

DEA intended to allow group exemption by application. A group is defined as those formulations having identical function and containing the same listed chemical(s). The Notice of Proposed Rulemaking states (63 FR 49511) "The application may be submitted for a single mixture or a group of mixtures containing the same listed chemical at equal concentration with variations in the concentration of the other non-listed chemicals in the mixture. Consideration will also be given to applications for mixtures in which the concentration of the listed chemical varies without regard to the specific concentrations of the other non-listed chemicals in the mixture. In either group, variation of the concentration of any chemical within the mixture that will result in a change in the function of the mixture will disqualify the mixture from the group."

DEA will address below the shortcoming in the proposed § 1310.13 that does not clearly establish group exemption. In addition, DEA shall establish that a single formulation may be granted an exemption while allowing variation in the formulation without the need to reapply. This is in anticipation that reformulation may be necessary to meet a customer's needs. Variation may be for listed and non-listed chemicals.

A group of mixtures may be exempted within a single application. However, not all formulations are required to have the same non-listed chemicals to be included in a group. A group application may be submitted to include several formulations being marketed simultaneously or for a single product that is reformulated within specified concentration ranges. The latter may be for a custom application that requires adjusting the properties for optimum performance. Therefore, reapplication will not be necessary for new formulations that fall within a stated concentration range. The Administrator may determine that a specific mixture does not qualify as part of a group, and that one or more mixtures submitted as part of a group does not qualify for exemption.

The usefulness of a mixture in clandestine operations depends on the number, type and concentrations of chemicals in the mixture. Therefore, an application for group exemption will identify both listed and non-listed components as well as their concentrations. A new application will not be necessary if a formulation is added to the group that contains the listed and non-listed chemicals within the concentration range specified in the original application. DEA must be

notified in writing if the manufacturer adds a new mixture to the group.

DEA must be informed if a qualitative change, not indicated on the original application, removes non-listed chemical(s) from a formulation exempt under a group. This is necessary to prevent mixtures being altered from an unusable state, as evaluated in the application, to a mixture that can be used by traffickers. If such a change (*i.e.*, removal of non-listed chemical(s) from the formulation) renders the mixture valuable to traffickers, DEA can remove the exemption for that member of the group. DEA must be informed of such a change; however, a new application will not be necessary. DEA will either add the new formulation to the group or deny exempt status for that particular formulation. Section 1310.13 will be modified to reflect this and other conditions mentioned above.

#### Applicability of Exemption to Manufacturers

Two comments requested that once a mixture is granted an exemption it should apply to all manufacturers of the same mixture. DEA proposed that all manufacturers apply separately. This requirement was proposed for several different reasons.

DEA requires that a manufacturer submit the exact formulation when applying for an exemption. That is necessary to properly evaluate the mixture. Manufacturers of a similar product could not know if their formulation is the same as an exempted mixture unless the formulation is made public. Since some formulations are assumed to be trade secrets, DEA cannot reveal those formulations.

Exempt chemical mixtures will be made public by publication in the **Federal Register**. Exempt formulations will be maintained in a Table in the Code of Federal Regulations. DEA, however, will only publish those formulations that the manufacturer allows to be made public. Due to the complexity of multiple ingredient formulations, such a Table may become unreasonably large.

DEA will therefore require that each manufacturer apply for exemption by the application process. However, manufacturers may submit a joint application where each manufacturer listed in the application formulates the same mixture. All manufacturers listed in the application will obtain a decision from DEA regarding the regulatory status of the mixture. Also, a manufacturer that suspects that they formulate a mixture similar to one granted exemption status may inform

DEA that a similar formulation has already been evaluated by DEA.

Once a mixture is exempted, all downstream distributions for that formulation are exempt from regulation. Persons will not be regulated if they repackage and distribute a mixture exempted by the application process.

#### Time Period for Application Processing

Three commentors suggested that a 21-day deadline be established to determine whether a mixture is exempt by the application process. One person suggested that a 5-day deadline be imposed for approval of the application. A time frame was requested so manufacturers could establish internal compliance procedures before shipments are made.

While DEA will attempt to expedite the review of each application, it is not practical to establish a time limit for determining whether a mixture or a mixture group is exempt. The time to determine the status of an individual application is dependent on several variables that can not be controlled. Factors include the number of applications received, the number of mixtures contained in an application, the possible need to obtain additional technical information from the applicant, the possible need to obtain additional internal technical information on chemicals in the mixture and to analyze all factors. These and other factors make a time limit impractical.

### III. Final Rule Provisions

#### *Upon Publication of the Final Notice, What Specific Requirements Will Apply to Regulated Chemical Mixtures Containing the 6 Chemicals?*

A chemical mixture (other than the category of products consisting of unaltered harvested plant material) that contains ephedrine, N-methylephedrine, N-methylpseudoephedrine, norpseudoephedrine, phenylpropanolamine, or pseudoephedrine above the concentration limit as defined in the "Table of Concentration Limits" will be treated as a List I chemical. Transactions that meet or exceed the cumulative monthly threshold for the listed chemical shall be regulated transactions. Persons interested in handling a regulated mixture must comply with the following:

**Registration.** Any person who distributes, imports or exports a regulated mixture, or proposes to engage in such activities, or is a broker or trader in an international transaction (as defined in 21 U.S.C. 802(42)), with