Dated: July 20, 2007.

Deborah J. Spero,

Acting Commissioner, Customs and Border Protection.

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DEPARTMENT OF JUSTICE

Drug Enforcement Administration

21 CFR Part 1310

[Docket No. DEA–284I]

RIN 1117–AB11

Elimination of Exemptions for Chemical Mixtures Containing the List I Chemicals Ephedrine and/or Pseudoephedrine

AGENCY: Drug Enforcement Administration (DEA), Department of Justice.

ACTION: Interim rule with request for comments.

SUMMARY: This Interim Rule removes the Controlled Substances Act (CSA) exemptions for chemical mixtures containing ephedrine and/or pseudoephedrine with concentration limits at or below five percent. The Combat Methamphetamine Epidemic Act of 2005 (CMEA) added additional controls on ephedrine and pseudoephedrine and mandated that DEA limit the domestic production and importation of materials containing ephedrine and pseudoephedrine to quantities necessary for medical, scientific and other legitimate purposes (21 U.S.C. 952(a)(1) as amended). DEA is eliminating exemptions for these chemical mixtures. As such, all ephedrine and pseudoephedrine chemical mixtures, regardless of concentration and form, shall be subject to the regulatory provisions of the CSA.

DEA is not prohibiting the importation, exportation, manufacture, or distribution of chemical mixtures containing ephedrine or pseudoephedrine in concentrations less than or equal to five percent. Rather, DEA is regulating the importation, exportation, manufacture, and distribution of these chemical mixtures by requiring persons who handle these chemical mixtures to register with DEA, maintain certain records common to business practice, and file certain reports, regarding these chemical mixtures. Chemical mixtures containing the List I chemicals ephedrine and pseudoephedrine will still be available for use.

DATES: Effective August 24, 2007.

Persons seeking registration must apply on or before August 24, 2007 in order to continue their business pending final action by DEA on their application. Written comments must be postmarked, and electronic comments must be sent, on or before September 24, 2007.

ADDRESSES: To ensure proper handling of comments, please reference ''Docket No. DEA–284I'' on all written and electronic correspondence. Written comments being sent via regular mail should be sent to the Deputy Administrator, Drug Enforcement Administration, Washington, DC 20537, Attention: DEA Federal Register Representative/ODL. Written comments sent via express mail should be sent to DEA Headquarters, Attention: DEA Federal Register Representative/ODL, 2401 Jefferson-Davis Highway, Alexandria, VA 22301. Comments may be sent directly to DEA electronically by sending an electronic message to *dea.diversion.policy@usdoj.gov*. Comments may also be sent electronically through *http://www.regulations.gov* using the electronic comment form provided on that site. An electronic copy of this document is also available at the *http://www.regulations.gov* Web site. DEA will accept attachments to electronic comments in Microsoft Word, WordPerfect, Adobe PDF, or Excel file formats only. DEA will not accept any file format other than those specifically listed here.

Posting of Public Comments: Please note that all comments received are considered part of the public record and made available for public inspection online at *http://www.regulations.gov*. Such information includes personal identifying information (for example, name, address, etc.) voluntarily submitted by the commenter.

If you want to submit personal identifying information (such as your name, address, etc.) as part of your comment, but do not want it to be posted online, you must include the phrase ''PERSONAL IDENTIFYING INFORMATION'' in the first paragraph of your comment. You must also place all the personal identifying information you do not want posted online in the first paragraph of your comment and identify the information you want redacted.

If you want to submit confidential business information as part of your comment but do not want it to be posted online, you must include the phrase ''CONFIDENTIAL BUSINESS INFORMATION'' in the first paragraph of your comment. You must also prominently identify confidential business information to be redacted within the comment. If a comment has so much confidential business information that it cannot be effectively redacted, all or part of that comment may not be posted on *http://www.regulations.gov*.

Personal identifying information and confidential business information identified and located as set forth above will be redacted and placed in the agency's public docket file, and, where possible, posted online. If you wish to inspect the agency's public docket file in person by appointment, please see the **FOR FURTHER INFORMATION** paragraph.

FOR FURTHER INFORMATION CONTACT: Christine A. Sannerud, PhD, Chief, Drug & Chemical Evaluation Section, Office of Diversion Control, Drug Enforcement Administration, Washington, DC 20537, telephone (202) 307–7183, fax (202) 353–1263, or e-mail *ode@dea.usdoj.gov*.

SUPPLEMENTARY INFORMATION:

I. Background

Status of Dietary Supplements Containing Ephedrine and/or Pseudoephedrine

Dietary supplements containing the List I chemicals ephedrine or pseudoephedrine are regulated as chemical mixtures under the Controlled Substances Act (CSA). DEA originally exempted these products from CSA regulatory control if the total concentration of the ephedrine and/or pseudoephedrine was at or below five percent, in an effort to reduce the regulatory burden on the dietary and nutritional supplement industry (68 FR 23195, May 1, 2003). However, on February 11, 2004, the Food and Drug Administration (FDA) issued a Final Rule (69 FR 6787) declaring dietary supplements containing ephedrine alkaloids adulterated under the Federal Food, Drug, and Cosmetic Act (the FFD&C Act) because these dietary supplements present an unreasonable risk of illness or injury. Effective April 12, 2004, the rule prohibits the sale of dietary supplements containing ephedrine alkaloids such as ephedra (also known as Ma Huang, sida cordifolia and pinellia). The effect of the FDA rule was to ban the lawful marketing of these products.

DEA notes that the FDA ban addresses only the marketing of dietary supplements containing ephedrine alkaloids. The raw materials used to manufacture these dietary supplements are not restricted by the FDA ban. Accordingly, to control those materials, DEA must address the importation, exportation, manufacture, or distribution of chemical mixtures with

concentration limits of ephedrine and/or pseudoephedrine at or below five percent. The importation, exportation, manufacture, and distribution of chemical mixtures with concentration limits at or below five percent ephedrine and/or pseudoephedrine are addressed by the CSA and its implementing regulations. As there yet may be legitimate uses for chemical mixtures with concentration limits at or below five percent, the importation, exportation, manufacture, and distribution of these chemical mixtures (for purposes other than use in dietary supplements containing ephedrine alkaloids) are not prohibited by either FDA's ban regarding the marketing of such dietary supplements or by DEA law and regulations. Accordingly, as discussed further below, for DEA to regulate the importation, exportation, manufacture, and distribution of chemical mixtures containing ephedrine and/or pseudoephedrine with concentration limits at or below five percent, DEA must remove these chemical mixtures from their exempt status under CSA regulations.

DEA recognizes that ephedra materials containing ephedrine and/or pseudoephedrine are used legitimately by practitioners of Traditional Chinese Medicine. This rulemaking does not restrict the utilization of such material for such legitimate purposes. This rulemaking will simply require importers and suppliers of such material to comply with DEA recordkeeping, registration, quota and import/export requirements.

Plant Material Included in This Regulatory Action

The ephedrine alkaloids, including, among others, ephedrine, pseudoephedrine, norephedrine, N-methylephedrine, norpseudoephedrine, N-methylpseudoephedrine, are chemical stimulants that occur naturally in some botanicals, but can be synthetically derived. The ingredient sources of the ephedrine alkaloids include raw botanicals (*i.e.*, plants) and extracts from botanicals. Ma Huang, ephedra, Chinese Ephedra, and epitonin are several names used for botanical ingredients, primarily from Ephedra sinica Stapf, ephedra equisetina Bunge, Ephedra intermedia var. tibetica Stapf and Ephedra distachya Linne. (the Ephedras), that are sources of ephedrine alkaloids (including ephedrine and pseudoephedrine). Other plant sources that contain such ephedrine alkaloids include Sida cordifolia L. and Pinellia ternata (Thunb.) Makino. Common names that have been used for the various plants that contain ephedrine alkaloids include sea grape, yellow horse, joint fir, popotillo, and country mallow. Although the proportions of the various ephedrine alkaloids in botanical species vary from one species to another, in most species used commercially, ephedrine is typically the predominant alkaloid in the raw material. In addition to chemical mixtures from synthetic sources, this rulemaking includes those plant sources that contain the ephedrine alkaloids, ephedrine and/or pseudoephedrine.

The names desert herb, squaw tea, Brigham tea, and Mormon tea refer to North American species of ephedra that do not contain ephedrine alkaloids but have been misused to identify ephedrine alkaloid containing ingredients. This rulemaking does not pertain to species of ephedra that do not contain ephedrine and/or pseudoephedrine.

Combat Methamphetamine Epidemic Act of 2005 (CMEA)

On March 9, 2006, the President signed the Combat Methamphetamine Epidemic Act of 2005 (CMEA), which is Title VII of the USA PATRIOT Improvement and Reauthorization Act of 2005. The CMEA mandates that DEA limit the domestic production and importation of materials containing ephedrine and pseudoephedrine (including ephedra) to quantities necessary for medical, scientific and other legitimate purposes (21 U.S.C. 826 and 952(a)(1) as amended). DEA is concerned about the illicit use of ephedra type material in the clandestine production of methamphetamine. While the legitimate market for dietary supplements containing such material has been cut by FDA's recent action, DEA has seen an increasing number of requests for importation of below-five percent ephedrine and/or pseudoephedrine material. DEA notes that there may be legitimate uses for these chemical mixtures. However, in light of FDA's action, DEA is concerned about the intended purpose of such material, especially given that such material has been seized in clandestine drug laboratories.

Chemical Mixture Regulatory Control History

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.

Chemical Mixture Definition

The CDTA created a definition of ''chemical mixture'' (21 U.S.C. 802(40)), and exempted chemical mixtures from the definition of ''regulated transaction.'' (21 U.S.C. 802(39)(A)(vi) as amended by CMEA) 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.'' (21 U.S.C. 802(40))

Chemical Mixtures Containing Ephedrine and Pseudoephedrine

Ephedrine and pseudoephedrine are List I chemicals. Listed chemicals that are classified as List I chemicals are important to the manufacture of controlled substances. Chemical mixtures containing both these List I chemicals include dietary and nutritional supplements. Prior to FDA's 2004 Final Rule, dietary and nutritional supplements containing both of these chemicals were readily available in the U.S., commonly sold to the public in drug and grocery stores, health and nutrition stores, and through direct marketing campaigns. These dietary and nutritional supplements contained ephedra plant material, or extracts from the ephedra plant. If these dietary and nutritional supplements met certain criteria under the FFD&CA, they were not recognized as drugs under the FFD&CA, but nonetheless were 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 (as long as they are in final FDA approved labeled package form) and instead are specifically addressed in 21 U.S.C. 802(39)(A)(iv) and (v) as amended by CMEA. Also see 21 CFR 1300.02(b)(28)(i).

Initial Chemical Mixture Controls

Prior to the Domestic Chemical Diversion Control Act of 1993 (DCDCA), enacted in April of 1994, transactions involving all chemical mixtures

(including dietary supplements) were exempt from recordkeeping, registration and other chemical regulatory control requirements of the CSA. 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.'' As such, only those chemical mixtures meeting these criteria would be exempted from control. Until regulations which delineated criteria and procedures for exempting specific chemical mixtures were finalized, as a practical interpretation of the law, DEA treated all chemical mixtures, including dietary and nutritional supplements, 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)). Unless exempted pursuant to law and regulations, the requirements for chemical mixtures included registration for certain handlers of List I chemicals, recordkeeping, reporting and security.

Concern Regarding 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.''

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 exempt from specific provisions of the CSA. This quantitative approach to identifying regulated mixtures was considered necessary due to the complexity of chemical-based commodities and the huge variety of products. These criteria were expected to exempt the vast majority of chemical mixtures containing listed chemicals from regulatory control. 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.

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.

DEA originally proposed a concentration limit 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 determined that a five percent concentration limit would be more appropriate. On May 1, 2003, DEA published a Final Rule (68 FR 23195) which established a concentration limit of five percent for chemical mixtures which contain ephedrine and/or pseudoephedrine.

If the concentration of the total ephedrine and/or pseudoephedrine was at or below the five percent limit in a chemical mixture, the mixture was automatically exempted from the registration, reporting, recordkeeping and security requirements of the CSA. That Final Rule primarily addressed those chemicals encountered in dietary and nutritional supplements.

The May 1, 2003, Final Rule also established an exemption for the category of products consisting of unaltered harvested plant material in 21 CFR 1310.12(d)(1). Finally, that rule provided 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 allows chemical mixtures not automatically exempt by the concentration limit to be considered for exempt status under the CSA.

Recent FDA Action Pertaining to Dietary Supplements Containing Ephedrine Alkaloids

In 2004, FDA issued a Final Rule declaring dietary supplements containing ephedrine alkaloids ''adulterated'' under the FFD&C Act (69 FR 6787, February 11, 2004). FDA issued this rule after concluding that these products present an unreasonable risk of illness or injury. FDA's Final Rule prohibits the sale of these products and FDA has been seizing dietary supplements containing ephedrine alkaloids since the Final Rule became effective in April 2004. The FDA Final Rule addressed the marketing of dietary supplements containing ephedrine alkaloids; it did not address the importation, exportation, manufacture or distribution of ephedrine and/or pseudoephedrine chemical mixtures with concentration limits at or below five percent, if the chemical mixture is not being marketed as a dietary supplement containing ephedrine alkaloids. DEA notes that there yet may be legitimate uses for such mixtures. As there yet may be legitimate uses for chemical mixtures with concentration limits at or below 5 percent, the importation, exportation, manufacture, and distribution of these chemical mixtures (for purposes other than use in dietary supplements containing ephedrine alkaloids) are not prohibited by either FDA's ban regarding the marketing of such dietary supplements or by DEA law and regulations. In spite of FDA's ban, and corresponding reduction in legitimate need for these chemical mixtures, DEA has seen a significant increase in the number of import requests for ephedra, sparking a concern that these chemical mixtures are being diverted for use in the illicit manufacture of methamphetamine.

Combat Methamphetamine Epidemic Act of 2005 (CMEA)

On March 9, 2006, the President signed the USA PATRIOT Improvement and Reauthorization Act of 2005 which included the Combat Methamphetamine Epidemic Act of 2005 (CMEA) (Title VII of Pub. L. 109–177). The CMEA placed additional controls on ephedrine and pseudoephedrine and tasked DEA with limiting the domestic production and importation of ephedrine and pseudoephedrine materials to quantities necessary for medical, scientific and other legitimate purposes (21 U.S.C. 826 and 952(a)(1) as amended).

The CMEA imposed new requirements regarding the retail sale of scheduled listed chemical products (products containing ephedrine,

pseudoephedrine, or phenylpropanolamine, that may be marketed or distributed lawfully in the United States under the FFD&CA as nonprescription products). In a separate rulemaking, ''Retail Sales of Scheduled Listed Chemical Products; Self-Certification of Regulated Sellers of Scheduled Listed Chemical Products'' [Docket No. DEA–291, RIN 1117–AB05] (71 FR 56008, September 26, 2006; corrected at 71 FR 60609, October 13, 2006), DEA promulgated regulations implementing these provisions. The CMEA also subjects material containing ephedrine, pseudoephedrine and phenylpropanolamine to manufacturing and import restrictions. Specifically, the CMEA requires that importers of all listed chemicals provide DEA with information regarding the transferee, (*i.e.*, the downstream customer) of the chemical, as well as information regarding the quantity of the chemical to be transferred. Importers are further required to provide DEA with a return declaration regarding each import after the transaction is completed (CMEA section 716, 21 U.S.C. 971(d) and (g), as amended). In a separate rulemaking, ''Implementation of the Combat Methamphetamine Epidemic Act of 2005; Notice of Transfers Following Importation or Exportation'' [Docket No. DEA–292, RIN 1117–AB06] (72 FR 17401, April 9, 2007; Temporary Stay of Certain Provisions 72 FR 28601, May 22, 2007), DEA promulgated regulations implementing these provisions. Further, the CMEA requires that the notice of importation (DEA Form 486) for ephedrine, pseudoephedrine, and phenylpropanolamine ''shall include all information known to the importer on the chain of distribution of such chemical from the manufacturer to the importer.'' (CMEA section 721, 21 U.S.C. 971(h) as amended). In a separate rulemaking, ''Information of Foreign Chain of Distribution for Certain List I Chemicals'' [Docket No. DEA–295, RIN 1117–AB07], DEA is promulgating regulations to implement this provision. Finally, the CMEA requires DEA to establish import and production quotas for ephedrine, pseudoephedrine, and phenylpropanolamine (CMEA sections 713 and 715, 21 U.S.C. 826 and 952 as amended). In a separate rulemaking, ''Import and Production Quotas for Certain List I Chemicals'' [Docket No. DEA–293, RIN 1117–AB08] (72 FR 37439, July 10, 2007) DEA promulgated regulations to implement these provisions.

DEA is removing the exemption for five percent ephedrine and/or pseudoephedrine, in part, to fulfill the Congressional mandate of restricting such material to quantities necessary for medical, scientific, and other legitimate purposes (21 U.S.C. 826 and 952(a)(1) as amended). Without removing the exemption for these products, DEA would be unable to effectively limit the importation of ephedrine and pseudoephedrine, as required by the CMEA.

Present Concerns: Use at Illicit Laboratories

DEA is also authorized to remove an exemption for particular exempt chemical mixtures if it finds evidence of diversion pursuant to 21 CFR 1310.12(e). This regulation provides that should DEA find such evidence, it can ''issue, and publish in the **Federal Register**, notification of the removal of an exemption.'' Interested parties are invited to file written comments or objections to the order within 60 days of the date of publication. If any comment or objection raises ''significant issues regarding any finding of fact or conclusion of law upon which the order is based, [DEA] shall immediately suspend the effectiveness of the order'' and reconsider the application for exemption in light of the comments received.

At most methamphetamine laboratories seized in the U.S., the precursor material was obtained via the diversion of OTC ephedrine or pseudoephedrine products marketed in tablet and capsule form. 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 this time, the frequency with which these dietary supplement products and extracts are encountered is small. From 1998 through 2005, DEA has documented 20 methamphetamine laboratories where ephedra materials have been seized. The source of precursor chemicals in a seized clandestine laboratory is often not evident, so it is likely that the number of seized laboratories that used such mixtures is actually greater. Ephedra, therefore, can and is being diverted for use as a precursor material for the illicit production of methamphetamine. Were DEA not to regulate chemical mixtures containing ephedrine and/or pseudoephedrine at or below the current five percent concentration limit, DEA is concerned that these products would be more widely diverted for illicit production of methamphetamine, particularly as traffickers look for easily-obtainable product due to the new retail sales, quota and import restrictions imposed by CMEA.

DEA Concerns Regarding Recent Importations

Recently DEA has seen an increasing number of requests for importation of large shipments of ephedra material in concentrations below the five percent ephedrine and pseudoephedrine exemption limit. Traditionally, such ephedra extract material has always been between 6–8 percent ephedrine and/or pseudoephedrine.

As noted above, DEA has seen chemical mixtures with concentration limits of ephedrine and/or pseudoephedrine at or below five percent in clandestine methamphetamine laboratories. Subsequent to implementing regulations which allowed an exemption for below five percent material, DEA has witnessed increased ability of clandestine laboratory operators to extract ephedrine and pseudoephedrine from various bulk materials (including low concentration mixtures). These extraction procedures are shared via the Internet. While these mixtures may contain low concentrations of ephedrine and/or pseudoephedrine, they can be a ready source of supply for methamphetamine traffickers.

Therefore, due to the existing clandestine methamphetamine laboratory problem and 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 the new limitations imposed by the CMEA, DEA is removing the exemption for chemical mixtures having a total concentration of less than (or equal to) five percent ephedrine or pseudoephedrine and is removing the exemption for unaltered ephedra plant material.

Action Taken in This Interim Rule

This Interim Rule announces the removal of the exemption for chemical mixtures having a total concentration of ephedrine and/or pseudoephedrine of five percent (or less). By removing these exemptions, all chemical mixtures containing ephedrine and/or pseudoephedrine will be regulated chemical mixtures subject to control under the Controlled Substances Act, including registration, recordkeeping, reporting, and security controls. This action will be effective August 24, 2007.

This rulemaking also removes the exemption for the category of products consisting of harvested plant material which is specified in 21 CFR 1310.12(d)(1). Harvested plant material (*i.e.*, ephedra) that contains ephedrine, N-methylephedrine, N-methylpseudoephedrine, norpseudoephedrine, phenylpropanolamine, and/or pseudoephedrine, meeting the definition of chemical mixture, shall no longer be exempt from CSA provisions, even when the plant material is unaltered from its natural state.

II. Provisions Specifically Applying to Regulated Chemical Mixtures Containing These List I Chemicals

Effective August 24, 2007, any chemical mixture that contains ephedrine or pseudoephedrine will be treated as a List I chemical. Transactions that meet or exceed the cumulative monthly threshold for the listed chemical, set forth at 21 CFR 1310.04, shall be regulated transactions. Persons interested in handling a regulated mixture must comply with the following:

Registration. Any person who manufactures, distributes, imports or exports a regulated mixture, or proposes to engage in such activities, 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 chemical handlers are set forth in 21 CFR part 1309.

Separate registration is required for manufacture, 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 manufactured, distributed, imported, or exported by a person (21 CFR 1309.23). Effective August 24, 2007, any person manufacturing, distributing, importing, or exporting 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, provided that DEA receives a properly completed application for registration on or before August 24, 2007. The temporary exemption for such persons will remain in effect until DEA takes final action on their application for registration.

The temporary exemption applies solely to the registration requirement; all other chemical control requirements, including recordkeeping and reporting, are effective on August 24, 2007. Therefore, all transactions of chemical mixtures containing ephedrine or pseudoephedrine 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. Section 1310.03(c) requires that regulated persons who engage in a transaction with a nonregulated person or who engage in an export transaction that involves ephedrine or pseudoephedrine, including drug products containing these chemicals, and uses or attempts to use the Postal Service or any private or commercial carrier must file monthly reports of each such transaction.

Imports/Exports. All imports/exports and brokered transactions of regulated mixtures containing ephedrine and/or pseudoephedrine shall comply with the CSA (21 U.S.C. 952, 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 1309.22).

Security. Regulated persons must provide effective controls and procedures to guard against theft and diversion of regulated mixtures. Regulated persons must store the regulated mixtures in containers sealed so that tampering will be evident; if the mixture cannot be stored in a sealed container, access to the chemicals must be controlled (21 CFR 1309.71).

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

Administrative Procedure Act

The Administrative Procedure Act (APA) generally requires that agencies, prior to issuing a new rule, publish a notice of proposed rulemaking in the **Federal Register**. The APA also provides, however, that agencies may be excepted from this requirement when ''the agency for good cause finds (and incorporates the finding and a brief statement of reasons therefor in the rules issued) that notice and public procedure thereon are impracticable, unnecessary, or contrary to the public interest.'' 5 U.S.C. 553(b)(B).

With publication of this interim rule, DEA is invoking this ''good cause'' exception to the APA's notice requirement based on the combination of several extraordinary factors. Section 713 of the CMEA (21 U.S.C. 826 as amended) requires the establishment of production quotas for the List I chemicals ephedrine, pseudoephedrine, and phenylpropanolamine. DEA implemented these requirements in a separate rulemaking, ''Import and

Production Quotas for Certain List I Chemicals'' [Docket No. DEA–293, RIN 1117–AB08] (72 FR 37439, July 10, 2007). DEA cannot establish such quotas if certain products containing these List I chemicals are not regulated. To not regulate these products while at the same time establishing production quotas would create a loophole which traffickers could exploit domestically. CMEA also mandates that imports of ephedrine, pseudoephedrine, and phenylpropanolamine are prohibited except for such quantities as the Attorney General (DEA by delegation) finds necessary to provide for medical, scientific, or other legitimate purposes (CMEA section 715, 21 U.S.C. 952 as amended). DEA is further required to establish import quotas for these three List I chemicals. In order for DEA to establish quotas and meet its obligation to prohibit imports except those necessary to provide for a medical, scientific, or other legitimate purpose, as required by the CMEA, DEA must exercise regulatory control over chemical mixtures containing pseudoephedrine and ephedrine. To exercise this control, DEA must eliminate the exemption for chemical mixtures containing these List I chemicals.

DEA is concerned about the increasing number of requests for importation of below-five percent ephedrine or pseudoephedrine material. After the recent FDA action which bans dietary supplements containing such material, DEA has not been able to determine the legitimate need for importation of such material. Therefore, in an effort to eliminate the undocumented importation and domestic distribution of such material, and to comply with all of the new requirements imposed by the CMEA discussed above, DEA is removing these exemptions.

As has been discussed previously in this rulemaking, DEA has seized chemical mixtures containing ephedrine and/or pseudoephedrine with concentrations of less than five percent at 20 domestic clandestine laboratories over the past several years. The source of precursor chemicals in a seized clandestine laboratory is often not evident, so it is likely that the number of seized laboratories that used such mixtures is actually greater. Further, the CMEA specifically prohibits all importation of ephedrine, pseudoephedrine, and phenylpropanolamine except those quantities which the Attorney General finds to be necessary for medical, scientific, and other legitimate purposes. These seizures, coupled with the new requirements limiting importation of ephedrine, pseudoephedrine, and phenylpropanolamine, as well as the establishment of production and import quotas for these three List I chemicals, necessitate that DEA remove the concentration limit for these previously exempt chemical mixtures. Engaging in traditional notice and comment rulemaking would prevent DEA from complying with the mandates of CMEA to limit the importation and domestic production of these materials.

Were DEA not to regulate chemical mixtures containing ephedrine and/or pseudoephedrine at or below the current five percent concentration limit, DEA is concerned that these products would be more widely diverted for illicit production of methamphetamine, particularly with the new quota and import restrictions imposed by CMEA. Accordingly, DEA finds that it is impracticable to conduct notice and comment rulemaking regarding the removal of the exemption for chemical mixtures with concentration limits at or below the current five percent limit. If DEA did not act in this manner, traffickers would have ready access to chemical mixtures which DEA has demonstrated are being used currently to illicitly manufacture methamphetamine. Allowing such illicit manufacture to continue during the pendancy of rulemaking would be contrary to the public interest and the intent of the Combat Methamphetamine Epidemic Act of 2005. The broad scope of the new law, as well as the expedited effective dates, is a clear reflection of Congress' concern about the nation's growing methamphetamine epidemic and its desire to act quickly to prevent further illicit use of these chemicals.

In light of these factors, DEA finds that ''good cause'' exists to issue this interim rule without engaging in traditional notice and comment rulemaking. In so doing, DEA recognizes that exceptions to the APA's notice and comment procedures are to be ''narrowly construed and only reluctantly countenanced.'' *Am. Fed'n of Gov't Employees* v. *Block,* 655 F2d 1153, 1156 (D.C. Cir. 1981) (quoting New Jersey Dep't of Envt. Prot. v. EPA, 626 F.2d 1038, 1045 (D.C. Cir. 1980)). Based on the totality of the circumstances associated with the CMEA, DEA finds that invocation of the ''good cause'' exception is justified.

Further, the APA also provides that, while agencies are generally required to publish final rules at least 30 days before they become effective, they may be exempt from this requirement as well ''for good cause found and published with the rule.'' 5 U.S.C. 553(d)(3). As discussed previously, DEA has recently seen a significant increase in the number of requests for importation of large quantities of these chemical mixtures. After the recent FDA action which bans dietary supplements containing such material, DEA has not been able to determine the legitimate need for importation of such material. DEA is concerned about the potential illicit use of such material for clandestine methamphetamine manufacture, particularly as traffickers look for easily-obtainable product due to the retail sales limits recently imposed by the CMEA. Delaying the effective date of this rule could provide a significant loophole for domestic illicit methamphetamine manufacturers to take advantage of for their illegal activities. Therefore, DEA finds good cause not to delay the effective date of this rule.

Regulatory Flexibility Act

The Deputy Administrator hereby certifies that this rulemaking has been drafted in accordance with the provisions of the Regulatory Flexibility Act (RFA) (5 U.S.C. 605(b)). The (RFA) applies to rules that are subject to notice and comment. As explained above, DEA has determined that public notice and comment are not necessary. Consequently, the RFA does not apply. DEA notes, however, that as explained in the discussion under Executive Order 12866, the costs of this rule are low, requiring only registration, maintenance of records, reports on unusual transactions, thefts or losses, and mail order transactions, and security. Other than the registration fee and the reports, these requirements can generally be met by standard business practices.

DEA has determined that dietary supplements containing ephedrine alkaloids, including bulk material used to formulate these supplements, are the principal chemical mixtures that contain ephedrine and/or pseudoephedrine. Dietary supplements containing such ephedrine alkaloids have been banned by FDA. Due to (1) The CMEA mandate that DEA limit the domestic production and importation of materials containing ephedrine and pseudoephedrine to quantities necessary for medical, scientific and other legitimate purposes; (2) the elimination of the previous lawful status of such products as dietary supplements; and (3) the potential illicit use of such products as precursor material for illicit production of methamphetamine, DEA is removing the exemption for low concentration material, including harvested plant

material. This industry is comprised mainly of small businesses, as defined by U.S. Small Business Administration (SBA) regulations (13 CFR part 121). However, the lawful marketing of dietary supplements containing ephedrine alkaloids has been banned by FDA. As such, this regulatory action is not expected to impact any manufacturers whose product can still lawfully be marketed under the FFD&CA. Persons who import or distribute chemical mixtures containing ephedrine and/or pseudoephedrine at or below the previously-exempt five percent concentration limit will be affected by this rule. This rule will not have a significant economic impact on those persons. However, DEA is seeking comment specifically regarding the potential impacts of this regulation.

DEA is not prohibiting the importation, exportation, manufacture, or distribution of chemical mixtures containing ephedrine or pseudoephedrine in concentrations less than or equal to five percent. Rather, DEA is regulating the importation, exportation, manufacture, and distribution of these chemical mixtures by requiring persons who handle these chemical mixtures to register with DEA, maintain certain records common to business practice, and file certain reports, regarding these chemical mixtures. Chemical mixtures containing the List I chemicals ephedrine and pseudoephedrine will still be available for use.

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 (OMB).

The rule will impose relatively low costs on regulated persons. Other than the annual registration fee of $1,247, there are few costs associated with the rule. The records required on regulated transactions can be met with standard business records. Reports on unusual sales, thefts, and losses will be filed infrequently by any one person. Those who sell covered mixtures and deliver them to the end user through the mail or other delivery services will have to file a monthly report. The monthly report requires only the registrant's name and registration number, the purchaser's name and address, the shipping address (if different), the name and quantity of the chemical, and the date of shipment; all of this information is available from standard business and shipping records. These reports may be filed electronically. The security requirements do not exceed standard business practices for the protection of both the security and quality of these products. DEA has not determined the number of firms potentially affected by the rule, but does not expect it to be high.

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 $120,000,000 or more (adjusted for inflation) 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.

Paperwork Reduction Act

The Drug Enforcement Administration is eliminating the current exemption for chemical mixtures with concentration limits of the List I chemicals ephedrine and/or pseudoephedrine of less than or equal to five percent. This means that all chemical mixtures containing the List I chemicals ephedrine and/or pseudoephedrine are regulated chemical mixtures, regardless of concentration limits.

Due to this change in the regulations, all persons who import, export, manufacture, or distribute chemical mixtures containing these two List I chemicals will be required to register with DEA. They will also be required to file reports regarding certain transactions, should certain criteria be met.

DEA does, however, provide a mechanism whereby a person may seek an exemption from these regulatory requirements for a specific chemical mixture, if DEA determines that such a chemical mixture cannot be used by traffickers to manufacture controlled substances illicitly.

DEA notes that the lawful marketing of dietary supplements containing this material has been banned by FDA. As such, this regulatory action is expected to impact no manufacturers, whose product can still lawfully be marketed under the FFD&CA.

Therefore, as the impact of this regulation is minimal, DEA is making minor adjustments to the OMB information collections entitled ''Application for Registration Under Domestic Chemical Diversion Control Act of 1993 and Renewal Application for Registration under Domestic Chemical Diversion Control Act of 1993'' (OMB control number 1117–0031, DEA Form 510), ''Report of Mail Order Transactions'' (OMB control number 1117–0033), and ''Import/Export Declaration for List I and List II Chemicals'' (OMB control number 1117–0023). DEA is specifically seeking comment regarding the number of persons who may be affected by this regulation.

Congressional Review Act

This rule is not a major rule as defined by Section 804 of the Small Business Regulatory Enforcement Fairness Act of 1996 (Congressional Review Act). 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 in 21 CFR Part 1310

Drug traffic control, Exports, Imports, List I and List II chemicals, Reporting and Recordkeeping requirements.

■ For the reasons set out above, 21 CFR part 1310 is amended as follows:

PART 1310—RECORDS AND REPORTS OF LISTED CHEMICALS AND CERTAIN MACHINES [AMENDED]

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

Authority: 21 U.S.C. 802, 827(h), 830, 871(b), 890.

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

§ 1310.09 Temporary exemption from registration.

* * * * *

(j) Each person required by section 302 of the Act (21 U.S.C. 822) to obtain

a registration to manufacture, distribute, import, or export regulated chemical mixtures which contain ephedrine, and/or pseudoephedrine, pursuant to Sections 1310.12 and 1310.13, is temporarily exempted from the registration requirement, provided that DEA receives a properly completed application for registration or application for exemption on or before August 24, 2007. 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, 1313, and 1315 of this chapter remain in full force and effect. Any person who manufactures, 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.

■ 3. Section 1310.12 is amended as follows:

■ A. By revising the Table of Concentration Limits in paragraph (c) by revising the entries for ''Ephedrine, its salts, optical isomers, and salts of optical isomers'' and ''Pseudoephedrine, its salts, optical isomers, and salts of optical isomers''; and

■ B. By removing paragraph (d)(1) and redesignating paragraphs (d)(2) through (d)(5) as paragraphs (d)(1) through (d)(4) as follows:

§ 1310.12 Exempt chemical mixtures.

* * * * *

(c) * * *

TABLE OF CONCENTRATION LIMITS

	DEA chemical code number	Concentration (percent)	Special conditions
List I Chemicals			
* * *	*	*	* *
Ephedrine, its salts, optical isomers, and salts of optical isomers.	8113	Not exempt at any concentration.	Chemical mixtures containing any amount of ephedrine and/or pseudoephedrine, and their salts, optical isomers and salts of optical isomers are not exempt due to concentration, unless otherwise exempted.
* * *	*	*	* *
Pseudoephedrine, its salts, optical isomers, and salts of optical isomers.	8112	Not exempt at any concentration.	Chemical mixtures containing any amount of ephedrine and/or pseudoephedrine, and their salts, optical isomers and salts of optical isomers are not exempt due to concentration, unless otherwise exempted.
* * *	*	*	* *
List II Chemicals			
* * *	*	*	* *

* * * * *

Dated: July 2, 2007.

Michele M. Leonhart,

Deputy Administrator.

[FR Doc. E7–14295 Filed 7–24–07; 8:45 am]

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LIBRARY OF CONGRESS

Copyright Office

37 CFR Part 202

[Docket No. RM 2007–7]

Technical Amendments to online registration of claims to copyright; corrections

AGENCY: Copyright Office, Library of Congress

ACTION: Interim Regulations for online registration; correction.

SUMMARY: The Copyright Office published in the **Federal Register** on July 6, 2007, an interim regulation implementing an online copyright registration system. This document makes technical corrections to that interim regulation.

DATES: Effective on July 25, 2007.

FOR FURTHER INFORMATION CONTACT: Tanya Sandros, Acting General Counsel, or Nanette Petruzzelli, Special Legal Advisor to the Register for Reengineering, Copyright Office, Library of Congress, Washington, DC 20540. Telephone: (202) 707–8380. Telefax: (202) 707–8366.

SUPPLEMENTARY INFORMATION: The Copyright Office published an interim regulation in the Federal Register on July 6, 2007, which, for the purpose of implementing an online registration system, amended its regulations governing the procedures by which the public submits, and the Office processes, copyright registrations and