

and/or when we ask for it at a later time. Failure to cooperate will result in denial of benefits. We will permit an exception to the photograph requirement when an individual has a sincere religious objection. This pilot will be in effect for a six-month period after these final rules become effective.

(b) *Designated pilot geographic areas means:*

(1) All SSA field offices in the State of South Carolina.

(2) The Augusta, Georgia SSA field office.

(3) All SSA field offices in the State of Kansas.

(4) Selected SSA field offices located in New York City.

#### **PART 416—SUPPLEMENTAL SECURITY INCOME FOR THE AGED, BLIND, AND DISABLED**

■ 3. The authority citation for subpart C of part 416 continues to read as follows:

**Authority:** Secs. 702(a)(5), 1611, and 1631(a), (d), and (e) of the Social Security Act (42 U.S.C. 902(a)(5), 1382, and 1383(a), (d), and (e)).

■ 4. Add new § 416.327 under the existing heading, **Applications**, to read as follows:

#### **Applications**

\* \* \* \* \*

##### **§ 416.327 Pilot program for photographic identification of disability benefit applicants in designated geographic areas.**

(a) To be eligible for SSI disability or blindness benefits in the designated pilot geographic areas during the time period of the pilot, you or a person acting on your behalf must give SSA permission to take your photograph and make this photograph a part of the claims folder. You must give us this permission when you apply for benefits and/or when we ask for it at a later time. Failure to cooperate will result in denial of benefits. We will permit an exception to the photograph requirement when an individual has a sincere religious objection. This pilot will be in effect for a six-month period after these final rules become effective.

(b) *Designated pilot geographic areas means:*

(1) All SSA field offices in the State of South Carolina.

(2) The Augusta, Georgia SSA field office.

(3) All SSA field offices in the State of Kansas.

(4) Selected SSA field offices located in New York City.

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## **DEPARTMENT OF JUSTICE**

### **Drug Enforcement Administration**

#### **21 CFR Parts 1300 and 1310**

[Docket No. DEA-137F1]

RIN 1117-AA31

#### **Exemption of Chemical Mixtures Containing the List I Chemicals Ephedrine, N-Methylephedrine, N-Methylpseudoephedrine, Norpseudoephedrine, Phenylpropanolamine, and Pseudoephedrine**

**AGENCY:** Drug Enforcement Administration (DEA), Justice.

**ACTION:** Final rule.

**SUMMARY:** On September 16, 1998, the Drug Enforcement Administration (DEA) published a Notice of Proposed Rulemaking (NPRM) to implement provisions of the Controlled Substances Act (CSA) pertaining to the regulation of chemical mixtures which contain any of 34 listed chemicals. The NPRM was published to implement CSA requirements that only those chemical mixtures identified by regulation be exempt from applicable regulatory controls.

The NPRM proposed criteria for the determination of whether a chemical mixture shall qualify for automatic exemption from CSA regulatory controls. Additionally, the NPRM defined an application process by which manufacturers may apply for an exemption for chemical mixtures that do not qualify for automatic exemption.

Due to concerns regarding the potential illicit use of chemical mixtures which contain ephedrine, N-methylephedrine, N-methylpseudoephedrine, norpseudoephedrine, phenylpropanolamine, and/or pseudoephedrine (as precursor material for the production of methamphetamine and related amphetamines), DEA is hereby finalizing the portion of the NPRM pertaining to these six chemicals. Final regulations for all remaining listed chemicals will be published under separate rulemaking, upon completion of a thorough review of applicable comments.

**DATES:** Effective June 2, 2003. Persons seeking registration must apply on or before June 30, 2003 in order to continue their business pending final action by DEA on their application.

**FOR FURTHER INFORMATION CONTACT:** Frank Sapienza, Chief, Drug & Chemical Evaluation Section, Office of Diversion Control, Drug Enforcement

Administration, Washington, DC 20537, telephone (202) 307-7183.

#### **SUPPLEMENTARY INFORMATION:**

##### **I. Background**

This final rule addresses the List I chemicals ephedrine, N-methylephedrine, N-methylpseudoephedrine, norpseudoephedrine, phenylpropanolamine, and pseudoephedrine as they occur in chemical mixtures. The rule establishes a concentration limit for each of these six listed chemicals. If the concentration of the listed chemical is at or below the limit, in a chemical mixture, then the mixture will be automatically exempted from the registration, reporting, recordkeeping and security requirements of the Controlled Substances Act. All chemical mixtures containing any of these six List I chemicals above the established concentration levels are subject to the requirements of the CSA. This final rule primarily addresses these chemicals as encountered in dietary and nutritional supplements. Actions taken in this final rule will not adversely impact the public's access to these products.

DEA originally proposed a concentration level of two percent for chemical mixtures containing ephedrine and/or pseudoephedrine. However, based on the comments received from the NPRM (63 FR 49506, Sept. 16, 1998), DEA has determined that a two percent concentration level would create significant regulatory burdens for the affected industry. Therefore, based on comments received, DEA has determined that a five percent concentration level will permit access to these products, while ensuring that these products are unlikely to be subject to diversion for the illegal manufacture of methamphetamine.

This final rule also establishes an exemption for the category of products consisting of unaltered harvested plant material, which DEA believes are not subject to diversion regardless of the concentration of the List I chemical in the product. Finally, this rule provides for a process whereby a manufacturer of a product which would otherwise be subject to regulation may request an exemption for that specific product. This process will allow chemical mixtures not automatically exempt by the concentration limit to be considered for exempt status under the CSA.

## Background

### *What Chemical Controls Have Been Established in the United States?*

The Chemical Diversion and Trafficking Act of 1988 (Pub. L. 100-690)(CDTA) was passed by Congress to curtail the diversion of specific chemicals used in the illicit manufacture of controlled substances. The CDTA established recordkeeping and reporting requirements necessary for DEA to identify and track chemical diversion. While the CDTA achieved initial success in curtailing the diversion of chemicals, traffickers soon found and took advantage of certain shortcomings in the law. In the United States (U.S.), traffickers were able to obtain needed supplies by purchasing products that were exempted from regulation under the CDTA. Such products include chemical mixtures.

### *What Are Chemical Mixtures?*

The Chemical Diversion and Trafficking Act of 1988 (CDTA) created a definition of "chemical mixture" (21 U.S.C. 802(40)), and exempted chemical mixtures from regulatory coverage. The Domestic Chemical Diversion Control Act of 1993 (DCDCA), enacted in April of 1994, created a provision dealing with the exemption of chemical mixtures. Chemical mixtures are defined as "a combination of two or more chemical substances, at least one of which is not a list I chemical or a list II chemical, except that such term does not include any combination of a list I chemical or a list II chemical with another chemical that is present solely as an impurity."

### *How Are Ephedrine, N-methylephedrine, N-methylpseudoephedrine, Norpseudoephedrine, Phenylpropanolamine, and Pseudoephedrine Used in Chemical Mixtures and What Are the Regulatory Consequences?*

Ephedrine, N-methylephedrine, N-methylpseudoephedrine, norpseudoephedrine, phenylpropanolamine, and pseudoephedrine are List I chemicals. The only chemical mixtures containing these List I chemicals, of which DEA is aware, are dietary and nutritional supplements. Dietary and nutritional supplements are readily available, being commonly sold to the public in drug and grocery stores, health and nutrition stores, and through direct marketing campaigns. These dietary and nutritional supplements contain material from the ephedra plant, or extract from the ephedra plant. If these

dietary and nutritional supplements meet certain criteria under the Federal Food, Drug, and Cosmetic Act (FDCA), they are not recognized as drugs under the FDCA, but are nonetheless considered to be chemical mixtures governed by DEA law and regulations. In contrast, over-the-counter (OTC) and prescription drug products containing these listed chemicals are not considered chemical mixtures and instead are specifically addressed in 21 U.S.C. 802(39)(A)(iv). *Also see 21 CFR 1300.02(b)(28)(i)*. Therefore, this final rulemaking has no impact upon OTC and prescription drug products lawfully marketed under the FDCA.

### *How Have Chemical Mixtures Been Regulated Until Now?*

Prior to the enactment of the DCDCA, the term "regulated transaction" was defined to exclude "any transaction in a chemical mixture" (21 U.S.C. 802(39)(A)(v)). Therefore, transactions involving all chemical mixtures (including dietary supplements) were exempt from recordkeeping, registration and other chemical regulatory control requirements of the CSA.

### *How Did the DCDCA Affect Regulation of Chemical Mixtures?*

With passage of the DCDCA, all chemical mixtures became subject to regulatory requirements for listed chemicals under the law, unless specifically exempted by DEA. These requirements included registration for certain handlers of List I chemicals, recordkeeping, reporting, and security. Thus, all dietary and nutritional supplements containing listed chemicals became subject to DEA regulation. However, pending promulgation of final regulations governing exemption, dietary supplements containing ephedrine, N-methylephedrine, N-methylpseudoephedrine, norpseudoephedrine, phenylpropanolamine, and pseudoephedrine remained exempt from the requirements of the CSA.

### *What Changes in the Law Did the DCDCA Make With Respect to Chemical Mixtures?*

The DCDCA amended the CSA (21 U.S.C. 802(39)(A)(v)) to limit the application of the above stated exemption and provided the Attorney General with the authority to exempt a chemical mixture containing a listed chemical if it is "formulated in such a way that it cannot be easily used in the illicit production of a controlled substance" and "the listed chemical or chemicals contained in the mixture

cannot be readily recovered." Until regulations which delineate criteria and procedures for exempting specific chemical mixtures are finalized, DEA has treated all chemical mixtures as being exempt from the chemical regulatory requirements of the CSA. (Note that OTC and prescription drug products are not considered chemical mixtures and are addressed separately under 21 U.S.C. 802(39)(A)(iv)).

### *Why Is DEA Concerned About Chemical Mixtures?*

Some chemical mixtures can be and have been used by traffickers in the illicit manufacture of controlled substances. This exemption provided traffickers with an unregulated source for obtaining these chemicals. To address these problems, the DCDCA amended the exemption to provide that only those chemical mixtures specified by regulation would be exempt from the definition of "regulated transaction".

### *What Regulatory Controls Has DEA Previously Proposed for the Control of Chemical Mixtures?*

Regulations regarding the exemption of chemical mixtures were initially proposed by DEA on October 13, 1994 (59 FR 51888). In response to industry concerns, the proposed regulations were withdrawn on December 9, 1994 (59 FR 63738). After consulting with the private sector and carefully considering industry and other concerns, new regulations regarding chemical mixtures were proposed on September 16, 1998 (63 FR 49506). The comment period, which was twice extended, closed on April 16, 1999.

There are thousands of chemical mixtures in legitimate commerce, the majority of which are not useful to the illicit laboratory operator. The NPRM proposed criteria for the determination of whether a chemical mixture would be automatically exempt from CSA regulatory controls. Additionally, the NPRM defined an application process by which manufacturers may apply for an exemption for chemical mixtures that do not qualify for automatic exemption.

The DEA proposed that each chemical be assigned a concentration limit that, if found at or below the limit, will cause the mixture to be treated as a nonregulated chemical. This quantitative approach to identifying regulated mixtures is considered necessary due to the complexity of chemical-based commodities and the huge variety of products. These criteria are expected to exempt the vast majority of chemical mixtures containing listed chemicals. The NPRM included the proposed creation of a "Table of

Concentration Limits,” in 21 CFR 1310.12. This table lists the concentration limits for each listed chemical.

While the concentration limits will be sufficient for many chemical mixtures, there are certain categories of mixtures that fall outside the limits provided, but are not considered to be likely sources of diversion. Therefore the DEA also proposed the exemption of three categories of chemical mixtures. The NPRM proposed that (1) waste materials regulated by the Environmental Protection Agency (EPA); (2) completely formulated paints and coatings; and (3) harvested plant material containing listed chemicals, shall remain exempt regardless of concentration.

In recognition that not all mixtures that qualify for exemption can be identified by concentration or category, the DEA also proposed an application process to exempt additional mixtures which are not likely to be diverted for use in the illicit production of controlled substances.

#### *How Will This Rulemaking Affect Access to the Products?*

As noted previously, the only products affected by this rulemaking include dietary and nutritional supplements. These products are readily available to the general public through a variety of commercial outlets, including grocery and health stores, and direct marketing campaigns. These products are available to the public without a prescription.

To permit access to these products, while their diversion for the illicit manufacture of controlled substances is limited, DEA worked with members of the dietary and nutritional supplements manufacturing industry to determine an appropriate concentration level for each of these listed chemicals. DEA was assured by members of the affected industry, through discussions between the Administration and manufacturers, that the concentration levels discussed in this rulemaking would allow manufacturers to continue their manufacturing processes without harm to the product. Indeed, as discussed below, DEA received and incorporated comments from the affected industry suggesting these concentration levels rather than those originally proposed by DEA. At the same time, these levels are sufficient to prevent the diversion of these products for the illicit manufacture of controlled substances. This rulemaking will not affect the public's access to these products, nor, according to members of the industry, will these concentration levels have an

adverse impact on the manufacturers of dietary and nutritional supplements.

#### *The U.S. Department of Health and Human Services (HHS) and Food and Drug Administration (FDA) Recently Expressed Concerns Regarding the Safety of Dietary Supplements Containing Ephedra (i.e. Ephedrine and Pseudoephedrine). Does This DEA Regulation Mean That DEA Has Determined That Dietary Supplements Containing Less Than 5 Percent Ephedrine and Pseudoephedrine Are Safe for Human Consumption?*

No, this regulation does not attempt to address the issue of safety or human consumption of any products containing these listed chemicals. This regulation only deals with the issue of the potential illicit use of dietary supplements (and other chemical mixtures) containing ephedrine/pseudoephedrine as precursor material for the production of methamphetamine.

On February 28, 2003 the U.S. Department of Health and Human Services (HHS) and Food and Drug Administration (FDA) announced a series of actions designed to protect the public from potentially serious risks from the use of dietary supplement products containing ephedra. The announcement cites new evidence in the medical literature and in adverse event reports, of heightened concerns that dietary supplements containing ephedra may represent a “significant and unreasonable risk of illness and injury.” DEA recognizes that determinations regarding the safety of such dietary supplement products are the purview of HHS/FDA. This rule does not address the issue of safety or human consumption of such products.

DEA has met with HHS/FDA staff on numerous occasions to discuss DEA's chemical mixture rule. HHS/FDA staff have been extremely supportive of DEA efforts to implement regulations which will subject materials containing greater than 5 percent ephedrine/pseudoephedrine to CSA regulatory controls in order to prevent their use in the illicit production of methamphetamine. Any future action directed at dietary supplements by HHS/FDA will be separate from (and in addition to) the regulatory requirements implemented in this final rule.

#### *What Action Is DEA Taking in This Final Rule?*

##### **1. Establishment of Chemical Mixture Regulations for Six Listed Chemicals**

While the September 16, 1998 Notice of Proposed Rulemaking “Exemption of

Chemical Mixtures” (63 FR 49506) pertained to the regulation of chemical mixtures which contained any of 34 listed chemicals, this rulemaking finalizes only those portions of the NPRM pertaining to six specific chemicals: ephedrine, N-methylephedrine, N-methylpseudoephedrine, norpseudoephedrine, phenylpropanolamine, and pseudoephedrine. These chemicals are precursors to methamphetamine and related substances.

##### **a. Establishment of Concentration Limits**

This final rule establishes a concentration limit for each of these six listed chemicals. If the concentration of the listed chemical is at or below the limit, then the mixture will be automatically exempted and therefore treated as a nonregulated chemical mixture. These concentration limits are provided in the “Table of Concentration Limits,” in 21 CFR 1310.12. The weight of the free base will be used to determine the concentration of a listed chemical if it is a salt. A mixture is exempt if the concentration of the listed chemical or chemicals is less than or equal to the percentages and other conditions described in the “Table of Concentration Limits.”

Therefore (1) a chemical mixture having a total concentration of ephedrine and/or pseudoephedrine of less than or equal to five percent by weight will be automatically exempt; (2) a chemical mixture having a total concentration of N-methylephedrine and/or N-methylpseudoephedrine of less than or equal to 0.1 percent by weight will be automatically exempt; and (3) a chemical mixture having a total concentration of phenylpropanolamine and/or norpseudoephedrine of less than or equal to 0.6 percent by weight, will be automatically exempt.

##### **b. Exemption of Harvested Plant Material Containing These Six Listed Chemicals**

This final rulemaking also establishes an exemption for a category of chemical mixtures which contain ephedrine, N-methylephedrine, N-methylpseudoephedrine, norpseudoephedrine, phenylpropanolamine, and/or pseudoephedrine. While these mixtures may have higher concentration limits than provided above, the DEA believes they are not a likely source of diversion due to their inherent composition. Therefore, this rule also establishes an

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

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

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.

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



respect to a regulated mixture containing a List I chemical, shall obtain a registration pursuant to the CSA (21 U.S.C. 822). Regulations describing registration for list I handlers are set forth in 21 CFR part 1309.

Separate registration is required for retail distribution, non-retail distribution, importing, and exporting. A separate registration is required for each principal place of business at one general physical location where list I chemicals are distributed, imported, or exported by a person (21 CFR 1309.23). Effective June 30, 2003, any person distributing, importing, exporting or serving as a broker or trader in an international transaction involving any amount of a regulated mixture will become subject to the registration requirement under the CSA. DEA recognizes, however, that it is not possible for persons who are subject to the registration requirement to immediately complete and submit an application for registration and for DEA to immediately issue registrations for those activities. Therefore, in order to allow continued legitimate commerce in regulated mixtures, DEA is establishing in 21 CFR 1310.09 a temporary exemption from the registration requirement for persons desiring to engage in activities with regulated mixtures that are subject to registration requirements, provided that DEA receives a properly completed application for registration on or before June 30, 2003. The temporary exemption for such persons will remain in effect until DEA takes final action on their application for registration.

Any person whose application for exemption is subsequently denied by DEA must obtain a registration with DEA. A temporary exemption from the registration requirement will also be provided for these persons, provided that DEA receives a properly completed application for registration on or before 30 days following the date of official DEA notification that the application for exemption has not been approved. The temporary exemption for such persons will remain in effect until DEA takes final action on their registration application.

The temporary exemption applies solely to the registration requirement; all other chemical control requirements, including recordkeeping and reporting, are effective on June 2, 2003. Therefore, all transactions of the chemical mixture will be regulated, if at or above threshold, while an application for registration or exemption is pending. This is necessary because not regulating these transactions could result in

increased diversion of chemicals desirable to drug traffickers.

Additionally, the temporary exemption does not suspend applicable federal criminal laws relating to the regulated mixture, nor does it supersede state or local laws or regulations. All handlers of a regulated mixture must comply with applicable state and local requirements in addition to the CSA regulatory controls.

**Records and Reports.** The CSA (21 U.S.C. 830) requires certain records to be kept and reports to be made involving listed chemicals. Regulations describing recordkeeping and reporting requirements are set forth in 21 CFR part 1310. A record must be made and maintained for two years after the date of a regulated transaction involving a list I chemical. Only a distribution, receipt, sale, importation, exportation, brokerage or trade of a regulated mixture above the established threshold is a regulated transaction (21 CFR 1300.02(b)(28)).

Each regulated bulk manufacturer of a regulated mixture shall submit manufacturing, inventory and use data on an annual basis (21 CFR 1310.05(d)). Bulk manufacturers producing the mixture solely for internal consumption, e.g. formulating a nonregulated mixture, are not required to submit this information. Existing standard industry reports containing the required information are acceptable, provided the information is readily retrievable from the report.

21 CFR 1310.05 requires that each regulated person shall report to DEA any regulated transaction involving an extraordinary quantity, an uncommon method of payment or delivery, or any other circumstance that causes the regulated person to believe that the listed chemical will be used in violation of the CSA.

**Imports/Exports.** All import/exports and brokered transactions of regulated mixtures shall comply with the CSA (21 U.S.C. 957 and 971). Regulations for importation and exportation of list I chemicals are described in 21 CFR part 1313. Separate registration is necessary for each activity (21 CFR part 1309.22).

**Administrative Inspection.** Places, including factories, warehouses, or other establishments and conveyances, where regulated persons may lawfully hold, manufacture, or distribute, dispense, administer, or otherwise dispose of a regulated mixture or where records relating to those activities are maintained, are controlled premises as defined in 21 CFR 1316.02(c). The CSA (21 U.S.C. 880) allows for administrative inspections of these controlled premises

as provided in 21 CFR part 1316 subpart A.

## Regulatory Certifications

### *Regulatory Flexibility Act*

DEA, pursuant to 21 U.S.C. 802(39)(A)(v), is defining criteria for the exemption of chemical mixtures containing one or more of the List I chemicals ephedrine, N-methylephedrine, N-methylpseudoephedrine, norpseudoephedrine, phenylpropanolamine, and pseudoephedrine from regulatory control. To implement an exemption, a concentration limit is placed on each chemical, or combination of chemicals, which defines its regulatory status. In addition, an application process is established to exempt chemical mixtures, not automatically exempt by these provisions, from the regulatory process.

DEA has determined that dietary supplements, including bulk material used to formulate these supplements, are the principle chemical mixtures that utilize ephedrine and pseudoephedrine. While DEA is aware that some dietary supplements are sources for methamphetamine precursors, DEA is also aware that most of these supplements are not viable sources for diversion of precursor chemicals.

DEA sought information from the affected industry prior to publishing the Proposed Rule to exempt chemical mixtures. Information gathered prior to drafting a proposed rule indicated that the majority of chemical mixtures most likely to be affected contain not more than 1.2 percent ephedrine. To ensure that most legitimately marketed dietary supplements are not regulated, DEA proposed a two percent concentration limit on ephedrine/pseudoephedrine. This amount was greater than the highest concentration of ephedrine/pseudoephedrine in the final product, as related to DEA by the industry.

However, a comment received in response to the NPRM suggested that the percent concentration of ephedrine and pseudoephedrine be raised from two percent to five percent. The commentor states that it represents individual member companies with hundreds of thousands of independent distributors. One member company alone is said to have over 100,000 distributors. The commentor suspects that its members will be regulated if a two percent concentration limit is finalized. Registration costs for this number of new registrants would result in a significant regulatory action.



This industry is comprised mainly of small businesses, as defined by U.S. Small Business Administration (SBA) regulations (13 CFR 121.201). However, DEA is finalizing the concentration limit at a level suggested by the commentor, which will not require registration by these hundreds of thousands of businesses and distributors. In addition, other industry representatives have informed DEA that the alkaloid concentration of most dietary supplements is less than two percent. Therefore, DEA concludes that the majority of dietary supplements will be exempt from regulatory provisions of the CSA if a five percent concentration limit for ephedrine/pseudoephedrine is established.

The commentor informed DEA that there are approximately 12 importers and approximately six manufacturers of bulk ephedra. A bulk manufacturing process may involve taking the natural ephedra extract and spiking it with ephedrine hydrochloride. Therefore, DEA will assume that all six manufacturers will need to register, although some may qualify as end-users and not need to register.

DEA is also finalizing in this Rulemaking a process by which manufacturers may request exemption from DEA for specific products. This process will allow chemical mixtures not automatically exempt by the concentration limit to be considered for exempt status under the CSA. This will ensure that certain chemical mixtures, including dietary supplements having formulations useless to traffickers, but not automatically exempt by provision, can be granted exempt status.

Therefore, in accordance with the Regulatory Flexibility Act (5 U.S.C. 605(b)), the Acting Administrator has reviewed this Final Rule and by approving it certifies that this regulation will not have a significant economic impact upon a substantial number of small entities.

#### *Executive Order 12866*

This regulation has been drafted and reviewed in accordance with Executive Order 12866, section 1(b), Principles of Regulation. DEA has determined that this rule is a "significant regulatory action" under Executive Order 12866, section 3(f), Regulatory Planning and Review, and accordingly this rule has been reviewed by the Office of Management and Budget.

#### *Executive Order 12988*

This regulation meets the applicable standards set forth in sections 3(a) and 3(b)(2) of Executive Order 12988.

#### *Executive Order 13132*

This rulemaking does not preempt or modify any provision of state law; nor does it impose enforcement responsibilities on any state; nor does it diminish the power of any state to enforce its own laws. Accordingly, this rulemaking does not have federalism implications warranting the application of Executive Order 13132.

#### *Unfunded Mandates Reform Act of 1995*

This rule will not result in the expenditure by state, local, and tribal governments, in the aggregate, or by the private sector, of \$100,000,000 or more in any one year, and will not significantly or uniquely affect small governments. Therefore, no actions were deemed necessary under the provisions of the Unfunded Mandates Reform Act of 1995.

#### *Small Business Regulatory Enforcement Fairness Act of 1996*

This rule is not a major rule as defined by Section 804 of the Small Business Regulatory Enforcement Fairness Act of 1996. This rule will not result in an annual effect on the economy of \$100,000,000 or more; a major increase in costs or prices; or significant adverse effects on competition, employment, investment, productivity, innovation, or on the ability of United States-based companies to compete with foreign-based companies in domestic and export markets.

#### **List of Subjects**

##### *21 CFR Part 1300*

Controlled substances, Definitions, Drug traffic control, List I and List II chemicals.

##### *21 CFR Part 1310*

Drug traffic control, List I and List II chemicals, Reporting and recordkeeping requirements.

■ For the reasons set out above, 21 CFR parts 1300 and 1310 are amended as follows:

#### **PART 1300—[AMENDED]**

■ 1. The authority citation for part 1300 continues to read as follows:

**Authority:** 21 U.S.C. 802, 871(b), 951, 958(f).

2. Section 1300.02 is amended by revising paragraph (b)(28)(i)(E) to read as follows:

##### **§ 1300.02 Definitions relating to listed chemicals.**

\* \* \* \* \*

(b) \* \* \*

(28) \* \* \*

(i) \* \* \*

(E) Any transaction in a chemical mixture designated in § 1310.12 and § 1310.13 that the Administrator has exempted from regulation.

\* \* \* \* \*

#### **PART 1310—[AMENDED]**

■ 1. The authority citation for part 1310 continues to read as follows:

**Authority:** 21 U.S.C. 802, 830, 871(b).

■ 2. Section 1310.04 is amended by adding a new paragraph (h) to read as follows:

##### **§ 1310.04 Maintenance of records.**

\* \* \* \* \*

(h) The thresholds and conditions in paragraphs (f) and (g) of this section will apply to transactions involving regulated chemical mixtures. All regulated chemical mixtures containing List I chemicals will have the threshold determined by taking the weight of the listed chemical in the regulated mixture.

■ 3. Section 1310.09 is amended by adding a new paragraph (e) to read as follows:

##### **§ 1310.09 Temporary exemption from registration.**

\* \* \* \* \*

(e) Each person required by section 302 of the Act (21 U.S.C. 822) to obtain a registration to distribute, import, or export regulated chemical mixtures which contain ephedrine, N-methylephedrine, N-methylpseudoephedrine, norpseudoephedrine, phenylpropanolamine, and/or pseudoephedrine, pursuant to §§ 1310.12 and 1310.13, is temporarily exempted from the registration requirement, provided that DEA receives a proper application for registration or application for exemption on or before June 30, 2003. The exemption will remain in effect for each person who has made such application until the Administration has approved or denied that application. This exemption applies only to registration; all other chemical control requirements set forth in parts 1309, 1310, and 1313 of this chapter remain in full force and effect. Any person who distributes, imports or exports a chemical mixture whose application for exemption is subsequently denied by DEA must obtain a registration with DEA. A temporary exemption from the registration requirement will also be provided for these persons, provided that DEA receives a properly completed application for registration on or before 30 days following the date of official DEA notification that the application for

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.

(b) Any manufacturer seeking an exemption for a chemical mixture, not exempt under § 1310.12, from the application of all or any part of the Act, may apply to the Administrator, Drug Enforcement Administration, Department of Justice, Washington, DC 20537.

(c) An application for exemption under this section shall contain the following information:

(1) The name, address, and registration number, if any, of the applicant;

(2) The date of the application;

(3) The exact trade name(s) of the applicant's chemical mixture and:

(i) If the applicant formulates or manufactures the chemical mixture for other entities, the exact trade names of the chemical mixtures and the names of the entities for which the chemical mixtures were prepared; and

(ii) If a group of mixtures (*e.g.* formulations having identical function and containing the same listed chemical(s)), the information required in paragraph (c)(3)(i) of this section and a brief narrative of their use.

(4) (i) The complete qualitative and quantitative composition of the chemical mixture (including all listed and all non-listed chemicals); or

(ii) If a group of mixtures, the concentration range for the listed chemical and a listing of all non-listed chemicals with respective concentration ranges.

(5) (i) The chemical and physical properties of the mixture and how they differ from the properties of the listed chemical or chemicals; and

(ii) If a group of mixtures, how the group's properties differ from the properties of the listed chemical.

(6) A statement that the applicant believes justifies an exemption for the chemical mixture or group of mixtures. The statement must explain how the chemical mixture(s) meets the exemption criteria set forth in paragraph (a) of this section.

(7) A statement that the applicant accepts the right of the Administrator to terminate exemption from regulation for the chemical mixture(s) granted exemption under this section.

(8) The identification of any information on the application that is

considered by the applicant to be a trade secret or confidential and entitled to protection under U.S. laws restricting the public disclosure of such information.

(d) The Administrator may require the applicant to submit such additional documents or written statements of fact relevant to the application that he deems necessary for determining if the application should be granted.

(e) Within 30 days after the receipt of an application for an exemption under this section, the Administrator will notify the applicant of acceptance or rejection of the application. If the application is not accepted, an explanation will be provided. The Administrator is not required to accept an application if any information required pursuant to paragraph (c) of this section or requested pursuant to paragraph (d) of this section is lacking or not readily understood. The applicant may, however, amend the application to meet the requirements of paragraphs (c) and (d) of this section. If the exemption is granted, the applicant shall be notified in writing and the Administrator shall issue, and publish in the **Federal Register**, an order on the application. This order shall specify the date on which it shall take effect. The Administrator shall permit any interested person to file written comments on or objections to the order. If any comments or objections raise significant issues regarding any findings of fact or conclusions of law upon which the order is based, the Administrator may suspend the effectiveness of the order until he has reconsidered the application in light of the comments and objections filed. Thereafter, the Administrator shall reinstate, terminate, or amend the original order as deemed appropriate.

(f) The Administrator may, at any time, terminate or modify an exemption for any product pursuant to paragraph (e) 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 exempt product or group of exempt products for which evidence of diversion has been found. This order shall specify 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 may suspend the effectiveness of the order until he has reconsidered the order in light of comments and objections filed. Thereafter, the Administrator shall reinstate, terminate, or amend the original order as determined appropriate.

(g) A manufacturer of an exempted chemical mixture shall notify DEA in writing, of any change in the quantitative or qualitative composition of a chemical mixture that has been granted an exemption by application. Changes include those greater than the range of concentration given in the application or that remove non-listed chemical(s) given in the application as part of the formulation. A new application will be required only if reformulation results in a new product having a different commercial application or can no longer be defined as part of a group of exempted chemicals. DEA must be notified of reformulation at least 30 days in advance of marketing the reformulated mixture. For a change in name or other designation, code, or any identifier, a written notification is required. DEA must be notified of any changes at least 60 days in advance of the effective date for the change.

(h) Each manufacturer seeking exemption must apply for such an exemption. A formulation granted exemption by publication in the **Federal Register** will not be exempted for all manufacturers.

(i) The following chemical mixtures, in the form and quantity listed in the application submitted (indicated as the "date") are designated as exempt chemical mixtures for the purposes set forth in this section and 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):

#### EXEMPT CHEMICAL MIXTURES

Manufacturer	Product name <sup>1</sup>	Form	Date
[RESERVED]			

<sup>1</sup> Designate product line if a group.

Dated: March 7, 2003.

**John B. Brown III,**

*Acting Administrator.*

[FR Doc. 03-10565 Filed 4-30-03; 8:45 am]

BILLING CODE 4410-09-P

## ENVIRONMENTAL PROTECTION AGENCY

### 40 CFR Part 52

[MD139-3098a; FRL-7478-1]

#### Approval and Promulgation of Air Quality Implementation Plans; Maryland; Revisions to Regulation for Control of Fuel-Burning Equipment, Stationary Internal Combustion Engines, and Certain Fuel-Burning Installations

**AGENCY:** Environmental Protection Agency (EPA).

**ACTION:** Direct final rule.

**SUMMARY:** EPA is taking direct final action to approve revisions to the Maryland State Implementation Plan (SIP). The revisions amend provisions of Maryland's regulation for Control of Fuel-Burning Equipment, Stationary Internal Combustion Engines, and Certain Fuel-Burning Installations. EPA is approving these revisions in accordance with the requirements of the Clean Air Act.

**DATES:** This rule is effective on June 30, 2003 without further notice, unless EPA receives adverse written comment by June 2, 2003. If EPA receives such comments, it will publish a timely withdrawal of the direct final rule in the **Federal Register** and inform the public that the rule will not take effect.

**ADDRESSES:** Written comments should be mailed to Makeba Morris, Acting Chief, Air Quality Planning and Information Services Branch, Mailcode 3AP21, U.S. Environmental Protection Agency, Region III, 1650 Arch Street, Philadelphia, Pennsylvania 19103. Copies of the documents relevant to this action are available for public inspection during normal business hours at the Air Protection Division, U.S. Environmental Protection Agency, Region III, 1650 Arch Street, Philadelphia, Pennsylvania 19103; the Air and Radiation Docket and Information Center, U.S. Environmental Protection Agency, 1301 Constitution Avenue, NW., Room B108, Washington, DC 20460; and Maryland Department of the Environment, 1800 Washington Boulevard, Suite 705, Baltimore, Maryland, 21230.

**FOR FURTHER INFORMATION CONTACT:** Marilyn Powers, (215) 814-2308, or by e-mail at [powers.marilyn@epa.gov](mailto:powers.marilyn@epa.gov).

#### SUPPLEMENTARY INFORMATION:

##### I. Background

On November 6, 2002, the Maryland Department of the Environment (MDE) submitted a formal revision to its State Implementation Plan (SIP). The SIP revision (#02-06) consists of administrative and clarifying amendments to regulation 26.11.09 for Control of Fuel-Burning Equipment, Stationary Internal Combustion Engines, and Certain Fuel-Burning Installations, and includes the establishment of an alternative NO<sub>x</sub> emission standard for a specific subcategory of sources subject to this regulation.

##### II. Summary of SIP Revision

Code of Maryland Administrative Regulation (COMAR) 26.11.09 establishes emission standards for fuel burning equipment, including standards for visible emissions, particulate matter emissions and NO<sub>x</sub> emissions. The amendments to COMAR 26.11.09 effect the following changes to the regulation:

1. Visible emissions requirements in Regulations .05 were revised to remove references to the Ringlemann Smoke Chart, and in lieu of the Ringlemann number, the percent opacity corresponding to that number is now required, resulting in no change to the standard.

2. Particulate matter standards in Regulation .06 and .09 were revised to remove emission limit applicability for fuel burning equipment which burn only gas or distillate fuel. The definitions in Regulation .01 were revised to clarify the definition for gas fuels. The particulate matter standards will now apply only to residual fuel-fired equipment as defined in Regulation .01. Since the uncontrolled emissions from gas or distillate fuel-fired equipment do not exceed the particulate matter emission standards in the regulation, this revision is approvable.

3. The requirement for observation of visible emissions by a Bacharach Smoke Test in Regulation .09 was removed. Visible emissions observations in accordance with EPA-approved methods are addressed by and required under a separate regulation under COMAR.

4. Regulation .08 was amended to revise the emission standard for coal-fired units having a capacity between 100 MMBtu and 250 MMBtu. Low NO<sub>x</sub> burners were installed on three coal-fired boilers to meet requirements for Reasonably Available Control

Technology for NO<sub>x</sub> (NO<sub>x</sub> RACT). NO<sub>x</sub> RACT was completed at considerable cost, however, the emission standard of 0.5 pounds NO<sub>x</sub> per MMBtu per hour could not be achieved under normal operating conditions. Continuous emissions monitoring (CEM) data showed that NO<sub>x</sub> RACT achieves the emission standard only when operating at maximum capacity, and that during normal operations NO<sub>x</sub> is reduced to 0.65 pounds per MMBTU. Installation of additional controls would result in NO<sub>x</sub> RACT which would be well above reasonable cost effectiveness. This revision will not negatively impact Maryland's Rate of Progress plan nor its attainment demonstration for the ozone national ambient air quality standards previously submitted by the state of Maryland, and is thus approvable.

##### III. Final Action

EPA is approving Maryland's SIP Revision to its regulation under COMAR 26.11.09 as submitted. EPA is publishing this rule without prior proposal because the Agency views this as a noncontroversial amendment and anticipates no adverse comment. However, in the "Proposed Rules" section of today's **Federal Register**, EPA is publishing a separate document that will serve as the proposal to approve the SIP revision if adverse comments are filed. This rule will be effective on June 30, 2003 without further notice unless EPA receives adverse comment by June 2, 2003. If EPA receives adverse comment, EPA will publish a timely withdrawal in the **Federal Register** informing the public that the rule will not take effect. EPA will address all public comments in a subsequent final rule based on the proposed rule. EPA will not institute a second comment period on this action. Any parties interested in commenting must do so at this time. Please note that if EPA receives adverse comment on an amendment, paragraph, or section of this rule and if that provision may be severed from the remainder of the rule, EPA may adopt as final those provisions of the rule that are not the subject of an adverse comment.

##### IV. Statutory and Executive Order Reviews

###### A. General Requirements

Under Executive Order 12866 (58 FR 51735, October 4, 1993), this action is not a "significant regulatory action" and therefore is not subject to review by the Office of Management and Budget. For this reason, this action is also not subject to Executive Order 13211, "Actions Concerning Regulations That