

sales of 21,008 kg for 2011; when compared to 2009 this represents a 45 percent increase in sales reported by these firms. DEA notes that in 2011 there were significant increased sales of phenylpropanolamine (for conversion) for the manufacture of amphetamine. DEA believes that current reported 2011 sales of phenylpropanolamine (for conversion) supplied by DEA registered manufacturers best represent the legitimate need for phenylpropanolamine (for conversion). There were no reported exports of

phenylpropanolamine (for conversion). DEA has not received any requests to synthesize phenylpropanolamine in 2011. Based on the information provided to DEA, DEA is proposing to increase the 2011 assessment of annual needs for phenylpropanolamine (for conversion) from 21,800 kg to 29,500 kg.

As of April 18, 2011, the data provided to DEA for review of ephedrine (for sale), phenylpropanolamine (for sale), and ephedrine (for conversion) demonstrated no significant changes in

demand or net disposals. Thus, DEA has determined that the assessment of annual needs for these chemicals—ephedrine (for sale), phenylpropanolamine (for sale), and ephedrine (for conversion)—shall remain unchanged.

The Administrator, therefore, proposes the following adjustment of the 2011 assessment of annual needs for the List I chemicals ephedrine, pseudoephedrine, and phenylpropanolamine:

List I chemicals	2011 Assessment of annual needs	Proposed adjustment to the 2011 assessment of annual needs
Ephedrine (for sale)	4,200 kg	No Change.
Phenylpropanolamine (for sale)	5,300 kg	No Change.
Pseudoephedrine (for sale)	280,000 kg	299,000 kg.
Phenylpropanolamine (for conversion)	21,800 kg	29,500 kg.
Ephedrine (for conversion)	18,600 kg	No Change.

In finalizing the adjustment of the 2011 assessment of annual needs for ephedrine, pseudoephedrine and phenylpropanolamine, DEA will consider any additional changes in demand, changes in the national rate of net disposal, or changes in the rate of net disposal by the registrants holding individual manufacturing or import quotas for the chemical, in accordance with 21 CFR part 1315.

Comments

Pursuant to 21 CFR 1315.13, any interested person may submit written comments on or objections to these proposed determinations. Based on comments received in response to this Notice, the Administrator may hold a public hearing on one or more issues raised. In the event the Administrator decides in her sole discretion to hold such a hearing, the Administrator will publish a notice of any such hearing in the **Federal Register**. After consideration of any comments and after a hearing, if one is held, the Administrator will publish in the **Federal Register** a Final Order determining any adjustment of the assessment of annual needs.

Dated: August 31, 2011.

Michele M. Leonhart,
Administrator.

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DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. DEA-353P]

Proposed 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 with request for comments.

SUMMARY: This notice proposes the initial year 2012 assessment of annual needs for certain List I chemicals ephedrine, pseudoephedrine, and phenylpropanolamine.

DATES: Electronic comments must be submitted and written comments must be postmarked on or before October 14, 2011. Commenters should be aware that the electronic Federal Docket Management System will not accept comments after midnight Eastern Time on the last day of the comment period.

ADDRESSES: To ensure proper handling of comments, please reference "Docket No. DEA-353P" on all electronic and written correspondence. DEA encourages all comments be submitted electronically through <http://www.regulations.gov> using the electronic comment form provided on that site. An electronic copy of this document is also available at the <http://www.regulations.gov> Web site for easy reference. Paper comments that duplicate the electronic submission are not necessary as all comments

submitted to <http://www.regulations.gov> will be posted for public review and are part of the official docket record. Should you, however, wish to submit written comments via regular or express mail, they should be sent to the Drug Enforcement Administration, *Attention:* DEA Federal Register Representative/ODL, 8701 Morrisette Drive, Springfield, VA 22152.

FOR FURTHER INFORMATION CONTACT: Christine A. Sannerud, PhD, Chief, UN Reporting and Quota Section, Drug Enforcement Administration, 8701 Morrisette Drive, Springfield, Virginia 22152, *Telephone:* (202) 307-7184.

SUPPLEMENTARY INFORMATION:

Posting of Public Comments

Please note that all comments received are considered part of the public record and made available for public inspection online at <http://www.regulations.gov> and in the DEA's public docket. Such information includes personal identifying information (such as your name, address, etc.) voluntarily submitted by the commenter.

If you want to submit personal identifying information (such as your name, address, etc.) as part of your comment, but do not want it to be posted online or made available in the public docket, you must include the phrase "Personal Identifying Information" in the first paragraph of your comment. You must also place all the personal identifying information you do not want posted online or made available in the public docket in the first paragraph of your comment and identify what information you want redacted.

If you want to submit confidential business information as part of your comment, but do not want it to be posted online or made available in the public docket, you must include the phrase "Confidential Business Information" in the first paragraph of your comment. You must also prominently identify confidential business information to be redacted within the comment. If a comment has so much confidential business information that it cannot be effectively redacted, all or part of that comment may not be posted online or made available in the public docket.

Personal identifying information and confidential business information identified and located as set forth above will be redacted, and the comment, in redacted form, will be posted online and placed in the DEA's public docket file. Please note that the Freedom of Information Act applies to all comments received. If you wish to inspect the agency's public docket file in person by appointment, please see the **FOR FURTHER INFORMATION CONTACT** paragraph.

Background

The proposed 2012 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 chemical 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 of such chemicals.

In proposing the 2012 assessment of annual needs for ephedrine, pseudoephedrine, and phenylpropanolamine, DEA has taken into account the criteria that DEA is required to consider in accordance with 21 U.S.C. 826(a) and 21 CFR 1315.11. DEA proposes the assessment of annual needs for 2012 by considering (1) Total net disposal of the chemical by all manufacturers and importers during the current and two preceding years; (2) trends in the national rate of net disposals of each chemical; (3) total actual (or estimated) inventories of the chemical and of all substances manufactured from the chemical, and trends in inventory accumulation; (4) projected demand for each chemical as indicated by procurement and import quotas requested pursuant to 21 CFR 1315.32; and (5) other factors affecting the medical, scientific, research, industrial, and importation needs in the United States, lawful export

requirements, and reserve stocks, as the Administrator finds 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. DEA notes, pursuant to 21 CFR 1315.13 the DEA may adjust the assessments of annual needs for ephedrine, pseudoephedrine or phenylpropanolamine that has been previously fixed pursuant to 21 CFR 1315.11.

Analysis

In determining the 2012 assessments, DEA has used the calculation methodology described previously in the 2010 and 2011 assessment of annual needs (74 FR 60294 and 75 FR 79407 respectively). Additionally, DEA considered the total net disposals (*i.e.* sales) of these List I chemicals for the current and preceding two years, actual and estimated inventories, projected demand (2012), industrial use, and export requirements from data provided by DEA registered manufacturers and importers in procurement quota applications (DEA 250), manufacturing quota applications (DEA 189), import quota applications (DEA 488), and declarations for import and export. DEA notes that the inventory, acquisition (purchases) and disposition (sales) data provided by DEA registered manufacturers and importers reflects the most current information available.

In finalizing the 2012 assessment of annual needs for ephedrine, pseudoephedrine, and phenylpropanolamine, DEA will consider the information contained in additional applications for 2012 import, manufacturing, and procurement quotas from DEA registered manufacturers and importers that DEA receives after the date of drafting this notice, June 22, 2011, as well as the comments that DEA receives in response to this proposal.

The Administrator, therefore, proposes the following assessment of annual needs for the List I chemicals ephedrine, pseudoephedrine, and phenylpropanolamine for 2012, expressed in kilograms of anhydrous base:

List I chemicals	Proposed year 2012 assessment of annual needs (kg)
Ephedrine (for sale)	3,400
Phenylpropanolamine (for sale)	5,200
Pseudoephedrine (for sale) ..	240,000
Phenylpropanolamine (for conversion)	26,200
Ephedrine (for conversion) ...	12,000

Comments

Pursuant to 21 CFR 1315.11, any interested person may submit written comments on or objections to these proposed determinations. Based on comments received in response to this Notice, the Administrator may hold a public hearing on one or more issues raised. In the event the Administrator decides in her sole discretion to hold such a hearing, the Administrator will publish a notice of any such hearing in the **Federal Register**. After consideration of any comments and after a hearing, if one is held, the Administrator will publish in the **Federal Register** a Final Order determining the assessment of annual needs for 2012 of ephedrine, pseudoephedrine, and phenylpropanolamine.

Dated: September 1, 2011.

Michele M. Leonhart,
Administrator.

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DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. DEA-343R]

Controlled Substances: 2011 Proposed Aggregate Production Quotas

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

ACTION: Notice with request for comments.

SUMMARY: This notice proposes to adjust the 2011 aggregate production quotas for several controlled substances in schedules I and II of the Controlled Substances Act (CSA) and separately proposes to establish aggregate production quotas for five synthetic cannabinoids temporarily controlled in Schedule I.

DATES: Electronic comments must be submitted and written comments must