

15 U.S.C. 4301 *et seq.* (“the Act”), Green Seal, Inc. (“Green Seal”) has filed written notifications simultaneously with the Attorney General and the Federal Trade Commission disclosing additions or changes to its standards development activities. The notifications were filed for the purpose of extending the Act’s provisions limiting the recovery of antitrust plaintiffs to actual damages under specified circumstances. Specifically, Green Seal has issued new standards for specialty cleaning products and a comprehensive revision to the standard for reusable bags.

On January 26, 2011, Green Seal filed its original notification pursuant to Section 6(a) of the Act. The Department of Justice published a notice in the **Federal Register** pursuant to Section 6(b) of the Act on March 7, 2011 (76 FR 12370).

The last notification was filed with the Department on June 28, 2011. A notice was published in the **Federal Register** pursuant to Section 6(b) of the Act on August 3, 2011 (76 FR 46843).

Patricia A. Brink,
Director of Civil Enforcement, Antitrust Division.

[FR Doc. 2011–31752 Filed 12–9–11; 8:45 am]

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DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. DEA–353E]

Established 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 initial 2012 assessment of annual needs for the List I chemicals ephedrine, pseudoephedrine, and phenylpropanolamine.

DATES: *Effective Date:* December 12, 2011.

FOR FURTHER INFORMATION CONTACT: John W. Partridge, Chief, Liaison and Policy Section, Drug Enforcement Administration, 8701 Morrisette Drive, Springfield, Virginia 22152, *Telephone:* (202) 307–7184.

SUPPLEMENTARY INFORMATION:

Background

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 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. 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 September 14, 2011, a notice entitled “Proposed Assessment of Annual Needs for the List I Chemicals Ephedrine, Pseudoephedrine, and Phenylpropanolamine for 2012” was published in the **Federal Register** (76 FR 56809). That notice proposed 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 assessments on or before October 14, 2011.

Comments Received

DEA received one comment regarding the proposed assessment of annual needs for pseudoephedrine. The commenter stated that “the quotas should be increased to cover our needs. The appropriate DEA Form 250 will be

submitted shortly pertaining to the items for which we submitted comments.” As of October 17, 2011, the commenter was not registered to manufacture the chemical pseudoephedrine and DEA had not received the commenter’s request for 2012 quota for pseudoephedrine. DEA will consider the commenter’s request for quota after they become registered to manufacture pseudoephedrine and submit a quota application pursuant to 21 CFR 1315.22.

Conclusion

In determining the 2012 assessments, DEA took 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 has increased the assessment of annual need for ephedrine (for sale) and pseudoephedrine (for sale) over the proposed amount based on additional data that was received regarding 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. The relevant inventory, acquisition (purchases), and disposition (sales) data was 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 received by DEA as of October 17, 2011. After reviewing the additional data, DEA determined that an increase in the proposed assessment of annual need for ephedrine (for sale) and pseudoephedrine (for sale) was warranted. This notice reflects that increase.

In accordance with 21 U.S.C. 826 and 21 CFR 1315.11, the Administrator hereby determines that the 2012 assessment of annual needs for ephedrine, pseudoephedrine, and phenylpropanolamine, expressed in kilograms of anhydrous acid or base, is established as follows:

List I chemical	Established 2012 assessment of annual needs (kg)
Ephedrine (for sale)	4,000
Phenylpropanolamine (for sale)	5,200
Pseudoephedrine (for sale)	258,000
Phenylpropanolamine (for conversion)	26,200
Ephedrine (for conversion)	12,000

The assessment of annual needs may be adjusted at a later date pursuant to 21 CFR 1315.13.

Dated: December 1, 2011.

Michele M. Leonhart,
Administrator.

[FR Doc. 2011-31777 Filed 12-9-11; 8:45 am]

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DEPARTMENT OF JUSTICE

Drug Enforcement Administration

Importer of Controlled Substances; Notice of Registration

By Notice dated September 27, 2011, and published in the **Federal Register** on October 7, 2011, 76 FR 62446, Fisher Clinical Services, Inc., 7554 Schantz Road Allentown, Pennsylvania 18106, 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
Noroxymorphone (9668)	II
Sufentanil (9740)	II
Tapentadol (9780)	II

The company plans to import the listed substances for analytical research and clinical trials.

No comments or objections have been received. DEA has considered the factors in 21 U.S.C. 823(a) and 952(a) and determined that the registration of Fisher Clinical Services, Inc. to import the basic classes of controlled substances is consistent with the public interest and with United States obligations under international treaties, conventions, or protocols in effect on May 1, 1971. DEA has investigated Fisher Clinical Services, Inc. to ensure that the company's registration is consistent with the public interest. The investigation has included inspection and testing of the company's physical security systems, verification of the company's compliance with state and local laws, and a review of the company's background and history. Therefore, pursuant to 21 U.S.C. 952(a) and 958(a), and in accordance with 21 CFR 1301.34, the above named company is granted registration as an importer of the basic classes of controlled substances listed.

Dated: December 5, 2011.

Joseph T. Rannazzisi,
Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration.

[FR Doc. 2011-31776 Filed 12-9-11; 8:45 am]

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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 October 17, 2011, Hospira Inc., 1776 North Centennial Drive, McPherson, Kansas 67460-1247, made application by renewal to the Drug Enforcement Administration (DEA) to be registered as an importer of Remifentanil (9739), a basic class of controlled substance listed in schedule II.

The company plans to import Remifentanil for use in dosage form manufacturing.

Any bulk manufacturers who are presently, or are applying to be, registered with DEA to manufacture such basic class of controlled substance 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 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 January 11, 2012.

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, 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: December 5, 2011.

Joseph T. Rannazzisi,
Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration.

[FR Doc. 2011-31766 Filed 12-9-11; 8:45 am]

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DEPARTMENT OF JUSTICE

Drug Enforcement Administration

Importer of Controlled Substances; Notice of Application

Pursuant to Title 21 Code of Federal Regulations 1301.34(a), this is notice that on September 12, 2011, Johnson Matthey, Inc., Pharmaceutical Materials, 2003 Nolte Drive, West Deptford, New Jersey 08066-1742, made application by renewal to the Drug Enforcement Administration (DEA) for registration as an importer of the following basic classes of controlled substances listed in schedule II:

Drug	Schedule
Coca Leaves (9040)	II
Thebaine (9333)	II
Opium, raw (9600)	II
Noroxymorphone (9668)	II
Poppy Straw Concentrate (9670)	II

The company plans to import the listed controlled substances as raw materials, to be used in the manufacture of bulk controlled substances, for distribution to its customers.

No comments, objections, or requests for any hearings will be accepted on any application for registration or re-registration to import crude opium, poppy straw, concentrate of poppy straw, and coca leaves. Comments and requests for hearings on applications to import narcotic raw material are not appropriate, in accordance with 72 FR 3417 (2007).

In regards to the non-narcotic raw material, the company plans to import gram amounts to be used as reference standards for sale to its customers. Any bulk manufacturer who is presently, or is applying to be, registered with DEA to manufacture such basic classes of controlled substances listed in schedule I or II, which fall under the authority of section 1002(a)(2)(B) of the Act (21 U.S.C. 952(a)(2)(B)) may, in the circumstances set forth in 21 U.S.C.