Environmental Analysis

12. Commission regulations require that an Environmental Assessment or an Environmental Impact Statement be prepared for any Commission action that may have a significant adverse effect on the human environment.[9] The Commission has categorically excluded certain actions from this requirement as not having a significant adverse effect on the human environment. No environmental consideration is necessary for the promulgation of a rule concerning information gathering, analysis or dissemination.[10] Because this NOPR concerns the elimination of an information collection, no environmental consideration is necessary.

Regulatory Flexibility Act Certification

13. The Regulatory Flexibility Act of 1980 (RFA) [11] generally requires either a description and analysis of a rule that will have a significant economic impact on a substantial number of small entities or a certification that the rule will not have a significant economic impact on a substantial number of small entities. Most utilities to which this proposed rule applies would not fall within the RFA's definition of small entity.[12] Consequently, the Commission certifies that this NOPR, if adopted, will not have a significant economic impact on a substantial number of small entities. Moreover, elimination of the Form 423 will reduce the burden on all entities, including small entities.

Comment Procedures

14. The Commission invites interested persons to submit comments on the changes proposed in this NOPR to be adopted, including any related matters or alternative proposals that commenters may wish to discuss. Comments are due December 20, 2007. Comments must refer to Docket No. RM07–18–000, and must include, in the comments, the commenter's name, the organization represented, if applicable, and the address. Comments may be filed either in electronic or paper format.

15. Comments may be filed electronically via the eFiling link found under the Documents & Filings heading on the Commission's Web site at *http://www.ferc.gov*. The Commission accepts most standard word processing formats, but requests commenters to submit comments in a text-searchable format rather than a scanned image format. Commenters filing electronically do not need to make a paper filing. Commenters that are not able to file comments electronically must send an original and 14 copies of their comments to: Federal Energy Regulatory Commission, Secretary of the Commission, 888 First Street NE., Washington, DC 20426.

16. All comments will be placed in the Commission's public files and may be viewed, printed, or downloaded remotely as described in the Document Availability section below. Commenters on this proposal are not required to serve copies of their comments on other commenters.

Document Availability

17. In addition to publishing the full text of this document in the **Federal Register**, the Commission provides all interested persons an opportunity to view and/or print the contents of this document via the Internet through the Commission's Home Page (*http://www.ferc.gov*) and in the Commission's Public Reference Room during normal business hours (8:30 a.m. to 5 p.m. Eastern time) at 888 First Street, NE., Room 2A, Washington, DC 20426.

18. From the Commission's Home Page on the Internet, the full text of this document is available in the Commission's document management system, eLibrary, in PDF and Microsoft Word format for viewing, printing, and downloading. To access this document in eLibrary, type the docket number (excluding the last three digits of the docket number), in the Docket Number field.

19. User assistance is available for eLibrary and the Commission's Web site during normal business hours. For assistance, please contact FERC Online Support at (202) 502–6652 (toll-free at 1–866–208–3676), e-mail *ferconlinesupport@ferc.gov*, or contact the Public Reference Room at (202) 502–8371, TTY (202) 502–8659, e-mail: *public.referenceroom@ferc.gov*.

List of Subjects

18 CFR Part 141

Electric power, Reporting and recordkeeping requirements.

18 CFR Part 385

Administrative practice and procedure, Electric power, Penalties, Pipelines, Reporting and recordkeeping requirements

By direction of the Commission.

Kimberly D. Bose,

Secretary.

In consideration of the foregoing, the Commission proposes to amend parts 141 and 385, Chapter I, Title 18, *Code of Federal Regulations*, as follows:

PART 141—STATEMENTS AND REPORTS (SCHEDULES)

1. The authority citation for part 141 continues to read as follows:

Authority: 15 U.S.C. 79; 16 U.S.C. 791a–828c, 2601–2645; 31 U.S.C. 9701; 42 U.S.C. 7101–7352.

§ 141.61 [Removed and reserved]

2. Section 141.61 is removed and reserved.

PART 385—RULES OF PRACTICE AND PROCEDURE

3. The authority citation for part 385 continues to read as follows:

Authority: 5 U.S.C. 551–557; 15 U.S.C. 717–717z, 3301–3432; 16 U.S.C.791a–825v, 2601–2645; 28 U.S.C. 2461; 31 U.S.C. 3701, 9701; 42 U.S.C. 7101–7352, 16441, 16451–16463; 49 U.S.C. 60502; 49 App. U.S.C. 1–85 (1988).

§ 385.2011 [Amended]

4. Section 385.2011, paragraph (a)(8) is removed and reserved.

[FR Doc. E7–22550 Filed 11–19–07; 8:45 am]

BILLING CODE 6717–01–P

[9] *Regulations Implementing the National Environmental Policy Act*, Order No. 486, 52 FR 47897 (Dec. 17, 1987), FERC Stats. & Regs. ¶ 30,783 (1987) (*codified at* 18 CFR Part 380).

[10] 18 CFR 380.4(a)(5).

[11] 5 U.S.C. 601–12.

[12] 5 U.S.C. 601(3), *citing* to section 3 of the Small Business Act, 15 U.S.C. 632. Section 3 of the Small Business Act defines a ''small business concern'' as a business that is independently owned and operated and that is not dominant in its field of operation. The Small Business Size Standards component of the North American Industry Classification System (NAICS) defines a small electric utility as one that, including its affiliates, is primarily engaged in the generation, transmission, and/or distribution of electric energy for sale and whose total electric output for the preceding fiscal year did not exceed four million MWh. 13 CFR 121.201.

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

21 CFR Part 1310

[Docket No. DEA–296P]

RIN 1117–AB10

Removal of Thresholds for the List I Chemicals Pseudoephedrine and Phenylpropanolamine

AGENCY: Drug Enforcement Administration, Department of Justice.

ACTION: Notice of proposed rulemaking.

SUMMARY: The Drug Enforcement Administration (DEA) is proposing to remove 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: Written comments must be postmarked, and electronic comments must be sent, on or before January 22, 2008.

ADDRESSES: To ensure proper handling of comments, please reference ''Docket No. DEA–296'' on all written and electronic correspondence. Written comments being sent via regular mail should be sent to the Deputy Assistant Administrator, Office of Diversion Control, 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, 8701 Morrissette Drive, Springfield, VA 22152. Comments may be directly sent 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 formats 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* and in the Drug Enforcement Administration's public docket. Such information includes personal identifying information (such as your 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 or made available in the public docket, 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 or made available in the public docket in the first paragraph of your comment and identify what 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 or made available in the public docket, 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 online or made available in the public docket.

Personal identifying information and confidential business information identified and located as set forth above will be redacted and the comment, in redacted form, will be posted online and placed in the Drug Enforcement Administration's public docket file. 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: Mark W. Caverly, Chief, Liaison and Policy Section, Office of Diversion Control, Drug Enforcement Administration, Washington, DC 20537 at (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 Controlled Substances Import and Export Act (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 1399. 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.

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 (products 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. The CMEA also subjects material containing ephedrine, pseudoephedrine, and phenylpropanolamine to manufacturing and import restrictions. Specifically, CMEA amended section 1002 of the Controlled Substances Act (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. 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. Further, 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 § 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 § 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.

Ephedrine, Pseudoephedrine, and Phenylpropanolamine

The List I chemicals ephedrine, pseudoephedrine, and phenylpropanolamine all serve as precursor chemicals for the illicit manufacture of controlled substances. Ephedrine and pseudoephedrine are the primary precursors used in the synthesis of the controlled substances 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 OTC in combination with the active ingredient guaifenesin.

As a prescription drug, ephedrine is used in parenteral (injectable) form in hospitals as part of an anesthesiology kit. 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 provisions for OTC 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 This Rule

In this rule, DEA is addressing two issues related to CMEA implementation. First, DEA is proposing 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 is proposing to clarify that all distribution, importation, and exportation transactions involving drug products containing ephedrine, pseudoephedrine, or phenylpropanolamine are regulated transactions.

Thresholds

Under the existing regulations (21 CFR 1310.04), the threshold for non-retail distribution, import, and export 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. DEA has not established a threshold for ephedrine; 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. 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 its proposed 2007 assessment of annual needs for ephedrine, pseudoephedrine, and phenylpropanolamine on October 19, 2006 (71 FR 61801). DEA published regulations implementing procedures for import and production quotas on July 10, 2007 (72 FR 37439).

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 another rulemaking, ''Registration Requirements for List I Chemicals'' [Docket No. DEA–294, RIN 1117–AB09], DEA is revising 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 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, would 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 low 50 percent conversion rate of pseudoephedrine to methamphetamine, a person could annually manufacture approximately 12.5 pounds of methamphetamine with that total sum of sub-threshold quantities. DEA analysis for 2006 estimates that the national range in the street price for one pound of methamphetamine (powder) is between $2,500 and $48,000. To further implement the Combat Methamphetamine Epidemic Act of 2005, 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 low 50 percent conversion rate of phenylpropanolamine to amphetamine, a person could annually manufacture approximately 33 pounds of amphetamine with that total sum of sub-threshold quantities. The resulting amphetamine would have street value comparable to methamphetamine. To further implement the Combat Methamphetamine Epidemic Act of 2005, this rule seeks to curb the availability of phenylpropanolamine at the wholesale level for illicit purposes.

Currently, DEA is notified of all imports and exports of these chemicals which exceed the established thresholds or for which no threshold is established. DEA does not, however, receive import and export notifications for imports and exports of listed chemicals less than established thresholds. If DEA does not eliminate the threshold for imports and exports 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.

To establish the controls that Congress mandated and limit imports and production to that needed for legitimate uses, DEA is proposing to eliminate 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, would be subject to the reporting and recordkeeping requirements. Any manufacturer or importer of prescription drug products containing one of the chemicals would 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 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 (''over-the-counter'') 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).

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

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.

Trafficking groups widely used a procedure for converting ephedrine to methamphetamine that employed hydriodic acid and red phosphorus (HI/Red P). Use of the HI/Red P technique

(also known as a ''hydriodic acid reduction'' or ''ephedrine reduction'') exploded across the western and southwestern United States through the 1980s, and by 1990 accounted for 90 percent of all clandestine laboratory seizures reported to DEA.

With the rapid increase in the use of the HI/Red P technique through the 1980s came increased law enforcement pressure. Purchases of bulk ephedrine were loosely monitored, and legitimate domestic suppliers of ephedrine began restricting or denying sales of bulk ephedrine to questionable buyers. In response, clandestine manufacturers turned to foreign suppliers, and thefts and diversion of bulk shipments of ephedrine also began to increase across the United States.

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.

The extraction of the precursor chemical ephedrine from OTC tablets was an easy task. The tablets were simply ground using a kitchen blender and ephedrine extracted with an appropriate solvent. Upon filtration and evaporation of the solution, the traffickers were able to isolate the ephedrine bulk powder. Traffickers began widely exploiting what became known as the ''tablet loophole.''

Soon after, DEA began encountering ''ephedrine extraction laboratories'' whose primary purpose was to recover ephedrine from OTC tablets and capsules, either for resale on the black market or for use in associated clandestine methamphetamine laboratories. Many laboratories combined ephedrine extraction and methamphetamine production.

Over the next three years, a number of well-publicized seizures of rogue businesses (and prosecutions of their owners) began to impact the tablet manufacturing industry, and the 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 efforts to circumvent the provisions of the DCDCA, OTC tablet manufacturers began marketing new ephedrine combination products (i.e., ephedrine/guaifenesin tablets), which were exempt from DCDCA controls. The most dramatic shift forced by the CDTA and DCDCA, however, was a rapid transition from ephedrine to pseudoephedrine as the primary precursor for illicit methamphetamine manufacture. Although bulk pseudoephedrine was formally controlled under the CDTA in 1989, OTC products containing pseudoephedrine remained exempt under both the CDTA and DCDCA. In contrast to ephedrine, pseudoephedrine was present in a wide variety of pharmaceutical products, including hundreds of OTC cold and allergy preparations, and formal monitoring and control was considered (at that time) to be problematic. OTC pseudoephedrine-containing products, therefore, represented an easy precursor source for clandestine laboratory operators. By the mid-1990s, illicit methamphetamine laboratories using pseudoephedrine surpassed those still using ephedrine.

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

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 more than 10,010 methamphetamine laboratories were seized in calendar year 2004 and 5,883 laboratories in calendar year 2005 (as reported to EPIC through 05/08/07). According to EPIC, from January 2000 through December 2006, there were 7,087 laboratories reportedly using ephedrine and 46,290 reportedly using pseudoephedrine as precursor material for methamphetamine production. Additionally EPIC reports the seizure of 52 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.

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.

Note: Pseudoephedrine and ephedrine can also serve as precursor material for the manufacture of the schedule I controlled substance methcathinone. From January 2000 through December 2006, there were 165 methcathinone laboratory seizures reported to EPIC.

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 cooks 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.

Findings

Therefore, based on the above discussion, the Administrator of the Drug Enforcement Administration, pursuant to the authority delegated by the Attorney General, finds, pursuant to the criteria 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, pursuant to the authority delegated by the Attorney General, 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 would be subject to the chemical regulatory control provisions of the CSA. DEA is proposing to add a new section 1310.14 removing 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 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 proposing to correct 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 will 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.

As discussed above, the current thresholds create a loophole that could be exploited by traffickers who can turn below-existing-threshold quantities of List I chemicals into valuable, sought-after quantities of methamphetamine and/or amphetamine. The diversion of below-threshold quantities of these precursor chemicals could result in the illicit production of significant quantities of methamphetamine and/or amphetamine. CMEA was enacted to prevent this illicit production. Congress specifically imposed a 3.6 gram daily sales limit, and a 9 gram 30-day purchase limit for all transactions involving scheduled listed chemical products, as well as a 7.5 gram 30-day sales limit for sales of scheduled listed chemical products made by mobile retail vendors and mail order distributors. Congress, through the CMEA, also limited the quantity of scheduled listed chemical products an individual may import into the United States to not more than 7.5 grams during a 30-day period by means of shipping through any private or commercial carrier or the Postal Service. Congress further limited importation of ephedrine, pseudoephedrine, and phenylpropanolamine, prohibiting all imports except ''such quantities * * * as the Attorney General finds to be necessary to provide for medical, scientific, or other legitimate purposes,'' (21 U.S.C. 952(a)(1)). It is inconsistent with Congressional intent to limit retail sales and purchases, and importation, of scheduled listed chemical products while allowing producers and traffickers to import or purchase from distributors quantities 100 times greater than retail sales limits without subjecting those transactions to any controls.

As noted previously, below-threshold transactions are not documented to DEA; thus, DEA has no knowledge of the movement, including importation and exportation, of below-threshold quantities of pseudoephedrine and phenylpropanolamine. Specifically, non-retail distribution, import, and export transactions involving less than 1 kilogram of pseudoephedrine (approximately 2.2 pounds), or less than 2.5 kilograms of phenylpropanolamine (approximately 5.5 pounds), per month per customer would be exempt from DEA recordkeeping and reporting requirements. DEA cannot monitor, and does not receive reports on, these import, export, and distribution transactions. As discussed previously, the diversion of below-threshold quantities of these precursor chemicals could result in the illicit production of significant quantities of methamphetamine and/or amphetamine.

Not removing the thresholds would also create a loophole in the system of import and production quotas established by the CMEA and implemented in an Interim Final Rule with Request for Comment (72 FR 37439, July 10, 2007). Without the reporting of all such transactions involving ephedrine, pseudoephedrine, and phenylpropanolamine to DEA, it would be more difficult for DEA to establish an assessment of annual national needs and to administer individual quotas for these List I chemicals. DEA would have incomplete information regarding these chemicals on which to base its assessments and quotas.

Finally, this rule seeks to clarify that ephedrine, pseudoephedrine, and phenylpropanolamine have been, and continue to be, diverted for the illicit manufacture of controlled substances. By making this statement, this document hereby would formally

include ephedrine, pseudoephedrine, and phenylpropanolamine, and drug products containing ephedrine, pseudoephedrine, and phenylpropanolamine, within the scope of the definition of ''regulated transaction'' found at 21 U.S.C. 802(39). This rule is necessary to avoid possible confusion in interpreting and applying the CMEA definition of ''regulated transaction.''

DEA notes that the effect of eliminating the thresholds will 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. DEA does not expect any new registrations to result from the change. 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 would be to report suspicious small 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. DEA, 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 scheduled listed chemicals, 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 would 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 small 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 would require 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 proposes to reduce 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 30 days and will necessitate submission of a subsequent return declaration. The receipt of these additional forms increases the hour burden by 34 hours annually. 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, has 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 are published to obtain comments from the public and affected agencies. All comments and suggestions, or questions regarding additional information, to include obtaining a copy of the information collection instrument with instructions, should be directed to Mark W. Caverly, Chief, Liaison and Policy Section, Office of Diversion Control, Drug Enforcement Administration, Washington, DC 20537.

Written comments and suggestions from the public and affected agencies concerning the collection of information are encouraged. Your comments on the information collection-related aspects of this rule should address one or more of the following four points:

(1) Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

(2) Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;

(3) Enhance the quality, utility, and clarity of the information to be collected; and

(4) Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, e.g., permitting electronic submission of responses.

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.

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. 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 below table presents information regarding the number of respondents, responses, and associated burden hours.

	Number of respondents	Number of responses	Average time per response	Total (hours)
.				
Form 486 (export)	239	8,050	0.2 hour (12 minutes)	1,610
Form 486 (Export Return Declaration)	239	8,050	0.08 hour (5 minutes)	670.9
Form 486 (import)	230	2,450	0.25 hour (15 minutes)	612.5
Form 486 (import return declaration)*	230	2,695	0.08 hour (5 minutes)	224.6
Form 486 (international transaction)	9	111	0.2 hour (12 minutes)	22.2
Form 486 (international transaction return declaration)	9	111	0.08 hour (5 minutes)	9.25
Quarterly reports for imports of acetone, 2-butanone, and toluene.	110	440	0.5 hour (30 minutes)	220
Total	239			3,369.45

*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: 3,370 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 proposed to be 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 1310.04 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), 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 section 1300.02(b)(28)(i)(D) 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 pseudoephedrine, its salts, optical isomers, and salts of optical isomers.

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

Dated: November 7, 2007.

Michele M. Leonhart,

Deputy Administrator.

[FR Doc. E7–22560 Filed 11–19–07; 8:45 am]

BILLING CODE 4410–09–P

DEPARTMENT OF THE TREASURY

Alcohol and Tobacco Tax and Trade Bureau

27 CFR Parts 4 and 9

[Notice No. 77; Re: Notice No. 36]

RIN: 1513–AA92

Proposed Establishment of the Calistoga Viticultural Area (2003R–496P)

AGENCY: Alcohol and Tobacco Tax and Trade Bureau, Treasury.