Dated: July 1, 2009.

John K. Rabiej,

Chief, Rules Committee Support Office.

[FR Doc. E9–16018 Filed 7–8–09; 8:45 am]

BILLING CODE 2210–55–M

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

Importer of Controlled Substances; Notice of Application

Pursuant to 21 U.S.C. 958(i), the Attorney General shall, prior to issuing a registration under this section to a bulk manufacturer of a controlled substance in schedule I or II, and prior to issuing a regulation under 21 U.S.C. 952(a)(2), authorizing the importation of such a substance, provide manufacturers holding registrations for the bulk manufacture of the substance an opportunity for a hearing.

Therefore, in accordance with Title 21 Code of Federal Regulations (CFR), 1301.34(a), this is notice that on February 13, 2009, Rhodes Technologies, 498 Washington Street, Coventry, Rhode Island 02816, made application by renewal to the Drug Enforcement Administration (DEA) to be registered as an importer of the basic classes of controlled substances listed in schedule II:

Drug	Schedule
Raw Opium (9600)	II
Concentrate of Poppy Straw (9670)	II

The company plans to import narcotic raw materials to be used in ancillary activities including product development and analytical studies.

No comments, objections, or requests for any hearings will be accepted on any application for registration or re-registration to import raw opium and concentrate of poppy straw. As explained in the Correction to Notice of Application pertaining to Rhodes Technologies, 72 FR 3417 *(2007)*, comments and requests for hearings on applications to import narcotic raw material are not appropriate.

Any bulk manufacturer who is presently, or is applying to be, registered with DEA to manufacture such basic classes of controlled substances may file comments or objections to the issuance of the proposed registration and may, at the same time, file a written request for a hearing on such application pursuant to 21 CFR 1301.43, and in such form as prescribed by 21 CFR 1316.47.

Any such comments or objections should be addressed, in quintuplicate, to the Drug Enforcement Administration, Office of Diversion Control, Federal Register Representative (ODL), 8701 Morrissette Drive, Springfield, Virginia 22152; and must be filed no later than August 10, 2009.

This procedure is to be conducted simultaneously with, and independent of, the procedures described in 21 CFR 1301.34(b), (c), (d), (e), and (f). As noted in a previous notice published in the **Federal Register** on September 23, 1975, (40 FR 43745–46), all applicants for registration to import a basic class of any controlled substance in schedule I or II are, and will continue to be, required to demonstrate to the Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration, that the requirements for such registration pursuant to 21 U.S.C. 958(a); 21 U.S.C. 823(a); and 21 CFR 1301.34(b), (c), (d), (e), and (f) are satisfied.

Dated: June 24, 2009.

Joseph T. Rannazzisi,

Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration.

[FR Doc. E9–16296 Filed 7–8–09; 8:45 am]

BILLING CODE 4410–09–P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. DEA–314E]

Established Assessment of Annual Needs for the List I Chemicals Ephedrine, Pseudoephedrine, and Phenylpropanolamine for 2009

AGENCY: Drug Enforcement Administration (DEA), Justice.

ACTION: Notice of Assessment of Annual Needs for 2009.

SUMMARY: This notice establishes the initial 2009 Assessment of Annual Needs for certain List I chemicals in accordance with the Combat Methamphetamine Epidemic Act of 2005 (CMEA), enacted on March 9, 2006.

DATES: *Effective Date:* August 10, 2009.

FOR FURTHER INFORMATION CONTACT: Christine A. Sannerud, Ph.D., Chief, Drug and Chemical Evaluation Section, Drug Enforcement Administration, 8701 Morrissette Drive, Springfield, Virginia 22152, Telephone: (202) 307–7183.

SUPPLEMENTARY INFORMATION: Section 713 of the Combat Methamphetamine Epidemic Act of 2005 (Title VII of Pub. L. 109–177) (CMEA) amended Section 306 of the Controlled Substances Act (CSA) (21 U.S.C. 826) by adding ephedrine, pseudoephedrine, and phenylpropanolamine to existing language to read as follows: ''The Attorney General shall determine the total quantity and establish production quotas for each basic class of controlled substance in schedules I and II and for ephedrine, pseudoephedrine, and phenylpropanolamine to be manufactured each calendar year to provide for the estimated medical, scientific, research, and industrial needs of the United States, for lawful export requirements, and for the establishment and maintenance of reserve stocks.'' Further, section 715 of CMEA amended 21 U.S.C. 952 ''Importation of controlled substances'' by adding the same List I chemicals to the existing language in paragraph (a), and by adding a new paragraph (d) to read as follows:

(a) Controlled substances in schedule I or II and narcotic drugs in schedule III, IV, or V; exceptions

It shall be unlawful to import into the customs territory of the United States from any place outside thereof (but within the United States), or to import into the United States from any place outside thereof, any controlled substance in schedule I or II of subchapter I of this chapter, or any narcotic drug in schedule III, IV, or V of subchapter I of this chapter, or ephedrine, pseudoephedrine, and phenylpropanolamine, except that—

(1) such amounts of crude opium, poppy straw, concentrate of poppy straw, and coca leaves, and of ephedrine, pseudoephedrine, and phenylpropanolamine, as the Attorney General finds to be necessary to provide for medical, scientific, or other legitimate purposes * * * may be so imported under such regulations as the Attorney General shall prescribe.

* * * * *

(d)(1) With respect to a registrant under section 958 who is authorized under subsection (a)(1) to import ephedrine, pseudoephedrine, or phenylpropanolamine, at any time during the year the registrant may apply for an increase in the amount of such chemical that the registrant is authorized to import, and the Attorney General may approve the application if the Attorney General determines that the approval is necessary to provide for medical, scientific, or other legitimate purposes regarding the chemical.

Editor's Note: This excerpt of the amendment is published for the convenience of the reader. The official text is published at 21 U.S.C. 952(a) and (d)(1).

Background and Legal Authority

Section 713 of the Combat Methamphetamine Epidemic Act of 2005 (CMEA) (Title VII of Pub. L. 109–177) amended section 306 of the Controlled Substances Act (CSA) (21

U.S.C. 826) to require that the Attorney General establish quotas to provide for the annual needs for ephedrine, pseudoephedrine, and phenylpropanolamine. Section 715 of the CMEA amended 21 U.S.C. 952 by adding ephedrine, pseudoephedrine, and phenylpropanolamine to the existing language concerning importation of controlled substances.

The 2009 Assessment of Annual Needs represents those quantities of ephedrine, pseudoephedrine, and phenylpropanolamine which may be manufactured domestically and/or imported into the United States in 2009 to provide adequate supplies of each chemical for: The estimated medical, scientific, research, and industrial needs of the United States; lawful export requirements; and the establishment and maintenance of reserve stocks.

The responsibility for establishing the assessment has been delegated to the Administrator of the DEA by 28 CFR Section 0.100. The Administrator, in turn, has redelegated this function to the Deputy Administrator, pursuant to 28 CFR Section 0.104.

On December 29, 2008, a notice entitled, ''Assessment of Annual Needs for the List I Chemicals Ephedrine, Pseudoephedrine, and Phenylpropanolamine for 2009'' was published in the **Federal Register** (73 FR 79508). This notice established, on an interim basis, the 2009 Assessment of Annual Needs for ephedrine (for sale), ephedrine (for conversion), pseudoephedrine (for sale), phenylpropanolamine (for sale) and phenylpropanolamine (for conversion). All interested persons were invited to comment on or object to the interim assessments on or before January 28, 2009.

Comments Received

DEA received a total of four comments, one regarding the assessment for ephedrine (for sale) and the other three regarding the assessment for phenylpropanolamine (for sale). The first commenter was from a law firm representing an industry group comprised of distributors and retailers of over-the-counter (OTC) medications. This commenter believes that quota requests for ephedrine (for sale) are not comparable to the products sold and recommended that the 2009 ephedrine assessment be the same as the 2008 assessment (*i.e.* 11,500 kg).

The second comment was from a DEA registered chemical manufacturer of phenylpropanolamine who requested that DEA ''consider revising the calculation methodology for establishing (individual) quotas'' and also encouraged ''the establishment of a safety reserve'' for the list I chemicals.

The third and fourth comments were received from two distributors of veterinary prescription products containing phenylpropanolamine. These commenters encouraged DEA to consider in its evaluation the medical needs of the companion animal population and for DEA to include in its phenylpropanolamine (for sale) assessment a safety reserve to ensure an uninterrupted supply of the substance. All comments received during the comment period are discussed further below.

DEA did not receive any comments on its Interim Final Assessment of Annual Needs for ephedrine (for conversion), phenylpropanolamine (for conversion), and pseudoephedrine (for sale). DEA is adjusting the interim established assessment for these chemicals based on additional information provided by DEA registered importers and manufacturers whose quota applications were received as of April 1, 2009 (*i.e.* one year after the April 1, 2008, application due date). DEA also is providing the underlying data used in establishing these assessments.

Comment Regarding DEA's Interim Final Assessment for Ephedrine (For Sale)

DEA received one comment on its Interim Final assessment for ephedrine (for sale) from a law firm representing an industry group comprised of distributors and retailers of over-the-counter (OTC) medications. The comment stated that ''DEA's projection of decreased demand is inaccurate'' and recommended that the 2009 ephedrine assessment be the same as the 2008 (for sale) assessment (*i.e.* 11,500 kg). The commenter made the following statements: (1) ''On an annualized basis, the level of 941 [sic] kg requested as of July 2008 (134 kg per month) may well grow to 1,608 kg for all of 2009;'' (2) ''Comparing requests for raw materials to actual sales of finished product does not provide an accurate basis to measure consumer demand or medical need;'' (3) ''DEA's projection of decreased demand is not based on the medical needs of consumers, but on the effects of increased regulation and decreased supply;'' and (4) the commenter stated its concern with the DEA's reliance on data provided by IMS Health's (IMS) National Sales Perspective™ (NSP) database.

DEA Response

In response to the first comment that ''On an annualized basis, the level of 941 [sic] kg requested as of July 2008 (134 kg per month) may well grow to 1,608 kg for all of 2009,'' DEA believes that the commenter misinterpreted its original statement. DEA stated the following in its interim assessment:

> At the time DEA drafted the 2009 proposed assessment (*i.e.,* July 15, 2008), DEA considered applications for procurement quotas from DEA registered manufacturers of ephedrine. These applications were due on or before April 1, 2008. These firms requested authority to purchase a total of 921 kg of ephedrine (for sale) in 2009. (73 FR 79510)

The commenter interpreted the statement above to mean that the manufacturers' request to purchase 921 kg represented purchase requirements for the first 7 months of the calendar year, or 134 kg/month (134.4 kg × 7 = 941 kg [sic]). By this logic, the commenter believed the annual requirement for ephedrine could be as much as 1,608 kg (134 kg × 12 months = 1,608 kg). This is an incorrect interpretation. DEA registered manufacturers of ephedrine that had submitted applications on or before July 15, 2008, requested the authority to purchase a total of 921 kg of ephedrine for the entire calendar year of 2009. This means that the total annual requirement of ephedrine (for sale) for 2009 for the United States was 921 kg, as reported by DEA registered manufacturers.

In response to the commenter's second comment that ''comparing requests for raw materials to actual sales of finished product does not provide an accurate basis to measure consumer demand or medical need,'' DEA notes that the regulations require DEA to consider the ''projected demand for each chemical [ephedrine] as indicated by procurement and import quotas requested pursuant to section 1315.32.'' (see 21 CFR 1315.11(b)(4)). DEA also notes that requests for raw material consider not only the raw material necessary to meet medical needs, but also the raw material needed for other uses. For instance, raw material requests include the additional quantities necessary to bring a finished product to market, to cover production losses occurring during manufacturing and packaging operations, to allow for quality assurance/control testing, and to provide additional quantities for the reserve stocks of distributors and retailers.

The commenter's third comment is that the DEA's projection of decreased demand is not based on the medical needs of consumers, but on the effects of increased regulation and decreased supply. In response to this comment, DEA notes that the regulation at 21 CFR 1315.11(b) clearly articulates those

factors that DEA is to consider when making its determination, which include:

1. Total net disposal of the chemical by all manufacturers and importers during the current and preceding two 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 section 1315.32, and
5. Other factors * * * as the Administrator finds relevant.

Medical need could impact one or several of these factors. For instance, increased medical need could result in an increased number of quota applications, decreased inventories, and changes upward in the national rate of disposals. Thus, it is not necessary to consider medical need separately from the factors mandated by the regulation.

Finally, in response to the fourth comment, in which the commenter noted its ''concern over the DEA's reliance on data provided by IMS in proposing the 2009 assessment,'' DEA notes that data provided by IMS Health provides national estimates of sales at the retail level which are used to consider trends in the rate of net disposals (*i.e.*, sales) as mandated by regulation. The most recent IMS data available reports retail level sales totaling 1,267 kg in 2007 and 1,489 kg in 2008; this represents an 18 percent increase in retail sales from 2007 to 2008. During the same period registered manufacturers of ephedrine reported sales totaling approximately 5,409 kg in 2007 and 2,465 kg in 2008; this represents a 54 percent decrease in sales reported by these firms from 2007 to 2008. The retail sales reported by IMS Health are expected to be lower than the sales to distributors and retailers reported by manufacturers because a manufacturer's sales include quantities which are necessary to provide reserve stocks for distributors and retailers. DEA also believes that manufacturers' sales in 2007 may have been artificially inflated as manufacturers, distributors, and retailers built unusually large reserve stocks due to concerns over newly codified regulations that were thought to limit or restrict the availability of substances. DEA thus believes that the manufacturers' reported sales of 2,465 kg fairly represent the net disposals of ephedrine products. DEA notes that IMS data is one of several considerations that DEA uses to evaluate trends and projected demand of ephedrine-based products. As the calculations and methodology demonstrate, the assessment of annual needs for ephedrine is based primarily on the information provided by DEA registered manufacturers and importers of ephedrine products.

DEA has received additional quota applications from DEA registered manufacturers and importers for the 2009 assessment year. Based on an analysis of the underlying data from quota applications received through April 1, 2009, DEA is establishing the 2009 assessment of annual needs for ephedrine (for sale) at 3,400 kg.

Ephedrine Data

EPHEDRINE (FOR SALE) DATA FOR 2009 ASSESSMENT OF ANNUAL NEEDS

[Kilograms]

Ephedrine	2006	2007	2008[1]	2009 Request
Sales * (DEA 250)	5,435	5,409	2,465	3,088
Imports ** (DEA 488)	3,886	10,480	2,104	2,678
Export Declarations (DEA 486)	313	168	91	n/a
Inventory * (DEA 250)	1,245	1,457	423	n/a
IMS *** (NSP)	1,256	1,267	1,489	n/a

* Reported sales and inventory from applications for 2009 procurement quotas (DEA 250) received as of April 1, 2009.
** Reported imports from applications for 2009 import quotas (DEA 488) received as of April 1, 2009.
*** IMS Health, IMS National Sales Perspectives™, January 2006 to December 2008, Retail and Non-Retail Channels, Data Extracted April 1, 2009.

Underlying Data and DEA's Analysis

The DEA considered total net disposals (*i.e.* sales) of ephedrine for the current and preceding two years, actual and estimated inventories, projected demand (2009), industrial use, and export requirements from data provided by DEA registered manufacturers and importers in procurement quota applications (DEA 250), from manufacturing quota applications (DEA 189), and from import quota applications (DEA 488).[2]

DEA further considered trends as derived from information provided in applications for import, manufacturing, and procurement quotas and in import and export declarations. DEA notes that the inventory, acquisitions (purchases) and disposition (sales) data provided by DEA registered manufacturers and importers reflects the most current information provided by manufacturers and importers. This information includes applications which have been newly submitted, amended or withdrawn as of April 1, 2009, for the 2009 quota year.

Ephedrine Calculation

DEA calculated the 2009 Assessment of Annual Needs for ephedrine as follows. DEA developed a calculation that considers the criteria defined in 21 U.S.C. 826: Estimated medical, scientific, research, and industrial needs of the United States; lawful export requirements; and the establishment and maintenance of reserve stocks.

As of April 1, 2009, DEA registered manufacturers of dosage form products containing ephedrine reported sales totaling approximately 5,409 kg in 2007 and 2,465 kg in 2008; this represents a 54 percent decrease in sales reported by these firms from 2007 to 2008. Additionally, exports of ephedrine products from the United States as reported on export declarations (DEA 486), totaled 168 kg in 2007 and 91 kg in 2008; this represents a 46 percent decrease from levels observed in 2007. DEA also considered information on trends in the national rate of net disposals from sales data provided by IMS Health's NSP database. IMS NSP data reported the average sales volume of ephedrine for the calendar years 2007 and 2008 to be approximately 1,378 kg.

[1] 2008 data represents estimated sales, imports, and inventories as reported on applications for quotas.

[2] Applications and instructions for procurement, import and manufacturing quotas can be found at *http://www.deadiversion.usdoj.gov/quotas/quota_apps.htm.*

DEA notes that the 2008 sales figure reported by manufacturers (2,465 kg) is higher than the sales reported by IMS (1,378 kg). As previously explained, this is expected because a manufacturer's reported sales include quantities which are necessary to provide reserve stocks for distributors and retailers. DEA in considering the manufacturer's reported sales thus believes that 2,465 kg fairly represents the U.S. sales of ephedrine for 2009 and that 91 kg fairly represents the export requirements of ephedrine.

For the establishment and maintenance of reserve stocks, DEA notes that 21 CFR 1315.24 allows for an inventory allowance (reserve stock) of 50 percent of a manufacturer's estimated sales. DEA also considered the estimated 2008 year end inventory as reported by DEA registrants in determining the inventory allowance.

DEA calculated the ephedrine (for sale) assessment by the following methodology:

2008 sales + reserve stock + export requirement − existing inventory = AAN

2,465 + (50 percent * 2,465) + 91 − 423 = 3,366 kg ephedrine (for sale) for 2009

This calculation suggests that DEA's Assessment of Annual Needs for ephedrine can be revised to 3,400 kg rather than the 1,500 kg established in the Interim Final Rule. DEA notes that this upward revision is attributed to DEA's consideration of applications for 2009 quotas received as of April 1, 2009, a one-year time period since the application due date.

Accordingly, DEA is establishing the Assessment of Annual Needs for ephedrine (for sale) at 3,400 kg.

Comments Regarding DEA's Interim Final Assessment for Phenylpropanolamine (For Sale)

The second commenter, a manufacturer of phenylpropanolamine products used by veterinary professionals, urged DEA ''to consider revising the calculation methodology for establishing quotas'' to consider whether the market need was met in the prior year. Additionally, the commenter suggested that there ''should be a factor inserted in the calculation that would more accurately reflect market need and the changing demand.'' The commenter also encouraged ''the establishment of a safety reserve so that the DEA and manufacturers can be responsive to the ever-changing health care needs of companion animals.''

The third and fourth comments were received from two distributors that sell phenylpropanolamine products used by veterinarians. These commenters stated that ''To base quotas on last year's sales and inventories and formulas does not allow for the increased need.'' The commenters encouraged DEA ''to consider increasing the quotas based on the aging of the companion animal population.'' Additionally, the commenter encouraged DEA ''to work with individual manufacturers of PPA in order to assure the uninterrupted supply of PPA.''

DEA Response

As a preliminary matter, this **Federal Register** notice establishes the assessment of annual needs for List I chemicals and the methodology used by the DEA to set that number. The assessment of annual needs is different than individual quotas and this rulemaking does not address the regulatory process for evaluating individual import, manufacturing and procurement quotas issued to DEA registered manufacturers and importers.

With regard to the establishment of the assessment of annual needs for phenylpropanolamine (for sale), DEA believes that the sales information provided in requests for quotas for the manufacture of phenylpropanolamine products fairly represents the legitimate medical needs of the companion animal population. Additionally, DEA notes that the requirements of the two distributors and one manufacturer of phenylpropanolamine were considered as part of the assessment for phenylpropanolamine. DEA notes that there was a 3 percent increase in reported sales of phenylpropanolamine from 2007 to 2008. For the 2009 assessment, DEA has determined that the higher 2008 sales fairly represent the manufacturing requirements of phenylpropanolamine. In calculating the assessment, DEA provides for quantities to support sales of phenylpropanolamine and also for a reserve stock of 50 percent. This is not only consistent with the 50 percent inventory allowance permitted under 21 CFR 1315.24, but also provides manufacturers with sufficient material to account for slight increases in demand that may occur in 2009.

Additionally, DEA notes that pursuant to 21 CFR 1315.32, DEA registered manufacturers and importers may request adjustments to their individual quotas at any time. This option allows the DEA and DEA registrants to respond to the changing needs of the companion animal population.

Considering that 2008 was the first year of implementation of quotas for the List I chemicals, DEA is revising the 2009 assessments to consider applications received as of April 1, 2009 (*i.e.* one year after the April 1, 2008, application due date). This ensures that DEA considered the most recent information provided by DEA registered manufacturers and importers for 2009. A summary of the underlying data from quota applications and other sources, as well as DEA's analysis of that data, are provided below.

Phenylpropanolamine (For Sale) Data

PHENYLPROPANOLAMINE (FOR SALE) DATA FOR 2009 ASSESSMENT OF ANNUAL NEEDS

[Kilograms]

Phenylpropanolamine (for sale)	2006	2007	2008 [3]	2009 Request
Sales * (DEA 250)	4,179	4,224	4,362	5,462
Imports ** (DEA 488)	1,119	9,381	3,032	5,295
Export Declarations (DEA 486)	0	1,002	0	n/a
Inventory * (DEA 250)	3,555	3,976	1,696	n/a

* Reported sales and inventory from applications for 2009 procurement quotas (DEA 250) and manufacturing quotas (DEA 189) received as of April 1, 2009.

** Reported imports from applications for 2009 import quotas (DEA 488) received as of April 1, 2009.

[3] 2008 data represents estimated sales, imports, and inventories as reported on applications for quotas.

Phenylpropanolamine (for sale) Analysis

DEA utilized the same general methodology and calculation to establish the assessment for phenylpropanolamine (for sale) as was described for the assessment of ephedrine (for sale), above.

As of April 1, 2009, DEA registered manufacturers of dosage form products containing phenylpropanolamine reported sales totaling approximately 4,224 kg in 2007 and 4,362 kg in 2008; this represents a 3 percent increase in sales reported by these firms from 2007 to 2008. DEA notes that phenylpropanolamine is sold primarily as a veterinary product for the treatment for canine incontinence and is not approved for human consumption. IMS Health's NSP Data does not capture sales of phenylpropanolamine to these channels and is therefore not included.

DEA calculated the phenylpropanolamine (for sale) assessment by the following methodology:

2008 sales + reserve stock + export requirement − existing inventory = AAN

4,362 + (50 percent * 4,362) + 0 − 1,696 = 4,847 kg phenylpropanolamine (for sale) for 2009

This calculation suggests that DEA's Assessment of Annual Needs for phenylpropanolamine (for sale) can be revised to be 4,900 kg rather than the 4,500 kg established in the Interim Final Rule.

DEA is establishing the Assessment of Annual Needs for phenylpropanolamine (for sale) at 4,900 kg.

Pseudoephedrine, Ephedrine (for Conversion), and Phenylpropanolamine (for Conversion)

DEA did not receive any comments on its interim Assessment of Annual Needs for pseudoephedrine, ephedrine (for conversion), and phenylpropanolamine (for conversion). However, DEA is providing the underlying data, analysis, methodology and calculation for the establishment of the assessments for these List I chemicals. These assessments reflect new information received from applications for quota received as of April 1, 2009 (*i.e.* one year after the April 1, 2008 application due date).

Pseudoephedrine (for Sale) Data

PSEUDOEPHEDRINE (FOR SALE) DATA FOR 2009 ASSESSMENT OF ANNUAL NEEDS

[Kilograms]

Pseudoephedrine (for sale)	2006	2007	2008 [4]	2009 Request
Sales * (DEA 250)	232,721	215,877	262,159	273,659
Sales * (DEA 189)	56,563	100,300	111,292	105,967
Imports ** (DEA 488)	133,802	225,973	165,708	205,783
Export Declarations (DEA 486)	37,069	42,142	85,756	n/a
Inventory * (DEA 250)	83,104	115,307	89,921	n/a
IMS *** (NSP)	207,509	183,382	151,013	n/a

* Reported sales and inventory from applications for 2009 procurement quotas (DEA 250) and manufacturing quotas (DEA 189) received as of April 1, 2009.

** Reported imports from applications for 2009 import quotas (DEA 488) received as of April 1, 2009.

*** IMS Health, IMS National Sales Perspectives™, January 2006 to December 2008, Retail and Non-Retail Channels, Data Extracted April 1, 2009.

Pseudoephedrine (for Sale) Analysis

DEA utilized the same general methodology and calculations to establish the assessment for pseudoephedrine (for sale) as was described for the assessment of ephedrine (for sale), above.

As of April 1, 2009, DEA registered manufacturers of dosage form products containing pseudoephedrine reported sales totaling approximately 215,877 kg in 2007 and 262,159 kg in 2008; this represents a 21 percent increase in sales reported by these firms from 2007 to 2008. During the same period exports of pseudoephedrine products from the United States as reported on export declarations (DEA 486) totaled 42,142 kg in 2007 and 85,756 kg in 2008; this represents a 103 percent increase from levels observed in 2007. Additionally, DEA considered information on trends in the national rate of net disposals from sales data provided by IMS Health. IMS NSP data reported the average retail sales volume of pseudoephedrine for the calendar years 2007 and 2008 to be approximately 167,171 kg. DEA thus believes that 262,159 kg of sales reported by manufacturers fairly represents the U.S. sales of pseudoephedrine for 2009 and that 85,756 kg fairly represents the export requirements of pseudoephedrine. DEA notes that manufacturer reported sales (262,159 kg) are higher than the retail sales reported by IMS (167,171 kg). This is expected because a manufacturer's reported sales include quantities which are necessary to provide reserve stocks for distributors and retailers. DEA calculated the pseudoephedrine (for sale) assessment by the following methodology:

2008 sales + reserve stock + export requirement − existing inventory = AAN

262,159 + (50 percent * 262,159) + 85,756 − 89,921 = 389,074 kg pseudoephedrine (for sale) for 2009

This calculation suggests that based on quota applications received as of April 1, 2009, DEA's Assessment of Annual Needs for pseudoephedrine (for sale) should be established at 390,000 kg rather than the 380,000 kg established in the December 29, 2008 Interim Final Rule. DEA is establishing the Assessment of Annual Needs for pseudoephedrine (for sale) at 390,000 kg.

Phenylpropanolamine (for Conversion) Data

[4] 2008 data represents estimated sales, imports, and inventories as reported on applications for quotas.

PHENYLPROPANOLAMINE (FOR CONVERSION) DATA FOR 2009 ASSESSMENT OF ANNUAL NEEDS

[Kilograms]

Phenylpropanolamine (for conversion)	2006	2007	2008 [5]	2009 Request
Sales * (DEA 250)	8,004	9,991	15,498	13,606
Imports ** (DEA 488)	14,476	9,370	15,776	14,175
Export Declarations (DEA 486)	0	0	0	n/a
Inventory * (DEA 250)	4,863	3,742	4,566	n/a
APQ Amphetamine ***	17,000	22,000	22,000	n/a

* Reported sales and inventory from applications for 2009 procurement quotas (DEA 250) received as of April 1, 2009.
** Reported imports from applications for 2009 import quotas (DEA 488) received as of April 1, 2009.
*** Amphetamine Aggregate Production Quota History *http://www.deadiversion.usdoj.gov/quotas/quota_history.htm.*

Phenylpropanolamine (for Conversion) Analysis

As of April 1, 2009, DEA registered manufacturers of phenylpropanolamine (for conversion) requested the authority to purchase a total of 13,606 kg phenylpropanolamine (for conversion). Additionally, DEA registered importers of phenylpropanolamine (for conversion) requested the authority to import a total of 14,175 kg of phenylpropanolamine (for conversion). DEA had not received any requests to synthesize phenylpropanolamine in 2009.

DEA has determined that 13,606 kg of phenylpropanolamine (for conversion) would be insufficient to meet the requirements for phenylpropanolamine for the production of amphetamine as established by DEA as the Aggregate Production Quota (APQ) for amphetamine (*i.e.,* 22,000 kg for 2008). 13,606 kg would be sufficient to manufacture only 30 percent of the APQ of amphetamine. DEA further considered manufacturer's conversion yields of phenylpropanolamine to amphetamine of 50 percent in its calculation of the phenylpropanolamine assessment. DEA calculated the phenylpropanolamine (for conversion) assessment by the following methodology:

(2008 APQ/50 percent yield) + reserve stock − inventory = AAN

(22,000/50 percent yield) + 50 percent * (22,000/50 percent yield) − 4,566 = 61,434 kg PPA (for conversion) for 2009

This calculation suggests that DEA's Assessment of Annual Needs for phenylpropanolamine (for conversion) should be established as 62,000 kg, as established in the Interim Final Rule.

DEA is establishing the Assessment of Annual Needs for phenylpropanolamine (for conversion) at 62,000 kg.

Ephedrine (for Conversion) Data

EPHEDRINE (FOR CONVERSION) DATA FOR 2009 ASSESSMENT OF ANNUAL NEEDS

[Kilograms]

Ephedrine (for conversion)	2006	2007	2008 [6]	2009 Request
Sales * (DEA 250)	49,973	100,093	133,209	112,277
Imports ** (DEA 488)	43,612	107,230	122,683	111,365
Inventory * (DEA 250)	77	28	10	n/a
APQ Methamphetamine ***	3,130	3,130	3,130	n/a

* Reported sales and inventory from applications for 2009 procurement quotas (DEA 250) and manufacturing quotas (DEA 189) received as of April 1, 2009.
** Reported imports from applications for 2009 import quotas (DEA 488) received as of April 1, 2009.
*** Methamphetamine Aggregate Production Quota History *http://www.deadiversion.usdoj.gov/quotas/quota_history.htm*

Ephedrine (for Conversion) Analysis

For ephedrine (for conversion), DEA utilized the same general methodology and calculation as was described for the assessment of phenylpropanolamine (for conversion), above.

As of April 1, 2009, DEA registered manufacturers of ephedrine (for conversion) requested the authority to purchase a total of 112,277 kg ephedrine (for conversion) for the manufacture of two substances: methamphetamine and pseudoephedrine.

DEA in its methodology considered the ephedrine (for conversion) requirements for the manufacture of these two substances: methamphetamine and pseudoephedrine. DEA has determined the established assessments for the manufacture of these two substances are the best indicators of the need for ephedrine (for conversion). The assessment of need for methamphetamine was determined by DEA as the Aggregate Production Quota (APQ) for methamphetamine. The assessment of need for pseudoephedrine was determined by DEA as the estimated sales of pseudoephedrine as referenced in the 2008 Annual Assessment of Need (AAN) for pseudoephedrine. Reported sales of ephedrine (for conversion) are included as reference to DEA's methodology.

DEA further considered the reported conversion yields of these substances. These firms reported a conversion yield of 39 percent for the synthesis of methamphetamine. DEA cannot disclose the conversion yield for the synthesis of pseudoephedrine because this information is proprietary to the one manufacturer involved in this type of manufacturing.

DEA calculated the ephedrine (for conversion) assessment by the following methodology:

methamphetamine requirement + pseudoephedrine requirement = AAN

The calculation for the ephedrine (for conversion) requirement for the

[5] 2008 data represents estimated sales, imports, and inventories as reported on applications for quotas.

[6] 2008 data represents estimated sales, imports, and inventories as reported on applications for quotas.

manufacture of methamphetamine is as follows:

(2008 APQ methamphetamine/39 percent yield) + reserve stock − inventory = ephedrine (for manufacture of methamphetamine)

(3,130/39 percent yield) + 50 percent * (3,130/39 percent yield) − 35 = 12,003 kg

The calculation for the ephedrine (for conversion) requirement for the manufacture of pseudoephedrine leads to a result of 106,424 kg. DEA cannot provide the details of the calculation because this would reveal the conversion yield for the synthesis of pseudoephedrine, which is proprietary to the one manufacturer involved in this type of manufacturing.

Therefore, the assessment for ephedrine was determined by the sum total of the ephedrine (for conversion) requirements as described by the following methodology:

methamphetamine requirement + pseudoephedrine requirement = AAN

12,003 + 106,424 = 118,427 kg ephedrine (for conversion) for 2009

This calculation suggests that based on applications received as of April 1, 2009, DEA's Assessment of Annual Needs for ephedrine (for conversion) should be established as 120,000 kg rather than the 110,000 kg established on an interim basis in the December 29, 2008, notice. Under this rulemaking, DEA is establishing the Assessment of Annual Needs for ephedrine (for conversion) as 120,000 kg.

Conclusion

DEA has carefully considered the comments received in connection with the 2009 Assessment of Annual Needs. Based on information provided in the comments, along with information provided by DEA-registered manufacturers and importers of these List I chemicals on applications for individual import, manufacturing, and procurement quotas pursuant to DEA regulations, DEA has fully addressed the relevant issues set forth in the comments. Therefore, under the authority vested in the Attorney General by Section 306 of the CSA (21 U.S.C. 826), and delegated to the Administrator of the DEA by 28 CFR Section 0.100, and redelegated to the Deputy Administrator pursuant to 28 CFR Section 0.104, the Deputy Administrator hereby orders that the 2009 Assessment of Annual Needs for ephedrine, pseudoephedrine, and phenylpropanolamine, expressed in kilograms of anhydrous acid or base, be established as follows:

List I chemical	Established 2009 Assessment of Annual Needs
Ephedrine (for sale)	3,400
Ephedrine (for conversion)	120,000
Pseudoephedrine (for sale)	390,000
Phenylpropanolamine (for sale)	4,900
Phenylpropanolamine (for conversion)	62,000

The Office of Management and Budget has determined that notices of quotas are not subject to centralized review under Executive Order 12866.

This action 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 action does not have any federalism implications warranting the application of Executive Order 13132.

The Deputy Administrator hereby certifies that this action will not have a significant economic impact upon a substantial number of small entities whose interests must be considered under the Regulatory Flexibility Act, 5 U.S.C. 601–612. The establishment of Assessment of Annual Needs for ephedrine, pseudoephedrine, and phenylpropanolamine is mandated by law. The assessments are necessary to provide for the estimated medical, scientific, research and industrial needs of the United States; for lawful export requirements; and the establishment and maintenance of reserve stocks. Accordingly, the Deputy Administrator has determined that this action does not require a regulatory flexibility analysis.

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

This action 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.

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

Dated: June 26, 2009.

Michele M. Leonhart,

Deputy Administrator.

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DEPARTMENT OF JUSTICE

Drug Enforcement Administration

Importer of Controlled Substances; Notice of Registration

By Notice dated June 7, 2007, and published in the **Federal Register** on June 20, 2007, 72 FR 34040, Cambrex Charles City, Inc., 1205 11th Street, Charles City, Iowa 50616–3466, made application by letter to the Drug Enforcement Administration (DEA) to be registered as an importer of the basic classes of controlled substances listed in schedule II:

Drug	Schedule
Opium, raw (9600)	II
Poppy Straw Concentrate (9670)	II

The company plans to import the basic classes of controlled substances for manufacture of active pharmaceutical ingredients for sale to its customers.

No comments or objections have been received. DEA has considered the factors in 21 U.S.C. 823(a) and 952(a) and determined that the registration of Cambrex Charles City, Inc. to import the basic classes of controlled substances is consistent with the public interest and with United States obligations under international treaties, conventions, or protocols in effect on May 1, 1971, at this time. DEA has investigated Cambrex Charles City, Inc. to ensure that the company's registration is consistent with the public interest. The investigation has included inspection and testing of the company's physical security systems, verification of the company's compliance with state and local laws, and a review of the company's background and history. Therefore, pursuant to 21 U.S.C. 952(a) and 958(a), and in accordance with 21 CFR 1301.34, the above named company is granted registration as an importer of the basic classes of controlled substances listed.