

- Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;
- Evaluate the accuracy of the agencies' estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;
- Enhance the quality, utility, and clarity of the information to be collected; and
- Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, e.g., permitting electronic submission of responses.

Overview of This Information Collection

(1) *Type of Information Collection:* Extension of a currently approved collection.

(2) *Title of the Form/Collection:* Notification of Change of Mailing or Premise Address.

(3) *Agency form number, if any, and the applicable component of the Department of Justice sponsoring the collection:* Form Number: None. Bureau of Alcohol, Tobacco, Firearms and Explosives.

(4) *Affected public who will be asked or required to respond, as well as a brief abstract:* Primary: Not-for-profit institutions. Other: Business or other for-profit. Licensees and permittees whose mailing address will change must notify the Chief, Federal Explosives Licensing Center, at least 10 days before the change. The information is used by ATF to identify correct locations of storage of explosives licensees/ permittees and location of storage of explosives materials for purposes of inspection as well as to notify permittee/ licensees of any change in regulations or laws that may affect their business activities.

(5) *An estimate of the total number of respondents and the amount of time estimated for an average respondent to respond:* It is estimated that 1,000 respondents will take 10 minutes to respond via letter to the Federal Explosives Licensing Center.

(6) *An estimate of the total public burden (in hours) associated with the collection:* There are an estimated 170 annual total burden hours associated with this collection.

If additional information is required contact: Lynn Bryant, Department

Clearance Officer, Policy and Planning Staff, Justice Management Division, Department of Justice, Patrick Henry Building, Suite 1600, 601 D Street, NW., Washington, DC 20530.

Dated: September 9, 2009.

Lynn Bryant,

Department Clearance Officer, PRA, U.S. Department of Justice.

[FR Doc. E9-22042 Filed 9-11-09; 8:45 am]

BILLING CODE 4410-FY-P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. DEA-326P]

Assessment of Annual Needs for the List I Chemicals Ephedrine, Pseudoephedrine, and Phenylpropanolamine for 2010: Proposed

AGENCY: Drug Enforcement Administration (DEA), Justice.

ACTION: Notice of proposed annual assessment of needs for 2010.

SUMMARY: This notice proposes the initial year 2010 Assessment of Annual Needs for certain List I chemicals in accordance with the Combat Methamphetamine Epidemic Act (CMEA) of 2005, enacted on March 9, 2006. The CMEA requires DEA to establish production quotas and import quotas for ephedrine, pseudoephedrine, and phenylpropanolamine. The CMEA places additional regulatory controls upon the manufacture, distribution, importation, and exportation of the three List I chemicals.

DATES: Written comments must be postmarked, and electronic comments must be sent, on or before October 14, 2009.

ADDRESSES: To ensure proper handling of comments, please reference "Docket No. DEA-326P" on all written and electronic correspondence. Written comments being sent via regular mail should be sent to the Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration, 8701 Morrisette Drive, Springfield, Virginia 22152, attention: DEA Federal Register Representative/ODL. Written comments sent via express mail should be sent to DEA Headquarters, Attention: DEA Federal Register Representative/ODL, 8701 Morrisette Drive, Springfield, Virginia 22152. Comments may be directly sent to DEA electronically by sending an electronic message to dea.diversion.policy@usdoj.gov.

However, persons wishing to request a

hearing should note that such requests must be written and manually signed; requests for a hearing will not be accepted via electronic means. 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 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 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 proposed 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 to provide adequate supplies of each substance to meet the estimated medical, scientific, research, and industrial needs of the United States; lawful export requirements; and the establishment and maintenance of reserve stocks.

As of August 4, 2009, the DEA had received a total of 134 applications for 2010 import, procurement and

manufacturing quotas for ephedrine, pseudoephedrine and phenylpropanolamine. As a comparison, for the 2009 quota year DEA has received 201 applications for import, procurement and manufacturing quotas. DEA calculated the 2010 Assessment of Annual Needs for the List I chemicals using the calculation methodology described in both the interim and final 2009 Assessment of Annual Needs (73 FR 79508 and 74 FR 32954, respectively). The phenylpropanolamine (for conversion) calculation has been modified to account for additional information. These calculations take into account the criteria that DEA is required to consider in accordance with 21 U.S.C. 826 and its implementing regulations (21 CFR 1315.11).

In finalizing the assessments for these List I chemicals, DEA will consider the information contained in additional applications for 2010 import, manufacturing and procurement quotas from DEA registered manufacturers and importers that DEA receives after August 4, 2009, as well as the comments

that DEA receives in response to this proposal.

Underlying Data and DEA's Analysis

In determining the proposed 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 Data

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

Ephedrine	2007	2008	2009	2010 Request
Sales* (DEA 250)	1,509	1,988	2,107	2,486
Imports** (DEA 488)	1	3	42	17
Export Declarations (DEA 486)	168	91	10	n/a
Inventory* (DEA 250)	714	421	176	n/a
IMS*** (NSP)	1,235	1,460	n/a	n/a

*Reported sales and inventory from applications for 2010 procurement quotas (DEA 250)

**Reported imports from applications for 2010 import quotas (DEA 488)

***IMS Health, IMS National Sales Perspectives™, January 2007 to December 2008, Retail and Non-Retail Channels, Data Extracted August 4, 2009.

Ephedrine Analysis

DEA calculated the proposed 2010 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 August 4, 2009, DEA registered manufacturers of dosage form products containing ephedrine requested the authority to purchase a total of 2,486 kg ephedrine (for sale) in 2010. DEA registered manufacturers of ephedrine

reported sales totaling approximately 1,988 kg in 2008 and 2,107 kg in 2009; this represents a 6 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 91 kg in 2008 and 10 kg in 2009; this represents a 90 percent decrease from levels observed in 2008. The average of the 2008 and 2009 exports of ephedrine products is approximately 51 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 2007 and 2008 to be

approximately 1,348 kg. DEA notes that the 2009 sales figure reported by manufacturers (2,107 kg) is higher than the average sales reported by IMS for the previous two years (1,348 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 2,107 kg fairly represents the U.S. sales of ephedrine for 2010 and that 51 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

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

http://www.dea/diversion.usdoj.gov/quotas/quota_apps.htm.

sales. DEA also considered the estimated 2009 year end inventory as reported by DEA registrants in determining the inventory allowance.

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

2009 sales + reserve stock + export requirement – existing inventory = AAN
 $2,107 + (50\% * 2,107) + 51 - 176 = 3,036$ kg ephedrine (for sale) for 2010
 This calculation suggests that DEA's Assessment of Annual Needs for

ephedrine should be proposed to be 3,100 kg. Accordingly, DEA is proposing the 2010 Assessment of Annual Needs for ephedrine (for sale) at 3,100 kg.

Phenylpropanolamine (for Sale) Data

PHENYLPROPANOLAMINE (FOR SALE) DATA FOR 2010 ASSESSMENT OF ANNUAL NEEDS

[Kilograms]

Phenylpropanolamine (for sale)	2007	2008	2009	2010 Request
Sales* (DEA 250)	3,674	4,119	4,452	5,680
Imports** (DEA 488)	73	79	134	263
Export Declarations (DEA 486)	1,002	0	3	n/a
Inventory* (DEA 250)	3,498	2,045	573	n/a

* Reported sales and inventory from applications for 2010 procurement quotas (DEA 250) received as of August 4, 2009.

** Reported imports from applications for 2010 import quotas (DEA 488) received as of August 4, 2009.

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 August 4, 2009, DEA registered manufacturers of dosage form products containing phenylpropanolamine requested the authority to purchase 5,680 kg phenylpropanolamine (for sale) in 2010. DEA registered manufacturers of phenylpropanolamine reported sales totaling approximately 4,119 kg in 2008 and 4,452 kg in 2009; this represents a 7.5% increase in sales reported by these firms from 2008 to 2009. Additionally, exports of phenylpropanolamine

products from the U.S. 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 phenylpropanolamine products is approximately 2 kg. DEA thus believes that 4,452 kg fairly represents the U.S. sales of phenylpropanolamine for 2010 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:

2009 sales + reserve stock + export requirement – existing inventory = AAN
 $4,452 + (50\% * 4,452) + 2 - 573 = 6,107$ kg phenylpropanolamine (for sale) for 2010

This calculation suggests that DEA's 2010 Assessment of Annual Needs for phenylpropanolamine (for sale) should be proposed at 6,100 kg. Accordingly, DEA is proposing the 2010 Assessment of Annual Needs for phenylpropanolamine (for sale) at 6,100 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)	204,028	179,566	236,650	196,912
Sales* (DEA 189)	100,300	64,781	33,600	32,760
Imports** (DEA 488)	44,499	60,300	147,002	78,884
Export Declarations (DEA 486)	42,142	85,757	18,974	n/a
Inventory* (DEA 250)	132,838	114,795	61,613	n/a
IMS*** (NSP)	180,172	149,110	n/a	n/a

* Reported sales and inventory from applications for 2010 procurement quotas (DEA 250) and manufacturing quotas (DEA 189) received as of August 4, 2009.

** Reported imports from applications for 2010 import quotas (DEA 488) received as of August 4, 2009.

*** IMS Health, IMS National Sales Perspectives™, January 2007 to December 2008, Retail and Non-Retail Channels, Data Extracted August 4, 2009.

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 August 4, 2009, DEA registered manufacturers of dosage form products containing pseudoephedrine requested the authority to purchase 196,912 kg pseudoephedrine. DEA registered manufacturers of pseudoephedrine reported sales totaling approximately 179,566 kg in 2008 and 236,650 kg in

2009; this represents a 24 percent increase in sales reported by these firms from 2008 to 2009. During the same period exports of pseudoephedrine products from the U.S. as reported on export declarations (DEA 486) totaled 85,757 kg in 2008 and 18,974 kg in 2009; this represents a 78 percent

decrease from levels observed in 2008. The average of the 2008 and 2009 exports is 52,366 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 2007 and 2008 to be approximately 164,641 kg. DEA thus believes that 236,650 kg of sales reported by manufacturers fairly represents the U.S. sales of pseudoephedrine for 2010 and that 52,366 kg fairly represents the export

requirements of pseudoephedrine. DEA notes that manufacturer reported sales for 2009 (236,650 kg) are higher than the average retail sales reported by IMS for the previous two years (164,641 kg). This is expected because a manufacturer's reported sales include quantities which are necessary to provide reserve stocks for distributors and retailers.

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

2009 sales + reserve stock + export requirement – existing inventory = AAN
 $236,650 + (50\% * 236,650) + 52,366 - 61,613 = 345,728$ kg pseudoephedrine (for sale) for 2010.

This calculation suggests that DEA's 2010 Assessment of Annual Needs for pseudoephedrine (for sale) should be proposed at 346,000 kg. Accordingly, DEA is proposing the 2010 Assessment of Annual Needs for pseudoephedrine (for sale) at 346,000 kg.

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	10,834	13,582	14,900
Imports** (DEA 488)	1,000	3,225	6,514	6,108
Export Declarations (DEA 486)	0	0	0	n/a
Inventory* (DEA 250)	3,581	5,533	4,103	n/a
APQ Amphetamine***	17,000	22,000	22,000	n/a

* Reported sales and inventory from applications for 2010 procurement quotas (DEA 250) received as of August 4, 2009.

** Reported imports from applications for 2010 import quotas (DEA 488) received as of August 4, 2009.

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

Phenylpropanolamine (for Conversion) Analysis

As of August 4, 2009, DEA registered manufacturers of phenylpropanolamine (for conversion) requested the authority to purchase a total of 14,900 kg phenylpropanolamine for the manufacture of amphetamine. DEA registered manufacturers of phenylpropanolamine reported sales of phenylpropanolamine totaling approximately 10,834 kg in 2008 and 13,582 kg in 2009; this represent a 20 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), 13,582 kg, fairly represents U.S. requirements for 2010 and zero kg fairly represents the export requirements of phenylpropanolamine (for conversion).

Phenylpropanolamine is used in the production of legitimate amphetamine products. DEA has established an Aggregate Production Quota (APQ) for amphetamine of 22,000 kg for 2009. DEA notes amphetamine is primarily manufactured by the conversion of the schedule II controlled substance phenylacetone to amphetamine. DEA did not consider this alternative synthesis route in the 2009 Assessment of Annual Needs for phenylpropanolamine (for conversion).

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

(2009 sales) + reserve stock + export requirement – inventory = AAN
 $(13,582) +$
 $50\% * (13,582) + 0 - 4,103 = 16,270$ kg PPA (for conversion) for 2009

This calculation suggests that DEA's 2009 Assessment of Annual Needs for phenylpropanolamine (for conversion) should be proposed at 16,500 kg. Accordingly, DEA is proposing the 2010 Assessment of Annual Needs for phenylpropanolamine (for conversion) at 16,500 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)	99,622	64,522	40,403	40,646
Imports** (DEA 488)	99,594	64,128	39,897	40,000
Inventory* (DEA 250)	13	160	254	n/a
APQ Methamphetamine***	3,130	3,130	3,130	n/a

* Reported sales and inventory from applications for 2010 procurement quotas (DEA 250) and manufacturing quotas (DEA 189) received as of August 4, 2009.

** Reported imports from applications for 2010 import quotas (DEA 488) received as of August 4, 2009.

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

Ephedrine (for Conversion) Analysis

As of August 4, 2009, DEA registered manufacturers of ephedrine (for conversion) requested the authority to purchase a total of 40,646 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:

methamphetamine requirement + pseudoephedrine requirement = AAN

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) – 46 = 11,993 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, 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
11,993 + 63,157 = 75,150 kg ephedrine (for conversion) for 2010

This calculation suggests that DEA's 2010 Assessment of Annual Needs for ephedrine (for conversion) should be proposed at 75,000 kg. Accordingly, DEA is proposing the 2010 Assessment of Annual Needs for ephedrine (for conversion) at 75,000 kg.

Conclusion

In finalizing the 2010 assessments for these list I chemicals, DEA will use the methodology and calculations presented above. The numbers used in the calculations may be adjusted upwards or downwards based on the additional applications for 2010 import, manufacturing and procurement quotas received after August 4, 2009. DEA urges registered importers and manufacturers to submit applications for 2010 import, manufacturing and procurement quota so that DEA may include information from those applications when finalizing these assessments in accordance with 21 CFR 1315.

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 proposes the following 2010 Assessment of Annual Needs for the List I chemicals ephedrine, pseudoephedrine, and phenylpropanolamine for 2010, expressed in kilograms of anhydrous base:

List I Chemicals	Proposed Year 2010 Assessment of Annual Needs
Ephedrine (for sale) ..	3,100 kg.
Phenylpropanolamine (for sale).	6,100 kg.
Pseudoephedrine (for sale).	346,000 kg.
Phenylpropanolamine (for conversion).	16,500 kg.
Ephedrine (for conversion).	75,000 kg.

Ephedrine (for conversion) refers to the industrial use of ephedrine, *i.e.*, that which will be converted to another basic drug class such as pseudoephedrine or methamphetamine used for the manufacture of prescription weight loss drug. Phenylpropanolamine (for conversion) refers to the industrial use of phenylpropanolamine, *i.e.*, that

which will be converted to another basic drug class such as amphetamine for the manufacture of drug products. The "for sale" assessments refer to the amount of ephedrine, pseudoephedrine, and phenylpropanolamine intended for ultimate use in products containing these List I chemicals.

All interested persons are invited to submit their comments in writing or electronically regarding this proposal following the procedures in the ADDRESSES section of this document. A person may object to or comment on the proposal relating to any of the above-mentioned substances without filing comments or objections regarding the others. If a person believes that one or more of these issues warrant a hearing, the individual should so state and summarize the reasons for this belief. Persons wishing to request a hearing should note that such requests must be written and manually signed; requests for a hearing will not be accepted via electronic means. In the event that comments or objections to this proposal raise one or more issues which the Deputy Administrator finds warrant a hearing, the Deputy Administrator shall order a public hearing by notice in the **Federal Register**, summarizing the issues to be heard and setting the time for the hearing as per 21 CFR 1315.13(e).

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: September 2, 2009.

Michele M. Leonhart,

Deputy Administrator.

[FR Doc. E9-22043 Filed 9-11-09; 8:45 am]

BILLING CODE 4410-09-P

DEPARTMENT OF LABOR

Employee Benefits Security Administration

148th Meeting of the Advisory Council on Employee Welfare and Pension Benefit Plans; Notice of Meeting

Pursuant to the authority contained in Section 512 of the Employee Retirement Income Security Act of 1974 (ERISA), 29 U.S.C. 1142, the Advisory Council on Employee Welfare and Pension Benefit Plans will hold a public teleconference meeting on September 29, 2009.

The meeting will take place in Room N3437 A-B, U.S. Department of Labor, 200 Constitution Avenue, NW., Washington, DC 20210. Public access is available only in this room (i.e. not by telephone). The meeting will run from

11:30 a.m. to approximately 5:30 p.m. The purpose of the open meeting is to discuss reports/recommendations for the Secretary of Labor on the issues of (1) Stable Value Funds and Retirement Security in the Current Economic Conditions, (2) Promoting Retirement Literacy and Security by Streamlining Disclosures to Participants and Beneficiaries, and (3) Approaches for Retirement Security in the United States. Descriptions of these topics are available on the Advisory Council page of the EBSA Web site at http://www.dol.gov/ebsa/aboutebsa/erisa_advisory_council.html.

Organizations or members of the public wishing to submit a written statement pertaining to the topic may do so by submitting 30 copies on or before September 22, 2009 to Larry Good, Executive Secretary, ERISA Advisory Council, U.S. Department of Labor, Suite N-5623, 200 Constitution Avenue NW., Washington, DC 20210. Statements also may be submitted as e-mail attachments in text or pdf format transmitted to good.larry@dol.gov. It is requested that statements not be included in the body of the e-mail. Statements received on or before September 22, 2009 will be included in the record of the meeting. Individuals or representatives of organizations wishing to address the Advisory Council should forward their requests to the Executive Secretary or telephone (202) 693-8668. Oral presentations will be limited to 10 minutes, time permitting, but an extended statement may be submitted for the record. Individuals with disabilities who need special accommodations should contact Larry Good by September 22 at the address indicated.

Signed at Washington, DC, this 10th day of September, 2009.

Michael L. Davis,

Deputy Assistant Secretary, Employee Benefits Security Administration.

[FR Doc. E9-22108 Filed 9-11-09; 8:45 am]

BILLING CODE 4510-29-P

DEPARTMENT OF LABOR

Occupational Safety and Health Administration

[Docket Nos. OSHA-2005-022, OSHA-2006-0028, OSHA-2006-0029, OSHA-2006-0040, OSHA-2006-0042, OSHA-2007-0039, OSHA-2007-0041, OSHA-2007-0042, OSHA-2009-0025, OSHA-2009-0026, OSHA-2009-0027]

Modifications to the Scope of NRTL Recognition

AGENCY: Occupational Safety and Health Administration (OSHA), Labor.

ACTION: Notice.

SUMMARY: This notice modifies the scopes of recognition of several Nationally Recognized Testing Laboratories resulting from the withdrawal of test standards by standards-developing organizations.

DATES: *Effective Date:* The effective date of this notice is September 14, 2009.

FOR FURTHER INFORMATION CONTACT: MaryAnn Garrahan, Director, Office of Technical Programs and Coordination Activities, NRTL Program, Occupational Safety and Health Administration, U.S. Department of Labor, 200 Constitution Avenue, NW., Room N-3655, Washington, DC 20210; phone: (202) 693-2110.

SUPPLEMENTARY INFORMATION:

I. Notice of Modifications

In this notice, the Occupational Safety and Health Administration (OSHA) is modifying the scopes of recognition of several Nationally Recognized Testing Laboratories (NRTLs). Specifically, one or more of the test standards that OSHA currently includes in the scopes of recognition of these NRTLs are no longer "appropriate test standards" under 29 CFR 1910.07(c) because the standards-developing organizations that wrote and published the standards withdrew the standards. Consequently, OSHA is deleting the test standards from the scope of recognition of each affected NRTL. Section IV of this notice ("Modifications to Each NRTL's Scope of Recognition") identifies the affected NRTLs.

To substitute other test standards for the standards being removed, OSHA's policy permits NRTLs to request, or OSHA to provide, recognition for comparable test standards, i.e., other appropriate test standards covering comparable product testing. The table in Section III ("Withdrawn Test Standards and Replacement Test Standards") identifies the test standards removed from the scopes of recognition of the affected NRTL, under the heading