

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

■ 4. A new section 1310.12 is added to read as follows:

**§ 1310.12 Exempt chemical mixtures.**

(a) The chemical mixtures meeting the criteria in paragraphs (c) or (d) of this section are exempted by the Administrator from application of

sections 302, 303, 310, 1007, and 1008 of the Act (21 U.S.C. 822, 823, 830, 957 and 958) to the extent described in paragraphs (b) and (c) of this section.

(b) No exemption granted pursuant to this § 1310.12 or § 1310.13 affects the criminal liability for illegal possession, distribution, exportation, or importation of listed chemicals contained in the exempt chemical mixture or the civil liability for unlawful acts related to exempt chemical mixtures, including

distribution in violation of 21 U.S.C. 842(a)(11).

(c) Mixtures containing a listed chemical in concentrations equal to or less than those specified in the "Table of Concentration Limits" are designated as exempt chemical mixtures for the purpose set forth in this section. The concentration is determined for liquid-liquid mixtures by using the volume or weight and for mixtures containing solids or gasses by using the unit of weight.

TABLE OF CONCENTRATION LIMITS

List I chemicals	DEA chemical code No.	Concentration (percent)	Special conditions
Ephedrine, its salts, optical isomers, and salts of optical isomers.	8113	5% by Weight, (weight includes capsule, if any).	Concentration based on any combination of ephedrine, pseudoephedrine, and their salts, optical isomers and salts of optical isomers
N-Methylephedrine, its salts, optical isomers, and salts of optical isomers.	8115	0.1% by Weight, (weight includes capsule, if any).	Concentration based on any combination of N-methylephedrine, N-methylpseudoephedrine and their salts, optical isomers and salts of optical isomers
N-methylpseudoephedrine, its salts, optical isomers, and salts of optical isomers.	8119	0.1% by Weight (weight includes capsule, if any).	Concentration based on any combination of N-methylpseudoephedrine, N-methylephedrine, and their salts, optical isomers and salts of optical isomers
Norpseudoephedrine, its salts, optical isomers, and salts of optical isomers.	8317	0.6% by Weight (weight includes capsule, if any).	Concentration based on any combination of norpseudoephedrine, phenylpropanolamine and their salts, optical isomers and salts of optical isomers
Phenylpropanolamine, its salts, optical isomers, and salts of optical isomers.	1225	0.6% by Weight (weight includes capsule, if any).	Concentration based on any combination of phenylpropanolamine, norpseudoephedrine and their salts, optical isomers and salts of optical isomers
Pseudoephedrine, its salts, optical isomers, and salts of optical isomers.	8112	5% by Weight, (weight includes capsule, if any).	Concentration based on any combination of pseudoephedrine, ephedrine, and their salts, optical isomers and salts of optical isomers

(d) The following categories of chemical mixtures are automatically exempt from the provisions of the Controlled Substances Act as described in paragraph (a) of this section:

(1) Harvested plant material that contains ephedrine, N-methylephedrine, N-methylpseudoephedrine, norpseudoephedrine, phenylpropanolamine, and/or pseudoephedrine, that is in its natural state or has been processed in a way (such as grinding, chopping, mulching or cutting) that preserves the natural constituents in the ratios that are found in the plant's natural state. Plant material subjected to chemical or physical extraction, concentration, chemical reaction, or other treatment that alters the plant's natural constituents or the ratios of the plant constituents are not exempt.

(2) [Reserved]

(e) The Administrator may, at any time, terminate or modify the exemption for any chemical mixture which has been granted an exemption pursuant to the concentration limits as specified in paragraph (c) of this section or pursuant to the category exemption as specified in paragraph (d) of this section. In

terminating or modifying an exemption, the Administrator shall issue, and publish in the **Federal Register**, notification of the removal of an exemption for a product or group of products for which evidence of diversion has been found, as well as the date on which the termination of exemption shall take effect. The Administrator shall permit any interested party to file written comments on or objections to the order within 60 days of the date of publication of the order in the **Federal Register**. If any such comments or objections raise significant issues regarding any finding of fact or conclusion of law upon which the order is based, the Administrator shall immediately suspend the effectiveness of the order until he may reconsider the order in light of comments and objections filed. Thereafter, the Administrator shall reinstate, terminate, or amend the original order as determined appropriate.

(f) The Administrator may modify any part of the criteria for exemption as specified in paragraphs (c) and (d) of this section upon evidence of diversion

or attempted diversion. In doing so, the Administrator shall issue and publish a Notice of Proposed Rulemaking in the **Federal Register**. The Administrator shall permit any interested persons to file written comments on or objections to the proposal. After considering any comments or objections filed, the Administrator shall publish in the **Federal Register** a final order.

■ 5. A new § 1310.13 is added to read as follows:

**§ 1310.13 Exemption of chemical mixtures; application.**

(a) The Administrator may, by publication of a Final Rule in the **Federal Register**, exempt from the application of all or any part of the Act a chemical mixture consisting of two or more chemical components, at least one of which is not a List I or List II chemical, if:

(1) The mixture is formulated in such a way that it cannot be easily used in the illicit production of a controlled substance; and

(2) The listed chemical or chemicals contained in the chemical mixture cannot be readily recovered.