of inoperability, to assure that the effectiveness of the of the security system is not reduced.

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Dated at Rockville, Maryland, this 26th day of August, 1998.

For the Nuclear Regulatory Commission.

L. Joseph Callan,

Executive Director for Operations.

[FR Doc. 98–24716 Filed 9–15–98; 8:45 am]

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DEPARTMENT OF JUSTICE

Drug Enforcement Administration

21 CFR Parts 1300 and 1310

[DEA Number 137P]

RIN 1117–AA31

Exemption of Chemical Mixtures

AGENCY: Drug Enforcement Administration (DEA), Justice.

ACTION: Proposed rule.

SUMMARY: The DEA is proposing regulations to implement those portions of the Domestic Chemical Diversion Control Act of 1993 [Pub. L. 103–200] (DCDCA) that exempt from regulation under the Controlled Substances Act (CSA) certain chemical mixtures that contained regulated chemicals. The DCDCA amended the CSA to require that only those chemical mixtures identified by regulation shall be exempt from application of DEA's regulatory controls. These proposed regulations identify those mixtures, or categories of mixtures, that will be exempt from regulation. This proposal also defines an application process that can be used to exempt chemical mixtures that do not meet the criteria for automatic exemption.

DATES: Written comments or objections must be submitted on or before November 16, 1998.

ADDRESSES: Comments and objections should be submitted in quintuplicate to the Acting Deputy Administrator, Drug Enforcement Administration, Washington, DC 20537, Attention: DEA Federal Register Representative/CCR.

FOR FURTHER INFORMATION CONTACT: Frank Sapienza, Chief, Drug and Chemical Evaluation Section, Office of Diversion Control, Drug Enforcement Administration, Washington, DC 20537, Telephone (202) 307–7138.

SUPPLEMENTARY INFORMATION: The Chemical Diversion and Trafficking Act of 1998 (PL 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. Foreign traffickers were able to obtain chemicals from sources outside the U.S., while taking advantage of U.S. brokers and traders because of these shortcomings. Additionally, taking action against unscrupulous suppliers proved difficult.

To address the weaknesses in the CDTA, Congress passed the Domestic Chemical Diversion Control Act of 1993 (DCDCA), which was enacted in April of 1994. One provision of the DCDCA dealt with the exemption of chemical mixtures, which 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.''

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 were exempt from recordkeeping and other chemical regulatory control requirements of the CSA. This exemption provided traffickers with an unregulated source for obtaining chemicals for use in the manufacture of controlled substances. Furthermore, this exemption was inconsistent with the requirements of Article 12, Paragraph 14 of the United Nations 1988 Convention on Psychotropic Substances. Article 12 states, in part, that ''The provisions of this article shall not apply to pharmaceutical preparations, nor to other preparations containing substances in Table I or Table II that are compounded in such a way that such substances cannot be easily used or recovered by readily applicable means''. To address these problems, the DCDCA amended the exemption to provide that only those chemical mixtures specified by regulation would be exempt.

The DCDCA amended the definition of a regulated transaction to exclude only those mixtures which the Attorney General has by regulation designated as exempt. This designation is ''based on a finding that the mixture is formulated in such a way that it cannot be easily used in the illicit production of a controlled substance and that the listed chemical or chemicals contained in the mixture cannot be readily recovered''. Accordingly, with this proposal, the DEA is seeking to enact regulations that prevent diversion of mixtures which contain listed chemicals, while removing from the regulatory scheme mixtures which meet the above legal criteria [21 U.S.C. 802(39)(A)(v)].

Chemical mixtures which contain listed chemicals are of concern to DEA if they can be used in the manufacturing of controlled substances. Laboratory operators have continually searched for unregulated sources of materials in their efforts to illegally manufacture controlled substances. These efforts have led to the diversion and illicit utilization of chemical mixtures.

Chemical mixtures can and do play a role in the illicit production of controlled substances such as heroin, cocaine and amphetamine related compounds, including methamphetamine. Some examples follow.

The chemicals used in the production of cocaine are included primarily on list II of the CSA. Suspicious shipments of mixtures containing solvents in list II to cocaine producing areas have been identified by DEA. Additionally, diversion of such chemical mixtures for the illicit production of cocaine in foreign countries has been established by DEA. DEA continually monitors the chemical composition of seized cocaine hydrochloride. The DEA laboratory system is able to detect the trace quantities of solvents present in seized cocaine hydrochloride. Such solvents are utilized in the final stage of cocaine production whereby cocaine base is converted to cocaine hydrochloride. Recent data indicate that a broader range of solvents and solvent combinations are being caused in cocaine processing. This laboratory data supports intelligence information that chemical mixtures are used in the production of cocaine hydrochloride.

Chemical mixtures also play a role in the production of methamphetamine, the most prevalent controlled substance illicitly synthesized in the United States. During calendar years 1994 through 1997, the DEA was involved in the domestic seizure of over 2,800 clandestine methamphetamine laboratories. The chemicals ephedrine and/or pseudoephedrine were utilized as the precursor material at the vast majority of these laboratories.

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.

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 in 1996 and 1997. During 1997, the DEA participated in more than 1,400 methamphetamine laboratory seizures. This figure does not take into account the many laboratory seizures conducted independently by state and local law enforcement agencies. The problem continues into 1998.

During the 1970's and early 1980's, P2P was the primary precursor used in the clandestine production of methamphetamine in the U.S. P2P was controlled as a Schedule II controlled substance in 1980 through the administrative provision authorizing control of immediate precursors under the CSA (21 U.S.C. 811(e)). In an attempt to circumvent the control of P2P, traffickers sought P2P in unregulated international markets and resorted to the manufacture of P2P in clandestine laboratories utilizing phenylacetic acid and acetic anhydride.

In the middle 1980's, U.S. clandestine laboratory operators began utilizing the ephedrine reduction method of manufacturing methamphetamine. Since ephedrine was unregulated at the time, most laboratory operators abandoned the P2P method and instead moved to the use of bulk ephedrine powder as their source of precursor material.

The Chemical Diversion and Trafficking Act of 1988 (CDTA) modified the Controlled Substances Act (CSA) to give DEA authority to exercise regulatory control of the chemicals used for the refinement and synthesis of illicitly manufactured controlled substances. The CDTA imposed recordkeeping, reporting, and import/export notification requirements for regulated transactions of listed chemicals in order to prevent the diversion of these chemicals to the illicit manufacture of controlled substances. The CDTA included bulk ephedrine and pseudoephedrine as listed chemicals.

However, under the CDTA, products containing a listed chemical which were marketed or distributed lawfully under the Federal Food, Drug, and Cosmetic Act were exempt from the CSA's chemical regulatory control provisions. This included over-the-counter (OTC) products which contained ephedrine and pseudoephedrine. Clandestine laboratory operators soon learned that they could obtain the needed precursor materials through the unregulated purchase of millions of dosage units of single-entity OTC ephedrine products.

This loophole in the law was closed by the passage of the Domestic Chemical Diversion Control Act (DCDCA) which became effective on April 16, 1994. This Act further amended the CSA and removed the exemption for those transactions involving products which are marketed or distributed lawfully under the Federal Food, Drug, and Cosmetic Act, if these products contain ephedrine as the only active medicinal ingredient. Thus, single entity ephedrine products became subject to the chemical regulatory control requirements of the CSA.

In response to these actions taken against OTC ephedrine products, clandestine laboratory operators again attempted to circumvent CSA chemical controls in an effort to obtain precursor material. The search for unregulated source of precursor material led to the diversion and illicit utilization of OTC pseudoephedrine products and combination OTC ephedrine products. In response, the Comprehensive Methamphetamine Control Act of 1996 placed regulatory controls on the sale and distribution of such OTC products.

Today, the vast majority (approximately 97 percent) of U.S. clandestine laboratories continue to utilize ephedrine and/or pseudoephedrine as the precursor material. At practically all of these laboratories, the precusor material was obtained via the diversion of ephedrine or pseudoephedrine products marketed in tablet and capsule form and was not obtained through the diversion of bulk powder.

While the vast majority of products seized at illicit methamphetamine laboratories were OTC drug products, dietary supplement products containing ephedrine and/or pseudoephedrine (i.e ephedra) have been seized at clandestine methamphetamine laboratories. At this time, the frequency with which these products are encountered is small. However, DEA studies indicate that the ephedrine/pseudoephedrine contained in this material can be readily recovered and ephedra material can be easily used in the production of methamphetamine. Ephedra (in the form of dietary supplements or ephedra extract), therefore, can and is being used as the source of precursor material for the illicit production of methamphetamine.

Regulation of chemical mixtures is appropriate to guard against their diversion if the products are not formulated in such a way that: (1) they cannot be easily used in the illicit production of a controlled substance; or (2) the listed chemicals cannot be readily recovered. The DCDCA provides DEA with the means to regulate the mixtures and yet allows enough flexibility to ensure that the impact of the regulations can legitimate commerce is minimized.

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 regarding the exemption of chemical mixtures were withdrawn on December 9, 1994 (59 FR 63738). Between withdrawal of the proposed regulations regarding the exemption of chemical mixtures and the publication of this action as a final rule, all transactions involving chemical mixtures as defined in 21 U.S.C. 802(40) remain exempt from the definition of regulated transaction under the CSA. Based on the discussions and input from industry, DEA is proposing new regulations regarding the exemption of chemical mixtures.

Following withdrawal of the initial proposal, DEA solicited input from, and engaged in discussions with, organizations representing the manufacturers and distributors of products containing listed chemicals. DEA met with representatives from associations (and affiliated members) representing chemical manufacturers, the paint and coating industry, flavor and fragrance manufacturers, chemical distributors and the dietary supplements industry. These different groups expressed unique concerns that the DEA attempted to address within this notice. More recently, however, the DEA has become aware of additional concerns raised by other segments of the affected industries including the dietary supplement industry. While DEA has received input from several associations and firms within these industries, because of the diversity of these industries, the DEA believes that others may have information that the DEA should consider. The DEA is therefore soliciting input from all sectors of the chemical and dietary supplements industry potentially affected by this proposed rulemaking. The DEA recognizes that there may be situations within unique segments of one or more of the affected industries which may not be specifically addressed in this

proposed rulemaking. These may involve products which are not automatically exempt and entities which would not likely be sources of diversion since their products cannot be easily used in the illicit production of a controlled substance or the listed chemicals, which they contain, cannot be readily recovered. In the event that not all exemption provisions for chemical mixtures are included, specific mixtures can be exempted by an application process. The application process is designed to exempt those chemical mixtures that are not automatically exempted under this proposal, but meet the criteria of Title 21 U.S.C. 802(39)(a)((v). As described below, these are processes which individual firms can use to apply for exemption from some or all regulatory controls.

One of the potentially affected industries is the dietary supplement industry which markets non-drug products containing ephedrine/pseudoephedrine. DEA has recently received information from a coalition of direct marketers of these dietary supplements regarding the perceived impact of the proposed regulations on their industry. The principal concern of the direct marketers is how the chemical registration, recordkeeping, reporting requirements may affect those individuals engaged in the direct marketing of the products to the public. DEA emphasizes that it does not foresee the need for the regulation of individuals engaged in the direct marketing of the products to the public, provided certain basic conditions are met. This is consistent with the established intent of the Comprehensive Methamphetamine Control Act of 1966 (MCA) with respect to OTC drug products. While the MCA placed certain regulatory controls on the sale and distribution of pseudoephedrine, phenylpropanolamine and combination ephedrine drug products, it went to great lengths to ensure continued public access to these products at the retail level for face-to-face transactions.

Correspondingly, DEA is proposing in this notice a process by which manufacturers may request exemption for their products. Additionally, DEA can exempt a category of transaction from regulation if it is determined to be unnecessary for enforcement of the CSA (21 U.S.C. 802(39)(a)(iii)) and can exempt any manufacturers or distributors, from the registration requirement if it is consistent with the public health and safety (21 U.S.C. 822(d)). DEA has already received and responded favorably to a request from a direct marketing organization of regulated drug products, excluding the individual marketers from regulations and requiring only that the wholesale activities be regulated. The information submitted by the coalition regarding the manner in which their dietary supplement products are marketed does not to be significantly different from the manner in which these OTC drug products are distributed.

Listed chemicals cover a wide sector of industry because of their varied uses. Some are routinely utilized in legitimately produced chemical formulations while others are not. The DEA has attempted to better understand the degree with which specific listed chemicals are formulated in chemical mixtures that are legitimately produced. An accurate assessment has proved difficult for various reasons. One reason is that, although some examples of formulated products were made available, many manufacturers either did not have this information or were reluctant to discuss their formulations due to concerns regarding the disclosure of trade secrets. Another reason is that chemical mixtures are used in a wide variety of industrial sectors. A complete assessment would involve many diverse sectors such as those involved in paints, coatings, plastics, refineries, and other industrial processes. Additionally, many chemical mixtures are intended for human consumption. These include food and dietary supplements, food additives, flavorings and fragrances.

After careful consideration of the available information, including the input from the chemical industry, DEA is proposing a three-tiered approach to the exemption of chemical mixtures. This approach best captures those chemical mixtures that are ''formulated in such a way that they cannot be easily used in the illicit production of a controlled substance and that the listed chemical or chemicals contained in the mixture cannot be readily recovered'', in accordance with Title 21 U.S.C. Section 802 (39)(A)(v). A mixture will be exempt if: (1) it contains a listed chemical at or below an established concentration limit; or (2) it falls within a specifically defined category; and (3) the manufacturer of the mixture applies for and is granted a specific exemption for the product.

I. Concentration Limits

DEA is proposing to use a system of concentration limits as the primary means to determine the regulatory status of chemical mixtures. The use of such a quantitative system is necessary due to the complexity of chemical-based commodities and the huge variety of products. The use of a narrative approach is too subjective and would be in danger of inconsistent interpretation, both by industry and DEA. Use of the concentration limit eliminates subjective interpretation; if the amount of listed chemical in a mixture is less than, or equal to, the concentration limit, then the mixture is exempt.

The concentration of a chemical in a mixture can be determined by either volume or weight, depending on the physical state of the mixture. It is more common to determine the concentration of a solid or gas based on weight, as this more accurately reflects the relative amounts of components in the mixture. The relative amount of a solid or gas in a mixture may not be accurately reflected if based on volume because the weight may change disproportionally relative to volume. The volume is commonly used to determine concentration in liquid—liquid mixtures. For listed chemicals that are liquids, the volume is proposed to be used in determining concentration. The density parameter allows for easy conversion between volume and weight for liquids. Concentration limits are proposed to be determined by weight if the listed chemical exist as a solid or gas at ambient temperature. The weight of the free base or acid will be used to determine the concentration of a listed chemical if it is a salt. A mixture is exempt if the listed chemical or chemicals are less than or equal to the percentages and other conditions described in the ''Table of Concentration Limits.''

Where a mixture contains more than one listed chemical, determining the concentration limit will depend on the properties of the chemicals included in the mixture. Some chemicals, such as the different solvents, are cumulative, i.e., the concentration of the mixture will be determined by adding the concentrations of each individual solvent in the mixture. This approach is necessary when chemicals can be interchanged to carry out an illicit manufacturing procedure. The combined volume of two or more such chemicals would be functionally equivalent to the same volume of either one of the chemicals. If the chemicals are not cumulative, then the concentration of each chemical is considered individually in determining if the mixture is regulated. Those chemicals that are cumulative are identified in the ''Table of Concentration Limits'' in the proposed new Section 1310.12(c).

List I Chemicals

The DEA proposes that N-acetylanthranilic acid, anthranilic acid,

benzyl cyanide, ethylamine, hydriodic acid, 3 4-methylenedioxyphenyl-2-propane, methylamine, nitroethane, phenylacetic acid, piperidine, piperonal, propionic anhydride, isosafrole and safrole have a concentration limit of 20 percent. List I chemicals are used as precursors with the exception of hydriodic acid which is a reagent in the production of controlled substances. These chemicals are extremely valuable to traffickers and, in concentrations of greater than 20 percent, represent a viable source of material for the illegal manufacture of controlled substances. The concentration limit proposed by the DEA takes into consideration the information supplied by the private sector and DEA concerns. The 20 percent limit for these chemicals maintains exemption status for chemical mixtures that are not likely to be diverted while excluding from regulation the majority of the present commerce in these mixtures, as identified by DEA. Safrole and isosafrole are sufficiently similar precursors when used clandestinely, that they will be cumulative. DEA is proposing the following concentration limits for the remaining List I chemicals:

Ephedrine and Pseudoephedrine—2 Percent

Combinations of ephedrine and pseudoephedrine will be cumulative because these two chemicals are completely interchangeable as precursors in the same reaction to make methamphetamine and methcathinone. Thus, if the total concentration of ephedrine and pseudoephedrine is greater than 2 percent, the mixture is treated by DEA as a regulated chemical.

Ephedrine and pseudoephedrine are major precursors for clandestine mathamphetamine and methcathinone production. As previously noted, clandestine laboratory operators have migrated to unregulated sources of precursor material. This has led to the diversion of marketed tablet and capsule pharmaceutical products containing ephedrine and pseudoephedrine. While OTC drug products have been a major source for these chemicals in clandestine laboratories, DEA has also identified non-drug products (i.e. ephedra extracts and dietary supplements) in seized laboratories.

Regulations pertaining to OTC drug products containing ephedrine and pseudoephedrine have been established under separate rulemaking. Non-drug products, including dietary and nutritional supplements are chemical mixtures and therefore shall be subject to these proposed provisions.

Representatives of retail sectors from the dietary and nutritional supplement industry have represented that their products contain amounts consistent with those found in most natural sources. The 2 percent limit has been deliberately proposed at a level greater than the concentrations found in most natural sources. Representatives of the dietary and nutritional supplement retail industry have represented in meetings that the proposed concentration limit would be adequate, however, DEA has subsequently become aware of concerns from other, previously unidentified segments of the dietary and nutritional supplement industry that the proposed regulations could have a significant impact on their operations. This new information revealed that the proposed limit may not be appropriate to exempt certain distributions from the regulatory process.

Of great concern to DEA, however, is the seizure of dietary supplements and ephedra bulk material at clandestine laboratories. Some of this seized material has been found to contain concentrations as low as 3 to 4 percent ephedrine/pseudoephedrine. The 2 percent threshold would therefore capture such material.

Under this proposal, products and material containing less than 2 percent would be automatically exempt. Additionally, harvested plant material will be exempt provided that it is unaltered from its natural state. Manufacturers of products containing greater than 2 percent would be able to apply for exemption based on the criteria in 21 U.S.C. 802(39)(A)(v). In meetings with dietary supplement firms and association, the DEA has requested information on the specific types, composition and volume of dietary supplement products in the marketplace. Responses to these inquires have been sparse.

The 2 percent concentration threshold was established in the consideration of a single entity product containing ephedrine/pseudoephedrine and combination products from which ephedrin/pseudoephedrine can be easily removed. It is likely that multiple ingredient products containing higher concentrations of ephedrin/pseudoephedrine may, in fact, be more difficult to use in the clandestine synthesis of methamphetamine. As such, these products would likely qualify for exemption.

To ensure that DEA has all possible information regarding both the extent and volume of this industry and the impact of any regulations on it, DEA is requesting comments from interested persons who market products that contain ephedrine and/or pseudoephedrine (either as dietary/nutritional supplements or as other products). Comments should identify the type of industry, including the number of companies/individuals involved and the annual volume of business they conduct; how the proposed regulatory requirements would impact that industry, (through the registration, recordkeeping, and reporting requirements), and within the confines of statutory requirements, any suggestions or comments on how the final regulations might better be tailored to the industry without compromising the basic mandate of the law to prevent the diversion of ephedrine and pseudoephedrine for the illicit manufacture of controlled substances.

The DCDCA initiated provisions for the regulatory control of chemical mixtures. However, the DCDCA included exemption provisions for chemical mixtures formulated in such a way that they 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. Accordingly, if a dietary supplement or any other formulations meet the exemption criteria, these chemical mixtures will receive exemption status. Therefore, the dietary and nutritional supplement industry is requested to provide information as to the nature of these products in relation to the exemption criteria and specify any unique attributes such as formulation, composition, or method of distribution which would prevent diversion for illicit uses. Additionally, the DEA invites comments in response to its concerns regarding the seizure of dietary supplements and ephedra bulk material at clandestine laboratories and the potential expanded role that these products may play in the illicit production of methamphetamine.

Norpseudoephedrine/Phenylpropanolamine—0.6 Percent

N-methylephedrine/N-Methylpseudoephedrine—0.1 Percent

In each set of the above chemical pairs, the chemicals are interchangeable in the clandestine synthesis of controlled substances. Therefore, the concentration limit is proposed to be determined by adding the concentration of each chemical in the pair.

These chemicals can be used in the manufacture of amphetamine and methamphetamine. Commercially, they are used in the manufacture of drug products and can appear in dietary and

nutritional supplements. As with ephedrine and pseudoephedrine, the limits are set higher than concentrations found in most natural sources, even when paired. Therefore, the limit should not affect the dietary and nutritional supplement products.

Benzaldehyde—30 Percent

Benzaldehyde is used for the clandestine manufacture of amphetamine and methamphetamine. DEA has identified it as being widely used in flavoring and as a source of derivatives.

Mixtures containing more than 30 percent benzaldehyde can be readily used in clandestine synthesis, especially when the other chemicals are solvents. This is also true when benzaldehyde is mixed with several other chemicals if those additional chemicals are not reactive in the synthetic pathways used to manufacture illicit substances. DEA is aware that this concentration limit may not capture most mixtures, especially with respect to flavoring and fragrance products. However, with the increasing effectiveness of the chemical controls against the diversion of other amphetamine/methamphetamine source materials, the potential for diversion of benzaldehyde, including mixtures, may increase significantly. The DEA is interested in soliciting comments from interested persons involved with chemical mixtures containing benzaldehyde. For products which contain greater than 30 percent benzaldehyde, the proposal establishes an application process by which individual or group exemptions can be obtained.

Ergonovine and Ergotamine—No Concentration Limit

DEA is proposing to regulate all mixtures containing ergonovine and ergotamine. The natural concentrations of these chemicals is on the order of a few hundredths of a percent. The alkaloids are precursors for the manufacture of hallucinogens that are potent in microgram dosages; little material is required to manufacture viable quantities of illicit drugs. Commercially, these chemicals are only found in prescription drug products, which are already exempt; therefore their regulation in chemical mixtures should not have any impact.

List II Chemicals

List II chemicals, while not precursors of the controlled substances, are essential for carrying out the illegal manufacture of controlled substances. DEA is proposing the following concentration limits for List II chemicals:

Acetone, Methyl Ethyl Ketone (MEK), Methyl Isobutyl Ketone (MIBK), Toluene, and Ethyl Ether—35 Percent

These chemicals are interchangeable and also are effective when used in combination in clandestine operations; therefore, they are cumulative.

These solvents are used, either singly or in combination, in the processing of cocaine hydrochloride. Commercially, they are used in a wide variety of industrial processes and represent the majority of mixtures affected by the chemical regulations. In reviewing the properties of these solvents, DEA has determined that in mixtures with concentrations of greater than 35 percent, either individually or in combination with another solvent, the mixture emulates the properties of the listed solvent. Therefore, the concentration limit for such mixtures is proposed to be 35 percent.

Acetic Anhydride, Benzyl Chloride, Hydrochloric Acid, Iodine and Sulfuric Acid—20 Percent

Potassium Permanganate—15 Percent

These chemicals are used as reagents and precursors in the process of manufacturing controlled substances. Reagents and precursors are typically solutes which are dissolved in a solvent in order for a chemical reaction to be carried out. Because they are dissolved, the amount of listed precursor or reagent needed is less than the amount of listed solvent needed to manufacture a controlled substance. This puts mixtures containing less than the 35 percent concentration limit, as set for solvents, at risk of diversion. Consequently, a 20 percent concentration limit is proposed for these chemicals, except for potassium permanganate, for which the proposed concentration limit is 15 percent. DEA has not identified any mixtures that contain potassium permanganate in concentrations greater than 15 percent.

II. Specific Mixture Categories

While the concentration limits will suffice for the majority of chemical mixtures, there are certain categories of mixtures that fall outside of the limits provided, but are not considered to be likely sources for diversion. DEA has identified three such categories: (1) waste materials regulated by the Environmental Protection Agency (EPA); (2) paints and coatings; and (3) harvested plant material.

(1) Waste mixtures that: (a) are subject to the requirements of 40 CFR Sections 262 and 263.20–22; (b) must be documented on U.S. Environmental Protection Agency Form 8700–22/22A (Uniform Hazardous Waste Manifest); and (c) are being distributed to another person solely for the purpose of disposal by incineration are exempt. These mixtures include only those that are covered by EPA regulations and have a 'cradle to grave' paper trail. Further, the exemption applies only to the extent that the Form 8700–22/22A is available for inspection and copying by DEA. If the generator fails to release, or permit the release, of the necessary information required by DEA, then the mixtures will be treated as a regulated mixture. Finally, any change in the requirements with respect to Form 8700–22/22A, including EPA exemption of a mixture or a waste management site, could result in modification or removal of the exemption.

(2) Completely formulated paints and coatings. DEA recognizes that while paints and coatings, as defined below, may contain a higher concentration of a listed chemical than allowed for exemption, they also contain other ingredients, such as pigments, that render them unsuitable as a source of supply for chemical traffickers.

For purposes of the exemption, a completely formulated paint or coating is defined as any clear or pigmented liquid, liquefiable, or mastic composition designed for application to a substrate in a thin layer which is converted to a clear or opaque solid protective, decorative, or functional adherent film after application. A completely formulated paint or coating contains all the components of the paint/coating mixed without the need to add any other material except a thinner for use in the final application. Included in this category are paints, clear coats, topcoats, primers, varnishes, sealers, adhesives, lacquers, stains, shellacs, inks and temporary protective coatings. To qualify for the exemption, a paint or coating must meet the American Society for Testing Materials specifications for the specific product.

(3) Harvested plant material. Harvested plant material that contains listed chemicals, while meeting the definition of chemical mixture, will be exempt provided that the plant material is unaltered from its natural state. Changes in the physical state that preserve the natural composition of the material, such as grining, 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 such

treatment, will disqualify the mixture from exemption.

III. Exemption By Application

For those chemical mixtures that may not otherwise qualify for an exemption, but are formulated in such a manner that the listed chemicals cannot be readily recovered from the mixture and the mixture itself cannot be used for illicit drug manufacture, DEA is proposing a procedure by which the manufacturer of the mixture may apply for an exemption of the mixture or group of mixtures. 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. The Administrator may determine that a specific mixture does not qualify as part of a group. Each manufacturer must request exemption status for its particular products; exemption of a product for one manufacturer does not carry over to the same or similar products for another manufacturer.

An application for exemption must contain identifying information about the applicant, qualitative and quantitative data regarding the mixture, and justification as to why the mixture should be exempted. DEA may request additional information on the formulation and distribution of the mixture or clarification of any submitted information, as needed. The application for exemption will contain a consent for the termination of exemption by decision of the Administrator upon evidence that the product has been diverted for the use of producing a controlled substance.

Termination of Exemption

The Administrator may terminate or modify the exemption for any chemical mixture that has been granted an exemption if evidence of diversion or attempted diversion is found. Evidence that a chemical mixture has been or is being used in the manufacuturing of a controlled substance will be adequate reason to revoke exemption status for a specific product or all similar chemical mixtures which the DEA determines can be used in the illicit manufacdturing process for which the evidence is obtained.

Procedures are given in this proposed rule for the termination of an exemption granted pursuant to 21 CFR 1310.12 or 1310.13 and differ according to whether removal of exemption status is product specific or by change of any criterion in 21 CFR 1310.12(c) or 1310.12(d). The DEA will issue and publish in the **Federal Register** notification of the termination of exemption of a specific 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 notice 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 reconsideration of the order in light of comments and objections filed. Thereafter, the Administrator shall reinstate, terminate, or amend the original order as deemed appropriate. The DEA shall send written notification to the manufacturer only in instances where the manufacturer of affected products has been readily identified, advising of an action prior to publication in the **Federal Register**.

Trade Secrets

Information required by the DEA to exempt a product includes qualitative and quantitative data for the product. Industry groups expressed concern regarding confidenticality and trade secrets. The DEA has considerable experience in safeguarding trade secrets. The issue of protection of confidential business information has been addressed by the DEA in the **Federal Register** Final Rule published on June 22, 1995 which finalized specific provisions of the DCDCA (60 FR 32453). The release of confidential business information that is protected from disclosure under Exemption 4 of the Freedom of Information Act, 5 U.S.C. 552(b)(4) (FOIA), is governed by Section 310 (c) of the CSA (21 U.S.C. 830(c)) and the Department of Justice procedures set forth in 28 CFR 16.7.

Section 310(c) of the CSA provides that information collected under Section 310 that is protected from disclosure under Exemption 4 may only be released in circumstances related to the enforcement of controlled substance or chemical laws, custom laws, or for compliance with U.S. obligations under treaty or international agreements. The Department of Justice procedures establish that if a FOIA request is received for release of information that is protected under Exemption 4, the submitter of the protected information must be notified of such a request, given an opportunity to object to the disclosure and allowed to provide justification as to why the information should not be disclosed.

Regulation of Chemical Mixtures

There are some chemical mixtures that will not meet the proposed exemption criteria and will be subject to regulation. It is proposed that the threshold be determined by taking the entire weight or volume of the regulated mixture for mixtures regulated due to the presence of acetone, ethyl ether, methyl ethyl ketone, methyl isobutyl ketone and toluene. In mixtures that contain two or more listed chemicals, other than acetone, ethyl ether, methyl ethyl ketone, methyl isobutyl ketone and toluene, each chemical shall be compared against its respective threshold. Where the mixture contains two or more chemicals that are cumulative, other than acetone, ethyl ether, methyl ethyl ketone, methyl isobutyl ketone and toluene, then the summed concentration of the listed chemicals that are cumulative will be considered; where the total weight of the cumulative listed chemicals exceeds the threshold for any one of the listed chemicals contained in the mixture, then the transaction will be regulated. Thresholds are proposed to be determined by taking the weight or volume of listed chemical contained in the mixture for all other listed chemicals.

Further, the provisions regarding excluded transactions, as set out in 21 CFR 1310.08, will apply equally to mixtures containing the specified chemicals.

Regulatory Flexibility and Small Business Concerns

The Domestic Chemical Diversion Control Act of 1993 replaced the existing blanket exemption from regulation for chemical mixtures with a provision that only those chemical mixtures specifically identified by regulation would be exempt from DEA's chemical controls, based on a finding that each mixture cannot be easily used in the illicit manufacture of a controlled substance and that the chemical(s) contained in the mixtures cannot be readily recovered. This change was necessary to make the U.S.'s chemical controls consistent with Article 12,

Paragraph 14 of the United Nations 1998 Convention Against Illicit Traffic in Narcotic Drugs and Psychotropic Substances (1988 Convention), which requires that chemical controls apply to the chemicals themselves and to products containing the chemicals that are compounded in such a way that such chemicals cannot be easily used or recovered by readily applicable means.

In considering application for the new requirement, DEA recognized that neither regulation nor exemption of all mixtures were a feasible approach. Regulation of all chemical mixtures would cast too broad a net, encompassing products that are not of significant concern to DEA as sources for the diversion of listed chemicals and resulting in an unnecessary regulatory burden on both industry and DEA. Also of significance, exemption of all chemical mixtures would leave products that are suitable for use in the illicit manufacture of controlled substances open for diversion. With the growing effectiveness of chemical controls, such unregulated mixtures could become a significant source of chemicals for diversion, which would be inconsistent with both DEA's mandate and the U.S.'s responsibilities under the 1988 Convention. Therefore, it was necessary to identify some middle ground that would minimize the impact on industry while still satisfying the intent of the requirement and the U.S.'s obligations under the 1988 Convention.

Originally, DEA proposed a system whereby manufacturers would request exemptions for their specific products. However, industry expressed concerns that the administrative burdens, for both industry and DEA, would be too great, given the number of chemical mixtures in commerce. Based on those concerns, DEA withdrew the proposal and opened a dialogue with representative from the manufacturing, distributing, and related segments of the chemical industry regarding how to best address the matter of exemption.

An important DEA objective in establishing exemption criteria was to obtain recommendations from the affected industry. The DEA met with several interested parties including associations representing chemical manufacturers, paint and coatings industry, flavor and extract manufacturing, dietary supplement manufacturers and distributors, and chemical distributors and affiliated members. These discussions, along with available DEA information pertaining to the illicit manufacture of controlled substances, were considered in the establishment of exemption criteria under this proposal. The DEA realizes that, because of the diverse industries affected by these regulations, not all interested persons may have been fully represented prior to the publication of this proposal. The DEA is therefore requesting that comments be submitted to help ensure that the concerns of all interested parties are considered.

Comments should identify the type of industry, including the number of companies/individuals involved and the annual volume of business they conduct; how the proposed regulatory requirements would impact that industry (through the registration, recordkeeping, and reporting requirements), and within the statutory requirements, any suggestions or comments on how the final regulations might better be tailored to the industry without compromising the basic mandate of the law to prevent the diversion of listed chemicals for the illicit manufacture of controlled substances.

The initial concern in addressing the matter of exemption was to establish a system for the identification of the categories of chemical mixtures to be exempted that would be objective and specific enough to allow nontechnical personnel to easily understand and apply the criteria and to allow accurate identification of those mixtures that could readily be used in the illicit manufacture of controlled substances while not encumbering those that could not.

Two options were considered: (1) The used of general product categories, such as paints, coatings, adhesives, and sealants; refinery and chemical plant streams; waste products; insecticides, pesticides, and herbicides; consumer products, including cosmetics; and solutions containing more than 5 percent solids by weight; and (2) the use of concentration limits, expressed as the percentage of chemical, either by volume or weight, that a mixture may contain.

Examination of the use of product categories revealed problems involving their subjective nature, which could lead to confusion regarding whether certain products might be included in the category. In addition, the lack of specificity in such a system would cause difficulties in identifying products that should not be included in a category because of the manner in which they are formulated. It quickly became apparent that use of product categories as the primary means to identify exempt chemical mixtures would require the development of a cumbersome, highly technical, and complicated set of definitions and criteria in order to identify the mixtures to be granted exemption.

The concentration limits, by contrast, provide a clear cut, objective means to identify whether a chemical mixture is or is not exempt. By focusing specifically on the amount of chemical contained in a given amount of mixture, which is of primary concern to DEA, the system provides and unequivocal standard that is easily understood by expert and layman alike. There is no need to establish a large, complex and highly technical set of definitions and crtiera that must be used to make a subjective determinations to what category a mixture belongs in and whether it meets the exemptions criteria or not.

While the system of concentration limits can be used satisfactorily with most chemical mixtures, it does not address those circumstances where the formulation of the mixture or the manner in which the mixture is distributed may be factors for consideration in determining exemption status. Therefore, DEA is proposing the use of certain limited categories for exemption. Additionally, DEA recognizes that there will be those individual products which may not meet the established exemption criteria but are deserving of consideration for exemption due to specific factors that may limit their use in the illicit manufacture of controlled substances. Therefore, provisions have been made in the proposed regulations for a system for which a manufacture may request exemption of a specific mixture.

Once the basic framework for the exemption process had been established, DEA consulted with representatives of the regulated industry, including chemical manufacturers and distributors, as well as the paint and coatings, the flavoring and fragrances, and the dietary and nutritional supplements industries, to identify the concentration limits or other criteria that would satisfy the requirements of the law with the least possible burden on regular commerce. The proposed concentration limits were based on consideration of how useful the mixtures would be in the illicit manufacture of controlled substances and how great a percentage of the mixtures in regular commerce could be exempted from regulation; the proposed limits provide a good balance between the requirements of the law and the need to minimize the impact of the law on legitimate commerce. Representatives of the chemical manufacturers and distributors have indicated that the proposed concentration limits should provide for

exemption of the majority of chemical mixtures in commerce.

In those instances where a chemical mixture will be subject to regulation, the regulatory requirements are not unduly burdensome and should not present any restriction on regular commerce. The primary requirement, recordkeeping, applies only to those transactions that meet or exceed the threshold established for the chemical contained in the mixture. The information required to be maintained in the records is minimal and can usually be found in the normal business records maintained by anyone following good business practices. Additionally, the chemicals contained in the mixture may be subject to other Federal or state recordkeeping requirements, in which case the records maintained may be used to satisfy DEA's requirement, provided the necessary information is readily available. In addition, this proposed rule will exempt persons from registration if the only List I chemicals which they distribute, import or export are contained in exempt mixtures; it is DEA's understanding that the bulk of chemical mixtures in commerce contain List II, rather than List I chemicals.

In summary, the proposed system provides for the exemption of the greatest possible population of mixtures while remaining consistent with the requirements of the law and obligations under the U.N. Convention. The combination of exemptions, together with the threshold system and requirement that registration be obtained only for activities involving List I chemicals allows for the lease possible burden and cost to industry. Therefore the Acting Deputy Administrator, in accordance with the Regulatory Flexibility Act (5 U.S.C. 605(b)), has reviewed this proposed rule and by approving it certifies that it will not have a significant economic impact on a substantial number of small business entities.

With respect to the specific economic and regulatory burdens associated with the regulation of chemical mixtures (in those instances where exemption is not possible), there are three different requirements to be considered:

Registration

This requirement applies solely to persons who distribute, import, or export List I chemicals, including those contained in regulated chemical mixtures. Registration is required on an annual basis. The initial registration cost is $595.00 and the annual registration renewal cost is $477.00. Completion of the application requires approximately 30 minutes.

The impact of the registration requirement will vary depending on the type of industry and type of transactions. As noted, the registration requirement applies only to List I chemicals.

Recordkeeping

Regulated persons must keep records regarding regulated transactions. The records must reflect the name, address, and, if required, DEA registration number of each party to the transaction; the date of the transaction; the name, quantity, and form of packaging of the listed chemical; the method of transfer (company truck, picked up by customer, etc.); and the type of identification used by the purchaser and any unique number on that identification.

As noted in 21 CFR 1310.06(b), normal business records shall be considered adequate for satisfying the recordkeeping requirement, if they contain the required information and are readily retrievable from the other business records of the regulated person. It has been DEA's experience that regulated persons at the non-retail level maintain such information in their normal business records; therefore, no additional burden is considered to apply. At the retail level, such information is not normally kept, therefore, any records to be maintained would have to be considered as part of the regulatory burden.

Reporting

Regulated persons must make reports of any regulated transactions involving an extraordinary quantity of a listed chemical, an uncommon method of payment or delivery, or any other circumstance that the regulated person believes may indicate that the listed chemical will be used in violation of the regulations (21 CFR 1310.05(a)(1)). Additionally, any unusual or excessive loss or disappearance of a listed chemical must be reported. It must be emphasized that this requirement does not apply to all sales of listed chemicals; it applies only to those sales involving suspicious/unusual circumstances or thefts/losses.

In addition to the above reporting requirement, the Comprehensive Methamphetamine Control Act of 1996 (MCA) established the requirement that each regulated person who engages in a transaction with a nonregulated person which involves ephedrine, pseudoephedrine, or phenylpropanolamine (including drug products containing those chemicals) and uses or attempts to use the Postal Service or any private or commercial carrier, shall, on a monthly basis, submit a report of each such transaction conducted during the previous month to the Attorney General (21 U.S.C. 830(b)(3)). This requirement has been the subject of much discussion and it is generally accepted that the manner in which it is written provides DEA with no discretion to exclude any person from the requirement. Legislative amendment of this requirement to allow DEA some measure of discretion in its application is being explored.

Total Regulatory Impact

The total regulatory impact of these requirements will vary based on the type of industry involved and the types of transactions being conducted. With the chemical industry, the total impact should be limited. DEA has been informed by representatives of the chemical industries that the bulk of chemical mixtures will contain List II chemicals. Further, many of the companies that handle List I chemical mixtures are already registered to handle List I chemicals. Therefore, the registration requirement will have limited impact on that industry.

With respect to the recordkeeping requirements, the bulk of the chemical mixture transactions are commercial in nature and involve materials that are subject to stringent Federal and state requirements; the information required to satisfy DEA's recordkeeping requirements will already be available as part of the business records being maintained by the regulated persons. Therefore, no additional burden is anticipated to satisfy the recordkeeping requirement. With respect to reporting, DEA is adjusting its existing, OMB approved information collection regarding Reports of Suspicious Orders or Theft/Loss of Listed Chemicals/ Machines (OMB Number 1117–0024), to increase the estimated number of annual reports by 2,000 and the estimated burden hours by 340 hours per year.

With the dietary and nutritional supplement industry, the issue is somewhat less clear. DEA has been informed by the manufacturers and distributors of products that are sold at retail that their products contain concentrations of ephedrine that are consistent with the proposed exemption limit; therefore, the retail side of the industry should experience little, if any, regulatory impact. However, DEA was recently contacted by representatives of a segment of the industry involved in the direct marketing of these products, who expressed grave concern regarding the potential impact of the requirements on direct marketers, especially the individual marketers selling small

amounts of the product to friends and neighbors.

DEA is well aware of the potential impact that the regulations could have on such operations, having dealt with the issue with respect to the direct marketing of drug products containing ephedrine, pseudoephedrine, and phenylpropanolamine. As was stated in the discussion regarding Exemption by Application earlier in this document, it is not the intent of DEA to regulate those individuals engaged in direct marketing sales of small amounts of these products in face-to-face transactions. In addition to the proposed regulations allowing for exemption by application, there are existing exemption procedures available for types of transactions and categories of persons. An exemption has already been provided to one direct marketing organization and discussions are underway with another to also provide an exemption provided certain circumstances are met. It must be noted that the exemptions apply to individuals engaged in direct marketing sales of small amounts of these products in face-to-face transactions; manufacturers and wholesale distributors of the products remain subject to the regulatory requirements.

Assessing the overall impact of the regulations on the dietary and nutritional supplement industry has been hampered by the lack of information regarding the overall scope and population of the industry. DEA has, along with others, requested demographic information from the industry; however, to date, we have not received the details necessary to adequately estimate the potential impact of the regulations. As stated elsewhere in this document, interested persons are invited to submit comments identifying the scope and population of the industry; the effect of the regulations on the industry, both in terms of the extent to which proposed and existing exemptions will exclude the industry from regulation and, where the exemptions do not extend, how the above requirements will impact the industry; and any comments or suggestions on how the regulations might be adjusted to address industry concerns without compromising their intent to prevent the diversion of listed chemicals to the illicit manufacture of controlled substances.

This proposed rule has been reviewed pursuant to Executive Order 12866 and has been determined to be a significant regulatory action. Therefore, it has been reviewed and approved by the Office of Management and Budget.

This action has been analyzed in accordance with the principles and criteria in Executive Order 12612, and it has been determined that this proposed rule does not have sufficient federalism implications to warrant the preparation of a Federalism Assessment.

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.

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

Definitions, Drug traffic control, Controlled substances, 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, it is proposed that 21 CFR parts 1300 and 1310 be 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 proposed to be amended by revising the 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 proposed to be amended by adding a new paragraph (h) as follows:

§ 1310.04 Maintenance of records.

* * * * *

(h) The thresholds and conditions in 21 CFR 1310.04(f) and 1310.04(g) will apply to transactions involving regulated chemical mixtures. All regulated chemical mixtures containing List I and List II chemicals with the exception of acetone, ethyl ether, methyl ethyl ketone, toluene and methyl isobutyl ketone will have the threshold determined by taking the weight of the listed chemical in the regulated mixture. Regulated chemical mixtures that contain one or more of the List II chemicals acetone, ethyl ether, methyl ethyl ketone, toluene and methyl isobutyl ketone will have the threshold determined by taking the entire weight of the mixture. The threshold for these mixtures will be 1500 kilograms for export to the western hemisphere except Canada and 150 kiograms for domestic transactions.

3. Part 1310 is proposed to be amended by adding new sections 1310.12 and 1310.13 as follows:

§ 1310.12 Exempt chemical mixtures.

(a) The chemical mixtures meeting the criteria in paragraphs (c), (d) and (g) 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. 822–3, 830, and 957–8) to the extent described in paragraphs (b) and (c) of this section.

(b) No exemption granted pursuant to § 1310.12 or § 1310.13 affects the criminal liability of illegal possession, distribution, exportation, or importation of listed chemicals contained in the exempt chemical mixture.

(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. Calculation of percent by weight or by volume is given in the Table along with the concentration limit and other relative information.

TABLE OF CONCENTRATION LIMITS

List I chemicals	The DEA chemical code no.	Concentration (percent)	Special conditions
N-Acetylanthranilic acid, its salts and esters.	8522	20% by weight	Concentration based on any combination of N-acetylanthranilic acid and its salts and esters.
Anthranilic acid, and its salts and esters	8530	20% by weight	Concentration based on any combination of anthranilic acid and its salts and esters.
Benzaldehyde	8256	30% by volume.	
Benzyl cyanide	8570	20% by volume.	
Ephedrine, its salts, optical isomers, and salts of optical isomers.	8113	2% by weight	Concentration based on any combination of ephedrine, pseudoephedrine, and their salts, optical isomers and salts of optical isomers.
Ergonovine and its salts	8675	Not exempt at any concentration.	Chemical mixtures containing any amount of ergonovine, including its salts, are not exempt.
Ergotamine and its salts	8676	Not exempt at any concentration.	Chemical mixtures containing any amount of ergotamine, including its salts, are not exempt.
Ethylamine and its salts	8678	20% by weight	Ethylamine or its salts in an inert carrier solvent is not considered a mixture. Weight is based on ethylamine in the mixture and not the combined weight of carrier solvent, if any.
Hydriodic acid	6695	20% by weight	Aqueous or alcoholic solutions are not considered mixtures.
Isosafrole	8704	20% by volume ...	Concentration in mixture cannot exceed 20% if taken alone or in any combination with safrole.
Methylamine, and its salts	8520	20% by weight	Methylamine or its salts in an inert carrier solvent is not considered a mixture. Weight is based on methylamine in the mixture and not the combined weight of carrier solvent, if any.
3,4-Methylenedioxyphenyl-2-propanone	8502	20% by weight.	
N-Methylephedrine, its salts, optical isomers, and salts of optical isomers.	8115	0.1% by weight ...	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 ...	Concentration based on any combination of N-methylpseudoephedrine N-methylephedrine, and their salts, optical isomers and salts of optical isomers.
Nitroethane	6724	20% by volume.	
Norpseudoephedrine, its salts, optical isomers, and salts of optical isomers.	8317	0.6% by weight ...	Concentration based on any combination of norpseudoephedrine, phenylpropanolamine and their salts, optical isomers and salts of optical isomers.
Phenylacetic acid, and its salts and esters.	8791	20% by weight	Concentration based on any combination of phenylacetic acid and its salts and esters.
Phenylpropanolamine, its salts, optical isomers, and salts of optical isomers.	1225	0.6% by weight ...	Concentration based on any combination of phenylpropanolamine, norpseudoephedrine and their salts, optical isomers and salts of optical isomers.
Piperidine, and its salts	2704	20% by volume ...	Concentration based on any combination of piperidine and its salts.
Piperonal	8750	20% by weight.	
Propionic anhydride	8328	20% by volume.	
Pseudoephedrine, its salts, optical isomers, and salts of optical isomers.	8112	2% by weight	Concentration based on any combination of pseudoephedrine, ephedrine, and their salts, optical isomers and salts of optical isomers.
Safrole	8323	20% by volume ...	Concentration in mixture cannot exceed 20% if taken alone or in any combination with isosafrole.

List II chemicals	The DEA chemical code no.	Concentration (percent)	Special conditions
Acetic Anhydride	8519	20% by volume.	
Acetone	6532	35% by volume ...	Limit applies to acetone or any combination of acetone, ethyl ether, methyl ethyl ketone, methyl isobutyl ketone and toluene if present in the mixture by summing the concentrations for each chemical.
Benzyl chloride	8568	20% by volume.	
Ethyl ether	6584	35% by volume ...	Limit applies to ethyl ether or any combination of acetone, ethyl ether, methyl ethyl ketone, methyl isobutyl ketone and toluene if present in the mixture by summing the concentrations for each chemical.
Hydrochloric acid	6545	20% by weight	Aqueous or alcoholic solutions are not considered mixtures.
Iodine	6699	20% by weight.	
Methyl ethyl ketone	6714	35% by volume ...	Limit applies to methyl ethyl ketone or any combination of acetone, ethyl ether, methyl ethyl ketone, methyl isobutyl ketone and toluene if present in the mixture by summing the concentrations for each chemical.

List II chemicals	The DEA chemical code no.	Concentration (percent)	Special conditions
Methyl isobutyl ketone	6715	35% by volume	Limit applies to methyl isobutyl ketone or any combination of acetone, ethyl ether, methyl ethyl ketone, methyl isobutyl ketone and toluene if present in the mixture by summing the concentrations for each chemical.
Potassium permanganate	6579	15% by weight.	
Sulfuric acid	6552	20% by weight	Aqueous solutions are not considered mixtures.
Toluene	6594	35% by volume	Limit applies to toluene or any combination of acetone, ethyl ether, methyl ethyl ketone, methyl isobutyl ketone and toluene if present in the mixture by summing the concentrations for each chemical.

(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) Chemical mixtures that are distributed directly to an incinerator for destruction and are subject to the United States Environmental Protection Agency documentation on EPA Form 8700–22 and 8700–22A, provided that the person distributing the mixture to the incinerator maintains and makes available to agents of the Administration upon request such documentation for a period of no less than two years.

(2) Completely formulated paints/coatings that meet the American Society for Testing Materials specifications for the product. A completely formulated paint/coating are only those formulations that contain all the components of the paint/coating for use in the final application without the need to add any additional substances except possibly a thinner. A completely formulated paint or coating is defined as any clear or pigmented liquid, liquefiable or mastic composition designed for application to a substrate in a thin layer that is converted to a clear or opaque solid protective, decorative or functional adherent film after application.

(3) Harvested plant material that is in its natural state or has been processed in a way 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.

(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 § 1310.12(c); or the exemption provisions for specific categories of chemical mixtures as specified in § 1310.12(d), if evidence of diversion or attempted diversion is found. 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 include a reference to the legal authority under which the order is based and 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 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 upon evidence of diversion or attempted diversion modify any part of the criteria for exemption as specified in § 1310.12(c) and § 1310.12(d). 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.

§ 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, pursuant to paragraph (a) of this section, may apply to the Administrator, Drug Enforcement Administration, Department of Justice, Washington, D.C. 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, 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;

(4) The complete qualitative and quantitative composition of the chemical mixture (including all listed and all non listed chemicals) and its intended use;

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

(6) A statement which the applicant believes is justification for granting an exemption for the chemical mixture. The statement must explain how the chemical mixture meets the exemption criteria set forth in paragraph (a) of this section.

(7) The application will include a statement that the applicant accepts the right of the Administrator to terminate exemption from regulation for the chemical mixture granted exemption

under § 1310.13 if evidence of diversion of the mixture, or similar mixture, is found.

(8) The identification of any information on the application which 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 which he deems necessary for determining if the application should be granted.

(e) Within a reasonable period of time after the receipt of an application for an exemption under this section, the Administrator will notify the applicant of acceptance or nonacceptance 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, which shall include a reference to the legal authority under which the order is based. This order shall specify the date on which it shall take effect. The Administrator shall permit any interested persons to file written comments on or objections to the order. If any comments or objections raise significant issues regarding any findings of fact or law upon which the order is based, the Administrator shall immediately 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 any product or product line granted an exemption 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 include a reference to the legal authority under which the order is based and 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 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.

(g) Any change in the quantitative or qualitative composition of a chemical mixture which has been granted an exemption by application will require a new application for exemption unless such change causes the newly formulated mixture to be automatically exempt by definition in § 1310.12. A new application is not necessary for a change in name or other designation, code, or any identifier. For such changes or additions a written notification is required. The DEA must be notified of any changes at least 60 days in advance of the effective date for the change.

(h) Each manufacturer which desires a mixture to be exempt must apply separately as only those products specifically named in this exempted category will be recognized. Companies which have similar products to those in an exempted category must request and receive separate approval for their product line.

(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:

EXEMPT CHEMICAL MIXTURES

Manufacturer	Product name	Form	Date
[Reserved] ...	.....	.....	.....

Dated: September 1, 1998.

Donnie R. Marshall,

Acting Deputy Administrator.

[FR Doc. 98–24293 Filed 9–15–98; 8:45 am]

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[PA 122–4078b; FRL–6160–7]

Approval and Promulgation of Air Quality Implementation Plans; Commonwealth of Pennsylvania; Enhanced Motor Vehicle Inspection and Maintenance Program

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: This action proposes approval of the Commonwealth of Pennsylvania's August 21, 1998 submission to supplement its State Implementation Plan (SIP) revision for the enhanced motor vehicle emissions inspection and maintenance (I/M) program. The Commonwealth's August 1998 submission addresses seven minor, de minimus deficiencies. In addition, Pennsylvania submitted a demonstration of the effectiveness of its decentralized network, as required by the National Highway Systems Designation Act of 1995 (NHSDA). Approval of this submission will remove all remaining de minimus conditions imposed by EPA in its January 28, 1997 interim conditional approval of the Commonwealth of Pennsylvania's March 1996 enhanced I/M SIP revision. This action proposes approval of Pennsylvania's decentralized network effectiveness demonstration. Because EPA is proposing approval of that demonstration, as well as all remaining de minimus deficiencies related to Pennsylvania's enhanced I/M SIP, EPA hereby proposes to convert the interim approval of the Commonwealth's I/M SIP, granted under the NHSDA, to full approval. Because Pennsylvania must still provide specific information related to one condition of EPA's January 28, 1998 approval, the Commonwealth's I/M SIP would remain conditionally approved under the Clean Air Act. In the Final Rules section of this **Federal Register**, EPA is issuing a direct final rule approving the Commonwealth's August 21, 1998 submission. The Agency views this rulemaking action as noncontroversial and anticipates no adverse public comment. A detailed rationale for the approval is set forth in the direct final rule and in the technical support document prepared by EPA for this action. If no adverse comments are received, no further activity is contemplated with relation to this rule. If EPA receives adverse comments, the direct final rule will be withdrawn and