

Aggregate production quotas for all other Schedule I and II controlled substances included in 21 CFR 1308.11 and 1308.12 remain at zero.

Dated: August 31, 2012.

Michele M. Leonhart,
Administrator.

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DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. DEA 353]

Final Adjusted Assessment of Annual Needs for the List I Chemicals Ephedrine, Pseudoephedrine, and Phenylpropanolamine for 2012

AGENCY: Drug Enforcement Administration (DEA), Department of Justice.

ACTION: Notice.

SUMMARY: This notice establishes the Final Adjusted 2012 Assessment of Annual Needs for the list I chemicals ephedrine, pseudoephedrine, and phenylpropanolamine.

DATES: *Effective Date:* September 10, 2012.

FOR FURTHER INFORMATION CONTACT: John W. Partridge, Chief, Liaison and Policy Section, Drug Enforcement Administration, 8701 Morrisette Drive, Springfield, VA 22152, Telephone: (202) 307-4654.

SUPPLEMENTARY INFORMATION: The 2012 Assessment of Annual Needs represents those quantities of ephedrine, pseudoephedrine, and phenylpropanolamine which may be manufactured domestically and imported into the United States in 2012 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 of such chemicals. Section 306 of the Controlled Substances Act (CSA) (21 U.S.C. 826) requires that the Attorney General establish an assessment of annual needs for ephedrine, pseudoephedrine, and phenylpropanolamine. This responsibility has been delegated to the Administrator of the DEA by 28 CFR 0.100.

On July 18, 2012, a notice entitled "Proposed Adjustment of the Assessment of Annual Needs for the List I Chemicals Ephedrine, Pseudoephedrine, and

Phenylpropanolamine for 2012" was published in the **Federal Register** (77 FR 42333). That notice proposed to adjust the 2012 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 August 17, 2012.

Comments Received

DEA did not receive any comments to the proposed adjustment of the assessment of annual needs for ephedrine (for sale), ephedrine (for conversion), pseudoephedrine (for sale), phenylpropanolamine (for sale), and phenylpropanolamine (for conversion).

Conclusion

In determining the adjusted 2012 assessments, DEA used the calculation methodology previously described in the 2010 and 2011 assessment of annual needs (74 FR 60294 and 75 FR 79407 respectively). DEA considered changes in demand, changes in the national rate of net disposal, and changes in the rate of net disposal by the registrants holding individual manufacturing or import quotas for the chemical; whether any increased demand or changes in the national and/or individual rates of net disposal are temporary, short term, or long term; whether any increased demand could be met through existing inventories, increased individual manufacturing quotas, or increased importation without increasing the assessment of annual needs; whether any decreased demand would result in excessive inventory accumulation by all persons registered to handle the particular chemical; and other factors affecting the medical, scientific, research, industrial, and importation needs in the United States, lawful export requirements, and reserve stocks, as found relevant.

Other factors that DEA considered include trends as derived from information provided in applications for import, manufacturing, and procurement quotas and in import and export declarations. The inventory, acquisition (purchases), and disposition (sales) data as provided by DEA-registered manufacturers and importers reflects the most current information available to DEA at the time of publication of this Notice. The underlying data used to determine the final 2012 assessment of annual needs is the same as that used in determining the proposed 2012 assessment of annual

needs, as published on September 14, 2011, at 76 FR 56809.

In accordance with 21 U.S.C. 826(a) and 21 CFR 1315.13, the Administrator hereby orders that the 2012 assessment of annual needs for ephedrine, pseudoephedrine, and phenylpropanolamine, expressed in kilograms of anhydrous acid or base, is adjusted and established as follows:

List I chemical	Final 2012 assessment of annual needs (kg)
Ephedrine (for sale)	4,300
Phenylpropanolamine (for sale)	5,800
Pseudoephedrine (for sale) ..	278,000
Phenylpropanolamine (for conversion)	26,200
Ephedrine (for conversion) ...	12,000

Dated: August 31, 2012.

Michele M. Leonhart,
Administrator.

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DEPARTMENT OF JUSTICE

Drug Enforcement Administration

Importer of Controlled Substances; Notice of Registration; Cambrex Charles City, Inc.

By Notice dated June 18, 2012, and published in the **Federal Register** on June 26, 2012, 77 FR 38085, Cambrex Charles City, Inc., 1205 11th Street, Charles City, Iowa 50616-3466, made application by renewal to the Drug Enforcement Administration (DEA) to be registered as an importer of the following basic classes of controlled substances:

Drug	Schedule
4-Anilino-N-phenethyl-4-piperidine (8333).	II
Phenylacetone (8501)	II
Opium, raw (9600)	II
Poppy Straw Concentrate (9670)	II

The company plans to import the listed controlled substances for internal use, and to manufacture bulk intermediates for sale to its customers. No comments or objections have been received. Comments and requests for hearings on applications to import narcotic raw material are not appropriate. 72 FR 3417 (2007).

DEA has considered the factors in 21 U.S.C. 823(a) and 952(a), and determined that the registration of Cambrex Charles City, Inc. to import the