FOR FURTHER INFORMATION CONTACT: David Tarler, Designated Federal Officer, Native American Graves Protection and Repatriation Review Committee, National NAGPRA Program, National Park Service, 1201 Eye Street, NW, 8th Floor (2253), Washington, DC 20005; telephone (202) 354–2108; email david__tarler@nps.gov.

Dated: November 21, 2008

David Tarler,

Designated Federal Officer,

Native American Graves Protection and Repatriation Review Committee.

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DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. DEA–314I]

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

AGENCY: Drug Enforcement Administration (DEA), Justice.

ACTION: Interim Established Assessment of Annual Needs with Request for Comment.

SUMMARY: This notice establishes, on an interim basis, the Assessment of Annual Needs for the List I chemicals ephedrine, pseudoephedrine, and phenylpropanolamine. DEA seeks comment regarding the Assessment of Annual Needs for those List I chemicals. The Assessment of Annual Needs for these chemicals will be proposed to be revised, pursuant to DEA regulations, during calendar year 2009. After consideration of the comments received, DEA will finalize the assessment for those chemicals, prior to proposing the revision of the assessment for those chemicals during calendar year 2009.

DATES: This notice is effective January 1, 2009. Written comments must be postmarked, and electronic comments must be sent, on or before January 28, 2009.

ADDRESSES: To ensure proper handling of comments, please reference ''Docket No. DEA–314I'' on all written and electronic correspondence. Written comments being sent via regular or express mail should be sent to the Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration, 8701 Morrissette Drive, Springfield, Virginia 22152, Attention: DEA **Federal Register** Representative/ODL. Comments may be sent to DEA by sending an electronic message to *dea.diversion.policy@usdoj.gov.* DEA will accept attachments to electronic comments in Microsoft Word, WordPerfect, Adobe PDF, or Excel file formats only. DEA will not accept any file format other than those specifically listed here.

FOR FURTHER INFORMATION CONTACT: Christine A. Sannerud, PhD, 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 (CMEA) 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 U.S., 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 U.S. from any place outside thereof (but within the U.S.), or to import into the U.S. 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 CMEA (Title VII of Pub. L. 109–177) amended section 306 of the 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 U.S. in 2009 to provide adequate supplies of each chemical for: the estimated medical, scientific, research, and industrial needs of the U.S.; 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 0.100. The Administrator, in turn, has redelegated this function to the Deputy Administrator, pursuant to 28 CFR 0.104.

On September 19, 2008, a notice entitled, ''Assessment of Annual Needs for the List I Chemicals Ephedrine, Pseudoephedrine, and Phenylpropanolamine for 2009: Proposed'' was published in the **Federal Register** (73 FR 54431). That notice proposed the initial 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 proposed assessments on or before October 20, 2008.

DEA received a total of two comments, one of which was from a law firm representing an industry group comprised of distributors and retailers of over-the-counter (OTC) medications. In that comment, the law firm requested that DEA ''indicate what data it reviewed and relied on to estimate trends and projected demands'' of

ephedrine. After consideration of this comment, DEA is providing the data used in developing the proposed assessment for each of the listed chemicals and is making additional information available in the administrative record.

As discussed below, it is necessary to implement this notice on an interim basis so that DEA can issue individual import, manufacturing, and procurement quotas to DEA registered importers and manufacturers. It is necessary to issue these quotas, for import and manufacturing of pharmaceutical products containing ephedrine, pseudoephedrine, and phenylpropanolamine in a timely manner to provide for an uninterrupted supply of these materials that are important to the public health.

Comments Received

The first comment received in response to the September 19, 2008, rulemaking was from a law firm representing an industry group comprised of distributors and retailers of OTC medications. This commenter raised concerns regarding the assessment for ephedrine (for sale).

The second comment was from a DEA registered chemical manufacturer. The second commenter requested that DEA consider its individual requirement for phenylpropanolamine (for conversion) in fixing the final assessment of annual needs.

In response to these comments, the assessments for phenylpropanolamine (for conversion) and ephedrine (for sale) are discussed below within the context of the comments received.

DEA did not receive any comments on its proposed Assessment of Annual Needs for ephedrine (for conversion), phenylpropanolamine (for sale), and pseudoephedrine (for sale). While no comments were received regarding the assessment of annual needs for these materials, this notice also provides the underlying data which was used in determining the assessments for these List I chemicals, to allow for additional comment. Additional information is available in the docket.

Comment Regarding DEA's Proposed Assessment for Ephedrine (for Sale)

The commenter, a law firm representing an industry group comprised of distributors and retailers of OTC medications indicated its belief that the proposed 2009 ephedrine assessment was ''both unsupported and insufficient to meet legitimate medical needs.'' The commenter recommended that the 2009 ephedrine assessment be the same as the 2008 ephedrine (for sale) assessment (*i.e.*, 11,500 kg). In its September 19, 2008, proposed Assessment, DEA proposed an assessment of 2,500 kg of ephedrine (for sale) for 2009. The commenter stated that DEA provided no actual data or support for its 80% reduction in the 2009 ephedrine (for sale) assessment and that DEA failed to indicate what data it reviewed and relied upon in making its proposal, and for that reason requested that DEA publish the factual basis for the 2009 proposed assessment for ephedrine (for sale). The commenter also stated its belief that DEA failed to provide any indication that it considered medical factors before it proposed the 2009 assessment.

DEA Response

In its proposal, DEA published the substance of the proposed Assessment of Annual Needs and provided a description of the subjects and issues involved, specifically:

> To develop the 2009 assessment of annual needs for the U.S., DEA considered applications for 2009 import, manufacturing, and procurement quotas received from DEA registered manufacturers and importers. DEA further considered information contained in import and export declarations (DEA–486) along with information relating to trends in the national rate of disposals, actual and estimated inventories, and projected demand for the List I chemicals ephedrine, pseudoephedrine and phenylpropanolamine in accordance with 21 CFR 1315.11. (73 FR 54432, September 19, 2008)

In response to this comment, this notice further details the underlying data summarized from quota applications, from import/export documents, and data from a third party vendor, IMS Health Inc. DEA notes that the information sources used for the 2009 assessment are different from the data sources considered by DEA in establishing the 2007 and 2008 assessments. Specifically, DEA was able to consider information obtained from applications for 2009 quotas. In contrast, when the 2007 and 2008 assessments were proposed, on October 19, 2006, and September 20, 2007, respectively, DEA either lacked quota applications altogether or believed that it did not have a sufficient number of applications from which to draw meaningful conclusions. With the absence of quota applications from DEA registered importers and manufacturers in those years (2006 and 2007), DEA relied on a report prepared by IMS Health Inc.[1] The report was commissioned by DEA specifically for that purpose. This year, however, DEA is able to use the data from quota applications and from information as specified in 21 CFR 1315.11.

A summary of the underlying data from quota applications and other sources, as well as DEA's analysis of that data, are provided below.

Ephedrine Data

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

[Kilograms]

Ephedrine	2006	2007	2008[2]	2009 Request
Sales* (DEA 250)	1,993	2,840	1,291	921
Imports** (DEA 488)	5,627	1,337	1,179	44
Export Declarations (DEA 486)	313	168	16	n/a
Inventory* (DEA 250)	856	1,795	468	n/a
IMS *** (NSP)	1,256	1,267	n/a	n/a

* Reported sales and inventory from applications for 2009 procurement quotas (DEA 250) received as of July 15, 2008.
** Reported imports from applications for 2009 import quotas (DEA 488) received as of July 15, 2008.
*** IMS Health, IMS National Sales Perspectives™, January 2006 to December 2007, Retail and Non-Retail Channels, Data Extracted July 15, 2008.

[1] 2005 Ephedrine/Pseudoephedrine Legitimate Medical Use Methodology and Final Report *http://www.deadiversion.usdoj.gov/meth/dea_ims_study_070307.pdf.*

[2] 2008 data represents estimated sales, imports, and inventories as reported on applications for quotas.

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).[3] The net disposals (i.e., sales) figures provided by DEA registered manufacturers on quota applications include the sales of ephedrine-based products that are used to treat asthma. In this regard, DEA considered ''medical factors'' in its assessment. For industrial use, ephedrine may be used as a chiral compound for the manufacture of non-controlled non-scheduled drug products. DEA did not receive requests for 2009 ephedrine for this industrial application.

Additionally, DEA considered data on trends in the national rate of net disposals from sales data provided by IMS Health's National Sales Perspective™ (NSP) database. Export data was provided from import and export declarations (DEA 486).

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. Additionally DEA considered import quota applications from DEA registered importers requesting authority to import a total of 44 kg of ephedrine (for sale). DEA had not received any requests to synthesize ephedrine in 2009.

DEA further considered information on trends in the national rate of net disposals from sales data provided by IMS Health's National Sales Perspective™ (NSP) database. IMS Health's NSP data provides national level monthly estimates of pharmaceutical product purchases by those that distribute/sell drug products to patients (retail pharmacies, hospitals, clinics, food chain stores, and etc.) and includes both prescription and OTC products. A detailed description of the methodology that IMS Health Inc. continues to use in assembling the NSP data can be found in IMS's publication, ''2005 Ephedrine/Pseudoephedrine Legitimate Medical Use Methodology and Final Report.'' [4] IMS NSP data reported the average sales volume of ephedrine for the calendar years 2006 and 2007 to be approximately 1,261 kg.

DEA further considered trends as derived from information provided in applications for import, manufacturing, and procurement quotas and in import and export declarations. Based on an analysis of the inventory, acquisitions (purchases) and disposition (sales) data provided by DEA registered manufacturers and importers on individual quota applications received as of July 15, 2008, for the 2009 quota year, manufacturers of dosage form products containing ephedrine reported sales totaling approximately 2,840 kg in 2007 and 1,291 kg in 2008; this represents a 55 percent decrease from sales reported by these firms from 2007 to 2008. During the same period, exports of ephedrine products from the U.S. as reported on export declarations (DEA 486), totaled 168 kg in 2007 and 16 kg in 2008; this represents a 90 percent decrease from levels observed in 2007. DEA notes that the import requirements are considered in respect to the sales of those substances or products produced there from. DEA notes for 2009 that DEA registered dosage form manufacturers requested authority to purchase a total of 921 kg of ephedrine which suggests that demand is expected to decrease again in 2009.

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 U.S.; lawful export requirements; and the establishment and maintenance of reserve stocks.

In determining the needs of the U.S., DEA noted that the estimated 2008 sales of ephedrine of 1,291 kg are consistent with the IMS NSP-reported average sales of ephedrine of 1,261 kg. DEA thus believes that 1,291 kg fairly represents the U.S. needs for 2009. For the establishment and maintenance of reserve stocks, DEA notes that 21 CFR 1315.24 allows for an inventory allowance (reserve stock) of 50% of a manufacturer's estimated sales. In determining the inventory allowance, however, DEA also considered the anticipated 2008 year end inventory as reported by DEA registrants.

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

2008 sales + reserve stock + export requirement − existing inventory = AAN 1,291 + (50%*1,291) + 16 − 468 = 1,485 kg ephedrine (for sale) for 2009

This calculation suggests that DEA's Assessment of Annual Needs for ephedrine should have been proposed to be 1,500 kg rather than the 2,500 kg actually proposed. Although DEA will revise the assessment of annual needs at least once during the 2009 calendar year, DEA's experience in the establishment of quotas has been to build a safety reserve into the assessment in the event that a DEA registered manufacturer failed to provide a timely quota application for DEA's consideration. As this notice provides for an opportunity to comment DEA is not including this safety reserve for those applicants who have failed to provide a timely application. DEA notes in its calculated assessment DEA provides for 50% reserve stock. All interested parties are invited to comment on the assessment.

Accordingly, DEA is establishing on an interim basis the Assessment of Annual Needs for ephedrine (for sale) as 1,500 kg.

Comment Regarding DEA's Proposed Assessment for Phenylpropanolamine (for conversion)

The commenter, a manufacturer that converts phenylpropanolamine to amphetamine requested DEA to consider its individual requirement for phenylpropanolamine (for conversion) in fixing the final assessment of annual needs.

DEA Response

A summary of the underlying data from quota applications and other sources, as well as DEA's analysis of that data, are provided below in response to this commenter's request for consideration of its revised requirements in determining the phenylpropanolamine (for conversion) assessment.

Phenylpropanolamine (for conversion) data

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

[4] 2005 Ephedrine/Pseudoephedrine Legitimate Medical Use Methodology and Final Report *http://www.deadiversion.usdoj.gov/meth/dea_ims_study_070307.pdf.*

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	13,712	16,923	16,522
Imports** (DEA 488)	15,594	7,731	16,367	2,525
Export Declarations (DEA 486)	0	0	0	n/a
Inventory* (DEA 250)	4,863	3,021	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 July 15, 2008.
** Reported imports from applications for 2009 import quotas (DEA 488) received as of July 15, 2008.
*** Amphetamine Aggregate Production Quota History *http://www.deadiversion.usdoj.gov/quotas/quota_history.htm*

At the time [5] DEA drafted the 2009 proposed assessment (*i.e.*, July 15, 2008), DEA reviewed procurement quota applications received from DEA registered manufacturers of phenylpropanolamine (for conversion). These firms requested the authority to purchase a total of 16,522 kg phenylpropanolamine (for conversion). Additionally DEA reviewed import quota applications from DEA registered importers requesting the authority to import a total of 2,525 kg of phenylpropanolamine (for conversion). DEA had not received any requests to synthesize phenylpropanolamine in 2009.

The commenter requested DEA to consider the commenter's increased revised requirements of 1,894 kg. DEA in its proposal considered the commenter's initial quota request in its original assessment for phenylpropanolamine (for conversion). Based on the upward revised requirements of the commenter, DEA registered manufacturers have requested the authority to purchase a total of 18,416 kg (16,522 kg + 1,894 kg) phenylpropanolamine (for conversion).

DEA determined that 18,416 kg of phenylpropanolamine (for conversion) would be insufficient to meet the historical requirements of 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). This amount 18,416 kg would be sufficient to manufacture 30% of the APQ of amphetamine (*i.e.*, 22,000 kg for 2008). DEA further considered manufacturer's conversion yields of phenylpropanolamine to amphetamine of 50% in its calculation of the phenylpropanolamine assessment. DEA calculated the phenylpropanolamine (for conversion) assessment by the following methodology:

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

(22,000 / 50% yield) + 50%*(22,000 / 50% 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 have been proposed as 62,000 kg rather than the 50,000 kg actually proposed. This upwards revision of the phenylpropanolamine assessment provides for a 50% inventory allowance which was not considered in DEA's original assessment.

After consideration of this comment, DEA is establishing, on an interim basis the Assessment of Annual Needs for phenylpropanolamine (for conversion) as 62,000 kg.

Pseudoephedrine, Ephedrine (for conversion), and Phenylpropanolamine for Sale

DEA did not receive any comments on its proposed Assessment of Annual Needs for ephedrine (for conversion), phenylpropanolamine (for sale), and pseudoephedrine (for sale). However, DEA is providing the underlying data and methodologies used in determining the assessment for these list I chemicals. In determining the assessments for pseudoephedrine (for sale) and phenylpropanolamine (for sale), DEA utilized the same general methodology and calculation as was described for the assessment of ephedrine (for sale), above. For ephedrine (for conversion), DEA utilized the same general methodology and calculation as was described for the assessment of phenylpropanolamine (for conversion), above. DEA is providing an additional opportunity for comments regarding these assessments.

Pseudoephedrine (for Sale) Data

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

[Kilograms]

Pseudoephedrine (for sale)	2006	2007	2008 [6]	2009 Request
Sales* (DEA 250)	157,205	242,043	225,898	148,992
Sales* (DEA 189)	56,563	99,902	65,650	105,967
Imports** (DEA 488)	125,269	241,264	235,682	27,905
Export Declarations (DEA 486)	37,069	42,142	41,459	n/a
Inventory* (DEA 250)	84,937	65,148	4,566	n/a
IMS*** (NSP)	207,499	183,333	n/a	n/a

* Reported sales and inventory from applications for 2009 procurement quotas (DEA 250) and manufacturing quotas (DEA 189) received as of July 15, 2008.
** Reported imports from applications for 2009 import quotas (DEA 488) received as of July 15, 2008.
*** IMS Health, IMS National Sales Perspectives™, January 2006 to December 2007, Retail and Non-Retail Channels, Data Extracted July 15, 2008.

[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.

Pseudoephedrine (for sale) Analysis

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

At the time DEA drafted the 2009 proposed assessments (i.e., July 15, 2008), DEA registered manufacturers dosage form products containing pseudoephedrine reported sales totaling approximately 242,043 kg in 2007 and 225,898 kg in 2008; this represents a seven percent decrease from sales reported by these firms from 2007 to 2008. During the same period exports of pseudoephedrine products from the U.S. as reported on export declarations (DEA 486), totaled 42,142 kg in 2007 and 41,459 kg in 2008; this represents a two percent decrease 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's National Sales Perspective™ (NSP) database. IMS NSP data reported the average sales volume of pseudoephedrine for the calendar years 2006 and 2007 to be approximately 195,416 kg. DEA in considering the manufacturers reported sales thus believes that 225,898 kg fairly represents the U.S. sales of pseudoephedrine for 2009 and that 41,459 kg fairly represents the export requirements of pseudoephedrine.

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

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

225,898 + (50%*225,898) + 41,459 − 4,566 = 375,740 kg pseudoephedrine (for sale) for 2009

This calculation suggests that DEA's Assessment of Annual Needs for pseudoephedrine (for sale) should have been proposed to be 380,000 kg rather than the 415,000 kg actually proposed in the September 19, 2008, notice. Under this rulemaking DEA is establishing, on an interim basis, the Assessment of Annual Needs for pseudoephedrine (for sale) as 380,000 kg.

Ephedrine (for Conversion) Data

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

[Kilograms]

Ephedrine (for conversion)	2006	2007	2008 [7]	2009 Request
Sales* (DEA 250)	50,107	100,256	69,576	111,282
Imports** (DEA 488)	297,941	112,302	81,897	110,382
Inventory* (DEA 250)	5,605	135	10,913	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 July 15, 2008.

** Reported imports from applications for 2009 import quotas (DEA 488) received as of July 15, 2008.

*** Methamphetamine Aggregate Production Quota History *http://www.deadiversion.usdoj.gov/quotas/quota_history.htm*

Ephedrine (for Conversion) Analysis

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

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 (for conversion). These firms requested the authority to purchase a total of 111,282 kg ephedrine (for conversion) for the manufacture of two substances: Methamphetamine and pseudoephedrine.

The assessment of need for these two substances (methamphetamine and pseudoephedrine) are determined by DEA as the Aggregate Production Quota (APQ) for methamphetamine and as the estimated sales of pseudoephedrine as referenced in the 2008 Annual Assessment of Need (AAN) for pseudoephedrine. DEA in its methodology considered the ephedrine (for conversion) requirements for the manufacture of these two substances: methamphetamine and pseudoephedrine. DEA further considered the reported conversion yields of these substances. These firms reported a conversion yield of 39% 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.

The sum total of these manufacturing requirements therefore is the ephedrine (for conversion) assessment. DEA determined these established assessments for the manufacture of these two substances are the best indicators of ephedrine (for conversion). Reported sales of ephedrine (for conversion) are included as reference to DEA's proposed methodology.

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

methamphetamine requirement + pseudoephedrine requirement = AAN

The calculation for the ephedrine (for conversion) requirements for the manufacture of methamphetamine are as follows:

(2008 APQ methamphetamine/39% yield) + reserve stock − inventory = ephedrine (for manufacture of methamphetamine) (3,130/39% yield) + 50%*(3,130/39% yield) − 10,913 = 1,125 kg

The calculation for the ephedrine (for conversion) requirements 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

1,125 + 106,424 = 107,549 kg ephedrine (for conversion) for 2009

DEA is establishing, on an interim basis, the Assessment of Annual Needs for ephedrine (for conversion) as 110,000 kg, as originally proposed. DEA will revise the assessment of annual needs at least once during the 2009 calendar year.

[7] 2008 data represents estimated sales, imports, and inventories as reported on applications for quotas.

Phenylpropanolamine (for Sale) Data

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

[Kilograms]

Phenylpropanolamine (for sale)	2006	2007	2008 [8]	2009 Request
Sales* (DEA 250)	4,718	5,502	3,938	6,721
Imports** (DEA 488)	5,751	5,714	4,400	7,532
Export Declarations (DEA 486)	0	1,002	0	n/a
Inventory* (DEA 250)	3,617	4,439	1,405	n/a

* Reported sales and inventory from applications for 2009 procurement quotas (DEA 250) and manufacturing quotas (DEA 189) received as of July 15, 2008.

** Reported imports from applications for 2009 import quotas (DEA 488) received as of July 15, 2008.

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[8] of ephedrine (for sale), above.

At the time DEA drafted the 2009 proposed assessments (i.e., July 15, 2008), DEA registered manufacturers dosage form products containing phenylpropanolamine reported sales totaling approximately 4,718 in 2006 and 5,502 kg in 2007 and 3,938 kg in 2008; this represents a 28 percent decrease from sales reported by these firms from 2007 to 2008 and a 17% decrease from 2006 to 2008. DEA notes phenylpropanolamine is sold primarily as a veterinary product for the treatment for canine incontinence and is not FDA approved for human consumption. IMS NSP Health Data does not capture sales of phenylpropanolamine to these channels and is therefore not included. DEA in considering the manufacturers reported sales thus believes that 3,983 kg fairly represents the U.S. sales of phenylpropanolamine for 2009.

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

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

3,938 + (50%*3,938) + 0 − 1,405 = 4,502 kg phenylpropanolamine (for sale) for 2009

This calculation suggests that DEA's Assessment of Annual Needs for phenylpropanolamine (for sale) should have been proposed to be 4,500 kg rather than the 7,500 kg actually proposed. As noted above, DEA is no longer including a safety reserve into the assessment because DEA clearly demonstrates the data and methodology with which DEA calculated the assessment. Further, this notice provides for an opportunity to comment.

DEA is establishing, on an interim basis the Assessment of Annual Needs for phenylpropanolamine (for sale) as 4,500 kg. For each of the established assessments, DEA will revise the assessment of annual needs at least once during the 2009 calendar year.

Conclusion

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 is publishing this notice establishing the assessment of annual needs effective January 1, 2009, on an interim basis. DEA believes that without the publication of this notice on an interim basis, DEA would be unable to issue quotas for the import and manufacture of the List I chemicals ephedrine, pseudoephedrine, and phenylpropanolamine. Without such quotas, regulated industry would be prevented from importing and manufacturing activities involving these chemicals.

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 0.100, and redelegated to the Deputy Administrator pursuant to 28 CFR 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)	1,500
Ephedrine (for conversion)	110,000
Pseudoephedrine (for sale)	380,000
Phenylpropanolamine (for sale)	4,500
Phenylpropanolamine (for conversion)	62,000

Regulatory Certifications

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

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

The CMEA of 2005 specifically amended 21 U.S.C. 826 to mandate the establishment of production quotas for the List I chemicals ephedrine, pseudoephedrine, and phenylpropanolamine. DEA has no discretion in this requirement and has established the same system of production quotas for these three List I chemicals as is currently established for controlled substances in Schedules I and II. Further, the CMEA amended 21 U.S.C. 952 to prohibit all importation of ephedrine, pseudoephedrine, and phenylpropanolamine except such amounts as the Attorney General finds to be necessary for medical, scientific, or other legitimate purposes. The Act further amended § 952 regarding import quotas for these three List I chemicals.

Taken together, §§ 826 and 952 require that DEA establish aggregate production quotas, herein referred to as an Assessment of Annual Needs, for these List I chemicals. Further, taken

[8] 2008 data represents estimated sales, imports, and inventories as reported on applications for quotas. Import and export declarations data extracted July 15, 2008.

together, §§ 826 and 952 require that DEA issue individual import and manufacturing quotas to registrants registered to import or manufacture ephedrine, pseudoephedrine, and phenylpropanolamine who apply for, and are granted, such individual quotas. As section 826 indicates, the Assessment of Annual Needs is established for each calendar year (21 U.S.C. 826(a)). The Attorney General, DEA by delegation, is required ''to limit or reduce individual production quotas to the extent necessary to prevent the aggregate of individual quotas from exceeding the amount determined necessary each year by the Attorney General,'' *i.e.*, the Assessment of Annual Needs (21 U.S.C. 826(b)). Thus, individual manufacturing and import quotas for ephedrine, pseudoephedrine, and phenylpropanolamine cannot be calculated without the establishment of the Assessment of Annual Needs.

If DEA were not to establish the initial Assessment of Annual Needs, while seeking additional comment, DEA would be unable to issue individual quotas to importers and manufacturers who had applied for, and were to be granted, such quotas. If DEA cannot issue such individual quotas prior to January 1, 2009, importers and manufacturers will have no means by which to acquire the List I chemicals ephedrine, pseudoephedrine, or phenylpropanolamine necessary for them to conduct business.

DEA believes that it is in the public interest to ensure that importers and manufacturers of products containing ephedrine, pseudoephedrine, and phenylpropanolamine be able to obtain these List I chemicals on and after January 1, 2009. DEA wishes to ensure that products containing these List I chemicals remain available to the public while interested parties are provided with further opportunity to comment on DEA's Assessment of Annual Needs. To ensure availability of these products, and to ensure continued legitimate commerce, including the importation and manufacture of products containing these List I chemicals, DEA finds good cause to publish this Assessment of Annual Needs on an interim basis while seeking additional comment. In so doing, DEA recognizes that exceptions to the APA's notice and comment procedures are to be ''narrowly construed and only reluctantly countenanced.'' *Am. Fed'n of Gov't Employees* v. *Block,* 655 F2d 1153, 1156 (D.C. Cir. 1981) (quoting *New Jersey Dep't of Envtl. Prot.* v. *EPA,* 626 F.2d 1038, 1045 (D.C. Cir. 1980)).

Under 5 U.S.C. 553(d), DEA must generally provide a 30-day delayed effective date for final rules. DEA may dispense with the 30-day delayed effective date requirement ''for good cause found and published with the rule.'' DEA believes that good cause exists to make this Interim Assessment of Annual Needs with Request for Comment effective January 1, 2009. As DEA noted previously, the 2009 Assessment of Annual Needs must be established, and individual quotas issued, on January 1, 2009, so as not to impede legitimate commerce in these List I chemicals during the calendar year. DEA believes that good cause exists not to delay the effective date of this notice by 30 days to ensure that the Assessment of Annual Needs may be established, and individual import and manufacturing quotas issued, by January 1, 2009.

Finally, DEA notes that the CSA and its implementing regulations allow registrants who have applied for or received a manufacturing quota to apply for an increase in that quota to meet the registrant's estimated disposal, inventory, or other requirements during the remainder of the year (21 U.S.C. 826(e), 21 CFR 1315.25(a), 1315.32(g)). Further, the CSA and its implementing regulations allow registrants who are authorized to import ephedrine, pseudoephedrine, or phenylpropanolamine to apply for an increase in the amount of the chemical the registrant is authorized to import (21 U.S.C. 952(d), 21 CFR 1315.36(b)). DEA notes that registrants may use these provisions to request increases in individual manufacturing and import quotas, respectively, pending any revisions of this Interim Assessment.

Regulatory Flexibility Act

The Deputy Administrator hereby certifies that this action will not have a significant economic impact on 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 the 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 U.S., 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.

Executive Order 12866

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

Executive Order 13132

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 federalism implications warranting the application of Executive Order 13132.

Executive Order 12988

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

Unfunded Mandates Reform Act of 1995

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.

Congressional Review Act

This action is not a major rule as defined by Section 804 of the Small Business Regulatory Enforcement Fairness Act of 1996. 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 U.S.-based companies to compete with foreign-based companies in domestic and export markets.

Dated: December 19, 2008.

Michele M. Leonhart,

Deputy Administrator.

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DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[DEA # 317E]

Controlled Substances: Established Initial Aggregate Production Quotas for 2009

AGENCY: Drug Enforcement Administration (DEA), Justice.

ACTION: Notice of aggregate production quotas for 2009.

SUMMARY: This notice establishes initial 2009 aggregate production quotas for