

(40 FR 43745–46), all applicants for registration to import a basic class of any controlled substance in schedule I or II are, and will continue to be, required to demonstrate to the Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration, that the requirements for such registration pursuant to 21 U.S.C. 958(a); 21 U.S.C. 823(a); and 21 CFR 1301.34(b), (c), (d), (e) and (f) are satisfied.

Dated: June 17, 2010.

**Joseph T. Rannazzisi,**

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

[FR Doc. 2010–15528 Filed 6–25–10; 8:45 am]

**BILLING CODE 4410–09–P**

## DEPARTMENT OF JUSTICE

### Drug Enforcement Administration

#### Importer of Controlled Substances; Notice of Application

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

Therefore, in accordance with 21 CFR 1301.34(a), this is notice that on March 22, 2010, Cerilliant Corporation, 811 Paloma Drive, Suite A, Round Rock, Texas 78665–2402, made application by letter to the Drug Enforcement Administration (DEA) to be registered as an importer of the basic classes of controlled substances listed in schedule I:

Drug	Schedule
Racemoramide (9645) .....	I
Tilidine (9750) .....	I

The company plans to import small quantities of the listed controlled substances for the manufacture of analytical reference standards.

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

Any such comments or objections should be addressed, in quintuplicate, to the Drug Enforcement Administration, Office of Diversion Control, Federal Register Representative (ODL), 8701 Morrisette Drive, Springfield, Virginia 22152; and must be filed no later than July 28, 2010.

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

**Joseph T. Rannazzisi,**

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

[FR Doc. 2010–15523 Filed 6–25–10; 8:45 am]

**BILLING CODE 4410–09–P**

## DEPARTMENT OF JUSTICE

### Drug Enforcement Administration

#### Manufacturer of Controlled Substances; Notice of Application

Pursuant to § 1301.33(a) of Title 21 of the Code of Federal Regulations (CFR), this is notice that on April 27, 2010, Varian, Inc., 25200 Commercentre Drive, Lake Forest, California 92630–8810, made application by renewal to the Drug Enforcement Administration (DEA) as a bulk manufacturer of the basic classes of controlled substances listed in schedule II:

Drug	Schedule
Phencyclidine (7471) .....	II
1-piperidinocyclohexanecarbonitrile (8603) .....	II
Benzoylcegonine (9180) .....	II

The company plans to manufacture small quantities of the listed controlled substances for use in diagnostic products.

Any other such applicant, and any person who is presently registered with DEA to manufacture such substances, may file comments or objections to the issuance of the proposed registration pursuant to 21 CFR 1301.33(a).

Any such written comments or objections should be addressed, in quintuplicate, to the Drug Enforcement Administration, Office of Diversion Control, Federal Register Representative (ODL), 8701 Morrisette Drive, Springfield, Virginia 22152; and must be filed no later than August 27, 2010.

Dated: June 17, 2010.

**Joseph T. Rannazzisi,**

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

[FR Doc. 2010–15526 Filed 6–25–10; 8:45 am]

**BILLING CODE 4410–09–P**

## DEPARTMENT OF JUSTICE

### Drug Enforcement Administration

[Docket No. DEA–326R]

#### Proposed 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 proposed revised 2010 assessment of annual needs for the List I chemicals ephedrine, pseudoephedrine, and phenylpropanolamine.

**SUMMARY:** This notice proposes revised 2010 assessment of annual needs for the List I chemicals ephedrine, pseudoephedrine, and phenylpropanolamine.

**DATES:** Written comments must be postmarked, and electronic comments must be sent, on or before July 28, 2010.

**ADDRESSES:** To ensure proper handling of comments, please reference “Docket No. DEA–326R” 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, Washington, DC 20537, 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](mailto: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 (CMEA) (Title VII of Pub. L. 109-177) 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).

The 2010 Assessment of Annual Needs (AAN) 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.

On November 20, 2009, DEA established the AAN for 2010 for the List I chemicals ephedrine, pseudoephedrine, and phenylpropanolamine (74 FR 60294). That Notice indicated that the Deputy Administrator of the DEA would adjust the AAN at a later date if necessary, as permitted by 21 CFR 1315.13.

DEA now proposes to revise the established assessments of annual needs for 2010 for these List 1 chemicals. In developing the proposed revisions, DEA has used the calculation methodology described in both the 2009 and 2010 AAN (74 FR 32954 and 74 FR 60294, respectively). 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 revised 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 the date of drafting this notice, March 10, 2010, as well as the comments that DEA receives in response to this proposal.

**Underlying Data and DEA's Analysis**

In determining the proposed revisions to 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).<sup>1</sup>

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) .....	2,838	2,662	2,801	3,430
Imports ** (DEA 488) .....	9,595	1,690	2,165	2,268
Export Declarations (DEA 486) .....	168	18	64	n/a
Inventory * (DEA 250) .....	1,428	626	191	n/a
IMS *** (NSP) .....	1,235	1,460	1,401	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 2009, Retail and Non-Retail Channels, Data Extracted March 10, 2010.

<sup>1</sup> Applications and instructions for procurement, import and manufacturing quotas can be found at

[http://www.deadiversion.usdoj.gov/quotas/quota\\_apps.htm](http://www.deadiversion.usdoj.gov/quotas/quota_apps.htm).

**Ephedrine (for Sale) Analysis**

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

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

As of March 10, 2010, DEA registered manufacturers of dosage form products containing ephedrine requested the authority to purchase a total of 3,430 kg ephedrine (for sale) in 2010. DEA registered manufacturers of ephedrine reported sales totaling approximately 2,662 kg in 2008 and 2,801 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 (2,801 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 2,801 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

2,801 + (50% \* 2,801) + 41 – 191 = 4,052 kg ephedrine (for sale) for 2010

This calculation suggests that DEA's AAN for ephedrine should be 4,100 kg. Accordingly, DEA is proposing to increase the 2010 AAN for ephedrine (for sale) from 3,600 kg to 4,100 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) .....	4,158	4,528	5,355	6,799
Imports ** (DEA 488) .....	5,787	3,425	6,626	7,266
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 March 10, 2010.

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

**Phenylpropanolamine (for Sale) Analysis**

DEA previously has established the 2010 AAN for phenylpropanolamine (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 phenylpropanolamine (for sale) that DEA used to determine the 2009 and 2010 AAN.

As of March 10, 2010, DEA registered manufacturers of dosage form products containing phenylpropanolamine requested the authority to purchase 6,799 kg phenylpropanolamine (for sale) in 2010. DEA registered manufacturers of phenylpropanolamine 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 phenylpropanolamine 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 phenylpropanolamine products is approximately 2 kg. DEA thus believes that 5,355 kg fairly represents the United States 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 veterinary channels and is therefore not included.

*DEA calculated the proposed revised phenylpropanolamine (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 phenylpropanolamine (for sale) for 2010

This calculation suggests that DEA's 2010 Assessment of Annual Needs for phenylpropanolamine (for sale) should be 7,400 kg. Accordingly, DEA is proposing to increase the 2010 AAN for phenylpropanolamine (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) .....	239,121	223,813	287,756	239,646
Sales * (DEA 189) .....	100,300	64,781	33,600	32,760
Imports ** (DEA 488) .....	231,683	170,614	274,492	261,528

## PSEUDOEPHEDRINE (FOR SALE) DATA FOR 2010 ASSESSMENT OF ANNUAL NEEDS (KILOGRAMS)—Continued

Pseudoephedrine (for sale)	2007	2008	2009	2010 request
Export Declarations (DEA 486) .....	42,132	47,199	35,264	n/a
Inventory * (DEA 250) .....	135,727	120,869	54,173	n/a
IMS *** (NSP) .....	180,221	149,227	140,269	n/a

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

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

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

**Pseudoephedrine (for Sale) Analysis**

DEA previously has established the 2010 AAN 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 AAN.

As of March 10, 2010, DEA registered manufacturers of dosage form products containing pseudoephedrine requested the authority to purchase 239,646 kg pseudoephedrine. DEA registered manufacturers of pseudoephedrine reported sales totaling approximately 223,813 kg in 2008 and 287,756 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 U.S. 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 144,748 kg. DEA thus believes that 287,756 kg of sales reported by manufacturers fairly represents the U.S. 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 (287,756 kg) are higher than the average retail sales reported by IMS for the previous two years (144,748 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 sales + reserve stock + export requirement – existing inventory = AAN  
 $287,756 + (50\% * 287,756) + 41,232 - 54,173 = 418,693$  kg pseudoephedrine (for sale) for 2010.

This calculation suggests that DEA's 2010 AAN for pseudoephedrine (for sale) should be 419,000 kg. Accordingly, DEA is proposing to increase the 2010 AAN for pseudoephedrine (for sale) from 404,000 kg to 419,000 kg.

**Phenylpropanolamine (for Conversion) Data**

## PHENYLPROPANOLAMINE (FOR CONVERSION) DATA FOR 2010 ASSESSMENT OF ANNUAL NEEDS (KILOGRAMS)

Phenylpropanolamine (for sale)	2007	2008	2009	2010 request
Sales * (DEA 250) .....	3,621	10,837	14,585	19,142
Imports ** (DEA 488) .....	8,250	12,019	11,373	33,698
Export Declarations (DEA 486) .....	0	0	0	n/a
Inventory * (DEA 250) .....	3,581	5,537	3,693	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 March 10, 2010.

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

\*\*\* Amphetamine Aggregate Production Quota History [http://www.deadiversion.usdoj.gov/quotas/quota\\_history.pdf](http://www.deadiversion.usdoj.gov/quotas/quota_history.pdf).

**Phenylpropanolamine (for Conversion) Analysis**

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

As of March 10, 2010, DEA registered manufacturers of phenylpropanolamine (for conversion) requested the authority to purchase a total of 19,142 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 represent 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 U.S. requirements for 2010 and zero kg

fairly represents the export requirements of phenylpropanolamine (for conversion).

Phenylpropanolamine (for conversion) is used for the manufacture of legitimate amphetamine products. DEA notes, most legitimate amphetamine is manufactured by the conversion of the schedule II controlled substance phenylacetone to amphetamine, rather than the conversion of phenylpropanolamine. DEA believes that the data provided in procurement, manufacturing, and import quota applications best represents the legitimate need for

phenylpropanolamine (for conversion) rather than total Aggregate Production Quota (APQ) for amphetamine.

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

(2009 sales) + reserve stock + export requirement – inventory = AAN  
 $(14,585) + 50\% * (14,585) + 0 - 3,693 = 18,185$  kg PPA (for conversion) for 2010

This calculation suggests that DEA's 2010 AAN for phenylpropanolamine

(for conversion) should be 18,200 kg. Accordingly, DEA is proposing to increase the 2010 AAN for phenylpropanolamine (for conversion) from 16,500 kg to 18,200 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	40,600
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	3,130

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

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

\*\*\* Methamphetamine Aggregate Production Quota History [http://www.deadiversion.usdoj.gov/quotas/quota\\_history.pdf](http://www.deadiversion.usdoj.gov/quotas/quota_history.pdf).

#### Ephedrine (for Conversion) Analysis

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

As of March 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 Aggregate Production Quota (APQ) for methamphetamine. DEA determined that the estimated sales of pseudoephedrine, as referenced in the 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.

*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)  
 $(3,130/39\% \text{ yield}) + 50\% * (3,130/39\% \text{ yield}) - 254 = 11,785$  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  
 $11,785 + 63,157 = 74,942$  kg ephedrine (for conversion) for 2010

This calculation suggests that DEA's 2010 AAN for ephedrine (for conversion) should be 75,000 kg. Accordingly, DEA is proposing that the 2010 AAN for ephedrine (for conversion) remain unchanged at 75,000 kg.

#### Conclusion

In finalizing the revised 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 March 10, 2010, in accordance with 21 CFR part 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 revised 2010 AAN for the List I chemicals ephedrine, pseudoephedrine, and phenylpropanolamine:

List I chemicals	Previously established initial 2010 assessment	Proposed revised 2010 assessment
Ephedrine (for sale) .....	3,600 kg	4,100 kg
Phenylpropanolamine (for sale) .....	6,400 kg	7,400 kg
Pseudoephedrine (for sale) .....	404,000 kg	419,000 kg
Phenylpropanolamine (for conversion) .....	16,500 kg	18,200 kg
Ephedrine (for conversion) .....	75,000 kg	No Change

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 AAN 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 AAN 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: June 19, 2010.

**Michele M. Leonhart,**

*Deputy Administrator.*

[FR Doc. 2010–15525 Filed 6–25–10; 8:45 am]

**BILLING CODE 4410–09–P**

## DEPARTMENT OF JUSTICE

### Antitrust Division

#### **United States, et al. v. Election Systems & Software, Inc.; Public Comments and Response on Proposed Final Judgment**

Pursuant to the Antitrust Procedures and Penalties Act, 15 U.S.C. 16(b)–(h), the United States hereby publishes below the comments received on the proposed Final Judgment in *United States, et al. v. Election Systems & Software Inc.*, Case No. 1:10–00380–JDB, which were filed in the United States District Court for the District of Columbia on June 17, 2010, together with the response of the United States to the comments.

Copies of the comments and the response are available for inspection at the Department of Justice Antitrust Division, 450 Fifth Street, NW., Suite 1010, Washington, DC 20530 (telephone: 202–514–2481), on the Department of Justice's Web site at <http://www.usdoj.gov/atr>, and at the Office of the Clerk of the United States District Court for the District of Columbia, 333 Constitution Avenue,

NW., Washington, DC 20001. Copies of any of these materials may be obtained upon request and payment of a copying fee.

**J. Robert Kramer II,**

*Director of Operations and Civil Enforcement.*

#### **United States District Court for the District of Columbia**

United States of America, et al.,

Plaintiffs, v. Election Systems and Software, Inc., Defendant.

Case No.: 1:10-cv-00380

Judge: Bates, John D.

Deck Type: Antitrust

Date Stamp:

Response of Plaintiff United States to Public Comments on the Proposed Final Judgment

Pursuant to the requirements of the Antitrust Procedures and Penalties Act, 15 U.S.C. § 16(b)–(h) (“APPA” or “Tunney Act”), the United States hereby responds to the public comments received regarding the proposed Final Judgment in this case. After careful consideration of the comments, the United States continues to believe that the proposed Final Judgment will provide an effective and appropriate remedy for the antitrust violations alleged in the Complaint. The United States will move the Court for entry of the proposed Final Judgment after the public comments and this response have been published in the Federal Register, pursuant to 15 U.S.C. § 16(d).

The United States and the States of Arizona, Colorado, Florida, Maine, Maryland, New Mexico, Tennessee, and Washington, and the Commonwealth of Massachusetts (the “Plaintiff States”), filed a civil antitrust Complaint on March 8, 2010, seeking injunctive and other relief to remedy the likely anticompetitive effects arising from the acquisition of Premier Election Solutions, Inc. and PES Holdings, Inc. (collectively, “Premier”), by Defendant Election Systems and Software, Inc. (“ES&S”). The Complaint alleged that ES&S’s acquisition of Premier likely would result in higher prices, a reduction in quality, and less innovation in the U.S. voting equipment systems market, in violation of Section 7 of the Clayton Act, 15 U.S.C. § 18.

Simultaneously with the filing of the Complaint, the United States filed a proposed Final Judgment and an Asset Preservation Stipulation and Order (“APSO”) signed by the plaintiffs and the defendant, consenting to the entry of the proposed Final Judgment after compliance with the requirements of the Tunney Act, 15 U.S.C. § 16. Pursuant to those requirements, the United States filed its Competitive Impact Statement