

exemption for the category of products consisting of harvested plant material.

Harvested plant material that contains ephedrine, N-methylephedrine, N-methylpseudoephedrine, norpseudoephedrine, phenylpropanolamine, and/or pseudoephedrine, while meeting the definition of chemical mixture, will be exempt provided the plant material is unaltered from its natural state. Changes in the physical state that preserve the natural composition of the material, such as grinding, chopping, mulching or cutting, do not affect the exemption status. However, changes that alter the natural composition of the material, such as that resulting from chemical or physical extraction, concentrating, enhancement or by chemical reaction, or any other treatment will disqualify the mixture from exemption.

**c. Establishment of an Application Procedure for Chemical Mixtures Which Do Not Qualify for Automatic Exemption**

In recognition that not all mixtures that warrant exemption can be identified solely by concentration or category criteria, this Final Rule also sets forth an application process to exempt additional mixtures. Mixtures that are not automatically exempted by virtue of their concentration or category may still qualify for exemption based upon a review of the mixture composition by DEA. However, DEA will only grant an exemption to those chemical mixtures (1) formulated in such a way that they cannot be easily used in the illicit production of a controlled substance; and (2) from which the listed chemical or chemicals contained in the chemical mixture cannot be readily recovered.

An application process is set forth in 21 CFR 1310.13 to allow possible exemption of chemical mixtures based on the formulation, even if the listed chemical exceeds the concentration limit.

***How Does This Final Rulemaking Affect Chemical Mixtures Containing Listed Chemicals Other Than the Six Chemicals Specified in This Rulemaking?***

Because this Final Rule pertains to only six listed chemicals, applications will only be accepted for chemical mixtures containing ephedrine, N-methylephedrine, N-methylpseudoephedrine, norpseudoephedrine, phenylpropanolamine, and/or pseudoephedrine. Final regulations for all remaining listed chemicals will be published under separate rulemaking

upon completion of a thorough review of applicable comments. Until publication of such a rulemaking, DEA will treat all transactions involving chemical mixtures containing these other listed chemicals as exempt from the definition of regulated transaction under the CSA.

***Why Is DEA Finalizing Provisions for Only Certain Listed Chemicals in This Rulemaking?***

Methamphetamine is the most prevalent controlled substance illicitly synthesized in the United States. The clandestine manufacture, distribution and abuse of methamphetamine are serious public health problems. Nationally, the Drug Abuse Warning Network (DAWN) has documented approximately 2,900 methamphetamine/speed related deaths in the United States between January 1992 and December 1996. The number of DAWN reported methamphetamine associated deaths for 1997 was 825 and 641 for 1998. For the years 1998 and 1999, the number of emergency room events associated with methamphetamine/speed were 11,490 and 10,447, respectively.

During calendar years 1994 through 1997, DEA was involved in the domestic seizure of 2,900 clandestine methamphetamine laboratories. Despite considerable efforts by Federal, state and local law enforcement, the illicit production, distribution and abuse of methamphetamine continue. Recent DEA seizure statistics indicate that the number of methamphetamine laboratory seizures has increased dramatically from 1996 through 2000. During 1998, DEA participated in the seizure of 1,623 methamphetamine laboratories. In 1999, the number rose to 2,127. These numbers do not include the thousands of laboratory seizures conducted independently by state and local law enforcement agencies. The chemicals ephedrine and/or pseudoephedrine were utilized as the precursor material at the vast majority of these laboratories.

***What Form of the Six Subject Chemicals Is Being Encountered at Illicit Laboratories?***

At most of these laboratories, the precursor material was obtained via the diversion of over-the-counter (OTC) products marketed in tablet and capsule form, not through the diversion of bulk powder. While the vast majority of products seized at illicit methamphetamine laboratories were OTC drug products, ephedra and ma huang extracts containing ephedrine, N-methylephedrine, N-methylpseudoephedrine,

norpseudoephedrine, phenylpropanolamine, and pseudoephedrine, and dietary supplement products (containing ephedra and ma huang extracts) have been seized at clandestine methamphetamine laboratories. At this time, the frequency with which these dietary supplement products and extracts are encountered is small. However, DEA studies confirm that the ephedrine contained in such extracts and some dietary supplement products can be readily recovered and can be easily used in the production of methamphetamine. Ephedra (in the form of dietary supplements or bulk ephedra extract), therefore, can and is being used as the source of precursor material for the illicit production of methamphetamine.

Recently, DEA has noted large increases in the number of ephedra dietary supplements being introduced into the marketplace. These products have a high level of ephedrine and are distributed by some companies whose OTC products have previously been identified at clandestine methamphetamine manufacturing laboratories. Several companies' advertisements tout that these new products are considered chemical mixtures and therefore are not subject to CSA regulatory controls. The introduction of some of these products may be creating an unregulated source of ephedrine (and related List I chemicals) for illicit use.

Therefore, due to (1) the growing methamphetamine clandestine laboratory problem; (2) the illicit use of extracts and dietary supplements (containing ephedrine and related List I chemicals) as precursor material for the clandestine production of methamphetamine and (3) the growth of new product introductions of dietary supplement products containing these chemicals, DEA has decided to finalize these provisions for the chemicals ephedrine, N-methylephedrine, N-methylpseudoephedrine, norpseudoephedrine, phenylpropanolamine, and pseudoephedrine.

***What Information Had DEA Collected Before Proposing Regulations on Chemical Mixtures?***

Prior to publication of the notice of proposed rulemaking "Exemption of Chemical Mixtures" (63 FR 49506) on September 16, 1998, the DEA attempted to learn as much as possible about the affected industry. The DEA first established contact with industry shortly after withdrawal of the regulations regarding the exemption of