

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.

[FR Doc. 2010–31853 Filed 12–17–10; 8:45 am]

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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).

All interested persons were invited to comment on or object to the proposed assessments on or before July 28, 2010.

Comments Received

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

including those quota applications that DEA received between the drafting of the June 28th notice and the drafting of this notice on August 10, 2010. DEA is providing the data used in developing the established assessments for each of the listed chemicals.

Underlying Data and DEA's Analysis

In determining the 2010 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 (2010), 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 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

EPHEDRINE (FOR SALE) DATA FOR 2010 ASSESSMENT OF ANNUAL NEEDS [Kilograms]

Ephedrine	2007	2008	2009	2010 Request
Sales* (DEA 250)	2,698	2,507	2,650	3,289
Imports** (DEA 488)	9,595	1,690	2,139	2,431
Export Declarations (DEA 486)	168	18	64	n/a
Inventory* (DEA 250)	1,373	626	191	n/a
IMS*** (NSP)	1,236	1,460	1,401	n/a

* Reported sales and inventory from applications for 2010 procurement quotas (DEA 250) received as of August 10, 2010.

** Reported imports from applications for 2010 import quotas (DEA 488) received as of August 10, 2010.

*** IMS Health, IMS National Sales Perspectives™, January 2007 to December 2009, Retail and Non-Retail Channels, Data Extracted August 10, 2010.

Ephedrine (for Sale) Analysis

DEA previously has established the 2010 assessment of annual needs for ephedrine (for sale) at 3,600 kg (74 FR 60298).

As noted above, DEA developed the revisions to the 2010 assessment of annual needs for ephedrine (for sale) using the same calculation and methodology that DEA used to determine the 2009 and 2010 assessment of annual needs.

As of August 10, 2010, DEA registered manufacturers of dosage form products containing ephedrine requested the authority to purchase a total of 3,289 kg ephedrine (for sale) in 2010. DEA registered manufacturers of ephedrine reported sales totaling approximately 2,507 kg in 2008 and 2,650 kg in 2009; this represents a 5 percent increase in sales reported by these firms from 2008 to 2009. Additionally, exports of ephedrine products from the United States as reported on export declarations (DEA 486) totaled 18 kg in 2008 and 64 kg in 2009; this represents a 72 percent increase from levels observed in 2008. The average of the 2008 and 2009 exports of ephedrine products is approximately 41 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 1,431 kg. DEA notes that the 2009 sales figure reported by manufacturers (2,650 kg) is higher than the average sales reported by IMS for the previous two years (1,431 kg). 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 2,650 kg fairly represents the United States sales of ephedrine for 2010 and that 41 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 2009 year end inventory as reported by DEA registrants in determining the inventory allowance.

DEA calculated the proposed revised ephedrine (for sale) assessment as follows:

2009 sales + reserve stock + export requirement – existing inventory = AAN
 $2,650 + (50\% * 2,650) + 41 - 191 = 3,825$ kg ephedrine (for sale) for 2010

This calculation suggests that DEA's assessment of annual needs for ephedrine should be 3,900 kg. DEA notes that its June 28, 2010, notice proposed to increase the ephedrine assessment to 4,100 kg. That proposal was based on information received as of March 10, 2010. Since that time DEA has received revised manufacture production data, i.e., sales and inventory information decreasing the reported sales of ephedrine for 2009. After calculating the ephedrine (for sale) assessment using the most current data—that reported by DEA registered manufactures as of August 10, 2010—DEA concludes that the proposed revised assessment of 4,100 kg would have been unnecessarily high. Accordingly, DEA is increasing the 2010 assessment of annual needs for ephedrine (for sale) from 3,600 kg to 3,900 kg.

Phenylpropanolamine (for Sale) data

¹ Applications and instructions for procurement, import and manufacturing quotas can be found at

http://www.deadiversion.usdoj.gov/quotas/quotas_apps.htm

PHENYLPROPANOLAMINE (FOR SALE) DATA FOR 2010 ASSESSMENT OF ANNUAL NEEDS
[Kilograms]

Phenylpropranolamine (for sale)	2007	2008	2009	2010 Request
Sales* (DEA 250)	4,158	4,528	5,355	7,480
Imports** (DEA 488)	5,787	3,425	6,626	7,271
Export Declarations (DEA 486)	1,002	0	3	n/a
Inventory* (DEA 250)	3,642	2,470	645	n/a

* Reported sales and inventory from applications for 2010 procurement quotas (DEA 250) received as of August 10, 2010.

** Reported imports from applications for 2010 import quotas (DEA 488) received as of August 10, 2010.

Phenylpropranolamine (for Sale) Analysis

DEA previously has established the 2010 assessment of annual needs for phenylpropranolamine (for sale) at 6,400 kg (74 FR 60298).

As noted above, DEA utilized the same general methodology and calculation to develop the proposed revised assessment for phenylpropranolamine (for sale) that DEA used to determine the 2009 and 2010 assessment of annual needs.

As of August 10, 2010, DEA registered manufacturers of dosage form products containing phenylpropranolamine requested the authority to purchase 7,480 kg phenylpropranolamine (for sale) in 2010. DEA registered manufacturers of phenylpropranolamine reported sales totaling approximately 4,528 kg in 2008

and 5,355 kg in 2009; this represents a 15.5% increase in sales reported by these firms from 2008 to 2009.

Additionally, exports of phenylpropranolamine products from the United States as reported on export declarations (DEA 486) totaled 0 kg in 2008 and 3 kg in 2009; this represents a 3 kg increase from levels observed in 2008. The average of the 2008 and 2009 exports of phenylpropranolamine products is approximately 2 kg. DEA thus believes that 5,355 kg fairly represents the United States sales of phenylpropranolamine for 2010 and that 2 kg fairly represents the export requirements of phenylpropranolamine. DEA notes that phenylpropranolamine 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 phenylpropranolamine to veterinary channels and is, therefore, not included.

DEA calculated the proposed revised phenylpropranolamine (for sale) assessment by the following methodology:

2009 sales + reserve stock + export requirement – existing inventory = AAN

$5,355 + (50\% * 5,355) + 2 - 645 = 7,390$ kg phenylpropranolamine (for sale) for 2010

This calculation suggests that DEA's 2010 Assessment of Annual Needs for phenylpropranolamine (for sale) should be 7,400 kg. Accordingly, DEA is increasing the 2010 assessment of annual needs for phenylpropranolamine (for sale) from 6,400 kg to 7,400 kg.

Pseudoephedrine (for Sale) Data

PSEUDOEPHEDRINE (FOR SALE) DATA FOR 2010 ASSESSMENT OF ANNUAL NEEDS
[Kilograms]

Pseudoephedrine (for sale)	2007	2008	2009	2010 Request
Sales* (DEA 250)	239,314	224,480	286,607	254,286
Sales* (DEA 189)	100,300	64,781	33,600	32,760
Imports** (DEA 488)	231,683	170,614	274,492	261,528
Export Declarations (DEA 486)	42,132	47,199	35,264	n/a
Inventory* (DEA 250)	136,039	121,374	68,100	n/a
IMS*** (NSP)	180,221	149,232	140,784	n/a

* Reported sales and inventory from applications for 2010 procurement quotas (DEA 250) and manufacturing quotas (DEA 189) received as of August 10, 2010.

** Reported imports from applications for 2010 import quotas (DEA 488) received as of August 10, 2010.

*** IMS Health, IMS National Sales Perspectives™, January 2007 to December 2009, Retail and Non-Retail Channels, Data Extracted August 10, 2010.

Pseudoephedrine (for Sale) Analysis

DEA previously has established the 2010 assessment of annual needs for pseudoephedrine (for sale) at 404,000 kg (74 FR 60298).

As noted above, DEA utilized the same general methodology and calculation to develop the proposed revised assessment for pseudoephedrine (for sale) that DEA used to determine the 2009 and 2010 assessment of annual needs.

As of August 10, 2010, DEA registered manufacturers of dosage form products

containing pseudoephedrine requested the authority to purchase 254,286 kg pseudoephedrine. DEA registered manufacturers of pseudoephedrine reported sales totaling approximately 224,480 kg in 2008 and 286,607 kg in 2009; this represents a 22 percent increase in sales reported by these firms from 2008 to 2009. During the same period exports of pseudoephedrine products from the United States as reported on export declarations (DEA 486) totaled 47,199 kg in 2008 and 35,264 kg in 2009; this represents a 25

percent decrease from levels observed in 2008. The average of the 2008 and 2009 exports is 41,232 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 145,006 kg. DEA thus believes that 286,607 kg of sales reported by manufacturers fairly represents the United States sales of pseudoephedrine for 2010 and that

41,232 kg fairly represents the export requirements of pseudoephedrine. DEA notes that manufacturer reported sales for 2009 (286,607 kg) are higher than the average retail sales reported by IMS for the previous two years (145,006 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 revised pseudoephedrine (for sale) assessment by the following methodology:

$$2009 \text{ sales} + \text{reserve stock} + \text{export requirement} - \text{existing inventory} = \text{AAN}$$

$$286,607 + (50\% * 286,607) + 41,232 - 68,100 = 403,043 \text{ kg pseudoephedrine (for sale) for 2010.}$$

This calculation suggests that DEA's 2010 assessment of annual needs for pseudoephedrine (for sale) should be 404,000 kg. DEA notes that its June 28, 2010, notice proposed to increase the pseudoephedrine assessment to 419,000 kg. That proposal was based on information received as of March 10, 2010. Since that time DEA has received additional request for quotas, revised manufacture production data, i.e., sales and inventory information, requests for withdrawal of quota, and request for adjustments to individual procurement quotas. As a result of this additional

information, the 2009 reported sales of pseudoephedrine decreased from 287,756 kg to 286,607 kg and the reported inventory increased from 54,173 kg to 68,001 kg. After calculating the pseudoephedrine (for sale) assessment using the most current data—that was reported by DEA registered manufactures as of August 10, 2010—DEA concludes that the proposed revised assessment of 419,000 kg would have been unnecessarily high. Accordingly, DEA has determined that the established 2010 AAN for pseudoephedrine of 404,000 kg is appropriate and requires no change.

Phenylpropanolamine (for Conversion) Data

PHENYLPROPANOLAMINE (FOR CONVERSION) DATA FOR 2010 ASSESSMENT OF ANNUAL NEEDS
[Kilograms]

Phenylpropanolamine (for conversion)	2007	2008	2009	2010 Request
Sales* (DEA 250)	3,621	10,837	14,585	14,910
Imports** (DEA 488)	8,250	12,019	11,373	28,408
Export Declarations (DEA 486)	0	0	0	n/a
Inventory* (DEA 250)	3,581	5,537	4,104	n/a
APQ Amphetamine***	22,000	22,000	24,500	23,500

* Reported sales and inventory from applications for 2010 procurement quotas (DEA 250) received as of August 10, 2010.

** Reported imports from applications for 2010 import quotas (DEA 488) received as of August 10, 2010.

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

Phenylpropanolamine (for Conversion) Analysis

DEA previously had established the 2010 assessment of annual needs for phenylpropanolamine (for conversion) at 16,500 kg (74 FR 60298). As noted above, DEA developed the proposed revisions to the 2010 assessment of annual needs for phenylpropanolamine (for conversion) using the same calculation and methodology that DEA used to determine the 2009 and 2010 assessment of annual needs.

As of August 10, 2010, DEA registered manufacturers of phenylpropanolamine (for conversion) requested the authority to purchase a total of 14,910 kg phenylpropanolamine for the manufacture of amphetamine. DEA registered manufacturers of phenylpropanolamine reported sales of phenylpropanolamine totaling approximately 10,837 kg in 2008 and 14,585 kg in 2009; this represents a 26 percent increase in sales reported by these firms from 2008 to 2009. There were no reported exports of phenylpropanolamine (for conversion). DEA has not received any requests to synthesize phenylpropanolamine in 2010. DEA has concluded that the 2009 sales of phenylpropanolamine (for

conversion), 14,585 kg fairly represents United States requirements for 2010 and zero kg fairly represents the export requirements of phenylpropanolamine (for conversion).

DEA believes 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) needed for the manufacture of amphetamine as follows:

$$(2009 \text{ sales}) + \text{reserve stock} + \text{export requirement} - \text{inventory} = \text{AAN}$$

$$(14,585) + 50\% * (14,585) + 0 - 4,104 = 17,774 \text{ kg PPA (for conversion) for 2010}$$

This calculation suggests that DEA's 2010 assessment of annual needs for phenylpropanolamine (for conversion) should be 17,800 kg. DEA notes that its June 28, 2010, notice proposed to increase the phenylpropanolamine (for conversion) assessment to 18,200 kg. That proposal was based on information received as of March 10, 2010. Since that time DEA has received additional request for quotas, revised manufacture production data, i.e., sales and inventory information, and request for adjustments to individual procurement quotas. As a result the 2009 reported inventory of phenylpropanolamine increased from 3,693 kg to 4,104 kg. After calculating the phenylpropanolamine (for conversion) assessment using the most current data—that reported by DEA registered manufactures as of August 10, 2010—DEA concludes that the proposed revised assessment of 18,200 kg would have been unnecessarily high. Accordingly, DEA is increasing the 2010 assessment of annual needs for phenylpropanolamine (for conversion) from 16,500 kg to 17,800 kg.

Ephedrine (for Conversion) Data

EPHEDRINE (FOR CONVERSION) DATA FOR 2010 ASSESSMENT OF ANNUAL NEEDS
[Kilograms]

Ephedrine (for conversion)	2007	2008	2009	2010 Request
Sales* (DEA 250)	99,594	64,522	40,387	40,600
Imports** (DEA 488)	99,594	64,128	39,897	40,204
Inventory* (DEA 250)	0	99	208	n/a
APQ Methamphetamine***	3,130	3,130	3,130	3,130

* Reported sales and inventory from applications for 2010 procurement quotas (DEA 250) and manufacturing quotas (DEA 189) received as of August 10, 2010.

** Reported imports from applications for 2010 import quotas (DEA 488) received as of August 10, 2010.

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

Ephedrine (for Conversion) Analysis

DEA previously has established the 2010 assessment of annual needs for ephedrine (for conversion) at 75,000 kg (74 FR 60298). As noted above, DEA developed the proposed revisions to the 2010 assessment of annual needs for ephedrine (for conversion) using the same calculation and methodology that DEA used to determine the 2009 and 2010 assessment of annual needs.

As of August 10, 2010, DEA registered manufacturers of ephedrine (for conversion) requested the authority to purchase a total of 40,600 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 APQ for methamphetamine. DEA determined that the estimated sales of pseudoephedrine by manufacturers, as referenced in the assessment of annual needs 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.

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

(2009 APQ methamphetamine/39% yield) + reserve stock – inventory = ephedrine (for manufacture of methamphetamine) (3,130/39% yield) + 50%*(3,130/39% yield) – 208 = 11,830 kg

The calculation for the ephedrine (for conversion) requirement for the manufacture of pseudoephedrine leads to a result of 63,157 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, DEA determined the proposed revised assessment for ephedrine (for conversion) by summing the amounts required for the manufacture of methamphetamine and pseudoephedrine:

methamphetamine requirement + pseudoephedrine requirement = AAN
11,830 + 63,157 = 74,987 kg ephedrine (for conversion) for 2010

This calculation suggests that DEA's 2010 assessment of annual needs for ephedrine (for conversion) should be 75,000 kg. Accordingly, DEA is leaving the 2010 assessment of annual needs for ephedrine (for conversion) unchanged at 75,000 kg.

DEA did not receive any comments on its Assessment of Annual Needs for ephedrine (for sale), ephedrine (for conversion), pseudoephedrine (for sale), phenylpropanolamine (for sale) and phenylpropanolamine (for conversion). DEA is finalizing the assessments for these List I chemicals based on information contained in additional applications for 2010 import, manufacturing and procurement quotas provided by DEA registered importers and manufacturers whose quota applications were received as of August 10, 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 Revised 2010 Assessment of Annual Needs for ephedrine, pseudoephedrine, and phenylpropanolamine, expressed in kilograms of anhydrous acid or base, be established as follows:

List I chemical	Final 2010 assess- ment of annual needs
Ephedrine (for sale) ..	3,900 kg
Phenylpropanolamine (for sale).	7,400 kg
Pseudoephedrine (for sale).	404,000 kg
Phenylpropanolamine (for conversion).	17,800 kg
Ephedrine (for conversion).	75,000 kg

Regulatory Certifications

Regulatory Flexibility Act

The Deputy Administrator hereby certifies that this action will not have a significant economic impact upon 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 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.

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 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 United States-based companies to compete with foreign-based companies in domestic and export markets.

Dated: December 13, 2010.

Michele M. Leonhart,
Deputy Administrator.

[FR Doc. 2010-31848 Filed 12-17-10; 8:45 am]

BILLING CODE 4410-09-P

DEPARTMENT OF JUSTICE

United States Parole Commission

[Public Law 94-409; 5 U.S.C. Sec. 552b]

Record of Vote of Meeting Closure

I, Isaac Fulwood, of the United States Parole Commission, was present at a meeting of said Commission, which started at approximately 12 p.m., on Tuesday, December 7, 2010, at the U.S. Parole Commission, 5550 Friendship Boulevard, 4th Floor, Chevy Chase, Maryland 20815. The purpose of the meeting was to decide two petitions for reconsideration pursuant to 28 CFR Section 2.27. Four Commissioners were present, constituting a quorum when the vote to close the meeting was submitted.

Public announcement further describing the subject matter of the

meeting and certifications of General Counsel that this meeting may be closed by vote of the Commissioners present were submitted to the Commissioners prior to the conduct of any other business. Upon motion duly made, seconded, and carried, the following Commissioners voted that the meeting be closed: Isaac Fulwood, Cranston J. Mitchell and Patricia K. Cushwa, J. Patricia Wilson Smoot.

In witness whereof, I make this official record of the vote taken to close this meeting and authorize this record to be made available to the public.

Dated: December 8, 2010.

Isaac Fulwood,

Chairman, U.S. Parole Commission.

[FR Doc. 2010-31860 Filed 12-17-10; 8:45 am]

BILLING CODE 4410-01-M

DEPARTMENT OF LABOR

Office of the Secretary

Agency Information Collection Activities; Submission for OMB Review; Comment Request; Diesel Particulate Matter Exposure of Underground Coal Miners

ACTION: Notice.

SUMMARY: The Department of Labor (DOL) hereby announces the submission of the Mine Safety and Health Administration (MSHA) sponsored information collection request (ICR) titled, "Diesel Particulate Matter Exposure of Underground Coal Miners," to the Office of Management and Budget (OMB) for review and approval for continued use in accordance with the Paperwork Reduction Act of 1995 (Pub. L. 104-13, 44 U.S.C. chapter 35).

DATES: Submit comments on or before January 19, 2011.

ADDRESSES: A copy of this ICR, with applicable supporting documentation; including a description of the likely respondents, proposed frequency of response, and estimated total burden may be obtained from the RegInfo.gov Web site, <http://www.reginfo.gov/public/do/PRAMain> or by contacting Michel Smyth by telephone at 202-693-4129 (this is not a toll-free number) or sending an e-mail to DOL_PRA_PUBLIC@dol.gov.

Submit comments about this request to the Office of Information and Regulatory Affairs, Attn: OMB Desk Officer for the Department of Labor, Mine Safety and Health Administration (MSHA), Office of Management and Budget, Room 10235, Washington, DC 20503, Telephone: 202-395-4816/Fax:

202-395-6881 (these are not toll-free numbers), e-mail:

OIRA_submission@omb.eop.gov.

FOR FURTHER INFORMATION CONTACT: Contact Michel Smyth by telephone at 202-693-4129 (this is not a toll-free number) or by e-mail at DOL_PRA_PUBLIC@dol.gov.

SUPPLEMENTARY INFORMATION: Federal Mine Safety and Health Act of 1977 (Mine Act) section 101(a) provides that the Secretary of Labor shall develop, promulgate, and revise, as may be appropriate, improved mandatory health or safety standards for the protection of life and prevention of injuries in coal or other mines. In addition, Mine Act section 103(h) mandates that mine operators keep any records and make any reports that are reasonably necessary for the MSHA to perform its duties under the Mine Act. The MSHA established standards and regulations for diesel-powered equipment in underground coal mines that provide additional important protection for coal miners who work on and around diesel-powered equipment. The standards were designed to reduce the risks to underground coal miners of serious health hazards that are associated with exposure to high concentrations of diesel particulate matter. The standards contain information collection requirements for underground coal mine operators in 30 CFR 72.503 (d), 72.510, 72.520, and 75.1915. As a result of 39 CFR 72.500, manufacturers of diesel equipment are affected under 30 CFR parts 7 or 36.

This information collection is subject to the PRA. A Federal agency generally cannot conduct or sponsor a collection of information, and the public is generally not required to respond to an information collection, unless it is currently approved by the OMB under the PRA and displays a currently valid OMB Control Number. In addition, notwithstanding any other provisions of law, no person shall generally be subject to penalty for failing to comply with a collection of information if the collection of information does not display a currently valid OMB control number. See 5 CFR 1320.5(a) and 1320.6. The DOL obtains OMB approval for this information collection under OMB Control Number 1219-0124. The current OMB approval is scheduled to expire on December 31, 2010; however, it should be noted that information collections submitted to the OMB receive a month-to-month extension while they undergo review. For additional information, see the related notice published in the **Federal Register** on September 16, 2010, (75 FR 56560).