

Basic class—Schedule II	Established 2011 quotas
Phencyclidine	24 g
Phenmetrazine	2 g
Phenylacetone	8,000,000 g
Racemethorphan	2 g
Remifentanyl	2,500 g
Secobarbital	260,002 g
Sufentanyl	7,000 g
Tapentadol	1,000,000 g
Thebaine	126,000,000 g

The Deputy Administrator further orders that aggregate production quotas for all other schedules I and II controlled substances included in 21 CFR 1308.11 and 1308.12 be established at zero.

The Office of Management and Budget has determined that notices of aggregate production 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 federalism implications warranting the application of Executive Order 13132.

The Deputy Administrator hereby certifies that this action will have no significant impact upon small entities whose interests must be considered under the Regulatory Flexibility Act, 5 U.S.C. 601 *et seq.* The establishment of aggregate production quotas for schedules I and II controlled substances is mandated by law and by international treaty obligations. The quotas are necessary to provide for the estimated medical, scientific, research, and industrial needs of the United States, for export requirements and the establishment and maintenance of reserve stocks. While aggregate production quotas are of primary importance to large manufacturers, their impact upon small entities is neither negative nor beneficial. 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 \$126,400,000 or more 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. 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: December 10, 2010.

Michele M. Leonhart,
Deputy Administrator.

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DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. DEA-350E]

Established Assessment of Annual Needs for the List I Chemicals Ephedrine, Pseudoephedrine, and Phenylpropanolamine for 2011

AGENCY: Drug Enforcement Administration (DEA), Justice.

ACTION: Notice of Assessment of Annual Needs for 2011.

SUMMARY: This notice establishes the initial 2011 Assessment of Annual Needs for certain List I chemicals in accordance with the Combat Methamphetamine Epidemic Act of 2005 (CMEA).

DATES: *Effective Date:* December 20, 2010.

FOR FURTHER INFORMATION CONTACT: Christine A. Sannerud, PhD, Chief, Drug and Chemical Evaluation Section, Drug Enforcement Administration, 8701 Morrisette 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 the 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 CMEA of 2005 (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 2011 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 2011 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 0.100. The Administrator, in turn, has redelegated this function to the Deputy Administrator, pursuant to 28 CFR 0.104.

On September 13, 2010, a notice entitled, "Assessment of Annual Needs for the List I Chemicals Ephedrine, Pseudoephedrine, and Phenylpropanolamine for 2011: Proposed" was published in the **Federal Register** (75 FR 55605). That notice proposed the 2011 Assessment of Annual Needs for ephedrine (for sale), ephedrine (for conversion), pseudoephedrine (for sale), pseudoephedrine (for conversion), phenylpropanolamine (for sale) and phenylpropanolamine (for conversion). All interested persons were invited to comment on or object to the assessments on or before October 13, 2010.

Comments Received

DEA received one comment regarding the assessment for annual needs for phenylpropanolamine (for conversion).

DEA discusses this comment in further detail below. DEA did not receive any comments to the Assessment of Annual Needs for ephedrine (for sale), ephedrine (for conversion), pseudoephedrine (for sale), and phenylpropanolamine (for sale). DEA is finalizing the assessments for these List I chemicals based on information contained in applications for 2011 import, manufacturing and procurement quotas provided by DEA registered importers and manufacturers as of October 21, 2010. DEA is providing the data used in developing the established assessments for each of the listed chemicals. DEA also notes that the Assessment of Annual Needs may be adjusted at a later date pursuant to 21 CFR 1315.13.

Comment Regarding DEA's Assessment for Phenylpropanolamine (For Conversion)

DEA received one comment regarding the assessment of annual need for phenylpropanolamine (for conversion). The comment was from a DEA registered manufacturer of phenylpropanolamine (for conversion) who converts phenylpropanolamine to amphetamine. The commenter stated that, "the proposed quantities for the material mentioned below is not sufficient to provide for adequate supplies for the medical, scientific, research and industrial needs of the United States, and for the lawful export requirements, and that the quotas should be increased to cover our needs * * *." Additionally, the commenter further stated, "the Phenylpropanolamine quota should be increased by 8,500,000 grams as base to allow for increased quantity of material to be purchased from our importer of record * * *."

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.

In calculating the assessment for phenylpropanolamine (for conversion) DEA considered the commenter's

phenylpropanolamine requirements, as submitted in the commenter's request for quota, along with the requirements of other manufacturers of phenylpropanolamine as stated in requests for 2011 quotas for the manufacture of phenylpropanolamine (for conversion) received as of October 21, 2010. The commenter suggested that the phenylpropanolamine assessment be increased by 8,500 kg. DEA notes that based on the sales information provided in pending 2011 requests for individual manufacturing quotas, the DEA is establishing the phenylpropanolamine (for conversion) at 21,800 kg, which represents an increase of 13,700 kg from the original 8,100 kg proposed phenylpropanolamine assessment (75 FR 55609). The full calculation is provided below.

Underlying Data and DEA's Analysis

DEA is establishing the assessment of annual needs based on information provided by DEA registered manufacturers and importers as of October 21, 2010. 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 determining the proposed 2011 assessments, DEA has considered the total net disposals (*i.e.* sales) of the List I chemicals for the current and preceding two years, actual and estimated inventories, projected demand (2011), 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).¹

DEA further considered trends as derived from information provided in applications for import, manufacturing, and procurement quotas and in import and in 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 available.

Ephedrine (for Sale) Data

¹ Applications and instructions for procurement, import and manufacturing quotas can be found at http://www.deadiversion.usdoj.gov/quotas/quota_apps.htm.

EPHEDRINE (FOR SALE) DATA FOR 2011 ASSESSMENT OF ANNUAL NEEDS (KILOGRAMS)

Ephedrine	2008	2009	2010	2011 Request
Sales* (DEA 250)	2,640	2,302	3,014	3,685
Imports** (DEA 488)	1,692	4,208	3,202	3,302
Export Declarations (DEA 486)	18	64	52	n/a
Inventory* (DEA 250)	603	432	457	n/a
IMS*** (NSP)	1,460	1,406	n/a	n/a

* Reported sales and inventory from applications for 2011 procurement quotas (DEA 250) received as of October 21, 2010.

** Reported imports from applications for 2011 import quotas (DEA 488) received as of October 21, 2010.

*** IMS Health, IMS National Sales Perspectives™, January 2008 to December 2009, Retail and Non-Retail Channels, Data Extracted October 21, 2010.

Ephedrine (for Sale) Analysis

DEA calculated the proposed 2011 Assessment of Annual Needs for ephedrine using the calculation developed to determine the 2009 Assessment of Annual Needs. This calculation 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 October 21, 2010, DEA registered manufacturers of dosage form products containing ephedrine requested the authority to purchase a total of 3,685 kg ephedrine (for sale) in 2011. DEA registered manufacturers of ephedrine reported sales totaling approximately 2,302 kg in 2009 and 3,014 kg in 2010; this represents a 24 percent increase in sales reported by these firms from 2009 to 2010. Additionally, exports of ephedrine products from the United States as

reported on export declarations (DEA 486) totaled 64 kg in 2009 and 52 kg in 2010; this represents a 19 percent decrease from levels observed in 2009. The average of the 2009 and 2010 exports of ephedrine products is approximately 58 kg. 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 2008 and 2009 to be approximately 1,433 kg. DEA notes that the 2010 sales figure reported by manufacturers (3,014 kg) is higher than the average sales reported by IMS for the previous two years (1,433 kg). This is expected because a manufacturer's reported sales include quantities which are necessary to provide reserve stocks for distributors and retailers. In considering the manufacturer's reported sales, DEA thus believes that 3,014 kg fairly represents the U.S. sales of ephedrine for 2011 and that 58 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 2010 year end inventory as reported by DEA registrants in determining the inventory allowance.

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

2010 sales + reserve stock + export requirement – existing inventory = AAN

3,014 + (50% * 3,014) + 58 - 457 = 4,122 kg ephedrine (for sale) for 2011

This calculation suggests that DEA's Assessment of Annual Needs for ephedrine should be established as 4,200 kg. Accordingly, DEA is establishing the 2011 Assessment of Annual Needs for ephedrine (for sale) at 4,200 kg.

Phenylpropanolamine (for Sale) Data

PHENYLPROPANOLAMINE (FOR SALE) DATA FOR 2011 ASSESSMENT OF ANNUAL NEEDS (KILOGRAMS)

Phenylpropanolamine (for sale)	2008	2009	2010	2011 Request
Sales* (DEA 250)	4,300	4,825	5,005	6,110
Imports** (DEA 488)	105	1,503	1,582	1,596
Export Declarations (DEA 486)	0	3	0	n/a
Inventory* (DEA 250)	2,455	2,483	2,261	n/a

* Reported sales and inventory from applications for 2011 procurement quotas (DEA 250) received as of October 21, 2010.

** Reported imports from applications for 2011 import quotas (DEA 488) received as of October 21, 2010.

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 October 21, 2010, DEA registered manufacturers of dosage form products containing phenylpropanolamine requested the authority to purchase 6,110 kg

phenylpropanolamine (for sale) in 2011. DEA registered manufacturers of phenylpropanolamine reported sales totaling approximately 4,825 kg in 2009 and 5,005 kg in 2010; this represents a 3.6 percent increase in sales reported by these firms from 2009 to 2010. Additionally, exports of phenylpropanolamine products from the U.S. as reported on export declarations (DEA 486) totaled 3 kg in 2009 and 0 kg in 2010; this represents a 3 kg decrease from levels observed in

2009. The average of the 2009 and 2010 exports of phenylpropanolamine products is approximately 2 kg. DEA thus believes that 5,005 kg fairly represents the U.S. sales of phenylpropanolamine for 2011 and that 2 kg fairly represents the export requirements of phenylpropanolamine. 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:

2010 sales + reserve stock + export requirement – existing inventory = AAN
 $5,005 + (50\% * 5,005) + 2 - 2,261 = 5,249$
 kg phenylpropanolamine (for sale) for 2011
 This calculation suggests that DEA's 2011 Assessment of Annual Needs for

phenylpropanolamine (for sale) should be established as 5,300 kg. Accordingly, DEA is establishing the 2011 Assessment of Annual Needs for phenylpropanolamine (for sale) at 5,300 kg.

Pseudoephedrine (for Sale) Data

PSEUDOEPHEDRINE (FOR SALE) DATA FOR 2011 ASSESSMENT OF ANNUAL NEEDS (KILOGRAMS)

Pseudoephedrine (for sale)	2008	2009	2010	2011 Request
Sales* (DEA 250)	200,235	193,092	203,734	218,037.
Sales* (DEA 189)	64,781	7,321	5,550	0.
Imports** (DEA 488)	138,602	164,906	168,618	220,926.
Export Declarations (DEA 486)	47,199	35,264	8,480	n/a.
Inventory* (DEA 250)	109,427	76,505	48,004	n/a.
IMS*** (NSP)	148,456	139,908	n/a	n/a.

* Reported sales and inventory from applications for 2011 procurement quotas (DEA 250) received as of October 21, 2010.

** Reported imports from applications for 2011 import quotas (DEA 488) received as of October 21, 2010.

*** IMS Health, IMS National Sales Perspectives™, January 2008 to December 2009, Retail and Non-Retail Channels, Data Extracted October 21, 2010.

Pseudoephedrine (for Sale) Analysis

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

As of October 21, 2010, DEA registered manufacturers of dosage form products containing pseudoephedrine requested the authority to purchase 218,037 kg pseudoephedrine. DEA registered manufacturers of pseudoephedrine reported sales totaling approximately 193,092 kg in 2009 and 203,734 kg in 2010; this represents a 5 percent increase in sales reported by these firms from 2009 to 2010. During the same period exports of pseudoephedrine products from the

U.S. as reported on export declarations (DEA 486) totaled 35,264 kg in 2009 and 8,480 kg in 2010; this represents a 76 percent decrease from levels observed in 2009. The average of the 2009 and 2010 exports is 21,872 kg.

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 2008 and 2009 to be approximately 144,182 kg. DEA thus believes that 203,734 kg of sales reported by manufacturers fairly represents the U.S. sales of pseudoephedrine for 2011 and that 21,872 kg fairly represents the export requirements for pseudoephedrine.

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

2010 sales + reserve stock + export requirement – existing inventory = AAN
 $203,734 + (50\% * 203,734) + 21,872 - 48,004 = 279,469$ kg
 pseudoephedrine (for sale) for 2011.

This calculation suggests that DEA's 2011 Assessment of Annual Needs for pseudoephedrine (for sale) should be established as 280,000 kg. Accordingly, DEA is establishing the 2011 Assessment of Annual Needs for pseudoephedrine (for sale) at 280,000 kg.

Phenylpropanolamine (for Conversion) Data

PHENYLPROPANOLAMINE (FOR CONVERSION) DATA FOR 2011 ASSESSMENT OF ANNUAL NEEDS (KILOGRAMS)

Phenylpropanolamine (for conversion)	2008	2009	2010	2011 Request
Sales* (DEA 250)	10,834	11,486	17,086	23,700
Imports** (DEA 488)	8,294	5,766	15,177	27,500
Export Declarations (DEA 486)	0	0	0	n/a
Inventory* (DEA 250)	5,533	3,145	3,854	n/a

* Reported sales and inventory from applications for 2011 procurement quotas (DEA 250) received as of received as of October 21, 2010.

** Reported imports from applications for 2011 import quotas (DEA 488) received as of October 21, 2010.

Phenylpropanolamine (for Conversion) Analysis

As of October 21, 2010, DEA registered manufacturers of phenylpropanolamine (for conversion) requested the authority to purchase a total of 23,700 kg phenylpropanolamine for the manufacture of amphetamine. DEA registered manufacturers of phenylpropanolamine reported sales of

phenylpropanolamine totaling approximately 11,486 kg in 2009 and 17,086 kg in 2010; this represents a 33 percent increase in sales reported by these firms from 2009 to 2010. There were no reported exports of phenylpropanolamine (for conversion). DEA has not received any requests to synthesize phenylpropanolamine in 2011. DEA has concluded that the 2010 sales of phenylpropanolamine (for

conversion), 17,086 kg, fairly represents U.S. requirements for 2011 and zero kg fairly represents the export requirements of phenylpropanolamine (for conversion).

DEA determined that the data provided in procurement, manufacturing, and import quota applications best represents the legitimate need for phenylpropanolamine (for conversion).

Phenylpropanolamine (for conversion) is used for the manufacture of legitimate amphetamine products, but DEA notes that most legitimate amphetamine is manufactured by converting phenylacetone, rather than phenylpropanolamine, to amphetamine. Basing the phenylpropanolamine (for conversion) calculation on the total Aggregate Production Quota (APQ) for amphetamine therefore would inaccurately inflate the

phenylpropanolamine (for conversion) assessment.

DEA calculated the phenylpropanolamine (for conversion) assessment for the manufacture of amphetamine as follows:

$$(2010 \text{ sales}) + \text{reserve stock} + \text{export requirement} - \text{inventory} = \text{AAN}$$

$$(17,086) + (50\% * 17,086) + 0 - 3,854 = 21,775 \text{ kg PPA (for conversion) for 2011}$$

This calculation suggests that DEA's 2011 Assessment of Annual Needs for phenylpropanolamine (for conversion) should be established as 21,800 kg. Accordingly, DEA is establishing the 2011 Assessment of Annual Needs for phenylpropanolamine (for conversion) at 21,800 kg.

Ephedrine (for Conversion) Data

EPHEDRINE (FOR CONVERSION) DATA FOR 2011 ASSESSMENT OF ANNUAL NEEDS (KILOGRAMS)

Ephedrine (for conversion)	2008	2009	2010	2011 Request
Sales* (DEA 250)	64,665	9,562	6,303	653
Imports** (DEA 488)	0	0	0	0
Inventory* (DEA 250)	233	99	152	n/a
APQ Methamphetamine***	3,130	3,130	3,130	n/a

* Reported sales and inventory from applications for 2011 procurement quotas (DEA 250) and manufacturing quotas (DEA 189) received as of October 21, 2010.

** Reported imports from applications for 2011 import quotas (DEA 488) received as of received as of October 21, 2010.

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

Ephedrine (for Conversion) Analysis

As of October 21, 2010, DEA registered manufacturers of ephedrine (for conversion) requested the authority to purchase a total of 653 kg ephedrine (for conversion) for the manufacture of two substances: methamphetamine and pseudoephedrine.

DEA considered the ephedrine (for conversion) requirements for the manufacture of methamphetamine and pseudoephedrine. DEA has determined that 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. DEA determined that the estimated sales of pseudoephedrine, as referenced in the Assessment of Annual Needs (AAN) for pseudoephedrine, represents the need 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. DEA registered manufacturers reported a conversion yield of 39 percent for the synthesis of methamphetamine from ephedrine. 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:

$$\text{methamphetamine requirement} + \text{pseudoephedrine requirement} = \text{AAN}$$

DEA calculated the ephedrine (for conversion) requirement for the manufacture of methamphetamine as follows:

$$(2010 \text{ APQ methamphetamine}/39 \text{ percent yield}) + \text{reserve stock} - \text{inventory} = \text{ephedrine (for manufacture of methamphetamine)}$$

$$(3,130/39 \text{ percent yield}) + 50 \text{ percent} * (3,130/39 \text{ percent yield}) - 152 = 11,887 \text{ kg}$$

The calculation for the ephedrine (for conversion) requirement for the manufacture of pseudoephedrine leads to a result of 6,692 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:

$$\text{methamphetamine requirement} + \text{pseudoephedrine requirement} = \text{AAN}$$

$$11,887 + 6,692 = 18,579 \text{ kg ephedrine (for conversion) for 2011}$$

This calculation suggests that DEA's 2011 Assessment of Annual Needs for ephedrine (for conversion) should be established as 18,600 kg. Accordingly, DEA is establishing the 2011 Assessment of Annual Needs for ephedrine (for conversion) at 18,600 kg.

Conclusion

DEA received one comment regarding the assessment for phenylpropanolamine (for conversion). DEA has carefully considered the comment received in connection with the 2011 Assessment of Annual Needs. DEA calculated the assessment for phenylpropanolamine (for conversion) using the data provided in applications for 2011 import, manufacturing and procurement quotas provided by DEA registered importers and manufacturers as of October 21, 2010. This data included the quota request submitted by the commenter. The results of the calculation led DEA to increase the phenylpropanolamine (for conversion) assessment from the proposed 8,100 kg to 21,800 kg.

DEA did not receive any comments on its Assessment of Annual Needs for ephedrine (for sale), ephedrine (for conversion), pseudoephedrine (for sale) and phenylpropanolamine (for sale). DEA is finalizing the assessments for these List I chemicals based on information contained in applications for 2011 import, manufacturing and procurement quotas provided by DEA registered importers and manufacturers as of October 21, 2010.

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 2011 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 2011 assessment of annual needs (kg)
Ephedrine (for sale)	4,200
Phenylpropanolamine (for sale)	5,300
Pseudoephedrine (for sale) ..	280,000
Phenylpropanolamine (for conversion)	21,800
Ephedrine (for conversion) ...	18,600

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: December 10, 2010.

Michele M. Leonhart,
Deputy Administrator.

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DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. DEA–326F]

Final Revised Assessment of Annual Needs for the List I Chemicals Ephedrine, Pseudoephedrine, and Phenylpropanolamine for 2010

AGENCY: Drug Enforcement Administration (DEA), Justice.

ACTION: Notice of Final Assessment of Annual Needs for 2010.

SUMMARY: This notice establishes the Final Revised 2010 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:* December 20, 2010.

FOR FURTHER INFORMATION CONTACT: Christine A. Sannerud, PhD, Chief, Drug & Chemical Evaluation Section, Drug Enforcement Administration (DEA), 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, 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).

The 2010 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 2010 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.

On June 28, 2010, a notice entitled, “Proposed Revised Assessment of Annual Needs for the List I Chemicals Ephedrine, Pseudoephedrine, and Phenylpropanolamine for 2010” was published in the **Federal Register** (75 FR 36684). This notice proposed the revised 2010 Assessment of Annual Needs for ephedrine (for sale), ephedrine (for conversion), pseudoephedrine (for sale), phenylpropanolamine (for sale) and phenylpropanolamine (for conversion).