

Any such written comments or objections being sent via regular mail should be addressed, in quintuplicate, to the Drug Enforcement Administration, Office of Diversion Control, Federal Register Representative (ODL), Washington, DC 20537, or any being sent via express mail should be sent to Drug Enforcement Administration, Office of Diversion Control, Federal Register Representative (ODL), 8701 Morrisette Drive, Springfield, Virginia 22152; and must be filed no later than February 25, 2008.

Dated: December 17, 2007.

Joseph T. Rannazzisi,
Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration.
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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 November 15, 2007, Organix Inc., 240 Salem Street, Woburn, Massachusetts 01801, made application by renewal to the Drug Enforcement Administration (DEA) to be registered as a bulk manufacturer of the basic classes of controlled substances listed in schedule I and II:

Drug	Schedule
Tetrahydrocannabinols (7370)	I
Cocaine (9041)	II

The company plans to manufacture the listed controlled substances in bulk for sale to its customers for research purposes.

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).

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Dated: December 17, 2007.

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

Drug Enforcement Administration

[Docket No. DEA-306E]

Established Assessment of Annual Needs for the List I Chemicals Ephedrine, Pseudoephedrine, and Phenylpropanolamine for 2008

AGENCY: Drug Enforcement Administration (DEA), Justice.
ACTION: Notice of Assessment of Annual Needs for 2008.

SUMMARY: This notice establishes the initial year 2008 Assessment of Annual Needs for certain List I chemicals in accordance with the Combat Methamphetamine Epidemic Act of 2005 (CMEA), enacted on March 9, 2006.

EFFECTIVE DATE: December 27, 2007.

FOR FURTHER INFORMATION CONTACT: Christine A. Sannerud, PhD, Chief, Drug & Chemical Evaluation Section, Drug Enforcement Administration, Washington, DC 20537, Telephone: (202) 307-7183.

SUPPLEMENTARY INFORMATION:

Background and Legal Authority

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) requiring that the Attorney General establish quotas to provide for the annual needs for ephedrine, pseudoephedrine, and phenylpropanolamine. Section 715 of the CMEA amended 21 U.S.C. 952 by adding ephedrine, pseudoephedrine and phenylpropanolamine to the existing language concerning importation of controlled substances.

The 2008 Assessment of Annual Needs represents those quantities of ephedrine, pseudoephedrine, and phenylpropanolamine which may be manufactured domestically and/or imported into the United States in 2008 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.

The responsibility for establishing the assessment has been delegated to the Administrator of the DEA by 28 CFR 0.100. The Administrator, in turn, has redelegated this function to the Deputy Administrator, pursuant to 28 CFR 0.104.

On September 20, 2007, a notice entitled, "Assessment of Annual Needs for the List I Chemicals Ephedrine, Pseudoephedrine, and Phenylpropanolamine for 2008: Proposed" was published in the **Federal Register** (72 FR 53911). This notice proposed the initial 2008 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 October 11, 2007.

Comments Received

DEA did not receive any comments or objections from the more than 1,050 DEA-registered manufacturers and importers directly impacted by this notice. However, DEA did receive one comment from a law firm representing a DEA-registered distributor of nonprescription (over-the-counter (OTC)) products containing ephedrine, pseudoephedrine, or phenylpropanolamine. When sold at retail, these products are referred to as scheduled listed chemical products.¹ This same commenter commented to DEA's proposed 2007 Assessment of Annual Needs which was published in the **Federal Register** on October 19, 2006 (71 FR 61801). The comment submitted to this notice is virtually identical to that previously considered by DEA in that the comment included the same reports. However, DEA notes that the current comment includes one new report and one new letter. The new report was prepared by an economist who was retained by the DEA-registered distributor being represented by the law firm. The letter was prepared by the statistician whose report was submitted as part of this commenter's comments to the 2007 proposed assessment.

The commenter's comments related to DEA's proposed assessments for ephedrine (for sale) and pseudoephedrine (for sale). These assessments are discussed below within

¹ Title 21 U.S.C. 802(45) defines a scheduled listed chemical product as "a product that contains ephedrine, pseudoephedrine, or phenylpropanolamine; and * * * may be marketed or distributed lawfully in the United States under the Federal Food, Drug, and Cosmetic Act as a nonprescription drug."