrine hydrochloride, which may be useful to traffickers. That form is more easily separated from other ingredients due to its affinity for water. DEA determined that exempting dietary supplements or "multiple ingredient" dietary supplements would create a loophole for the diversion of methamphetamine precursor. A supplement can be "standardized" to contain up to 25 mg of ephedrine with minimal additional ingredients that results in a high weight ratio of ephedrine and be legally marketed as a dietary supplement. Therefore, DEA has decided not to exempt dietary supplements as a category.

One commentor stated that methamphetamine cannot be produced from their dietary supplement products. The commentor sponsored an experiment to prove this assertion. The dietary supplement used in the experiment was calculated to contain one percent ephedrine by laboratory analysis. The laboratory report refers to a common "street method" for manufacturing methamphetamine. However, the sponsored experiment using this supplement was not successful in producing methamphetamine.

The comment concludes that the products described are representative of the formulations marketed by the dietary supplement industry, each containing less than five percent (by weight) ephedrine/pseudoephedrine. DEA agrees that those products containing less than five percent ephedrine, as represented by the label information provided to DEA, are not likely to be used in illicit laboratory operations. Therefore DEA has decided to raise the concentration limit for ephedrine/pseudoephedrine to five percent. For encapsulated products, the weight of the capsule is included in making this calculation.

Request for Increase in the Ephedrine Concentration Limit

One commentor requested that the concentration limit be raised to six percent for ephedrine, so that most of the existing ephedrine containing dietary supplement products would be exempt. Additionally the commentor recommended that DEA automatically exempt ephedra dietary supplements that contain multiple ingredients.

The commentor acknowledged that significant problems existed with some manufacturers "spiking" products with synthetically produced ephedrine.

Although the commentor states that they believe this practice has been mostly corrected, DEA must consider the likelihood of such practices. Voluntary compliance with standards of an organization or any special interest group can not prevent unscrupulous persons from distributing mixtures desired by traffickers. Without a concentration limit, products can be marketed as dietary supplements that are "spiked" to contain high levels of ephedrine with minimal additional ingredients. These formulations can be legally marketed as dietary supplements and be desirable to traffickers.

In another comment, a request was made to set the concentration limit to five percent. That comment states that multiple component dietary supplements containing ephedra alkaloids should be exempt at the five percent concentration limit for ephedrine and pseudoephedrine.

DEA is aware that bulk ephedra extract contains from six to eight percent ephedrine alkaloids. Raising the concentration limit to six percent for ephedrine would cause only those bulk mixtures that contain ephedrine alkaloids above six percent to be regulated.

DEA is aware that methamphetamine can be produced from ephedrine/pseudoephedrine when extracted directly from the raw plant material. A concentrate of this material would act as a more practical source for methamphetamine precursor. Therefore, DEA decided to regulate chemical mixtures consisting of bulk ephedra extract as a listed chemical. The ephedra extract typically has a concentration of ephedrine alkaloids of 6 percent or more. Therefore, DEA will exempt up to five percent ephedrine/pseudoephedrine contained in mixtures. That concentration limit is expected to exempt the vast majority of dietary supplements containing ephedrine/pseudoephedrine while allowing bulk ephedra extract to be treated as a regulated chemical.

Comments Pertaining to the Application Process

Single Application for Group Exemption

Three persons commented on the application process as being limited because it requires a separate application for each mixture. They suggest that the application process should account for a group or family of mixtures and allow for variation, sometimes necessary to meet customer needs, without having to reapply for exemption.