

Rules and Regulations

Federal Register

Vol. 75, No. 129

Wednesday, July 7, 2010

This section of the FEDERAL REGISTER contains regulatory documents having general applicability and legal effect, most of which are keyed to and codified in the Code of Federal Regulations, which is published under 50 titles pursuant to 44 U.S.C. 1510.

The Code of Federal Regulations is sold by the Superintendent of Documents. Prices of new books are listed in the first FEDERAL REGISTER issue of each week.

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

21 CFR Part 1310

[Docket No. DEA-296F]

RIN 1117-AB10

Removal of Thresholds for the List I Chemicals Pseudoephedrine and Phenylpropanolamine

AGENCY: Drug Enforcement Administration, Department of Justice.

ACTION: Final rule.

SUMMARY: The Drug Enforcement Administration (DEA) is removing the thresholds for importation, exportation, and domestic distributions of the List I chemicals pseudoephedrine and phenylpropanolamine. This rulemaking is being conducted as part of DEA's implementation of the Combat Methamphetamine Epidemic Act of 2005 and is needed to implement the Act's requirements for import and production quotas and to address the potential diversion of these chemicals. DEA is also clarifying that all transactions of drug products containing ephedrine, pseudoephedrine, and phenylpropanolamine, except retail transactions, are considered to be regulated transactions.

DATES: *Effective Date:* This rule is effective August 6, 2010.

FOR FURTHER INFORMATION CONTACT: Mark W. Caverly, Chief, Liaison and Policy Section, Office of Diversion Control, Drug Enforcement Administration, 8701 Morrisette Drive, Springfield, VA 22152, (202) 307-7297.

SUPPLEMENTARY INFORMATION:

DEA's Legal Authority

DEA implements the Comprehensive Drug Abuse Prevention and Control Act of 1970, often referred to as the Controlled Substances Act (CSA) and

the Controlled Substances Import and Export Act (CSIEA) (21 U.S.C. 801-971), as amended. DEA publishes the implementing regulations for these statutes in Title 21 of the Code of Federal Regulations (CFR), parts 1300 to end. These regulations are designed to ensure that there is a sufficient supply of controlled substances for legitimate medical, scientific, research, and industrial purposes and deter the diversion of controlled substances to illegal purposes. The CSA mandates that DEA establish a closed system of control for manufacturing, distributing, and dispensing controlled substances. Any person who manufactures, distributes, dispenses, imports, exports, or conducts research or chemical analysis with controlled substances must register with DEA (unless exempt) and comply with the applicable requirements for the activity. The CSA, as amended, also requires DEA to regulate the manufacture, distribution, retail sale, import, and export of chemicals that may be used to manufacture controlled substances illegally. Listed chemicals that are classified as List I chemicals are important to the manufacture of controlled substances. Those classified as List II chemicals may be used to manufacture controlled substances.

Combat Methamphetamine Epidemic Act of 2005

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 (Pub. L. 109-177). Among other actions, CMEA imposed new requirements regarding the retail sale of scheduled listed chemical products (drugs containing ephedrine, pseudoephedrine, or phenylpropanolamine, that may be marketed or distributed lawfully in the United States under the Federal Food, Drug and Cosmetic Act as nonprescription products) (21 U.S.C. 802(45)(A)). 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 (21 U.S.C. 830(d), (e); 21 CFR part 1314).

The CMEA also subjects material containing ephedrine, pseudoephedrine, and phenylpropanolamine to manufacturing and import restrictions. Specifically, CMEA amended section 1002 of the CSA (21 U.S.C. 952(a)(1)) by adding the List I chemicals ephedrine, pseudoephedrine, and phenylpropanolamine to those narcotic raw materials whose importation into the United States is prohibited except for such amounts as the Attorney General finds to be necessary to provide for medical, scientific, or other legitimate purposes. CMEA also amended section 306 of the Act (21 U.S.C. 826) to establish the total annual needs of ephedrine, pseudoephedrine, and phenylpropanolamine to provide for the estimated medical, scientific, research, and industrial needs of the United States, for lawful export requirements, and for the establishment and maintenance of reserve stocks. Individual manufacturing and procurement quotas for ephedrine, pseudoephedrine, and phenylpropanolamine were also required to be established for persons conducting manufacturing activities with those chemicals. 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; Final Rule 73 FR 73549, December 3, 2008), DEA promulgated regulations to implement these provisions (21 CFR part 1315).

Further, the CMEA requires that importers, exporters, and persons involved in international transactions of all listed chemicals, including ephedrine, pseudoephedrine, and phenylpropanolamine, 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, exporters, and persons involved in international transactions are further required to provide DEA with a return declaration regarding each import, export, or international transaction after the transaction is completed (CMEA § 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 (21 CFR 1313.16, 1313.17, 1313.26, 1313.27, 1313.32, 1313.35).

Finally, 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 § 721, 21 U.S.C. 971(h) as amended). In a separate rulemaking, "Information on Foreign Chain of Distribution for Ephedrine, Pseudoephedrine, and Phenylpropanolamine" [Docket No. DEA-295, RIN 1117-AB07] (73 FR 16793, March 31, 2008), DEA proposed regulations to implement this provision.

The List I chemicals ephedrine, pseudoephedrine, and phenylpropanolamine as single entity or combination products all serve as precursor chemicals for the illicit manufacture of controlled substances. Ephedrine and pseudoephedrine are the primary precursors used in the illicit synthesis of methamphetamine, a schedule II controlled substance, and methcathinone, a schedule I controlled substance. Phenylpropanolamine is the primary precursor used in the illicit synthesis of amphetamine, a schedule II controlled substance.

Licit Use

Ephedrine, pseudoephedrine, and phenylpropanolamine all have therapeutic uses in both over-the-counter and prescription drug products. Ephedrine is lawfully marketed under the Federal Food, Drug, and Cosmetic Act as an ingredient in nonprescription ("over-the-counter" (OTC)) drugs as a bronchodilator for the treatment of asthma. Ephedrine is also available as a nonprescription product in combination with the active ingredient guaifenesin, which is an expectorant.

As a prescription drug, ephedrine is used in parenteral (injectable) form in hospitals as part of anesthesiology kits. Ephedrine has the beneficial effect of increasing blood pressure very rapidly in the event of hypotensive crisis (*i.e.*, sudden loss of blood pressure sometimes experienced during surgery). Parenteral ephedrine is also sometimes used to relieve acute bronchospasm. Oral dosage forms of ephedrine are also available as prescription drugs for the treatment of asthma. These prescription drug products primarily consist of

ephedrine in combination with other active ingredients such as potassium iodide (an expectorant) and/or theophylline (a bronchospamolytic).

Pseudoephedrine is lawfully marketed under the Federal Food, Drug, and Cosmetic Act for over-the-counter use as a decongestant. Phenylpropanolamine has historically been marketed in the United States for OTC use as a decongestant and diet aid and there have been many legend (prescription) drug products that contain pseudoephedrine or phenylpropanolamine. In the vast majority of these preparations, pseudoephedrine or phenylpropanolamine were in combination with other active ingredients, such as antihistamines, expectorants, and/or antitussives.

In November 2000, the U.S. Food and Drug Administration (FDA) issued a public health advisory concerning phenylpropanolamine and requested that all drug companies discontinue marketing products containing phenylpropanolamine due to risk of hemorrhagic stroke. In response, many companies have voluntarily reformulated their products to exclude phenylpropanolamine. Subsequently, on December 22, 2005, the FDA published a Notice of Proposed Rulemaking (70 FR 75988) proposing to categorize all over-the-counter nasal decongestants and weight control drug products containing phenylpropanolamine preparations as Category II, nonmonograph, *i.e.*, not generally recognized as being safe for human consumption. Most products containing phenylpropanolamine intended for humans have been withdrawn from the market, but phenylpropanolamine is still sold by prescription for veterinary uses.

While ephedrine and pseudoephedrine are pharmacologically different (and have quite different therapeutic uses), they are directly substitutable in the production of methamphetamine. This is because of the similarity of the chemical structures of the two drugs.

Discussion of the NPRM

On November 20, 2007, DEA published a Notice of Proposed Rulemaking (NPRM) (72 FR 65248) addressing two issues related to CMEA implementation. First, DEA proposed to eliminate the thresholds for distribution, importation, and exportation of pseudoephedrine and phenylpropanolamine; the threshold for distribution, importation, and exportation of ephedrine was eliminated previously. Limits on retail transactions

are set in the CMEA and were addressed in DEA's Interim Rule regarding the retail provisions of the CMEA (71 FR 56008, September 26, 2006; corrected at 71 FR 60609, October 13, 2006). Second, DEA proposed to clarify that all distribution, importation, and exportation transactions involving drug products containing ephedrine, pseudoephedrine, or phenylpropanolamine are regulated transactions.

The comment period for the NPRM closed on January 22, 2008. DEA received one comment on the NPRM.

Thresholds

Under the existing regulations (21 CFR 1310.04), the threshold for non-retail distribution, import, export, and international transactions of pseudoephedrine is 1 kilogram and for phenylpropanolamine, 2.5 kilograms. A single transaction or multiple transactions in a month with a single customer that equal or exceed the threshold are considered regulated transactions and trigger the reporting and recordkeeping requirements of 21 CFR part 1310. If DEA has not established a monthly threshold for a List I chemical, then all transactions must be reported. DEA has not established a threshold for ephedrine; thus all non-retail distribution, import, and export transactions involving ephedrine are already subject to recordkeeping and reporting requirements.

CMEA mandates that DEA establish the total annual need for ephedrine, pseudoephedrine, and phenylpropanolamine to be manufactured or imported each calendar year to provide for the estimated medical, scientific, research, and industrial needs of the United States, for lawful export requirements, and for the establishment and maintenance of reserve stocks (21 U.S.C. 826). These requirements apply equally to products containing these three List I chemicals as they do to the List I chemicals themselves. To limit the supply of the chemicals to the amount needed to meet the national need, CMEA requires DEA to establish import and production quotas for all three chemicals. DEA published regulations implementing procedures for import and production quotas for the List I chemicals ephedrine, pseudoephedrine, and phenylpropanolamine on July 10, 2007 (72 FR 37439; Final Rule 73 FR 73549, December 3, 2008). DEA established the 2008 assessment of annual national needs for the List I chemicals ephedrine, pseudoephedrine, and phenylpropanolamine on December

26, 2007 (72 FR 73361) and has established the assessment of annual national needs every year thereafter.

To obtain the information needed to assess the national need and set quotas to limit imports and production to meet that need, DEA identified two inadequacies regarding its existing regulations. First, persons who manufacture or import prescription drugs containing the chemicals are not registered. In a separate rulemaking, "Registration Requirements for Importers and Manufacturers of Prescription Drug Products Containing Ephedrine, Pseudoephedrine, or Phenylpropanolamine" [Docket No. DEA-294, RIN 1117-AB09] (73 FR 3432, January 18, 2008), DEA proposed to revise its registration requirements to cover manufacturers and importers of prescription drugs containing these chemicals and will issue quotas to them although the distribution and export of prescription drugs containing the chemicals will continue to be exempt from DEA regulatory control.

The second inadequacy involves the thresholds that apply to pseudoephedrine and phenylpropanolamine. To determine the annual national need and set quotas, DEA must obtain information on all imports and production involving the chemicals, not just those that exceed the existing thresholds. The existing thresholds, although relatively low, potentially allow a considerable market in the chemicals to continue unregulated. For example, under the current 1 kilogram (2.2 pound) threshold for pseudoephedrine, a person could import or distribute more than 2 pounds a month, or approximately 25 pounds a year, of pseudoephedrine without exceeding the threshold and triggering DEA's controls. Assuming a conservative 50 percent conversion of pseudoephedrine to methamphetamine, a person could annually manufacture approximately 12.5 pounds of methamphetamine with that total sum of sub-threshold quantities. DEA trend reporting for 2008 indicated that the national price for one pound of methamphetamine hydrochloride (powder) ranged from as low as \$5,000 per pound in the DEA New Orleans and Washington DC Field Divisions, to as much as \$26,000 and \$27,000 per pound in the DEA New York and Atlanta Field Divisions, respectively. To further implement the CMEA, this rule seeks to curb the availability of pseudoephedrine at the wholesale level for illicit purposes.

Additionally, under the current 2.5 kilogram (5.5 pound) threshold for phenylpropanolamine, a person could

import or distribute more than 5 pounds a month, or approximately 66 pounds a year of phenylpropanolamine without exceeding the threshold and triggering DEA's controls. Assuming a conservative 50 percent conversion of phenylpropanolamine to amphetamine, a person could annually manufacture approximately 33 pounds of amphetamine with that total sum of sub-threshold quantities. To the extent that amphetamine is marketed on the street as methamphetamine, amphetamine often has a street value comparable to methamphetamine. To further implement the CMEA, this rule seeks to curb the availability of phenylpropanolamine at the wholesale level for illicit purposes.

Currently, DEA is notified of all imports, exports, and international transactions of these chemicals which exceed the established thresholds or for which no threshold is established. DEA does not, however, receive import, export, and international transaction notifications for imports, exports, and international transactions of listed chemicals less than established thresholds. If DEA does not eliminate the threshold for imports, exports, and international transactions of pseudoephedrine and phenylpropanolamine, DEA will not have complete and accurate information regarding the quantities of these chemicals imported into, and exported from, the United States. Further, manufacturers and distributors are not required to maintain records of distributions of listed chemicals at or below established thresholds. Without the maintenance of these records, DEA will not have complete and accurate information regarding the quantities of these chemicals being distributed domestically.

Comments Regarding Removal of Thresholds for Pseudoephedrine and Phenylpropanolamine

DEA did not receive any comments regarding the proposed removal of thresholds for the List I chemicals pseudoephedrine and phenylpropanolamine and therefore, is finalizing those provisions as proposed.

Thus, to establish the controls that Congress mandated and limit imports and production to that needed for legitimate uses, DEA is eliminating the thresholds for all transactions involving the List I chemicals pseudoephedrine and phenylpropanolamine. As discussed previously, no threshold currently exists for transactions involving the List I chemical ephedrine; thus, all transactions are regulated. Any registrant manufacturing, distributing,

importing, or exporting pseudoephedrine or phenylpropanolamine, in any quantity, either as bulk chemicals or in over-the-counter drug products, will be subject to the reporting and recordkeeping requirements. Any manufacturer or importer of prescription drug products containing one of the chemicals will also be subject to reporting and recordkeeping requirements.

Importation of the chemicals is allowed only if it is within an import quota that the importer has applied for and been granted by DEA. The one exception to the import limits provided in the CMEA is that an individual may import not more than 7.5 grams in any 30-day period of a scheduled listed chemical product (*i.e.*, a product containing ephedrine, pseudoephedrine, or phenylpropanolamine which may be marketed or distributed lawfully in the United States under the Federal Food, Drug, and Cosmetic Act as a nonprescription drug) by means of the U.S. Postal Service or a private or commercial carrier (21 U.S.C. 844(a)).

The distribution and export of prescription drug products containing the chemicals are not covered because DEA will be able to obtain the information it needs for the assessment of annual national needs from importers and manufacturers of these products. DEA has not determined that prescription drug products are being diverted.

Regulated Transactions

The definition of "regulated transaction" as amended by CMEA (21 U.S.C. 802(39)(A)(iv)) excludes:

(iv) Any transaction in a listed chemical that is contained in a drug that may be marketed or distributed lawfully in the United States under the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 *et seq.*), subject to clause (v), unless—

(I) The Attorney General has determined under section 204 of the Act (21 U.S.C. 814) that the drug or group of drugs is being diverted to obtain the listed chemical for use in the illicit production of a controlled substance; and

(II) The quantity of the listed chemical contained in the drug included in the transaction or multiple transactions equals or exceeds the threshold established for that chemical by the Attorney General.

Section 814 (b) states that:

In removing a drug or group of drugs from exemption * * * the Attorney General shall consider, with respect to a drug or group of drugs that is

proposed to be removed from exemption—

(1) The scope, duration, and significance of the diversion;

(2) Whether the drug or group of drugs is formulated in such a way that it cannot be easily used in the illicit production of a controlled substance; and

(3) Whether the listed chemical can be readily recovered from the drug or group of drugs.

DEA in this rule is clarifying that nonprescription (OTC) drug products containing ephedrine, pseudoephedrine, and phenylpropanolamine do not qualify for the exemption from the definition of “regulated transaction” based on the three factors listed in 21 U.S.C. 814(b) for the reasons discussed below.

Evaluation of Statutory Factors for Removal of Exemption From the Definition of “Regulated Transaction”

Note: For a more detailed discussion of DEA’s analysis regarding each factor, see the NPRM preamble (72 FR 65248, November 20, 2007).

Factor 1: Scope, Duration, and Significance of Diversion

Throughout the late 1970s, methamphetamine was illicitly produced primarily through the use of the precursor phenylacetone (phenyl-2-propanone (P2P)) by outlaw motorcycle gangs in the United States. In response to the use of P2P, DEA controlled P2P as a schedule II controlled substance in 1980, under the immediate precursor provisions of the CSA, specifically 21 U.S.C. 811(e). Clandestine laboratory operators responded by developing a variety of synthetic methods for producing P2P and also migrated to the use of ephedrine as precursor material.

In 1989, DEA control of chemicals was initiated with passage of the Chemical Diversion and Trafficking Act of 1988 (CDTA) (Subtitle A of Title VI of Pub. L. 100–690). This law placed recordkeeping and reporting requirements on a wide variety of precursors and essential chemicals used in every aspect of clandestine drug manufacture, including bulk powder ephedrine, pseudoephedrine, and phenylpropanolamine. In response to the regulations, traffickers moved to the illicit use of single-entity ephedrine OTC tablets as an unregulated source of precursor material for the production of methamphetamine.

In the early 1990s, a number of well-publicized seizures of rogue businesses (and prosecutions of their owners) began to impact the tablet

manufacturing industry, and a loophole allowing the sale of single-entity ephedrine products was closed in late 1993 with the passage of the Domestic Chemical Diversion Control Act of 1993 (DCDCA) (Pub. L. 103–200).

In 1996, the existing controls on precursor and essential chemicals imposed by the CDTA and DCDCA were further tightened with the passage of the Comprehensive Methamphetamine Control Act of 1996 (MCA) (Pub. L. 104–237). What followed was a series of legislative actions on both the Federal and State levels to tighten controls on pharmaceutical products that serve as precursor material for clandestine methamphetamine laboratories. At the Federal level, this effort included passage of the Methamphetamine Anti-Proliferation Act of 2000 (MAPA) (Title XXXVI of Pub. L. 106–310). Today, however, ephedrine and pseudoephedrine OTC products continue to serve as the primary precursor source for the illicit production of methamphetamine, which has spread across the entire United States in epidemic proportions.

Current Seizures

As DEA discussed in the NPRM, methamphetamine remains the primary drug produced in illicit laboratories within the United States. Data from the El Paso Intelligence Center’s (EPIC) Clandestine Laboratory Database indicates that 10,022 methamphetamine laboratories were seized in calendar year 2004, 6,021 laboratories in calendar year 2005, 3,977 laboratories in calendar year 2006, 3,097 laboratories in calendar year 2007, and 3,924 laboratories in calendar year 2008 (as reported to EPIC through November 27, 2009). According to EPIC, from January 1, 2000, through December 31, 2008, there were at least 7,385 laboratories reportedly using ephedrine and 51,102 reportedly using pseudoephedrine as precursor material for methamphetamine production. Additionally EPIC reports the seizure of 48 amphetamine laboratories (using phenylpropanolamine) during the same period. The vast majority of these laboratories used pharmaceutical products containing pseudoephedrine, ephedrine, and phenylpropanolamine as the source of precursor material.

Illicit Uses

Factor 2: Whether the Drug or Group of Drugs Is Formulated in Such a Way That It Cannot Be Easily Used in the Illicit Production of a Controlled Substance

Factor 3: Whether the Listed Chemical Can Be Readily Recovered From the Drug or Group of Drugs

As DEA discussed in the NPRM, the production of methamphetamine from ephedrine or pseudoephedrine can be accomplished via a series of reactions using widely available “recipes” and can be accomplished with little or no chemistry expertise. A variety of different methods exist to convert the precursor material to methamphetamine. If very small batches are made, there is not even a requirement to heat the reactants. For example, quantities of ephedrine or pseudoephedrine, iodine, and red phosphorous can be reacted with the addition of water and small quantities of methamphetamine can be produced. For larger batches the reactants are combined and heated for several hours. A variety of different reagents can be used to make the conversion to methamphetamine if the precursors ephedrine and pseudoephedrine are obtained. These reactants can also be used to convert phenylpropanolamine to amphetamine. Manufacturing procedures are readily available on the Internet and even unskilled persons can obtain a 50–70 percent yield of methamphetamine or amphetamine.

Pseudoephedrine and ephedrine can also serve as precursor material for the manufacture of the schedule I controlled substance methcathinone. From January 1, 2000, through December 31, 2008, there were 202 methcathinone laboratory seizures reported to EPIC.

As DEA discussed in the NPRM, there is a common misconception in industry and among some in the public that OTC drug products, particularly pseudoephedrine or ephedrine products in combination with other medically active ingredients (“combo products”), are somehow less likely to be diverted or are less desirable among clandestine laboratory operators for the manufacture of methamphetamine. This is not the case.

Most of the clandestine laboratories found in the United States are using tablets, either single-entity or combination. In many of the methamphetamine exhibits analyzed by DEA analytical laboratories, the presence of antihistamines is detected, indicating that combination products were used in the reactions.

While the vast majority of clandestine laboratories seized have used tableted pseudoephedrine and ephedrine products, gel caps and liquid dosage form products can easily serve as the source of precursor material for the production of methamphetamine. DEA

scientific studies show that liquid, gel cap, and combination products are easily used as the source of precursor material and the pseudoephedrine/ephedrine from these products can be easily extracted with appropriate reagents/solvents. These reagents/solvents are all readily available at hardware and auto parts stores in the United States.

The controlled substances produced from these chemicals, methamphetamine and amphetamine, have a high abuse potential. The public health consequences of the manufacture, trafficking, and abuse of these two substances are well known and documented.

Comments Regarding Clarification of Regulated Transactions

In response to the November 20, 2007, NPRM (72 FR 65248), DEA received one comment. The commenter expressed concerns regarding the findings made by DEA that concluded that OTC products containing either pseudoephedrine or ephedrine (in combination with other active ingredients) are (1) Easily used in the illicit production of a controlled substance (e.g. methamphetamine) and (2) the listed chemical can be readily recovered. The commenter further expressed concerns regarding the applicability of these findings to combination products in the form of liquids, gel caps and solid dosage forms. The commenter expressed concerns that the NPRM did not provide sufficient data to substantiate DEA's findings, including OTC combination product seizures and evidence of diversion of such materials. Additionally, the commenter asserted that ephedrine/guaifenesin combination products warrant special treatment and should not be subject to the proposed rulemaking.

DEA disagrees with the commenter's basic premise that ephedrine and pseudoephedrine combination products (in liquid, soft-gel capsule, and solid dosage form) have less utility in clandestine laboratory processing of methamphetamine. DEA laboratory extraction studies have scientifically demonstrated that such materials are easily used as precursor material in the production of methamphetamine. Additionally, such materials have been identified at seized clandestine methamphetamine laboratories, and contaminants identified in seized methamphetamine exhibits document the use of such products as precursor material. These data demonstrate that these materials are (1) easily used in the illicit production of methamphetamine and (2) the listed chemical can be

readily recovered. This has been documented in both DEA laboratory studies and in actual seizures.

Use of OTC Combination Products as Precursor Material

DEA's Office of Forensic Sciences has performed extraction studies demonstrating that combination OTC pseudoephedrine/ephedrine products (in soft-gel capsules, liquids, and solid forms, and containing combination ingredients) can be readily extracted and utilized as the source of precursor material for production of methamphetamine. These studies illustrated that such extractions were readily achievable and precursor materials were readily extractable.

Furthermore, the DEA Special Testing and Research Laboratory conducts in-depth analyses of seized methamphetamine samples. The information obtained from these analyses is derived from samples obtained and analyzed from a selective sampling of domestic and foreign seizures, and is not necessarily representative of all methamphetamine samples submitted to the DEA laboratory system. Among other things, the in-depth analytical procedures enable analysts to determine when combination OTC ephedrine and/or pseudoephedrine products are used as the source of precursor chemicals, due to impurities present in seized methamphetamine. The crude isolation procedures used in clandestine methamphetamine laboratories to extract l-ephedrine or d-pseudoephedrine from OTC products usually co-extract some of the other active ingredients commonly found in combination products. As a result, methamphetamine samples often contain one or more of the following co-ingredients: brompheniramine, chlorpheniramine, triprolidine, loratadine, carbinoxamine, and other common co-ingredients or their respective reaction by-products. Between Calendar Year 2005 and Calendar Year 2007, combination ephedrine and pseudoephedrine products were utilized as precursor material in 760 out of 1343 samples analyzed. For the reporting period ending July 2009, 78 out of 145 additional methamphetamine samples analyzed contained these co-ingredients, therefore illustrating that 54 percent of these samples were made using combination ephedrine or pseudoephedrine products.

Additionally, DEA's System to Retrieve Information on Drug Evidence (STRIDE) indicates that such products have been utilized as precursor material

in the manufacture of methamphetamine. For the period January 2004 through November 2009, approximately 725 methamphetamine exhibits analyzed by DEA laboratories contained the common OTC combination product ingredients chlorpheniramine, diphenhydramine, guaifenesin or triprolidine. The number of guaifenesin exhibits accounted for approximately 5 percent of these samples. For the period January 2004 through November 2009, approximately 299 additional exhibits were identified as containing ephedrine and/or pseudoephedrine in combination with guaifenesin.

Based upon DEA scientific extraction studies, actual seizures of OTC ephedrine and/or pseudoephedrine combination products (including gel capsules, liquids and tablets) and the analysis of seized methamphetamine containing co-ingredients commonly found in OTC products, DEA finds that such materials are (1) Easily used in the illicit production of a controlled substance (e.g., methamphetamine) and (2) the listed chemical can be readily recovered. DEA therefore finds that these sources of precursor material should be subject to regulatory controls under the CSA.

Findings

Therefore, based on the above discussion, the Administrator of the Drug Enforcement Administration, under the authority delegated by the Attorney General, finds, after considering the factors specified in 21 U.S.C. 814(b), that drug products containing the List I chemicals ephedrine, pseudoephedrine, and phenylpropanolamine are being diverted for the illicit production of controlled substances, namely methamphetamine and amphetamine. As DEA has discussed, these products have a demonstrated history over the past 20 years of diversion for illicit purposes. These List I chemicals are diverted regardless of formulation—liquid, nonliquid, gel capsule—and regardless of dosage strength. Accordingly, the Administrator of the Drug Enforcement Administration removes drug products containing the List I chemicals ephedrine, pseudoephedrine, and phenylpropanolamine from exemption from the definition of "regulated transaction" under 21 U.S.C. 802(39)(a)(iv). As such, unless otherwise exempted, such materials are subject to the chemical regulatory control provisions of the CSA. DEA is adding a new section 1310.14 that removes these drugs from the exemption.

The CSA has specifically exempted retail transactions involving scheduled listed chemical products from the definition of regulated transaction (21 U.S.C. 802(39)(a)(v)) and established a separate set of regulations, 21 CFR part 1314, that control those retail transactions (71 FR 56008, September 26, 2006; corrected at 71 FR 60609, October 13, 2006).

Technical Correction

While drafting this rulemaking, DEA became aware of an inaccurate citation in 21 CFR 1310.10, the section paralleling the criteria to be considered in evaluating the statutory factors for removal of exemption from the definition of "regulated transaction" at 21 U.S.C. 814 and discussed above. Specifically, the definition of "regulated transaction" cited in 21 CFR 1310.10 is inaccurate. Therefore, to alleviate any confusion, DEA is correcting this citation.

Regulatory Certifications

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. 601–612). Without this rule, DEA would not be able to effectively implement the quota and import provisions of CMEA.

As DEA has demonstrated throughout this document, traffickers and others in search of the chemicals necessary for clandestine manufacture of methamphetamine and amphetamine, are actively looking to exploit any loophole in chemical controls.

DEA notes that the effect of eliminating the thresholds for pseudoephedrine and phenylpropanolamine could impose a minimal burden on regulated entities. Although it is likely that many of the registrants who handle the two chemicals are small businesses under the Small Business Administration definition of small entities, the changes impose virtually no burden on these entities for three reasons. First, most, if not all, legitimate transactions at the import, export, manufacturing, and distribution level are in excess of the previous thresholds. Second, although it is possible that some registrants may have some transactions that will be newly regulated, the recordkeeping for these can be met with standard business records. The only information required in records for regulated transactions is the name and address of the seller and purchaser (plus their DEA registration numbers, if applicable); the date of the

transaction; the name, quantity, and form of packaging of the listed chemical; the method of transfer; and the method of identification used by the customer and any unique identification number associated with the identification. This information is normally included on purchase orders or invoices and the shipping papers and is needed to complete and track the transaction. As long as the purchaser can extract the records for examination, if necessary, no additional effort is needed. Because almost all business records for manufacturers, importers, and distributors are now generated and transmitted electronically, DEA does not expect that any registrant will need additional recordkeeping.

Third, if any person is importing or exporting in very small quantities, there may be some additional import/export declarations required, but these forms require less than half an hour to complete and file. The only other requirement is to report suspicious transactions. These reports also require less than a half hour to complete and file.

As noted above, DEA does not believe that legitimate importers or exporters are handling such small quantities. The purpose of this rule is to close a loophole that could be exploited by those seeking the chemicals for illicit purposes and to ensure that DEA can accurately assess the legitimate need. The Deputy Administrator, therefore, certifies that the rule will not have a significant economic impact on a substantial number of small entities.

Executive Order 12866

The Deputy Administrator further certifies that this rulemaking has been drafted in accordance with the principles in Executive Order 12866 section 1(b). It has been determined that this is "a significant regulatory action." Therefore, this action has been reviewed by the Office of Management and Budget. This rule supports implementation of provisions of the CMEA. The CMEA is expansive in its breadth, essentially reclassifying ephedrine, pseudoephedrine, and phenylpropanolamine as schedule II controlled substances for purposes of importation and production, imposes new retail restrictions on these products, and mandates new domestic and import quotas. Without this rule, traffickers could exploit below-threshold transactions, which are not reported to DEA and for which records are not required to be maintained, to divert valuable quantities of pseudoephedrine and phenylpropanolamine for the

clandestine manufacture of methamphetamine and/or amphetamine. Further, without this rule, DEA will not have complete information on which to base its assessment of the annual national needs for the List I chemicals ephedrine, pseudoephedrine, and phenylpropanolamine as DEA does not receive information regarding below-threshold transactions. This lack of information would create a loophole in the quota system, and would prevent DEA from fulfilling its legislative mandate that imports of pseudoephedrine and phenylpropanolamine be prohibited except for medical, scientific, or other legitimate purposes. Without this rule, DEA will not be able to effectively and fully implement the quota and import provisions of the CMEA.

As discussed above, DEA does not anticipate that this change will impose more than the minimal costs that would be associated with reporting transactions that the registrant thought suspicious and possibly filing forms for import and export notifications. The benefits of the rule are those associated with controlling access to chemicals used to manufacture methamphetamine, and other controlled substances, illicitly. As has been discussed extensively throughout this document, traffickers and others are actively looking to exploit any loophole in chemical controls to continue their operations. As noted previously, the current thresholds could permit a person to divert approximately 25 pounds of pseudoephedrine and 66 pounds of phenylpropanolamine annually, without exceeding existing thresholds. This rule closes a loophole that could result in the undocumented diversion of these chemicals for illicit production of significant quantities of methamphetamine and/or amphetamine. As noted previously in this rule, below-threshold transactions are not documented to DEA; the diversion of below-threshold quantities of these precursor chemicals could result in the illicit production of significant quantities of methamphetamine and/or amphetamine.

Executive Order 12988

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

Executive Order 13132

This rulemaking does not 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.

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.

Paperwork Reduction Act

This rule requires that records be maintained regarding distributions of the List I chemicals pseudoephedrine and phenylpropanolamine. These records are maintained as a normal course of business.

The rule also reduces the thresholds for the List I chemicals pseudoephedrine and phenylpropanolamine from 1 kilogram and 2.5 kilograms, respectively, to zero, thereby requiring that DEA receive advance notification of all importations and exportations of these List I chemicals. DEA notes that it already

receives some Import/Export Declarations if the cumulative amount of the transactions exceeds the thresholds on a monthly basis. Therefore, DEA does not believe that this change will significantly increase the burden associated with this information collection. Specifically, DEA estimates that 53 additional export notifications and 53 additional export return declarations will be received annually. Further, DEA estimates that 50 additional import declarations and 55 additional import return declarations will be received annually. DEA assumes 10 percent of all imports will not be transferred in the first thirty days and will necessitate submission of a subsequent return declaration. The receipt of these additional forms increases the hour burden by 55 hours annually. DEA did not receive any comments regarding the Paperwork Reduction Act aspects of the Notice of Proposed Rulemaking. Therefore, DEA is revising its existing information collection [OMB approval number 1117-0023 "Import/Export Declaration for List I and List II Chemicals", DEA Form 486] to reflect the increased burden associated with receipt of these import/export declarations.

The Department of Justice, Drug Enforcement Administration, submitted the following information collection request to the Office of Management and Budget for review and clearance in accordance with review procedures of the Paperwork Reduction Act of 1995. The proposed information collections were published in the NPRM to obtain comments from the public and affected agencies

Overview of Information Collection 1117-0023

(1) *Type of Information Collection:* Revision of a Currently Approved Collection.

(2) *Title of the Form/Collection:* Import/Export Declaration for List I and List II Chemicals.

(3) Agency form number, if any, and the applicable component of the Department sponsoring the collection:

Form number: DEA Form 486 and DEA Form 486A.

Component: Office of Diversion Control, Drug Enforcement Administration, U.S. Department of Justice

(4) Affected public who will be asked or required to respond, as well as a brief abstract:

Primary: Business or other for-profit.

Other: None.

Abstract: Persons importing, exporting, and conducting international transactions with List I and List II chemicals must notify DEA of those transactions in advance of their occurrence, including information regarding the person(s) to whom the chemical will be transferred and the quantity to be transferred. Persons must also provide return declarations, confirming the date of the importation, exportation, or international transaction and transfer, and the amounts of the chemical transferred. For the List I chemicals ephedrine, pseudoephedrine, and phenylpropanolamine, importers must report all information known to them on the chain of distribution of the chemical from the foreign manufacturer to the United States importer. This information is used to prevent shipments not intended for legitimate purposes.

(5) An estimate of the total number of respondents and the amount of time estimated for an average respondent to respond: A respondent may submit multiple responses. The table below presents information regarding the number of respondents, responses, and associated burden hours.

	Number of respondents	Number of responses	Average time per response	Total
Form 486 (export)	193	10,380	0.283 hour (17 minutes)	2,941 hours.
Form 486 (export Return Declaration)	193	10,380	0.166 hour (10 minutes)	1,730 hours.
Form 486 (import)	120	1,268	0.333 hour (20 minutes)	422.6 hours.
Form 486 (import return declaration)*	120	1,395	0.2 hour (12 minutes)	279 hours.
Form 486A (import)*	30	400	0.4 hour (24 minutes)	160 hours.
Form 486A (import return declaration)*	30	440	0.2 hour (12 minutes)	88 hours.
Form 486 (international transaction)	14	14	0.2 hour (12 minutes)	2.8 hours.
Form 486 (international transaction return declaration)	14	14	0.08 hour (5 minutes)	1.2 hours.
Quarterly reports for imports of acetone, 2-butanone, and toluene.	110	440	0.5 hour (30 minutes)	220 hours.
Total	193			5,844.6 hours.

*DEA assumes 10 percent of all imports will not be transferred in the first 30 days and will necessitate submission of a subsequent return declaration.

(6) An estimate of the total public burden (in hours) associated with the collection: 5,845 annual burden hours.

If additional information is required, contact: Lynn Bryant, Department Clearance Officer, United States Department of Justice, Justice Management Division, Policy and Planning Staff, Patrick Henry Building, Suite 1600, 601 D Street, NW., Washington, DC 20530.

List of Subjects in 21 CFR Part 1310

Drug traffic control, Exports, Imports, Reporting and recordkeeping requirements.

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

PART 1310—RECORDS AND REPORTS OF LISTED CHEMICALS AND CERTAIN MACHINES

■ 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 1310.04 is amended by revising paragraphs (f)(1)(i) table and (ii), (g)(1)(i) through (vii), and adding paragraphs (g)(1)(viii) and (ix) to read as follows:

§ 1310.04 Maintenance of records.

- * * * * *
- (f) * * *
- (1) * * *
- (i) * * *

Code	Chemical	Threshold by base weight
8522	N-Acetylanthranilic acid, its esters, and its salts	40 kilograms.
8530	Anthranilic acid, its esters, and its salts	30 kilograms.
8256	Benzaldehyde	4 kilograms.
8735	Benzyl cyanide	1 kilogram.
8675	Ergonovine and its salts	10 grams.
8676	Ergotamine and its salts	20 grams.
8678	Ethylamine and its salts	1 kilogram.
6695	Hydriodic acid	1.7 kilograms (or 1 liter by volume).
8704	Isosafrole	4 kilograms.
8520	Methylamine and its salts	1 kilogram.
8502	3,4-Methylenedioxyphenyl-2-propanone	4 kilograms.
8115	N-Methylephedrine, its salts, optical isomers, and salts of optical isomers	1 kilogram.
8119	N-Methylpseudoephedrine, its salts, optical isomers, and salts of optical isomers.	1 kilogram.
6724	Nitroethane	2.5 kilograms.
8317	Norpseudoephedrine, its salts, optical isomers, and salts of optical isomers	2.5 kilograms.
8791	Phenylacetic acid, its esters, and its salts	1 kilogram.
2704	Piperidine and its salts	500 grams.
8750	Piperonal (also called heliotropine)	4 kilograms.
8328	Propionic anhydride	1 gram.
8323	Safrole	4 kilograms.

(ii) For List I chemicals that are contained in scheduled listed chemical products as defined in § 1300.02(b)(34)(i) of this chapter, the thresholds established in paragraph (g) of this section apply only to non-retail distribution, import, and export. Sales of these products at retail are subject to the requirements of part 1314 of this chapter.

* * * * *

- (g) * * *
- (1) * * *

(i) Ephedrine, its salts, optical isomers, and salts of optical isomers;

(ii) Gamma-Butyrolactone (Other names include: GBL; Dihydro-2(3H)-furanone; 1,2-Butanolide; 1,4-Butanolide; 4-Hydroxybutanoic acid lactone; gamma-hydroxybutyric acid lactone)

(iii) Hypophosphorous acid and its salts (including ammonium hypophosphite, calcium hypophosphite, iron hypophosphite, potassium hypophosphite, manganese hypophosphite, magnesium hypophosphite, and sodium hypophosphite)

(iv) Iodine

(v) N-phenethyl-4-piperidone (NPP)

(vi) Pseudoephedrine, its salts, optical isomers, and salts of optical isomers

(vii) Phenylpropanolamine, its salts, optical isomers, and salts of optical isomers

(viii) Red phosphorus

(ix) White phosphorus (Other names: Yellow Phosphorus)

* * * * *

■ 3. Section 1310.10 is amended by revising paragraph (a) introductory text to read as follows:

§ 1310.10 Removal of the exemption of drugs distributed under the Food, Drug and Cosmetic Act.

(a) The Administrator may remove from exemption under § 1300.02(b)(28)(i)(D) of this chapter any drug or group of drugs that the Administrator finds is being diverted to obtain a listed chemical for use in the illicit production of a controlled substance. In removing a drug or group of drugs from the exemption the Administrator shall consider:

* * * * *

■ 4. Section 1310.14 is added to read as follows:

§ 1310.14 Removal of exemption from definition of regulated transaction.

The Administrator finds that the following drugs or groups of drugs are being diverted to obtain a listed chemical for use in the illicit production of a controlled substance and removes the drugs or groups of drugs from exemption under § 1300.02(b)(28)(i)(D) of this chapter pursuant to the criteria listed in § 1310.10 of this part:

(a) Nonprescription drugs containing ephedrine, its salts, optical isomers, and salts of optical isomers.

(b) Nonprescription drugs containing phenylpropanolamine, its salts, optical isomers, and salts of optical isomers.

(c) Nonprescription drugs containing pseudoephedrine, its salts, optical isomers, and salts of optical isomers.

Dated: June 19, 2010.

Michele M. Leonhart,
Deputy Administrator.

[FR Doc. 2010-16388 Filed 7-6-10; 8:45 am]

BILLING CODE 4410-09-P