components, parts, accessories, attachments and associated equipment that are not specifically designed or modified for aircraft on the Munitions List and all components and parts not on the Munitions List by virtue of the criteria set forth in the note to Category VIII(h) of 22 CFR part 121.

* * * * *

PART 774—[AMENDED]

■ 3. The authority citation for 15 CFR part 774 continues to read as follows:

Authority: 50 U.S.C. app. 2401 *et seq.*; 50 U.S.C. 1701 *et seq.*; 10 U.S.C. 7420; 10 U.S.C. 7430(e); 22 U.S.C. 287c, 22 U.S.C. 3201 *et seq.*; 22 U.S.C. 6004; 30 U.S.C. 185(s), 185(u); 42 U.S.C. 2139a; 42 U.S.C. 6212; 43 U.S.C. 1354; 46 U.S.C. app. 466c; 50 U.S.C. app. 5; 22 U.S.C. 7201 *et seq.*; 22 U.S.C. 7210; E.O. 13026, 61 FR 58767, 3 CFR, 1996 Comp., p. 228; E.O. 13222, 66 FR 44025, 3 CFR, 2001 Comp., p. 783; Notice of July 23, 2008, 73 FR 43603 (July 25, 2008).

■ 4. In Supplement No. 1 to part 774 (the Commerce Control List), Category 9—Propulsion Systems, Space Vehicles and Related Equipment, Export Control Classification Number (ECCN) 9A991 is amended by revising paragraph (a) of the ''Items'' paragraph in the List of Items Controlled section, to read as follows:

Supplement No. 1 to Part 774—The Commerce Control List

* * * * *

9A991 ''Aircraft'', n.e.s., and gas turbine engines not controlled by 9A001 or 9A101 and parts and components, n.e.s.

* * * * *

List of Items Controlled

Unit: * * *

Related Controls: * * *

Related Definitions: * * *

Items:

a. Military aircraft, demilitarized (not specifically equipped or modified for military operation), as follows:

a.1 Cargo aircraft bearing ''C'' designations and numbered C–45 through C–118 inclusive, C–121 through C–125 inclusive, and C–131, using reciprocating engines only.

a.2 Trainer aircraft bearing ''T'' designations and using reciprocating engines or turboprop engines with less than 600 horsepower (s.h.p.).

a.3 Utility aircraft bearing ''U'' designations and using reciprocating engines only.

a.4 All liaison aircraft bearing an ''L'' designation.

a.5 All observation aircraft bearing ''O'' designations and using reciprocating engines.

* * * * *

Dated: November 26, 2008.

Matthew S. Borman,

Deputy Assistant Secretary for Export Administration.

[FR Doc. E8–28654 Filed 12–2–08; 8:45 am]

BILLING CODE 3510–33–P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

21 CFR Parts 1300, 1315, and 1316

[Docket No. DEA–293F]

RIN 1117–AB08

Import and Production Quotas for Certain List I Chemicals

AGENCY: Drug Enforcement Administration (DEA), Justice.

ACTION: Final rule.

SUMMARY: On March 9, 2006, the President signed the Combat Methamphetamine Epidemic Act of 2005, which mandates that DEA establish total annual requirements, and individual import, manufacturing, and procurement quotas for ephedrine, pseudoephedrine, and phenylpropanolamine. DEA issued an Interim Final Rule establishing procedures for applying for individual import, manufacturing, and procurement quotas. DEA is finalizing the rule with one change, to extend the authority to sign certifications to persons granted power of attorney to do so by the registrant.

DATES: *Effective Date:* December 3, 2008.

FOR FURTHER INFORMATION CONTACT: Christine A. Sannerud, Ph.D., Chief, Drug and Chemical Evaluation Section, Office of Diversion Control, Drug Enforcement Administration, 8701 Morrissette Drive, Springfield, VA 22152; 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, importing, and exporting 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.

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 nonprescription (over-the-counter) (OTC) products, which the CMEA defined as ''scheduled listed chemical 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 are regulated under the CSA. (The law contained an exception from recordkeeping requirements for individual sales transactions consisting of a single

package of pseudoephedrine where the package contains not more than 60 milligrams.)

- DEA must establish an assessment of the annual needs for the estimated medical, scientific, research, and industrial needs of the United States, for lawful exports, and for maintenance of reserve stocks, for the three chemicals. That assessment establishes an upper limit on the quantity of the chemicals and products containing the chemicals that can be produced in or imported into 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.

Interim Final Rule

On July 10, 2007, DEA published an Interim Final Rule to establish the procedures for manufacturers to apply for manufacturing and procurement quotas and for importers to apply for import quotas, as required under CMEA (72 FR 37439). The Interim Final Rule created a new part 1315, which parallels the existing part 1303, which covers the same processes for controlled substances. The Interim Final Rule established the following requirements:

Production Quotas

Bulk manufacturers of the three chemicals are 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 a quota is applied. A bulk manufacturer must complete and file a DEA Form 189 on or before May 1 of each year for the following calendar year, as discussed further below. The applicant must provide the following information on the form:

- For the current and preceding two calendar 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.

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 is required to obtain a procurement quota to obtain the bulk chemicals or dosage forms. A separate procurement quota is required for each chemical. A manufacturer must be registered as a manufacturer to handle the chemical for which a quota is applied. A manufacturer must complete and file a DEA Form 250 on or before April 1 of each year for the following calendar year. 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 two 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 applicant must state the type of activity intended: Product development, repackaging, relabeling, manufacturing OTC finished product, or 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.

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 are required to obtain an import quota for each chemical covering both bulk chemicals and dosage forms. An importer must be registered as an importer of the chemical for which a quota is applied. An importer must complete and file a DEA Form 488 on or before April 1 of each year for the following calendar year. The applicant must provide 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 calendar 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. As noted above, 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 uses 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. The criteria to be considered in setting quotas are set forth in the CSA. Specifically, the CSA requires the Attorney General, DEA by delegation, to establish production quotas, referred to here as the assessment of annual national needs for the List I chemicals ephedrine, pseudoephedrine, and phenylpropanolamine, in terms of quantities of the listed chemical and not in terms of individual dosage forms (21 U.S.C. 826(a); 21 CFR 1315.11). The actual setting of the annual assessment is done after considering the factors in 21 CFR 1315.11, publishing a proposed annual assessment, and giving the regulated community an opportunity to comment before finalizing the annual assessment (21 CFR 1315.13). DEA published the initial established assessment of annual needs for 2008 on December 27, 2007 (72 FR 73361), proposed revisions and accepted comments thereto (73 FR 35410, June 23, 2008), and published the final 2008 assessment of annual national needs (73 FR 63732, October 27, 2008). DEA must limit or reduce individual production quotas to the extent necessary to prevent the aggregate of all individual quotas from exceeding the assessment of annual national needs (21 U.S.C. 826(b)). In establishing individual manufacturing quotas based on the assessment of annual national needs, DEA considers the manufacturer's estimated disposal, inventory, and other requirements for the calendar year; DEA also considers the manufacturer's current rate of disposal, the trend of the national disposal rate during the preceding calendar year, the manufacturer's production cycle and inventory position, the economic availability of raw materials, yield and stability problems, emergencies such as strikes and fires, and other factors (21 U.S.C. 826(c); 21 CFR 1315.23). DEA notes that the rule being finalized today does not establish the assessment or individual quotas; today's rule simply finalizes the establishment of procedures for collecting information from manufacturers and importers.

The assessment of annual needs 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 adopted the same process for manufacturing and procurement quotas for the three chemicals as was already in place for manufacturing and procurement quotas for controlled substances. Manufacturers may apply for increases in their manufacturing quotas (21 CFR 1315.25); DEA may reduce individual manufacturing quotas to prevent the total amount produced from exceeding the assessment of annual needs (21 CFR 1315.26). Manufacturers may abandon their quota by notifying DEA (21 CFR 1315.27).

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 (21 CFR 1315.32(g)). 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 (21 CFR 1315.32(h)).

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 (21 CFR 1315.36). 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 (21 U.S.C. 952(d); 21 CFR 1315.36(c)).

DEA may hold hearings, at the Administrator's sole discretion, to obtain factual evidence regarding the determination or adjustment of any assessment of annual national needs (21 CFR 1315.52(a)). Applicants or quota holders may request hearings on the issuance, adjustment, suspension, or denial of a quota (21 CFR 1315.52(b)). In hearings on the assessment of annual national needs, each interested party has the burden of proving any propositions of fact or law that the party asserts (21 CFR 1315.58(a)). At hearings on the issuance, adjustment, suspension, or denial of an individual quota, DEA has the burden of proving that the requirements for issuance, adjustment, suspension, or denial of an individual quota are met (21 CFR 1315.58(b)).

Discussion of Comments

DEA received five comments on the Interim Final Rule. Commenters included an association representing distributors of drug products containing ephedrine, pseudoephedrine, and phenylpropanolamine; two manufacturers; one distributor; and an association representing manufacturers and distributors of OTC products.

General Comments

One commenter supported the rule as written, three commenters requested clarification of certain aspects of the rule, and one commenter raised objections to the rule, although its comments actually addressed issues that were not the subject of the Interim Final Rule.

Three of the commenters raised issues about the actual assessment of annual needs for the List I chemicals ephedrine, pseudoephedrine, and phenylpropanolamine rather than the process manufacturers and importers will use to apply for a quota, which is the subject of this rulemaking. One distributor stated that DEA had failed to prove that convenience stores are a ''gray market'' for these products.

DEA Response: The issues raised about the assessment of annual needs

are beyond the scope of this Final Rule, which deals only with the procedures for applying for and obtaining quotas in general. Any comments on the establishment or revision of the annual assessment and the methodology used to develop it should be submitted in response to notices DEA may publish regarding the assessment of annual needs. This rule includes only the general approach for establishing and issuing the proposed and final assessments of annual needs and individual quotas and contains only the statutory criteria. The issues related to the sale of products containing the three List I chemicals at nonconventional outlets are also beyond the scope of this rule, which does not regulate distributors or retailers. Therefore, these comments are not addressed in this Final Rule.

Obtaining a Procurement Quota

One pharmaceutical manufacturer asked DEA to revise the requirement that the certification that an order is within the manufacturer's procurement quota be signed by a person eligible to sign a registration. The commenter noted that for controlled substances, the certification may be signed by a person who is eligible to sign the DEA Form 222 ''U.S. Official Order Form for Schedule I and II Controlled Substances'', which may be a person granted signing authority through a power of attorney.

DEA Response: DEA agrees with the commenter and is revising 21 CFR 1315.32(h) to permit the signature of a certification for procurement quota to be by an individual authorized to sign the registration, or a person granted power of attorney to sign the certification. DEA is also amending the regulations to add 21 CFR 1315.33, which establishes a process for granting and revoking power of attorney delegations. This process parallels the process in existence for controlled substance orders under part 1305.

Distinction Among Types of Outlets

One association representing manufacturers and distributors of OTC drug products supported the rule and DEA's tripartite distinction among manufacturers and importers: Those that handle prescription drugs, those that produce products sold mainly through conventional outlets, and those that sell certain high dosage unit products almost exclusively through nonconventional outlets. The commenter noted some inconsistencies in the references to these groups that the commenter stated could be confusing. A manufacturer also raised concerns about DEA's review of quota applications where the manufacturer's products are sold through conventional and nonconventional outlets.

DEA Response: DEA appreciates the support for this rulemaking expressed by the association. DEA emphasizes that each quota application will be reviewed on its own merits. DEA recognizes that many products are sold through both conventional and nonconventional outlets. As the 2002 Economic Census of the Retail Trade, Product Line, data indicate, nonconventional outlets handle only about three percent of sales of OTC medications. Products sold through both types of retail outlets, therefore, will be mainly sold through conventional outlets. As DEA stated in the Interim Final Rule, its concern with products sold through nonconventional outlets is with a limited number of high-dosage-unit products, sold almost exclusively through these outlets and the Internet. These high-dosage-unit products are generally not the bronchodilators used for asthma that commenters cited as a concern.

Assessment of Annual Needs

One manufacturer raised concerns about the consideration of data in the assessment of annual needs. The commenter stated that the trends in demand for ephedrine and pseudoephedrine appear to be changing as customers find the substitutes inadequate. The commenter asked that DEA consider both present and past trends.

DEA Response: DEA agrees with the commenter that changing trends in use need to be considered when establishing the assessment of annual needs for ephedrine, pseudoephedrine, and phenylpropanolamine. DEA notes that manufacturers and importers had an opportunity to comment on the proposed 2008 assessment of annual needs (72 FR 53911, September 20, 2007), and to submit additional information on demand to assist DEA in ensuring that the initial established assessment (72 FR 73361, December 27, 2007) met the legitimate medical, scientific, research, and industrial needs of the United States, for lawful exports, and for maintenance of reserve stocks. As required, DEA will revise the assessment of annual needs and will again seek comment from importers and manufacturers (21 CFR 1315.13).

Inventory Allowances

One manufacturer raised issues related to the inventory allowance for bulk manufacturers and asked that importers also be given inventory allowances. The commenter stated that unlike controlled substances, where imports are allowed only if domestic manufacturers cannot meet the need, with these chemicals most of the chemicals are imported. The commenter stated that providing inventory allowances only to bulk manufacturers would place other manufacturers that rely on imports for the chemical at a disadvantage. The commenter suggested that both manufacturers and importers be given a 20 percent inventory allowance.

DEA Response: DEA agrees with the commenter that the inventory allowance is an issue. Congress clearly intended that these chemicals should be closely regulated. In its Interim Final Rule establishing the procedures to implement individual procurement quotas, DEA established a 50 percent inventory allowance, the same allowance permitted for manufacturers of controlled substances. DEA believes that the 50 percent inventory allowance may be too great in some circumstances. Because this issue was not raised in the Interim Final Rule, however, DEA plans to address it in a separate rulemaking to give regulated entities an opportunity to comment.

Regarding the commenter's suggestion for an inventory allowance for importers and manufacturers obtaining procurement quotas, as noted previously, all importation of ephedrine, pseudoephedrine, and phenylpropanolamine is prohibited except such amounts as the Attorney General finds to be necessary to provide for the medical, scientific, and other legitimate needs of the United States (21 U.S.C. 952(a)). Further, CMEA specifically amended the CSA to require that importers specify, as part of the import declaration for all listed chemicals, the name of the transferee (''downstream customer'') of the chemicals and the quantity of the chemicals to be transferred (21 U.S.C. 971(d)). Thus, as importers must provide, prior to importation, the name of the transferee to whom the chemicals are to be transferred, there should be limited need for the importer to maintain an inventory of these chemicals.

Petition for Repeal

One distributor stated that the Interim Final Rule will cause harm to the national economy through loss of jobs at convenience stores due to loss of sales of ephedrine-based products. The commenter also claimed that the Interim Final Rule would cause harm to rural communities which would not be able to obtain the products and that DEA had underestimated the cost of the rule. The

commenter asked DEA to stay the Final Rule until DEA has ruled on its petition for repeal. The commenter also claimed that the Interim Final Rule quota was based on incomplete data and was, therefore, arbitrary and capricious and a violation of the Administrative Procedure Act. The commenter stated that DEA should have used notice and comment rulemaking for the Interim Final Rule. Finally, the commenter stated that the rule would not affect diversion and methamphetamine abuse.

DEA Response: The commenter appears to have misunderstood the nature of this rulemaking. The Interim Final Rule addressed only the procedures that importers and manufacturers must follow to apply for import, manufacturing, and procurement quotas for ephedrine, pseudoephedrine, and phenylpropanolamine. The rule did not establish the assessment of annual needs for ephedrine, pseudoephedrine, and phenylpropanolamine or individual quotas, nor did it address the subsequent distribution of scheduled listed chemical products. The Interim Final Rule had no impact on the convenience store industry, nor on the availability of scheduled listed chemical products at retail—either in urban or rural communities.

Regarding the cost of the Interim Final Rule, as DEA discussed in that rule, the only cost associated with this rulemaking is the cost of applying for import, manufacturing, or procurement quota. 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.

Regarding the commenter's claim that the Interim Final Rule was arbitrary and capricious, and that DEA should have used notice and comment rulemaking to implement the provisions of CMEA, DEA believes that it had good cause under the Administrative Procedure Act to publish the rule as an Interim Final Rule. As DEA explained in the Interim Final Rule, it published this procedural rule as an Interim Final Rule to ensure that it would have a process in place for importers and manufacturers to apply for quotas. Without publication of the Interim Final Rule, DEA would not be able to issue quotas, but the rule does not set quotas. Given that Congress mandated that these chemicals and products containing these chemicals could only be imported and manufactured if the importer or manufacturer had obtained a quota from DEA, delaying the implementation of the procedural steps for seeking quotas would have cut off the supply of the chemicals and products containing those chemicals.

In regard to the commenter's discussion of the economic impact of the Interim Final Rule, the comments regarding the actual availability of those List I chemicals, the establishment of the assessment of annual national needs, and the issuance of individual import, manufacturing, and procurement quotas, are beyond the scope of the Interim Final Rule. The comments apply to the assessment of annual needs, not the application procedures; there are no provisions in this procedural rule that affect the supply or distribution of these chemicals or that impose significant costs on applicants. DEA notes that this commenter provided almost identical comments to this Interim Final Rule as it did to DEA's notice ''Assessment of Annual Needs for the List I Chemicals Ephedrine, Pseudoephedrine, and Phenylpropanolamine for 2008: Proposed'' [Docket No. DEA–306] (72 FR 53911, September 20, 2007).[1] DEA provided an extensive response to the commenter's economic arguments to that notice in its notice ''Established Assessment of Annual Needs for the List I Chemicals Ephedrine, Pseudoephedrine, and Phenylpropanolamine for 2008'' [Docket No. DEA–306] (72 FR 73361, December 27, 2007).

The commenter claimed that DEA had not assessed the impact on small entities. DEA, however, did precisely that even though it was not required to do so. The Regulatory Flexibility Act (RFA) applies only to rules that have been proposed; it does not apply to Interim Final Rules. Nonetheless, DEA did consider the issue. The Interim Final Rule simply sets out the process by which importers and manufacturers may apply for quotas. The costs of the application process are very low and do not impose a significant economic impact on small entities. DEA notes that distributors, such as the commenter, are not subject to this rule. DEA included the wholesale sector in its economic analysis in the Interim Final Rule because that is where importers are usually classified under the North American Industry Classification System.

Finally, the commenter stated that the rule would not affect diversion and methamphetamine abuse. Congress mandated these rules as part of a series of actions to prevent diversion of scheduled listed chemical products, and the chemicals used to manufacture them, to clandestine laboratories. Since the states and, in 2006, DEA, imposed sales limits on these products, the number of clandestine laboratory seizures in the United States has fallen dramatically, indicating that the Congressionally mandated actions have been effective in limiting diversion of products to clandestine laboratories in the United States. International sources of methamphetamine are addressed by other parts of CMEA.

[1] All comments to both dockets may be found at *http://www.regulations.gov.*

Technical Corrections

While drafting this Final Rule, DEA noted that it had inadvertently required bulk manufacturers to complete and file DEA Form 189, Application for Individual Manufacturing Quota for a Basic Class of Controlled Substance and for Ephedrine, Pseudoephedrine, and Phenylpropanolamine, on or before April 1 of each year for the following calendar year (21 CFR 1315.22). This differs from the requirement for controlled substances; DEA Form 189 to request manufacturing quota for any basic class of controlled substance in Schedules I and II must be completed and filed on or before May 1 of each year for the following calendar year (21 CFR 1303.22). To alleviate potential confusion and ensure that the systems for controlled substances and ephedrine, pseudoephedrine, and phenylpropanolamine are as similar as possible, DEA is revising 21 CFR 1315.22 to require applicants for manufacturing quota for ephedrine, pseudoephedrine, and phenylpropanolamine to complete and file DEA Form 189 on or before May 1 of the year preceding the calendar year for which the manufacturing quota is being applied. DEA notes that only one registrant has applied for manufacturing quota. Therefore, DEA believes that this change will not significantly impact any registrant and will benefit the one registrant that currently utilizes this form.

Further, DEA noted that it had inadvertently not revised 21 CFR 1316.41, the section discussing the scope of the subpart related to administrative hearings, to include in the listing of CFR sections in which specific procedures regarding administrative hearings can be found sections 1315.50–1315.62. Therefore, for clarity, DEA is adding these sections to the listing of sections in which specific procedures regarding administrative hearings are found in 21 CFR 1316.41.

Adoption as Final Rule

The Interim Final Rule amending Parts 1300 and 1315 of Title 21, Code of Federal Regulations, which was

published in the **Federal Register** on July 10, 2007 at 72 FR 37439, is hereby adopted as a Final Rule as published, with one change. DEA is revising the provision in 21 CFR 1315.32(h) regarding who may sign the required certification that an order is within the ordering company's quota. This revision provides a benefit to registrants, permitting the signature of a certification for procurement quota to be by an individual authorized to sign the registration, or a person granted power of attorney to sign the certification. To accomplish this, DEA is also adding a new 21 CFR 1315.33 to establish a process for granting and revoking power of attorney status; this section parallels the provisions of 21 CFR 1305.05.

Regulatory Certifications

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

An agency may find good cause to exempt a rule from certain provisions of the Administrative Procedure Act (5 U.S.C. 553), including making the rule effective upon the date of publication. DEA finds good cause to make this rule effective upon publication, as this Final Rule provides a benefit or relieves a restriction by permitting the signature of a certification for procurement quota to be by an individual authorized to sign the registration, or a person granted power of attorney to sign the certification. To accomplish this, DEA is adding a new 21 CFR 1315.33 to establish a process for granting and revoking power of attorney status. The rest of this Final Rule merely confirms existing regulatory requirements implemented as part of the Interim Final Rule published July 10, 2007 at 72 FR 37439.

Regulatory Flexibility Act

The Acting Administrator hereby certifies that this rulemaking has been drafted in accordance with the Regulatory Flexibility Act (RFA) (5 U.S.C. 601–612). Because this rule is codifying statutory provisions, DEA has determined 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 may 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 is very small; they are 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

Executive Order 12866

The Acting 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 is some burden associated with applying for quotas. DEA estimates that the total cost of the quota application process is about $35,880 a year.

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. 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 Interim Final Rule implementing the retail sales provisions of CMEA (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

This Final Rule does not change existing requirements. Therefore, the

approved information collections that were published with the Interim Final Rule are not being revised.

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 1315

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

21 CFR Part 1316

Administrative practice and procedure, Authority delegations (Government agencies), Drug traffic control, Research, Seizures and forfeitures.

■ For the reasons set out above, 21 CFR parts 1315 and 1316 are amended as follows:

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

■ 1. The authority citation for part 1315 continues to read as follows:

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

■ 2. The introductory text of § 1315.22 is revised to read as follows:

§ 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 May 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:

* * * * *

■ 3. Section 1315.32(h) is revised to read as follows:

§ 1315.32 Obtaining a procurement quota.

* * * * *

(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 or by a person granted power of attorney under § 1315.33 to sign the certifications. A copy of such certification must be retained by the person procuring the quantity of ephedrine, pseudoephedrine, or phenylpropanolamine for two years from the date of the certification. 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.

* * * * *

■ 4. Section 1315.33 is added to read as follows:

§ 1315.33 Power of attorney.

(a) A registrant may authorize one or more individuals, whether or not located at his registered location, to sign certifications required under § 1315.32(h) on the registrant's behalf by executing a power of attorney for each such individual. The registrant shall retain the power of attorney in the files, with certifications required by § 1315.32(h), for the same period as any certification bearing the signature of the attorney. The power of attorney must be available for inspection together with other certification records.

(b) A registrant may revoke any power of attorney at any time by executing a notice of revocation.

(c) The power of attorney and notice of revocation must be similar to the following format:

Power of Attorney for certifications of quota for procurement of ephedrine, pseudoephedrine, and phenylpropanolamine

_____ (Name of registrant)
_____ (Address of registrant)
_____ (DEA registration number)

I, _____ (name of person granting power), the undersigned, who am authorized to sign the current application for registration of the above-named registrant under the Controlled Substances Act or Controlled Substances Import and Export Act, have made, constituted, and appointed, and by these presents, do make, constitute, and appoint _____ (name of attorney-in-fact), my true and lawful attorney for me in my name, place, and stead, to sign certifications of quota for procurement of ephedrine, pseudoephedrine, and phenylpropanolamine in accordance with Part 1315 of Title 21 of the Code of Federal Regulations. I hereby ratify and confirm all that said attorney must lawfully do or cause to be done by virtue hereof.

_____
(Signature of person granting power)

I, _____ (name of attorney-in-fact), hereby affirm that I am the person named herein as attorney-in-fact and that the signature affixed hereto is my signature.

(Signature of attorney-in-fact)
Witnesses:
1. _____
2. _____
Signed and dated on the ____ day of __, (year), at _____.

Notice of Revocation

The foregoing power of attorney is hereby revoked by the undersigned, who is authorized to sign the current application for registration of the above-named registrant under the Controlled Substances Act or the Controlled Substances Import and Export Act. Written notice of this revocation has been given to the attorney-in-fact _____ this same day.

_____
(Signature of person revoking power)
Witnesses:
1. _____
2. _____
Signed and dated on the ____ day of __, (year), at _____.

(d) A power of attorney must be executed by the person who signed the most recent application for DEA registration or reregistration; the person to whom the power of attorney is being granted; and two witnesses.

(e) A power of attorney must be revoked by the person who signed the most recent application for DEA registration or reregistration, and two witnesses.

PART 1316—ADMINISTRATIVE FUNCTIONS, PRACTICES, AND PROCEDURES

■ 5. The authority citation for subpart D of part 1316 continues to read as follows:

Authority: 21 U.S.C. 811, 812, 871(b), 875, 958(d), 965.

■ 6. Section 1316.41 is revised to read as follows:

§ 1316.41 Scope of subpart D.

Procedures in any administrative hearing held under the Act are governed generally by the rule making and/or adjudication procedures set forth in the Administrative Procedure Act (5 U.S.C. 551–559) and specifically by the procedures set forth in this subpart, except where more specific regulations (set forth in §§ 1301.51–1301.57, §§ 1303.31–1303.37, §§ 1308.41–1308.51, §§ 1311.51–1311.53, §§ 1312.41–1312.47, §§ 1313.51–1313.57, or §§ 1315.50–1315.62) apply.

Dated: November 26, 2008.

Michele M. Leonhart,

Acting Administrator.

[FR Doc. E8–28651 Filed 12–2–08; 8:45 am]

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DEPARTMENT OF DEFENSE

Department of the Navy

32 CFR Part 706

Certifications and Exemptions Under the International Regulations for Preventing Collisions at Sea, 1972

AGENCY: Department of the Navy, DoD.

ACTION: Final rule.

SUMMARY: The Department of the Navy is amending its certifications and exemptions under the International Regulations for Preventing Collisions at Sea, 1972 (72 COLREGS), to reflect that the Deputy Assistant Judge Advocate General (Admiralty and Maritime Law) of the Navy has determined that USS DALLAS (SSN 700) is a vessel of the Navy which, due to its special construction and purpose, cannot comply fully with certain provisions of the 72 COLREGS without interfering with its special function as a naval ship. The intended effect of this rule is to warn mariners in waters where 72 COLREGS apply.

DATES: This rule is effective December 3, 2008, and is applicable beginning 19 November 2008.

FOR FURTHER INFORMATION CONTACT: Commander M. Robb Hyde, JAGC, U.S. Navy, Deputy Assistant Judge Advocate General (Admiralty and Maritime Law), Office of the Judge Advocate General, Department of the Navy, 1322 Patterson Ave., S.E, Suite 3000, Washington Navy Yard, DC 20374–5066, telephone number: 202–685–5040

SUPPLEMENTARY INFORMATION: Pursuant to the authority granted in 33 U.S.C. 1605, the Department of the Navy amends 32 CFR Part 706.

This amendment provides notice that the Deputy Assistant Judge Advocate General (Admiralty and Maritime Law) of the Navy, under authority delegated by the Secretary of the Navy, has certified that USS DALLAS (SSN 700) is a vessel of the Navy which, due to its special construction and purpose, cannot comply fully with the following specific provisions of 72 COLREGS without interfering with its special function as a naval ship: Rule 21(a) pertaining to the location of the masthead lights over the fore and aft centerline of the ship. The Deputy Assistant Judge Advocate General (Admiralty and Maritime Law) has also certified that the lights involved are located in closest possible compliance with the applicable 72 COLREGS requirements.

Moreover, it has been determined, in accordance with 32 CFR Parts 296 and 701, that publication of this amendment for public comment prior to adoption is impracticable, unnecessary, and contrary to public interest since it is based on technical findings that the placement of lights on this vessel in a manner differently from that prescribed herein will adversely affect the vessel's ability to perform its military functions.

List of Subjects in 32 CFR Part 706

Marine safety, Navigation (Water), and Vessels.

■ For the reasons set forth in the preamble, amend Part 706 of title 32 of the Code of Federal Regulations as follows:

PART 706—CERTIFICATIONS AND EXEMPTIONS UNDER THE INTERNATIONAL REGULATIONS FOR PREVENTING COLLISIONS AT SEA, 1972

■ 1. The authority citation for 32 CFR Part 706 continues to read as follows:

Authority: 33 U.S.C. 1605.

■ 2. Section 706.2 is amended as follows:

■ A. In Table Two by adding, in numerical order, the following entry for USS DALLAS (SSN 700):

§ 706.2 Certifications of the Secretary of the Navy under Executive Order 11964 and 33 U.S.C. 1605.

* * * * *