Ivermectin in g/ton of feed	Combination in g/ton of feed	Indications for use	Limitations	Sponsor
(9) 1.8 to 11.8 (to provide 0.1 mg/kg of body weight per day)	Bacitracin methylene disalicylate, 250	Pregnant sows: As in paragraph (e)(8) of this section; and for control of clostridial enteritis caused by *Clostridium perfringens* in suckling piglets.	Feed as the only feed for 7 consecutive days. Withdraw 5 days before slaughter. Feed bacitracin methylene disalicylate Type C medicated feed to sows from 14 days before through 21 days after farrowing on premises with a history of clostridial scours.	050604
(10) 18.2 to 120 (to provide 0.1 mg/kg of body weight per day)		Adult and breeding swine: As in paragraph (e)(8) of this section.	Top dress on daily ration for individual treatment for 7 consecutive days. Withdraw 5 days before slaughter.	050604

Dated: June 27, 2007.

Bernadette Dunham,

Deputy Director, Center for Veterinary Medicine.

[FR Doc. E7–13369 Filed 7–9–07; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

21 CFR Parts 1300 and 1315

[Docket No. DEA–293I]

RIN 1117–AB08

Import and Production Quotas for Certain List I Chemicals

AGENCY: Drug Enforcement Administration (DEA), Justice.

ACTION: Interim final rule with request for comment.

SUMMARY: In March 2006, Congress enacted the Combat Methamphetamine Epidemic Act of 2005, which mandates that DEA establish total annual requirements, import quotas, individual manufacturing quotas, and procurement quotas for three List I chemicals—ephedrine, pseudoephedrine, and phenylpropanolamine. DEA is promulgating this rule to incorporate the statutory provisions and make its regulations consistent with the new requirements.

DATES: Effective Date: July 10, 2007. Comment Date: Written comments must be postmarked on or before September 10, 2007.

ADDRESSES: To ensure proper handling of comments, please reference ''Docket No. DEA–293'' on all written and electronic correspondence. Written comments being sent via regular mail should be sent to the Deputy Administrator, Drug Enforcement Administration, Washington, DC 20537, Attention: DEA Federal Register Representative/ODL. Written comments sent via express mail should be sent to DEA Headquarters, Attention: DEA Federal Register Representative/ODL, 2401 Jefferson-Davis Highway, Alexandria, VA 22301. Comments may be 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 format other than those specifically listed here.

Posting of Public Comments: Please note that all comments received are considered part of the public record and made available for public inspection online at *http://www.regulations.gov.* Such information includes personal identifying information (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, you must include the phrase ''PERSONAL IDENTIFYING INFORMATION'' in the first paragraph of your comment. You must also place all the personal identifying information you do not want posted online in the first paragraph of your comment and identify 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, you must include the phrase ''CONFIDENTIAL BUSINESS INFORMATION'' in the first paragraph of your comment. You must also prominently identify confidential business information to be redacted within the comment. If a comment has so much confidential business information that it cannot be effectively redacted, all or part of that comment may not be posted on *http://www.regulations.gov.*

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

FOR FURTHER INFORMATION CONTACT: Christine A. Sannerud, Ph.D., Chief, Drug and Chemical Evaluation Section, Office of Diversion Control, Drug Enforcement Administration, Washington, DC 20537 at (202) 307–7183.

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 (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, for lawful exports, and for maintenance of reserve stocks while deterring 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, 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). The Act amends the CSA by adding new provisions related to the importation, production, and sale of ephedrine, pseudoephedrine, and phenylpropanolamine, their salts, optical isomers, and salts of optical isomers, and products that contain any of the three chemicals.

Ephedrine, Pseudoephedrine, and Phenylpropanolamine

Ephedrine, pseudoephedrine, and phenylpropanolamine are List I chemicals because each can be the primary ingredient needed to manufacture controlled substances illegally. Ephedrine and pseudoephedrine are primary ingredients important in the illicit manufacture of methamphetamine, a Schedule II controlled substance, and methcathinone, a Schedule I controlled substance; phenylpropanolamine is a primary ingredient important in the illicit manufacture of amphetamine, also a Schedule II controlled substance. Each of the chemicals is also approved as an active pharmaceutical ingredient used in products with legitimate medical purposes. Ephedrine is used in prescription and over-the-counter (OTC) products as a bronchodilator (*e.g.*, for treating asthma). Pseudoephedrine, a decongestant, is a common ingredient in both prescription and OTC cold and allergy medications. Research by the National Association of Chain Drug Stores identified approximately 2,500 OTC products that contain pseudoephedrine. The Food and Drug Administration's National Drug Code (NDC) online directory of prescription drugs lists 158 products that contain ephedrine and about 1,250 that contain pseudoephedrine. In November, 2000, the 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 voluntarily reformulated their products to exclude phenylpropanolamine. Subsequently, on December 22, 2005, FDA published a Notice of Proposed Rulemaking (70 FR 75988) proposing to categorize all OTC 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.

Prior to the enactment of CMEA, ephedrine, pseudoephedrine, and phenylpropanolamine were subject to the same requirements as other List I chemicals as they apply to manufacture, non-retail distribution, import, and export. Any person who manufactured the chemical for distribution, distributed, imported, or exported the chemical was required to register with DEA and maintain records on transactions at or above certain threshold quantities. Bulk manufacturers filed annual reports regarding their manufacturing activities with DEA. Importers and exporters had to notify DEA in advance of importations or exportations unless the transaction was between a regulated person and a regular customer abroad or an importation by a regular importer; in that case, the importers and exporters had to notify DEA no later than the date of the transaction. Sales of OTC drug products containing one of the chemicals were subject to sales thresholds above which retail distributors were required to maintain records, but certain forms (blister packs) were generally not subject to control. Mail order sellers of the OTC drugs filed monthly reports. The manufacture, distribution, import, export, and retail sale of prescription products containing the chemicals were not regulated.

Combat Methamphetamine Epidemic Act of 2005

The Combat Methamphetamine Epidemic Act of 2005 (CMEA) amends the CSA to tighten controls on the manufacture, distribution, import, export, and retail sale of three List I chemicals—ephedrine, pseudoephedrine, and phenylpropanolamine, and drug products containing them. CMEA imposes the following changes:

- Sales limits apply to retail sales of OTC products. Regulated sellers are required to store the products behind the counter or in locked cabinets and maintain records on each sale, including verifying the name of the purchaser against an approved form of identification supplied by the purchaser. The exemption for blister packs has been removed. Thus, all products sold at retail (except individual sales transactions consisting of a single package of pseudoephedrine where the package contains not more than 60 milligrams) are regulated under the Controlled Substances Act.
- DEA must establish an assessment of the annual needs for estimated medical, scientific, research, and industrial needs of the United States, for lawful exports, and for reserve stocks, for the three chemicals. That assessment will set an upper limit on the quantity of the chemicals and products containing the chemicals that can be produced in or imported to the United States.
- Bulk manufacturers must obtain a manufacturing quota to produce any of the three chemicals.
- Manufacturers who purchase the bulk chemicals to produce products must obtain a procurement quota.
- Importers must obtain a quota to import the chemicals in bulk or in drug products.
- Importers, exporters, brokers, and traders must provide additional information on the persons to whom they intend to sell the chemicals prior to the sale. They must also provide a return declaration, providing actual information regarding the import, export, or international transaction.

Because the mandated changes affect different business activities, DEA is revising its regulations to implement these mandated changes through a series of rulemakings. This Interim Final Rule addresses the CMEA mandate for establishment of an assessment of annual needs and quotas to limit production and importation to those established needs.

Establishing Annual Needs

CMEA amended the CSA to add ephedrine, pseudoephedrine, and phenylpropanolamine to § 826 of the Act, which requires production quotas for controlled substances. The amendment essentially requires that the three chemicals be treated in the same way as Schedule I and II controlled substances. Under the CSA, DEA must limit the quantity of Schedule I and II controlled substances to that which is necessary to meet 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. DEA establishes the annual needs for each controlled substance, the ''aggregate production quota'', and uses that figure to issue manufacturing and procurement quotas. With very limited exceptions, imports of controlled substances are sold to manufacturers (which include repackagers). Because importers can only distribute controlled substances to DEA registrants and manufacturers can purchase only the amount authorized under their procurement quotas, DEA has not needed to issue import quotas to importers. The closed system of control that the CSA mandates for controlled substances means that DEA can track the importation, manufacture, and distribution of controlled substances.

The circumstances for the manufacturing and distribution of the three List I chemicals are different in a number of ways.

- Most of the bulk ephedrine, pseudoephedrine, and phenylpropanolamine used in the United States is imported. DEA is notified of these imports, but until now DEA has not obtained information on the purchasers of the imported chemicals. (DEA has promulgated separate regulations under CMEA that will require importers of all listed chemicals to indicate their downstream customers (72 FR 17401, April 9, 2007).) Although most imported bulk chemicals will be sold to manufacturers, it is possible that some bulk materials could be sold to distributors or exporters.
- Distributors are required to keep records of transactions involving these chemicals, but do not file reports with DEA on distributions.
- Dosage units of OTC drugs containing the chemicals are imported. Although these may be transferred to repackagers or relabelers (who are registered as manufacturers), some may be imported already packaged for retail sale and transferred to distributors or directly to retailers. Retailers may not be DEA registrants.
- Prescription drugs containing one of the chemicals may be imported. Until now, neither the importation, distribution, nor manufacture of these drugs has been subject to DEA regulations.

To assess the national needs and limit the quantity of the three chemicals to those national needs, DEA must collect information on manufacturing, imports, and exports and set production quotas for manufacturers and import quotas for importers. Because the chemicals are used in approximately 1,400 prescription products, DEA must cover the manufacture and import of these products as well as the more than 2,500 OTC drug products. In another rulemaking, DEA is revising its regulations to require that manufacturers and importers of prescription drug products containing any of the three chemicals must register with DEA. DEA is also revising, in a separate rulemaking, the thresholds applied to ephedrine, pseudoephedrine, and phenylpropanolamine so that all transactions will be regulated.

Discussion of the Rule

CMEA amends the CSA by adding ephedrine, pseudoephedrine, and phenylpropanolamine to each of the paragraphs in 21 U.S.C. 826, Production quotas for controlled substances. Section 826 requires DEA to establish total annual needs for each of the three chemicals and to limit manufacturing of the chemicals to the amount needed to provide for medical, scientific, research, and industrial purposes, for lawful exports, and for the maintenance of reserve stocks. In addition, CMEA amends 21 U.S.C. 952 (importation of controlled substances) by adding a new paragraph (d) to cover the importation of the three chemicals; the new paragraph indicates, along with language from the Conference report on CMEA, that Congress expected DEA to establish import quotas for the chemicals:

> Section 715. Restrictions on importation; authority to permit imports for medical, scientific, or other legitimate purposes Section 715 of the conference report is a new provision and extends the Attorney General's existing authority to set import quotas for controlled substances (see 21 U.S.C. Sec. 952) to pseudoephedrine, ephedrine, and phenylpropanolamine. This section allows registered importers to apply for temporary or permanent increases in a quota to meet legitimate needs. The Attorney General is required to act on all such applications within 60 days.

These sections of the CSA are implemented through a new part, 21 CFR part 1315. Most of the requirements for the assessment of annual national needs and for manufacturing and procurement quotas directly parallel the requirements for controlled substance quotas provided in part 1303.

Production Quotas

Under part 1315, bulk manufacturers of the three chemicals will be required to obtain annual manufacturing quotas. A separate quota is required for each chemical. A bulk manufacturer must be registered as a manufacturer to handle the chemical for which quota is applied. A bulk manufacturer must complete and file a DEA Form 189 by April 1 of each year for the following calendar year. The applicant must provide the following information on the form:

- For the current and preceding two years, the actual quantity manufactured, actual net disposals, and actual inventory as of December 31.
- For the next year, the desired quota, the name and registration number of each customer and the amount estimated to be sold to each, and any additional factors the applicant finds relevant to fixing the quota.

DEA notes that the above requirements are consistent with existing requirements for controlled substances quotas found in 21 CFR Part 1303.

Each manufacturer that purchases the chemicals in bulk or in dosage forms will be required to obtain a procurement quota to obtain the bulk chemicals or dosage forms. A separate procurement quota is required for each chemical. The applicant must apply using DEA Form 250. The applicant must provide the following information:

- A statement about the purpose(s) of the requested chemical and the quantity which will be used for each purpose during the next calendar year. The applicant should provide information about the quantities used (acquired, distributed, and inventory) for the current and preceding 2 calendar years.
- If the purpose is to manufacture dosage forms, the applicant must state the official name, common or usual name, chemical name, or brand name of that dosage form, and must include the strength.
- The company must state the type of activity intended: product development, repackaging, relabeling, manufacturing OTC finished product, manufacturing prescription finished product.
- If the purpose is to manufacture a controlled substance listed in Schedule I or II or another List I chemical, the applicant must state the quantity of the other substance or chemical that the applicant has applied to manufacture under § 1303.22 and the quantity of the first chemical needed to manufacture a specified unit of the second chemical.

DEA notes that the above requirements are consistent with existing requirements for controlled substances quotas found in 21 CFR Part 1303.

DEA recognizes that applicants may not have complete data on inventories and records for previous years because DEA has not required registrants to keep these records. Most manufacturers of

OTC products should have the information in the records they maintain on regulated transactions. Applicants who manufacture prescription products may not have full records for the initial filings. DEA notes that the provision of incomplete information as part of an application for quota in the initial year of implementation of quotas for ephedrine, pseudoephedrine, and phenylpropanolamine may not, in and of itself, prevent an applicant from obtaining quota. DEA has significant experience regarding the processing of quota applications for which incomplete information is present at the initial establishment of quota (e.g., a new formulation of a controlled substance). DEA will work with quota applicants to obtain information that could be used in the processing of the applicant's initial application.

Import Quotas

To track and control the quantity of each of the chemicals and drug products containing the chemicals, DEA must limit imports to a quantity consistent with the national needs. CMEA amended 21 U.S.C. 952(a) to state that ''It shall be unlawful to import * * * ephedrine, pseudoephedrine, and phenylpropanolamine * * * except that such amounts of * * * ephedrine, pseudoephedrine, and phenylpropanolamine as the Attorney General [DEA by delegation] finds necessary to provide for the medical, scientific, or other legitimate purposes * * *.'' Importers will be required to obtain an import quota for each chemical covering both bulk chemicals and dosage forms. Importers will be required to submit an application that includes the following information:

- The type of product (bulk chemical or finished forms to be transferred to a manufacturer or product to be sold for distribution).
- The quantity of each type of product.
- For the previous two years, the name, address, and DEA registration number (if applicable) of each customer and the amount sold; inventory as of December 31 for each form of the product (*i.e.*, bulk chemical, in-process material, or finished dosage form); and acquisitions (imports).

DEA recognizes that importers handling prescription products may not have historical records for their initial filings. If an importer is handling prescription drug products, it is possible that some of its customers may not be DEA registrants. DEA notes that the provision of incomplete information as part of an application for quota in the initial year of implementation of quotas for ephedrine, pseudoephedrine, and phenylpropanolamine may not, in and of itself, prevent an applicant from obtaining quota. DEA has significant experience regarding the processing of quota applications for which incomplete information is present at the initial establishment of quota (*e.g.*, a new formulation of a controlled substance). DEA will work with quota applicants to obtain information that could be used in the processing of the applicant's initial application.

Depending on the activities that a firm engages in, a firm may have to apply for multiple quotas. For example, a firm that imports ephedrine to bulk manufacture pseudoephedrine would need to obtain an import quota and a procurement quota for ephedrine and a manufacturing quota for pseudoephedrine. A manufacturer that imports bulk ephedrine and pseudoephedrine to produce dosage units of drugs containing the chemicals would need to obtain separate import and procurement quotas for each chemical.

DEA will use the information filed in support of the quota applications as one factor in the determination of an initial assessment of annual needs for each of the chemicals to ensure that the United States has sufficient quantities to meet medical, scientific, research, industrial, exportation, and reserve stock needs. DEA will publish its assessment by May 1 and then revise the assessment based on comments and further information before publishing a final assessment for the following year. The assessment establishes a ceiling on domestic manufacturing and importation of these chemicals. DEA may, at its discretion, seek additional information from applicants if needed to determine an appropriate level for the annual assessment ceiling. For example, because repackagers and relabelers handle products that are covered by other procurement or import quotas, DEA may need more details on customers from those seeking procurement quotas to ensure that it is not double counting quantities. This issue may arise particularly in reference to OTC products, where a manufacturer may produce dosage units that are repackaged or relabeled to be sold under multiple store brand labels.

DEA is adopting the same process for manufacturing and procurement quotas for the three chemicals as it currently applies to those quotas for controlled substances. Manufacturers may apply for increases in their manufacturing quotas; DEA may reduce individual manufacturing quotas to prevent the total amount produced from exceeding the assessment of annual needs. Manufacturers may abandon their quota by notifying DEA.

Manufacturers holding a procurement quota may apply for adjustment of the quota by applying to DEA with a statement indicating the need for an adjustment. Any manufacturer who holds a procurement quota must, before giving an order to another manufacturer or importer requiring the distribution of a covered chemical, certify in writing that the quantity being ordered does not exceed the unused portion of the person's procurement quota for the year. The certification must be signed by someone who is authorized to sign a DEA registration application.

As specified in the CMEA amendment to section 952 of the CSA, importers may apply for an increase in their quota and DEA may approve the application if DEA determines that the increase is needed to meet medical, scientific, or other legitimate purposes. For changes in the import quota, DEA will approve or deny the application within 60 days of receiving the application; if DEA does not reach a decision within the 60 days, the application is considered to be approved until DEA notifies the applicant in writing that the approval is terminated.

DEA may hold hearings, at the Administrator's sole discretion, to obtain factual evidence regarding the assessment of national needs. Applicants or quota holders may request hearings on the issuance, adjustment, suspension, or denial of a quota. In hearings on the assessment of national needs, each interested party has the burden of proving any proposition of facts or law that the party asserts. At hearings on the issuance, adjustment, suspension, or denial of a quota, DEA has the burden of proving that the requirements for issuance, adjustment, suspension, or denial of a quota are met.

Changes in Forms

DEA is amending DEA Form 189 (application for a manufacturing quota) and DEA Form 250 (application for a procurement quota). DEA Form 189 is being amended to include the List I chemicals ephedrine, pseudoephedrine, and phenylpropanolamine; adding a field to supply an e-mail address; and adding a field requesting information regarding the authority by which a product may be marketed under the Federal Food, Drug and Cosmetic Act (*e.g.*, NDA number or FDA monograph). DEA is soliciting comments on this provision. DEA included this requirement in the application to assist in making its determination that the

quota would be utilized for ''medical'' purposes. However, DEA notes that there are instances in which applications may not fall within this category (*e.g.*, quota used to support bona fide scientific research, industrial uses and product development efforts). DEA will consider applications for quota to support these activities even though the applicant would not be able to complete this portion of the application.

DEA Form 250 is being amended to include the List I chemicals ephedrine, pseudoephedrine, and phenylpropanolamine; adding a field to supply an e-mail address; permitting the use of List I Chemical Code Numbers as well as the DEA Drug Code numbers; and adding a field requesting information regarding the authority by which a product may be marketed under the Federal Food, Drug, and Cosmetic Act (*e.g.*, NDA number or FDA monograph). DEA is soliciting comments on this provision. DEA included this requirement in the application to assist in making its determination that the quota would be utilized for ''medical purposes.'' However, DEA notes that there are instances in which applications may not fall within this category (*e.g.*, quota used to support bona fide scientific research, industrial uses and product development efforts). DEA will consider applications for quota to support these activities even though the applicant would not be able to complete this portion of the application.

In addition, DEA has developed a new DEA Form 488 for applying for an import quota.

Imports for Personal Use

CMEA amended 21 U.S.C. 844 to make it unlawful for a person to knowingly purchase at retail more than 9 grams of ephedrine base, pseudoephedrine base, or phenylpropanolamine base in a scheduled listed chemical product in a 30-day period and further stated that no more than 7.5 grams of the 9 grams of each chemical may be imported by means of shipping through a private or commercial carrier or the Postal Service. Imports for personal use below these quantities are not subject to import quota requirements. Any person who wishes to import more than 7.5 grams of each of the chemicals in a 30-day period would have to register as an importer and obtain an import quota.

Section-by-Section Description of the Rule

DEA is amending the definition of ''regulated transaction'', found in 21 CFR § 1300.02, to reference new part 1315.

Subpart A of new part 1315 provides general information about part 1315. Section 1315.01 defines the scope of part 1315.

Section 1315.02 provides definitions. The definition of ''net disposal,'' which is in § 1300.01 and applies to controlled substances, is included here for the three List I chemicals. The final paragraph repeats the statutory provisions that each of the three chemicals includes their salts, optical isomers, and salts of optical isomers.

Section 1315.03 provides the personal use exemption from importer registration, import declaration, and import quotas.

Section 1315.05 specifies the persons to whom the part applies.

Subpart B, Sections 1315.11 and 1315.13 describe the process for determining the assessment of annual needs for each of the three chemicals and adjusting the assessment. The sections parallel §§ 1303.11 and 1303.13.

Subpart C, Sections 1315.21 through 1315.27 cover the requirements for individual manufacturing quotas. The sections are taken from §§ 1303.21 through 1303.27.

Subpart D addresses procurement and import quotas. Section 1315.30 describes what procurement and import quotas authorize and serves as an introduction to the requirements for these quotas.

Section 1315.32 specifies the requirements for obtaining a procurement quota and is based on § 1303.12.

Section 1315.34 covers the requirements for obtaining an import quota. The section specifies the information that an applicant must submit and indicates that DEA may request additional information, if necessary.

Section 1315.36 specifies the procedures for amending an import quota, as provided in 21 U.S.C. § 952(d).

Subpart E, §§ 1315.50 through 1315.62 cover the procedures for hearings on the assessment of annual needs and the issuance, adjustment, suspension, or denial of a quota. These sections are based on §§ 1303.31 through 1303.37.

Regulatory Certifications

Administrative Procedure Act (5 U.S.C. 553)

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

With publication of this Interim Final Rule, DEA is invoking this ''good cause'' exception to the APA's notice requirement based on the combination of several extraordinary factors. The Combat Methamphetamine Epidemic Act of 2005 specifically amended 21 U.S.C. 826 to mandate the establishment of production quotas for the List I chemicals ephedrine, pseudoephedrine, and phenylpropanolamine. DEA has no discretion in this requirement and is essentially creating the same system of production quotas for these three List I chemicals as is currently established for controlled substances in Schedules I and II. These regulations address the procedures for the implementation of these quotas, and DEA has endeavored to use existing procedures wherever possible for simplicity and ease of implementation.

Further, the CMEA amended 21 U.S.C. 952 to prohibit all importation of ephedrine, pseudoephedrine, and phenylpropanolamine except such amounts as the Attorney General finds to be necessary for medical, scientific, or other legitimate purposes. The Act further amended § 952 regarding import quotas for these three List I chemicals.

In a separate rulemaking, DEA implemented the retail provisions of the CMEA (71 FR 56008, September 26, 2006; corrected at 71 FR 60609, October 13, 2006), which included, among others:

- Sales limits
- Product packaging
- Product placement
- Logbook and verification of purchaser identity

These provisions limit the availability of scheduled listed chemical products at the retail level. While these products will be available for purchase, their diversion to the illicit production of methamphetamine will be more difficult due to the sales limits, logbook requirements, and other provisions. Congress, in crafting CMEA, recognized that limiting of product availability at the retail level could potentially encourage diversion of either drug products or the List I chemicals themselves higher in the supply chain—at the import, manufacture, and distribution levels. To address its

concern about ''what immediately moves in behind,'' (Rep. Souder, February 28, 2006, CR p. 423) Congress included provisions in CMEA to control the import, export, manufacture, and distribution of the three chemicals and products containing them. These provisions also will make it possible for the United States to meet the recommendations of the International Narcotics Control Board, which encouraged its member countries to provide for pre-export notifications and an assessment of legitimate need for these chemicals.

In a separate rulemaking (72 FR 17401, April 9, 2007) DEA implemented the ''spot market'' provisions of the CMEA related to the importation, exportation, and international transactions involving all listed chemicals. The provisions of section 716 of the CMEA implemented by that rulemaking require importers, exporters, brokers, and traders to notify DEA, before the transaction is to take place, of certain information regarding the transferee(s) (downstream customer(s)) and the listed chemicals to be transferred. Such information provides DEA with an opportunity to evaluate the transaction.

DEA must implement the quota provisions of the CMEA on an interim basis to ensure that product upstream from the retail level is not diverted for illicit purposes. It would be contrary to the public interest to allow the diversion of large amounts of ephedrine, pseudoephedrine, and phenylpropanolamine at the wholesale level while implementing controls at the retail level to limit sales of these very products.

The CMEA, as evidenced by the number of rulemakings DEA is issuing to implement it, sets forth a complex array of statutory requirements, with different effective dates, designed to prevent the use of certain List I chemicals in the illicit manufacture of methamphetamine and amphetamine. In addition, the CMEA, which, among other things, essentially reclassifies ephedrine, pseudoephedrine, and phenylpropanolamine as scheduled listed chemicals, imposes new retail restrictions on these products, and mandates new domestic and import quotas, is expansive in its breadth. The broad scope of the new law, as well as the expedited effective dates, is a clear reflection of Congress' concern about the nation's growing methamphetamine epidemic and its desire to act quickly to prevent further illicit use of these chemicals.

The retail and ''spot market'' provisions of the CMEA, which DEA has already implemented through separate rulemakings, limit the sale of ephedrine, pseudoephedrine, and phenylpropanolamine at retail and provide information to DEA regarding downstream customers of United States importers, exporters, brokers and traders. They do not, however, provide controls at the distribution, manufacturing, and importing levels of the distribution chain. To fully implement the CMEA as intended by Congress, and to work to combat the methamphetamine epidemic the United States is currently experiencing, DEA must utilize all tools at its disposal to control the importation, exportation, manufacture, and retail sale of ephedrine, pseudoephedrine, phenylpropanolamine, and products containing those three List I chemicals.

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

Under section 553(d) of the APA, DEA must generally provide a 30-day delayed effective date for final rules. DEA may dispense with the 30-day delayed effective date requirement ''for good cause found and published with the rule.'' DEA believes that good cause exists to make this rule effective upon publication. As DEA noted previously, rulemakings have already been implemented to limit the availability of scheduled listed chemical products at the retail level. The limiting of product availability at the retail level could potentially encourage diversion of either drug products or the List I chemicals themselves higher in the supply chain—at the import, manufacture, and distribution levels. Congress included provisions in CMEA to address this circumstance, and the quota provisions set forth in this rulemaking work toward that goal. DEA must implement the quota provisions of the CMEA upon publication to ensure that product upstream from the retail level is not diverted for illicit purposes.

Regulatory Flexibility Act

The Deputy Administrator hereby certifies that this rulemaking has been drafted in accordance with the Regulatory Flexibility Act (RFA) (5 U.S.C. 605(b)). The RFA applies only to proposed rules that are subject to notice and comment (5 U.S.C. 601(2)). Because this rule is codifying statutory provisions, DEA has determined, as explained above, that public notice and comment are not necessary. Consequently, the RFA does not apply.

DEA has nonetheless considered the impact of the rule on small entities. As discussed below, DEA estimates that about 310 firms in the manufacturing and wholesale sectors will be affected by this rule. About 250 of these may be small entities under the Small Business Administration definitions of small entities. For most of these firms the impact of the rule will be very small; they will be required to file an annual request for import or procurement quotas. DEA estimates that the cost of applying for a quota is about $96 for importers and $113 for manufacturers, which includes data collection and mailing. These costs do not represent a significant economic impact even on the smallest repackagers whose average revenues are above $54,000. The average revenues of the smallest firms in sectors subject to the rule for which the 2002 Economic Census has data are shown in Table 1.

TABLE 1.—AVERAGE REVENUES OF SMALLEST FIRMS BY AFFECTED SECTOR

Sector	Average revenue of smallest firms
Packaging and labeling	$54,271
Drug wholesalers	127,367
Chemical wholesalers	718,697
Pharmaceutical manufacturers	824,268

The larger impact of the rule will be in any reduction in sales that results from limits imposed by a firm's quotas. Only one firm manufactures bulk pseudoephedrine in the United States. This firm is owned by an Indian chemical manufacturer and is not a small entity. The rest of the firms affected by the rule can be divided into three sectors:

- Importers and manufacturers of prescription products containing the chemicals.
- Importers and manufacturers of OTC products that are sold primarily through drug stores, grocery stores, discount department stores, superstores, and electronic mail order houses.
- Importers and manufacturers of OTC products that are sold almost exclusively through independent

convenience stores or other small outlets.

The three sectors will be affected differently by the quotas. DEA will provide importers and manufacturers of prescription products with the quantities that they request unless DEA has some reason to believe that the prescription product is being diverted. These firms will not have a significant economic impact from the rule.

Importers and manufacturers of OTC products that are sold through conventional outlets are likely to receive the quotas requested adjusted only to account for general estimates of diversion and declines in demand. At this point, DEA has not estimated the adjustment needed to account for diversion, but expects that it will be small relative to the declines in demand that are resulting from the retail sales restrictions. As DEA has discussed in the retail rule (71 FR 56008, September 26, 2006; corrected at 71 FR 60609, October 13, 2006), most of the firms that manufacture these products for sales in conventional outlets also manufacture the substitutes. DEA does not expect that these firms will see a significant economic impact from the quotas, but is seeking comment on this issue.

DEA anticipates that the third sector will be more severely affected. This sector is comprised of a small number of companies that import or manufacture products in higher dosages than are normally purchased through conventional outlets and sell the product almost exclusively through nonconventional outlets, such as independent convenience stores, liquor stores, etc. Although some products sold mainly in drug stores, grocery stores, and large discount or warehouse stores are stolen or bought for illicit purposes, DEA's experience indicates that products sold almost exclusively through nonconventional outlets are far more likely to be diverted in substantial quantities. In investigations, DEA has found some of these stores selling products in quantities 20 to 40 times what such stores would be expected to sell to meet legitimate needs. Many of these manufacturers have, in the past, marketed products in packages that are no longer legal for retail sales because they contain more than 3.6 grams of the chemical. DEA has issued multiple warning letters to these manufacturers to inform them of the diversion of their products.

An application for a quota from these manufacturers of products sold primarily or exclusively through such outlets or from importers who sell to these manufacturers will be reviewed using the same standards used to review other applications for a quota. However, DEA notes that the agency has published many final orders in the **Federal Register** addressing the distribution of these products sold almost exclusively to nonconventional outlets, and has found that a significant percentage of such products have been diverted. DEA will consider the historical uses of such products when determining whether the quantities requested in a quota application are required to meet the legitimate needs of the market. Consequently, if the manufacturers of these products, and the importers supplying those manufacturers, request quotas that are consistent with a past pattern of known diversion, these firms may not receive quotas in the amounts requested. It is also possible that the number of outlets carrying their products will decline if these stores decide that CMEA requirements for retail sales are too onerous. Some of these firms may experience a significant economic impact, particularly if this product line generated a substantial portion of their sales. Some of these firms appear, based on their web sites, to have added substitutes to their product lines; others appear to have dropped the product line altogether. DEA is seeking comments on this issue.

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.

Regulated Entities. The firms subject to this rule are manufacturers and importers. At present, only one firm in the United States manufactures any of these chemicals in bulk and, therefore, only that firm will have to apply for a manufacturing quota. DEA reviewed a list of pseudoephedrine OTC and prescription products and ephedrine prescription products and identified about 240 firms based on their labeler codes. Each of these firms, plus any firms that repackage or relabel, will need to obtain procurement quotas. Based on 2005 DEA data, DEA estimates that about 69 firms with 91 locations are currently registered to import the chemicals; these firms will need to obtain import quotas if they are actually importing the chemicals. Although 91 locations are registered to import these chemicals, import notices indicate that many of these locations do not handle the chemicals. If other firms import prescription drug products that contain the chemicals they will also have to obtain import quotas. Based on these data, DEA estimates that 332 locations may apply for quotas if the demand for the chemicals and drug products remains the same (1 bulk manufacturer, 240 manufacturers, and 91 importers). Table 2 presents the number of potential applicants by sector. Registrants must apply for quotas for each registered location rather than by firm. Consequently, the number of manufacturing locations applying may be higher than listed if the firms handle the product at multiple locations. The importers are, in some cases, also manufacturers so that the total number of affected firms may be reduced. The total number of importer registrants includes firms with multiple registered locations.

TABLE 2.—POTENTIAL QUOTA APPLICANTS BY SECTOR

Type	Number
All Manufacturers	240
Small Manufacturers	211
Importer Registered Locations	91
Small Importer Firms	42

Costs. As detailed in the Regulatory Flexibility Act section, there will be some burden associated with applying for quotas. DEA estimates that the total cost of the quota application process will be about $35,880 a year.

As noted above, the larger cost of this rule is likely to be based on the extent to which the quotas constrain the market for OTC products containing ephedrine or pseudoephedrine. DEA assumes that the quotas will not affect the prescription drug market. DEA will establish its assessment of annual national needs for each of the chemicals, which will serve as a ceiling on the quantities for which quotas are granted. In setting an assessment of annual national need, DEA will consider the likelihood that OTC sales of scheduled listed chemical products may be reduced by the new restrictions on retail sales. Domestic demand for these products comes from three sources:

- Legitimate medical, scientific, and industrial needs and maintenance of reserve stocks.
- Exports.
- Illicit use-clandestine methamphetamine/amphetamine laboratories.

To establish the national needs and set individual quotas, DEA must first estimate the reduction in the volume of OTC sales due to the new retail

restrictions and the quantity of the chemicals now being diverted to illicit use. This information is needed so the degree of supply constraint implied by a given assessment can be understood. It will not be possible to make accurate estimates of these amounts until experience with the retail controls provides sufficient data. Similarly, accurate cost estimates cannot be developed until these data are available.

As DEA discussed in its Interim Final Rule on retail sales of scheduled listed chemical products (71 FR 56008, September 26, 2006; corrected at 71 FR 60609, October 13, 2006), DEA has no reliable information on the value of the OTC market for these products. Estimates range from $250 million to $1.5 billion annually prior to the sales restrictions. The effect of State laws restricting sales and of the anticipation of the CMEA restrictions appear to be reducing the market considerably, at least for imports of bulk materials. Data from the U.S. International Trade Commission on the change in the imports from January through August of 2006 over the same period in 2005 are shown in Table 3.

TABLE 3.—CHANGE IN IMPORTS JANUARY–AUGUST 2005 TO JANUARY–AUGUST 2006

	Percent change in value	Percent change in quantity
Ephedrine	−44.9	−64.1
Pseudoephedrine ..	−66.2	−70.4
Cough and cold dosage forms	−4.8	−15.9

DEA is requesting comments and data from importers and manufacturers about the change in their markets and its impact.

DEA notes that the figures in Table 3 reflect imports for both prescription and OTC drugs. Because DEA does not anticipate that quotas will have any effect on prescription drugs, it is likely that the decline in the retail market is considerable. However, even the highest estimate of the market pre-restriction indicates that the total cost of quota restrictions will be less than $100 million in any one year, the standard for an economically significant rule. If the highest estimate of the value of the market, $1.5 billion, were to remain unchanged after retail restrictions, quotas would have to restrict that market by 6.67 percent to reach the $100 million a year level. If, as is far more likely, the market is declining significantly absent the quotas, the quotas would have to restrict the market by more than 10 percent to reach the level of economically significant under the Executive Order. At this time, DEA does not believe that the level of diversion is 6.67 percent of sales on a national basis. Therefore, DEA does not consider that this rule will have a significant economic impact. DEA requests comments on this issue.

Benefits. Congress, in CMEA, imposed a set of requirements on the manufacture, import, and sale of the three chemicals. These requirements, taken together, are intended to limit production and sales of these chemicals to that needed for legitimate purposes. The reduction in demand for these chemicals that is already occurring will limit the world production and make less available for diversion on the international market. In terms of societal accounting, the principal benefit of quotas that constrain supply will stem from a reduction in diversion to domestic illicit production of methamphetamine and amphetamine. The reduced volume of diversion will cause a reduction in the number of domestic clandestine methamphetamine laboratories and domestic illicit production of methamphetamine. Constrained supply is expected to raise the price of the chemicals in the domestic market and, for the clandestine methamphetamine laboratories, increase the cost and difficulty of obtaining them. The constrained-supply effect will come from the retail restrictions as well as from the quota ceiling; it is difficult to make separate quantitative estimates of the results of these two causes.

Reduction in the number of clandestine methamphetamine laboratories reduces costs to Federal, State, and local governments of raiding these clandestine operations and cleaning up pollution at clandestine methamphetamine laboratory sites. As DEA detailed in its rule on retail sales (specifically 71 FR 56020, September 26, 2006), DEA, the States, and local governments spent more than $17 million in clean up costs in FY 2005. This cost covers only the removal of chemicals that could be reused from clandestine laboratory sites; the cost of cleaning up soil or property contamination is paid by the land owner, but if the owner cannot pay the cost, local governments bear the burden or the contamination remains. The costs also do not cover the time State and local governments spend investigating, arresting, and trying clandestine laboratory operators or the social costs related to children and others exposed to hazardous chemicals at these laboratories.

Paperwork Reduction Act

DEA is revising two information collections currently approved under the Paperwork Reduction Act of 1998, and establishing a new information collection to address new mandates established by the CMEA. The two information collections being revised are OMB approval number 1117–0006: ''Application for Individual Manufacturing Quota for a Basic Class of Controlled Substance and for Ephedrine, Pseudoephedrine, and Phenylpropanolamine'' (DEA Form 189), and OMB approval number 1117–0008: ''Application for Procurement Quota for Controlled Substances and Ephedrine, Pseudoephedrine, and Phenylpropanolamine'' (DEA Form 250). DEA is revising these collections by slightly revising the forms and increasing the estimated annual number of respondents and responses. Those changes have been discussed above, and are necessary for DEA to implement the provisions of the Combat Methamphetamine Epidemic Act of 2005. DEA is also establishing a new information collection: ''Application for Import Quota for Ephedrine, Pseudoephedrine, and Phenylpropanolamine'' (DEA Form 488).

The Department of Justice, Drug Enforcement Administration, has submitted the following information collection requests to the Office of Management and Budget (OMB) 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 collections 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 OMB 1117–0006:

(1) *Type of Information Collection:* revision of an existing collection.

(2) *Title of the Form/Collection:* Application for Individual Manufacturing Quota for a Basic Class of Controlled Substance and for Ephedrine, Pseudoephedrine, and Phenylpropanolamine.

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

Form Number: DEA Form 189.

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: 21 U.S.C. 826 and 21 CFR 1303.22 and 1315.22 require that any person who is registered to manufacture any basic class of controlled substances listed in Schedule I or II and who desires to manufacture a quantity of such class, or who desires to manufacture using the List I chemicals ephedrine, pseudoephedrine, or phenylpropanolamine, must apply on DEA Form 189 for a manufacturing quota for such quantity of such class or List I chemical.

(5) *An estimate of the total number of respondents and the amount of time estimated for an average respondent to respond:* Only one firm currently manufactures these chemicals in the United States so only one additional firm will need to file this form. DEA estimates that each form takes 0.5 hours (30 minutes) to complete. Therefore, the burden increase for this one firm associated with this rulemaking is 0.5 hours annually.

(6) *An estimate of the total public burden (in hours) associated with the collection:*

One individual respondent will spend 0.5 hours (30 minutes) annually completing this form for the List I chemicals ephedrine, pseudoephedrine, and phenylpropanolamine. This results in an annual public burden of 0.5 hours.

This form is already used to collect information regarding controlled substances quotas. For that aspect of this collection, 36 respondents submit 297 responses annually, for a public burden of 148.5 hours annually. DEA notes that the controlled substances aspect of this collection is not being adjusted or revised.

Therefore, in total, 37 firms take 0.5 hours (30 minutes) each to complete the form. This results in a total public burden of 149 hours annually.

Overview of information collection OMB 1117–0008:

(1) *Type of Information Collection:* revision of an existing collection.

(2) *Title of the Form/Collection:* Application for Procurement Quota for Controlled Substances and Ephedrine, Pseudoephedrine, and Phenylpropanolamine.

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

Form Number: DEA Form 250, 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: 21 U.S.C. 826 and 21 CFR 1303.12 and 1315.32 require that U.S. companies who desire to use any basic class of controlled substances listed in Schedule I or II or the List I chemicals ephedrine, pseudoephedrine, and phenylpropanolamine for purposes of manufacturing during the next calendar year shall apply on DEA Form 250 for procurement quota for such class or List I chemical.

(5) *An estimate of the total number of respondents and the amount of time estimated for an average respondent to respond:* DEA estimates that each form takes 1 hour to complete. DEA estimates that 240 individual respondents will respond to this form.

(6) *An estimate of the total public burden (in hours) associated with the collection:* 240 individual respondents will spend one hour annually completing this form for the List I chemicals ephedrine, pseudoephedrine, and phenylpropanolamine. This results in an annual public burden of 240 hours.

This form is already used to collect information regarding controlled substances quotas. For that aspect of this collection, 255 respondents submit 1,106 responses annually, for a public burden of 1,106 hours annually. DEA notes that the controlled substances aspect of this collection is not being adjusted or revised.

Therefore, the total public burden for this collection is 1,346 hours annually.

Overview of new information collection:

(1) *Type of Information Collection:* new collection.

(2) *Title of the Form/Collection:* Application for Import Quota for Ephedrine, Pseudoephedrine, and Phenylpropanolamine.

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

Form Number: DEA Form 488, 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: 21 U.S.C. 952 and 21 CFR 1315.34 require that persons who desire to import the List I chemicals ephedrine, pseudoephedrine, and phenylpropanolamine during the next calendar year shall apply on DEA Form 488 for import quota for such List I chemicals.

(5) *An estimate of the total number of respondents and the amount of time estimated for an average respondent to respond:* DEA estimates that 91 individual respondents will apply for import quotas. DEA estimates that each response will take one hour.

(6) *An estimate of the total public burden (in hours) associated with the collection:* DEA estimates that this collection will involve 91 annual public burden hours.

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

Executive Order 12988

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

Executive Order 13132

This rulemaking does not preempt or modify any provision of State law; nor

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

Unfunded Mandates Reform Act of 1995

This rule will not result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of $120,000,000 or more (adjusted for inflation) in any one year, and will not significantly or uniquely affect small governments. Therefore, no actions were deemed necessary under the provisions of the Unfunded Mandates Reform Act of 1995.

Congressional Review Act

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

List of Subjects

21 CFR Part 1300

Chemicals, Drug traffic control.

21 CFR Part 1315

Administrative practice and procedure, Chemicals, Drug traffic control, Imports, Reporting and recordkeeping requirements.

■ For the reasons set out above, 21 CFR Chapter II is amended as follows:

PART 1300—DEFINITIONS

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

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

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

§ 1300.02 Definitions related to listed chemicals.

* * * * *

(b) * * *

(28) * * *

(i) * * *

(B) A delivery of a listed chemical to or by a common or contract carrier for carriage in the lawful and usual course of the business of the common or contract carrier, or to or by a warehouseman for storage in the lawful and usual course of the business of the warehouseman, except that if the carriage or storage is in connection with the distribution, importation, or exportation of a listed chemical to a third person, this paragraph does not relieve a distributor, importer, or exporter from compliance with parts 1309, 1310, 1313, and 1315 of this chapter;

* * * * *

■ 3. Part 1315 is added to read as follows:

PART 1315—IMPORTATION AND PRODUCTION QUOTAS FOR EPHEDRINE, PSEUDOEPHEDRINE, AND PHENYLPROPANOLAMINE

Subpart A—General Information

Sec.

Subpart B—Assessment of Annual Needs

Subpart C—Individual Manufacturing Quotas

Subpart D—Procurement and Import Quotas

Subpart E—Hearings

Authority: 21 U.S.C. 802, 821, 826, 871(b), 952.

Subpart A—General Information

§ 1315.01 Scope.

This part specifies procedures governing the establishment of an assessment of annual needs, procurement and manufacturing quotas pursuant to section 306 of the Act (21 U.S.C. 826), and import quotas pursuant to section 1002 of the Act (21 U.S.C. 952) for ephedrine, pseudoephedrine, and phenylpropanolamine.

§ 1315.02 Definitions.

(a) Except as specified in paragraphs (b) and (c) of this section, any term contained in this part shall have the definition set forth in section 102 of the Act (21 U.S.C. 802) or part 1300 of this chapter.

(b) The term *net disposal* means, for a stated period, the sum of paragraphs (b)(1) through (b)(3) of this section minus the sum of paragraphs (b)(4) and (b)(5) of this section:

(1) The quantity of ephedrine, pseudoephedrine, or phenylpropanolamine distributed by the registrant to another person.

(2) The quantity of that chemical used by the registrant in the production of (or converted by the registrant into) another chemical or product.

(3) The quantity of that chemical otherwise disposed of by the registrant.

(4) The quantity of that chemical returned to the registrant by any purchaser.

(5) The quantity of that chemical distributed by the registrant to a registered manufacturer of that chemical for purposes other than use in the production of, or conversion into, another chemical or in the manufacture of dosage forms of that chemical.

(c) Ephedrine, pseudoephedrine, and phenylpropanolamine include their salts, optical isomers, and salts of optical isomers.

§ 1315.03 Personal use exemption.

A person need not register as an importer, file an import declaration, and obtain an import quota if both of the following conditions are met:

(a) The person purchases scheduled listed chemical products at retail and imports them for personal use, by means of shipping through any private or commercial carrier or the Postal Service.

(b) In any 30-day period, the person imports no more than 7.5 grams of ephedrine base, 7.5 grams of pseudoephedrine base, and 7.5 grams of phenylpropanolamine base in scheduled listed chemical products.

§ 1315.05 Applicability.

This part applies to all of the following:

(a) Persons registered to manufacture (including repackaging or relabeling) or to import ephedrine, pseudoephedrine, or phenylpropanolamine as bulk chemicals.

(b) Persons registered to manufacture (including repackaging or relabeling) or

to import prescription and over-the-counter drug products containing ephedrine, pseudoephedrine, or phenylpropanolamine that may be lawfully marketed and distributed in the United States under the Federal Food, Drug, and Cosmetic Act.

Subpart B—Assessment of Annual Needs

§ 1315.11 Assessment of annual needs.

(a) The Administrator shall determine the total quantity of ephedrine, pseudoephedrine, and phenylpropanolamine, including drug products containing ephedrine, pseudoephedrine, and phenylpropanolamine, necessary to be manufactured and imported during the following 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.

(b) In making his determinations, the Administrator shall consider the following factors:

(1) Total net disposal of the chemical by all manufacturers and importers during the current and 2 preceding years;

(2) Trends in the national rate of net disposal of each chemical;

(3) Total actual (or estimated) inventories of the chemical and of all substances manufactured from the chemical, and trends in inventory accumulation;

(4) Projected demand for each chemical as indicated by procurement and import quotas requested pursuant to § 1315.32; and

(5) Other factors affecting medical, scientific, research, and industrial needs in the United States, lawful export requirements, and the establishment and maintenance of reserve stocks, as the Administrator finds relevant, including changes in the currently accepted medical use in treatment with the chemicals or the substances which are manufactured from them, the economic and physical availability of raw materials for use in manufacturing and for inventory purposes, yield and stability problems, potential disruptions to production (including possible labor strikes), and recent unforeseen emergencies such as floods and fires.

(c) The Administrator shall, on or before May 1 of each year, publish in the **Federal Register**, general notice of an assessment of annual needs for ephedrine, pseudoephedrine, and phenylpropanolamine determined by him under this section. A notice of the publication shall be mailed simultaneously to each person registered to manufacture or import the chemical.

(d) The Administrator shall permit any interested person to file written comments on or objections to the proposed assessment of annual needs and shall designate in the notice the time during which the filings may be made.

(e) The Administrator may, but is not required to, hold a public hearing on one or more issues raised by the comments and objections filed with him. In the event the Administrator decides to hold such a hearing, he shall publish a notice of the hearing in the **Federal Register**. The notice shall summarize the issues to be heard and set the time for the hearing, which shall not be less than 30 days after the date of publication of the notice.

(f) After consideration of any comments or objections, or after a hearing if one is ordered by the Administrator, the Administrator shall issue and publish in the **Federal Register** the final order determining the assessment of annual needs for the chemicals. The order shall include the findings of fact and conclusions of law upon which the order is based. The order shall specify the date on which it shall take effect. A notice of the publication shall be mailed simultaneously to each person registered as a manufacturer or importer of the chemical.

§ 1315.13 Adjustments of the assessment of annual needs.

(a) The Administrator may at any time increase or reduce the assessment of annual needs for ephedrine, pseudoephedrine, or phenylpropanolamine that has been previously fixed pursuant to § 1315.11.

(b) In determining to adjust the assessment of annual needs, the Administrator shall consider the following factors:

(1) Changes in the demand for that chemical, changes in the national rate of net disposal of the chemical, and changes in the rate of net disposal of the chemical by registrants holding individual manufacturing or import quotas for that chemical;

(2) Whether any increased demand for that chemical, the national and/or changes in individual rates of net disposal of that chemical are temporary, short term, or long term;

(3) Whether any increased demand for that chemical can be met through existing inventories, increased individual manufacturing quotas, or increased importation, without increasing the assessment of annual needs, taking into account production delays and the probability that other individual manufacturing quotas may be suspended pursuant to § 1315.24(b);

(4) Whether any decreased demand for that chemical will result in excessive inventory accumulation by all persons registered to handle that chemical (including manufacturers, distributors, importers, and exporters), notwithstanding the possibility that individual manufacturing quotas may be suspended pursuant to § 1315.24(b) or abandoned pursuant to § 1315.27;

(5) Other factors affecting medical, scientific, research, industrial, and importation needs in the United States, lawful export requirements, and reserve stocks, as the Administrator finds relevant, including changes in the currently accepted medical use in treatment with the chemical or the substances that are manufactured from it, the economic and physical availability of raw materials for use in manufacturing and for inventory purposes, yield and stability problems, potential disruptions to production (including possible labor strikes), and recent unforeseen emergencies such as floods and fires.

(c) In the event that the Administrator determines to increase or reduce the assessment of annual needs for a chemical, the Administrator shall publish in the **Federal Register** general notice of an adjustment in the assessment of annual needs for that chemical as determined under this section. A notice of the publication shall be mailed simultaneously to each person registered as a manufacturer or importer of the chemical.

(d) The Administrator shall permit any interested person to file written comments on or objections to the proposal and shall designate in the notice the time during which such filings may be made.

(e) The Administrator may, but is not required to, hold a public hearing on one or more issues raised by the comments and objections filed with him. In the event the Administrator decides to hold such a hearing, he shall publish a notice of the hearing in the **Federal Register**. The notice shall summarize the issues to be heard and set the time for the hearing, which shall not be less than 10 days after the date of publication of the notice.

(f) After consideration of any comments or objections, or after a hearing if one is ordered by the Administrator, the Administrator shall issue and publish in the **Federal Register** the final order determining the assessment of annual needs for the chemical. The order shall include the

findings of fact and conclusions of law upon which the order is based. The order shall specify the date on which it shall take effect. A notice of the publication shall be mailed simultaneously to each person registered as a manufacturer or importer of the chemical.

Subpart C—Individual Manufacturing Quotas

§ 1315.21 Individual manufacturing quotas.

The Administrator shall, on or before July 1 of each year, fix for and issue to each person registered to manufacture in bulk ephedrine, pseudoephedrine, or phenylpropanolamine who applies for a manufacturing quota an individual manufacturing quota authorizing that person to manufacture during the next calendar year a quantity of that chemical. Any manufacturing quota fixed and issued by the Administrator is subject to his authority to reduce or limit it at a later date pursuant to § 1315.26 and to his authority to revoke or suspend it at any time pursuant to §§ 1301.36, 1309.43, 1309.44, or 1309.45 of this chapter.

§ 1315.22 Procedure for applying for individual manufacturing quotas.

Any person who is registered to manufacture ephedrine, pseudoephedrine, or phenylpropanolamine and who desires to manufacture a quantity of the chemical must apply on DEA Form 189 for a manufacturing quota for the quantity of the chemical. Copies of DEA Form 189 may be obtained from the Office of Diversion Control Web site, and must be filed (on or before April 1 of the year preceding the calendar year for which the manufacturing quota is being applied) with the Drug & Chemical Evaluation Section, Drug Enforcement Administration, Department of Justice, Washington, DC 20537. A separate application must be made for each chemical desired to be manufactured. The applicant must state the following:

(a) The name and DEA Chemical Code Number, as set forth in part 1310 of this chapter, of the chemical.

(b) For the chemical in each of the current and preceding 2 calendar years,

(1) The authorized individual manufacturing quota, if any;

(2) The actual or estimated quantity manufactured;

(3) The actual or estimated net disposal;

(4) The actual or estimated inventory allowance pursuant to § 1315.24; and

(5) The actual or estimated inventory as of December 31.

(c) For the chemical in the next calendar year,

(1) The desired individual manufacturing quota; and

(2) Any additional factors that the applicant finds relevant to the fixing of the individual manufacturing quota, including any of the following:

(i) The trend of (and recent changes in) the applicant's and the national rates of net disposal.

(ii) The applicant's production cycle and current inventory position.

(iii) The economic and physical availability of raw materials for use in manufacturing and for inventory purposes.

(iv) Yield and stability problems.

(v) Potential disruptions to production (including possible labor strikes).

(vi) Recent unforeseen emergencies such as floods and fires.

§ 1315.23 Procedure for fixing individual manufacturing quotas.

(a) In fixing individual manufacturing quotas for ephedrine, pseudoephedrine, and phenylpropanolamine, the Administrator shall allocate to each applicant who is currently manufacturing the chemical a quota equal to 100 percent of the estimated net disposal of that applicant for the next calendar year, adjusted—

(1) By the amount necessary to increase or reduce the estimated inventory of the applicant on December 31 of the current year to his estimated inventory allowance for the next calendar year, pursuant to § 1315.24, and

(2) By any other factors which the Administrator deems relevant to the fixing of the individual manufacturing quota of the applicant, including:

(i) The trend of (and recent changes in) the applicant's and the national rates of net disposal,

(ii) The applicant's production cycle and current inventory position,

(iii) The economic and physical availability of raw materials for use in manufacturing and for inventory purposes,

(iv) Yield and stability problems,

(v) Potential disruptions to production (including possible labor strikes), and

(vi) Recent unforeseen emergencies such as floods and fires.

(b) In fixing individual manufacturing quotas for a chemical, the Administrator shall allocate to each applicant who is not currently manufacturing the chemical a quota equal to 100 percent of the reasonably estimated net disposal of that applicant for the next calendar year, as determined by the Administrator, adjusted—

(1) By the amount necessary to provide the applicant his estimated inventory allowance for the next calendar year, pursuant to § 1315.24; and

(2) By any other factors which the Administrator deems relevant to the fixing of the individual manufacturing quota of the applicant, including any of the following:

(i) The trend of (and recent changes in) the national rate of net disposal.

(ii) The applicant's production cycle and current inventory position.

(iii) The economic and physical availability of raw materials for use in manufacturing and for inventory purposes.

(iv) Yield and stability problems.

(v) Potential disruptions to production (including possible labor strikes).

(vi) Recent unforeseen emergencies such as floods and fires.

(c) On or before March 1 of each year the Administrator shall adjust the individual manufacturing quota allocated for that year to each applicant in paragraph (a) of this section by the amount necessary to increase or reduce the actual inventory of the applicant to December 31 of the preceding year to his estimated inventory allowance for the current calendar year, pursuant to § 1315.24.

§ 1315.24 Inventory allowance.

(a) For the purpose of determining individual manufacturing quotas pursuant to § 1315.23, each registered manufacturer shall be allowed as a part of the quota an amount sufficient to maintain an inventory equal to either of the following:

(1) For current manufacturers, 50 percent of his average estimated net disposal for the current calendar year and the last preceding calendar year; or

(2) For new manufacturers, 50 percent of his reasonably estimated net disposal for the next calendar year as determined by the Administrator.

(b) During each calendar year each registered manufacturer shall be allowed to maintain an inventory of a chemical not exceeding 65 percent of his estimated net disposal of that chemical for that year, as determined at the time his quota for that year was determined. At any time the inventory of a chemical held by a manufacturer exceeds 65 percent of his estimated net disposal, his quota for that chemical is automatically suspended and shall remain suspended until his inventory is less than 60 percent of his estimated net disposal. The Administrator may, upon application and for good cause shown, permit a manufacturer whose quota is,

or is likely to be, suspended under this paragraph to continue manufacturing and to accumulate an inventory in excess of 65 percent of his estimated net disposal, upon such conditions and within such limitations as the Administrator may find necessary or desirable.

(c) If, during a calendar year, a registrant has manufactured the entire quantity of a chemical allocated to him under an individual manufacturing quota, and his inventory of that chemical is less than 40 percent of his estimated net disposal of that chemical for that year, the Administrator may, upon application pursuant to § 1315.25, increase the quota of such registrant sufficiently to allow restoration of the inventory to 50 percent of the estimated net disposal for that year.

§ 1315.25 Increase in individual manufacturing quotas.

(a) Any registrant who holds an individual manufacturing quota for a chemical may file with the Administrator an application on DEA Form 189 for an increase in the registrant's quota to meet the registrant's estimated net disposal, inventory, and other requirements during the remainder of that calendar year.

(b) The Administrator, in passing upon a registrant's application for an increase in the individual manufacturing quota, shall take into consideration any occurrences since the filing of the registrant's initial quota application that may require an increased manufacturing rate by the registrant during the balance of the calendar year. In passing upon the application the Administrator may also take into consideration the amount, if any, by which his determination of the total quantity for the chemical to be manufactured under § 1315.11 exceeds the aggregate of all the individual manufacturing quotas for the chemical, and the equitable distribution of such excess among other registrants.

§ 1315.26 Reduction in individual manufacturing quotas.

The Administrator may at any time reduce an individual manufacturing quota for a chemical that he has previously fixed to prevent the aggregate of the individual manufacturing quotas and import quotas outstanding or to be granted from exceeding the assessment of annual needs that has been established for that chemical pursuant to § 1315.11, as adjusted pursuant to § 1315.13. If a quota assigned to a new manufacturer pursuant to § 1315.23(b), or if a quota assigned to any manufacturer is increased pursuant to § 1315.24(c), or if an import quota issued to an importer pursuant to § 1315.34, causes the total quantity of a chemical to be manufactured and imported during the year to exceed the assessment of annual needs that has been established for that chemical pursuant to § 1315.11, as adjusted pursuant to § 1315.13, the Administrator may proportionately reduce the individual manufacturing quotas and import quotas of all other registrants to keep the assessment of annual needs within the limits originally established, or, alternatively, the Administrator may reduce the individual manufacturing quota of any registrant whose quota is suspended pursuant to § 1315.24(b) or §§ 1301.36, 1309.43, 1309.44, or 1309.45 of this chapter or is abandoned pursuant to § 1315.27.

§ 1315.27 Abandonment of quota.

Any manufacturer assigned an individual manufacturing quota for a chemical pursuant to § 1315.23 may at any time abandon his right to manufacture all or any part of the quota by filing with the Drug & Chemical Evaluation Section a written notice of the abandonment, stating the name and DEA Chemical Code Number, as set forth in part 1310 of this chapter, of the chemical and the amount which he has chosen not to manufacture. The Administrator may, in his discretion, allocate the amount among the other manufacturers in proportion to their respective quotas.

Subpart D—Procurement and Import Quotas

§ 1315.30 Procurement and import quotas.

(a) To determine the estimated needs for, and to insure an adequate and uninterrupted supply of, ephedrine, pseudoephedrine, and phenylpropanolamine the Administrator shall issue procurement and import quotas.

(b) A procurement quota authorizes a registered manufacturer to procure and use quantities of each chemical for the following purposes:

(1) Manufacturing the bulk chemical into dosage forms.

(2) Manufacturing the bulk chemical into other substances.

(3) Repackaging or relabeling the chemical or dosage forms.

(c) An import quota authorizes a registered importer to import quantities of the chemical for the following purposes:

(1) Distribution of the chemical to a registered manufacturer that has a procurement quota for the chemical.

(2) Other distribution of the chemical consistent with the legitimate medical and scientific needs of the United States.

§ 1315.32 Obtaining a procurement quota.

(a) Any person who is registered to manufacture ephedrine, pseudoephedrine, or phenylpropanolamine, or whose requirement of registration is waived pursuant to § 1309.24 of this chapter, and who desires to use during the next calendar year any ephedrine, pseudoephedrine, or phenylpropanolamine for purposes of manufacturing (including repackaging or relabeling), must apply on DEA Form 250 for a procurement quota for the chemical. A separate application must be made for each chemical desired to be procured or used.

(b) The applicant must state separately all of the following:

(1) Each purpose for which the chemical is desired.

(2) The quantity desired for each purpose during the next calendar year.

(3) The quantities used and estimated to be used, if any, for that purpose during the current and preceding 2 calendar years.

(c) If the purpose is to manufacture the chemical into dosage form, the applicant must state the official name, common or usual name, chemical name, or brand name of that form. If the dosage form produced is a controlled substance listed in any schedule, the applicant must also state the schedule number and National Drug Code Number, of the substance.

(d) If the purpose is to manufacture another chemical, the applicant must state the official name, common or usual name, chemical name, or brand name of the substance and the DEA Chemical Code Number, as set forth in part 1310 of this chapter.

(e) DEA Form 250 must be filed on or before April 1 of the year preceding the calendar year for which the procurement quota is being applied. Copies of DEA Form 250 may be obtained from the Office of Diversion Control Web site, and must be filed with the Drug & Chemical Evaluation Section, Drug Enforcement Administration, Department of Justice, Washington, DC 20537.

(f) The Administrator shall, on or before July 1 of the year preceding the calendar year during which the quota shall be effective, issue to each qualified applicant a procurement quota authorizing him to procure and use:

(1) All quantities of the chemical necessary to manufacture products that the applicant is authorized to manufacture pursuant to § 1315.23; and

(2) Such other quantities of the chemical as the applicant has applied to procure and use and are consistent with his past use, his estimated needs, and the total quantity of the chemical that will be produced.

(g) Any person to whom a procurement quota has been issued may at any time request an adjustment in the quota by applying to the Administrator with a statement showing the need for the adjustment. The application must be filed with the Drug & Chemical Evaluation Section, Drug Enforcement Administration, Department of Justice, Washington, DC 20537. The Administrator shall increase or decrease the procurement quota of the person if and to the extent that he finds, after considering the factors enumerated in paragraph (f) of this section and any occurrences since the issuance of the procurement quota, that the need justifies an adjustment.

(h) Any person to whom a procurement quota has been issued, authorizing that person to procure and use a quantity of ephedrine, pseudoephedrine, or phenylpropanolamine during the current calendar year, must, at or before the time of placing an order with another manufacturer or importer requiring the distribution of a quantity of the chemical, certify in writing to the other registrant that the quantity of ephedrine, pseudoephedrine, or phenylpropanolamine ordered does not exceed the person's unused and available procurement quota of the chemical for the current calendar year. The written certification must be executed by a person authorized to sign the registration application pursuant to § 1301.13 or § 1309.32(g) of this chapter. Registrants must not fill an order from persons required to apply for a procurement quota under paragraph (b) of this section unless the order is accompanied by a certification as required under this section.

(i) The certification required by paragraph (h) of this section must contain all of the following:

(1) The date of the certification.

(2) The name and address of the registrant to whom the certification is directed.

(3) A reference to the purchase order number to which the certification applies.

(4) The name of the person giving the order to which the certification applies.

(5) The name of the chemical to which the certification applies.

(6) A statement that the quantity (expressed in grams) of the chemical to which the certification applies does not exceed the unused and available procurement quota of the chemical, issued to the person giving the order, for the current calendar year.

(7) The signature of the individual authorized to sign a certification as provided in paragraph (h) of this section.

§ 1315.34 Obtaining an import quota.

(a) Any person who is registered to import ephedrine, pseudoephedrine, or phenylpropanolamine, or whose requirement of registration is waived pursuant to § 1309.24(c) of this chapter, and who desires to import during the next calendar year any ephedrine, pseudoephedrine, or phenylpropanolamine or drug products containing these chemicals, must apply on DEA Form 488 for an import quota for the chemical. A separate application must be made for each chemical desired to be imported.

(b) The applicant must provide the following information in the application:

(1) The applicant's name and DEA registration number.

(2) The name and address of a contact person and contact information (telephone number, fax number, e-mail address).

(3) Name of the chemical and DEA Chemical Code number.

(4) Type of product (bulk or finished dosage forms).

(5) For finished dosage forms, the official name, common or usual name, chemical name, or brand name, NDC number, and the authority to market the drug product under the Federal Food, Drug and Cosmetic Act of each form to be imported.

(6) The amount requested expressed in terms of base.

(7) For the current and preceding two calendar years, expressed in terms of base:

(i) Distribution/Sales—name, address, and registration number (if applicable) of each customer and the amount sold.

(ii) Inventory as of December 31 (each form—bulk, in-process, finished dosage form).

(iii) Acquisition—imports.

(c) For each form of the chemical (bulk or dosage unit), the applicant must state the quantity desired for import during the next calendar year.

(d) DEA Form 488 must be filed on or before April 1 of the year preceding the calendar year for which the import quota is being applied. Copies of DEA Form 488 may be obtained from the Office of Diversion Control Web site, and must be filed with the Drug & Chemical Evaluation Section, Drug Enforcement Administration, Department of Justice, Washington, DC 20537.

(e) The Administrator may at his discretion request additional information from an applicant.

(f) On or before July 1 of the year preceding the calendar year during which the quota shall be effective, the Administrator shall issue to each qualified applicant an import quota authorizing him to import:

(1) All quantities of the chemical necessary to manufacture products that registered manufacturers are authorized to manufacture pursuant to § 1315.23; and

(2) Such other quantities of the chemical that the applicant has applied to import and that are consistent with his past imports, the estimated medical, scientific, and industrial needs of the United States, the establishment and maintenance of reserve stocks, and the total quantity of the chemical that will be produced.

§ 1315.36 Amending an import quota.

(a) An import quota authorizes the registered importer to import up to the set quantity of ephedrine, pseudoephedrine, or phenylpropanolamine and distribute the chemical or drug products on the DEA Form 488. An importer must apply to change the quantity to be imported.

(b) Any person to whom an import quota has been issued may at any time request an increase in the quota quantity by applying to the Administrator with a statement showing the need for the adjustment. The application must be filed with the Drug & Chemical Evaluation Section, Drug Enforcement Administration, Department of Justice, Washington, DC 20537. The Administrator may increase the import quota of the person if and to the extent that he determines that the approval is necessary to provide for medical, scientific, or other legitimate purposes regarding the chemical. The Administrator shall specify a period of time for which the approval is in effect or shall provide that the approval is in effect until the Administrator notifies the applicant in writing that the approval is terminated.

(c) With respect to the application under paragraph (b) of this section, the Administrator shall approve or deny the application within 60 days of receiving the application. If the Administrator does not approve or deny the application within 60 days of receiving it, the application is deemed to be approved and the approval remains in effect until the Administrator notifies the applicant in writing that the approval is terminated.

Subpart E—Hearings

§ 1315.50 Hearings generally.

The procedures for the hearing related to assessment of annual needs or to the issuance, adjustment, suspension, or denial of a manufacturing, procurement, or import quota are governed generally by the adjudication procedures set forth in the Administrative Procedure Act (5 U.S.C. 551–559) and specifically by section 1002 of the Act (21 U.S.C. 952), by §§ 1315.52 through 1315.62 of this part, and by the procedures for administrative hearings under the Act set forth in §§ 1316.41 through 1316.67 of this chapter.

§ 1315.52 Purpose of hearing.

(a) The Administrator may, in his sole discretion, hold a hearing for the purpose of receiving factual evidence regarding any one or more issues (to be specified by him) involved in the determination or adjustment of any assessment of national needs.

(b) If requested by a person applying for or holding a procurement, import, or individual manufacturing quota, the Administrator shall hold a hearing for the purpose of receiving factual evidence regarding the issues involved in the issuance, adjustment, suspension, or denial of the quota to the person, but the Administrator need not hold a hearing on suspension of a quota under § 1301.36 or § 1309.43 of this chapter separate from a hearing on the suspension of registration under that section.

(c) Extensive argument should not be offered into evidence, but rather presented in opening or closing statements of counsel or in memoranda or proposed findings of fact and conclusions of law.

§ 1315.54 Waiver or modification of rules.

The Administrator or the presiding officer (with respect to matters pending before him) may modify or waive any rule in this part by notice in advance of the hearing, if he determines that no party in the hearing will be unduly prejudiced and the ends of justice will thereby be served. Such notice of modification or waiver shall be made a part of the record of the hearing.

§ 1315.56 Request for hearing or appearance; waiver.

(a) Any applicant or registrant entitled to a hearing under § 1315.52 and who desires a hearing on the issuance, adjustment, suspension or denial of a procurement, import, or individual manufacturing quota must, within 30 days after the date of receipt of the issuance, adjustment, suspension or denial of the application, file with the Administrator a written request for a hearing in the form prescribed in § 1316.47 of this chapter.

(b) Any interested person who desires a hearing on the determination of an assessment of annual needs must, within the time prescribed in § 1315.11(c), file with the Administrator a written request for a hearing in the form prescribed in § 1316.47 of this chapter, including in the request a statement of the grounds for the hearing.

(c) Any interested person who desires to participate in a hearing on the determination or adjustment of an assessment of annual needs, which hearing is ordered by the Administrator under § 1315.11(c) or § 1315.13(c), may do so by filing with the Administrator, within 30 days of the date of publication of notice of the hearing in the **Federal Register**, a written notice of his intention to participate in the hearing in the form prescribed in § 1316.48 of this chapter.

(d) Any person entitled to a hearing under § 1315.52 or entitled to participate in a hearing under paragraph (c) of this section may, within the period permitted for filing a request for a hearing or notice of appearance, file with the Administrator a waiver of an opportunity for a hearing, together with a written statement regarding his position on the matters of fact and law involved in such hearing. The statement, if admissible, shall be made a part of the record and shall be considered in light of the lack of opportunity for cross-examination in determining the weight to be attached to matters of fact asserted.

(e) If any person entitled to a hearing under § 1315.52 or entitled to participate in a hearing under paragraph (c) of this section fails to file a request for a hearing or notice of appearance or if he so files and fails to appear at the hearing, he shall be deemed to have waived his opportunity for the hearing unless he shows good cause for such failure.

(f) If all persons entitled to a hearing or to participate in a hearing waive or are deemed to waive their opportunity for the hearing or to participate in the hearing, the Administrator may cancel the hearing, if scheduled, and issue his final order under § 1315.62 without a hearing.

§ 1315.58 Burden of proof.

(a) At any hearing regarding the determination or adjustment of an assessment of annual needs each interested person participating in the hearing shall have the burden of proving any propositions of fact or law asserted by him in the hearing.

(b) At any hearing regarding the issuance, adjustment, suspension, or denial of a procurement, import, or individual manufacturing quota, the Administration shall have the burden of proving that the requirements of this part for such issuance, adjustment, suspension, or denial are satisfied.

§ 1315.60 Time and place of hearing.

(a) If any applicant or registrant requests a hearing on the issuance, adjustment, suspension, or denial of his procurement, import, or individual manufacturing quota under § 1315.54, the Administrator shall hold a hearing.

(b) Notice of the hearing shall be given to the applicant or registrant of the time and place at least 30 days prior to the hearing, unless the applicant or registrant waives such notice and requests the hearing be held at an earlier time, in which case the Administrator shall fix a date for such hearing as early as reasonably possible.

(c) The hearing shall commence at the place and time designated in the notice given under paragraph (b) of this section or in the notice of hearing published in the **Federal Register** pursuant to § 1315.11(c) or § 1315.13(c), but thereafter it may be moved to a different place and may be continued from day to day or recessed to a later day without notice other than announcement by the presiding officer at the hearing.

§ 1315.62 Final order.

As soon as practicable after the presiding officer has certified the record to the Administrator, the Administrator shall issue his order on the determination or adjustment of the assessment of annual needs or on the issuance, adjustment, suspension, or denial of the procurement, import, or individual manufacturing quota, as the case may be. The order shall include the findings of fact and conclusions of law upon which the order is based. The order shall specify the date on which it shall take effect. The Administrator shall serve one copy of his order upon each party in the hearing.

Dated: June 19, 2007.

Michele M. Leonhart,

Deputy Administrator.

[FR Doc. E7–13377 Filed 7–9–07; 8:45 am]

BILLING CODE 4410–09–P