

exercise all necessary functions with respect to the promulgation and implementation of 21 CFR part 1301, incident to the registration of manufacturers, distributors, dispensers, importers, and exporters of controlled substances (other than final orders in connection with suspension, denial, or revocation of registration) has been redelegated to the Deputy Assistant Administrator of the DEA Office of Diversion Control (“Deputy Assistant Administrator”) pursuant to section 7 of 28 CFR part 0, appendix to subpart R.

In accordance with 21 CFR 1301.33(a), this is notice that on September 7, 2015, Organix, Inc., 240 Salem Street, Woburn, Massachusetts 01801 applied to be registered as a bulk manufacturer of the following basic classes of controlled substances:

Controlled substance	Schedule
Gamma Hydroxybutyric Acid (2010)	I
Lysergic acid diethylamide (7315)	I
Marihuana (7360)	I
Tetrahydrocannabinols (7370)	I
Psilocybin (7437)	I
Psilocyn (7438)	I
Heroin (9200)	I
Morphine (9300)	II

The company plans to manufacture reference standards for distribution to its research and forensics customers. In reference to drug codes 7360 (marihuana) and 7370 (THC) the company plans to manufacture these drugs as synthetic. No other activities for these drug codes are authorized for this registration.

Dated: November 27, 2015.

**Louis J. Milione,**

*Deputy Assistant Administrator.*

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**DEPARTMENT OF JUSTICE**

**Drug Enforcement Administration**

[Docket No. DEA-392]

**Bulk Manufacturer of Controlled Substances Application: Noramco, Inc.**

**ACTION:** Notice of application.

**DATES:** Registered bulk manufacturers of the affected basic classes, and applicants therefore, may file written comments on or objections to the issuance of the proposed registration in accordance with 21 CFR 1301.33(a) on or before February 1, 2016.

**ADDRESSES:** Written comments should be sent to: Drug Enforcement

Administration, Attention: DEA **Federal Register** Representative/OD/D, 8701 Morrisette Drive, Springfield, Virginia 22152. Request for hearings should be sent to: Drug Enforcement Administration, Attention: Hearing Clerk/LJ, 8701 Morrisette Drive, Springfield, Virginia 22152.

**SUPPLEMENTARY INFORMATION:** The Attorney General has delegated her authority under the Controlled Substances Act to the Administrator of the Drug Enforcement Administration (DEA), 28 CFR 0.100(b). Authority to exercise all necessary functions with respect to the promulgation and implementation of 21 CFR part 1301, incident to the registration of manufacturers, distributors, dispensers, importers, and exporters of controlled substances (other than final orders in connection with suspension, denial, or revocation of registration) has been redelegated to the Deputy Assistant Administrator of the DEA Office of Diversion Control (“Deputy Assistant Administrator”) pursuant to section 7 of 28 CFR part 0, appendix to subpart R.

In accordance with 21 CFR 1301.33(a), this is notice that on October 6, 2015, Noramco, Inc., 500 Swedes Landing Road, Wilmington, Delaware 19801-4417 applied to be registered as a bulk manufacturer of the following basic classes of controlled substances:

Controlled substance	Schedule
Codeine-N-oxide (9053)	I
Dihydromorphine (9145)	I
Morphine-N-oxide (9307)	I
Amphetamine (1100)	II
Methylphenidate (1724)	II
Phenylacetone (8501)	II
Codeine (9050)	II
Dihydrocodeine (9120)	II
Oxycodone (9143)	II
Hydromorphone (9150)	II
Hydrocodone (9193)	II
Morphine (9300)	II
Oripavine (9330)	II
Thebaine (9333)	II
Opium extracts (9610)	II
Opium fluid extract (9620)	II
Opium tincture (9630)	II
Opium, powdered (9639)	II
Opium, granulated (9640)	II
Oxymorphone (9652)	II
Noroxymorphone (9668)	II
Tapentadol (9780)	II

The company plans to manufacture the above-listed controlled substances in bulk for distribution to its customers.

Dated: November 23, 2015.

**Louis J. Milione,**

*Deputy Assistant Administrator.*

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**DEPARTMENT OF JUSTICE**

**Drug Enforcement Administration**

[Docket No. DEA-392]

**Importer of Controlled Substances Registration: Catalent CTS, LLC**

**ACTION:** Notice of registration.

**SUMMARY:** Catalent CTS, LLC applied to be registered as an importer of a certain basic class of controlled substance. The Drug Enforcement Administration (DEA) grants Catalent CTS, LLC registration as an importer of this controlled substance.

**SUPPLEMENTARY INFORMATION:** By notice dated August 21, 2015, and published in the **Federal Register** on August 31, 2015, 80 FR 52509, Catalent CTS, LLC, 10245 Hickman Mills Drive, Kansas City, Missouri 64137 applied to be registered as an importer of a certain basic class of controlled substance. No comments or objections were submitted for this notice.

The DEA has considered the factors in 21 U.S.C. 823, 952(a) and 958(a) and determined that the registration of Catalent CTS, LLC to import the basic class of controlled substance is consistent with the public interest and with United States obligations under international treaties, conventions, or protocols in effect on May 1, 1971. The DEA investigated the company’s maintenance of effective controls against diversion by inspecting and testing the company’s physical security systems, verifying the company’s compliance with state and local laws, and reviewing 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 marihuana (7360), a basic class of controlled substance listed in schedule I.

The company plans to import finished pharmaceutical products containing cannabis extracts in dosage form for clinical trial studies.

This compound is listed under drug code 7360. No other activity for this drug code is authorized for this registration. Approval of permits applications will occur only when the registrant’s business activity is consistent with what is authorized under to 21 U.S.C. 952(a)(2). Authorization will not extend to the import of FDA approved or non-approved finished dosage forms for commercial sale.

Dated: November 27, 2015.

**Louis J. Milione,**

*Deputy Assistant Administrator.*

[FR Doc. 2015-30551 Filed 12-2-15; 8:45 am]

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## DEPARTMENT OF LABOR

### Office of the Secretary

#### Agency Information Collection Activities; Submission for OMB Review; Comment Request; Hazardous Waste Operations and Emergency Response

**AGENCY:** Office of the Secretary, Labor.

**ACTION:** Notice.

**SUMMARY:** On November 30, 2015 the Department of Labor (DOL) will submit the Occupational Safety and Health Administration (OSHA) sponsored information collection request (ICR) titled, "Hazardous Waste Operations and Emergency Response," to the Office of Management and Budget (OMB) for review and approval for continued use, without change, in accordance with the Paperwork Reduction Act of 1995 (PRA), 44 U.S.C. 3501 *et seq.* Public comments on the ICR are invited.

**DATES:** The OMB will consider all written comments that agency receives on or before January 4, 2016.

**ADDRESSES:** A copy of this ICR with applicable supporting documentation; including a description of the likely respondents, proposed frequency of response, and estimated total burden may be obtained free of charge from the RegInfo.gov Web site at [http://www.reginfo.gov/public/do/PRAViewICR?ref\\_nbr=201511-1218-003](http://www.reginfo.gov/public/do/PRAViewICR?ref_nbr=201511-1218-003) (this link will only become active on December 1, 2015) or by contacting Michel Smyth by telephone at 202-693-4129, TTY 202-693-8064, (these are not toll-free numbers) or by email at [DOL\\_PRA\\_PUBLIC@dol.gov](mailto:DOL_PRA_PUBLIC@dol.gov).

Submit comments about this request by mail or courier to the Office of Information and Regulatory Affairs, Attn: OMB Desk Officer for DOL-OSHA, Office of Management and Budget, Room 10235, 725 17th Street NW., Washington, DC 20503; by Fax: 202-395-5806 (this is not a toll-free number); or by email: [OIRA\\_submission@omb.eop.gov](mailto:OIRA_submission@omb.eop.gov). Commenters are encouraged, but not required, to send a courtesy copy of any comments by mail or courier to the U.S. Department of Labor-OASAM, Office of the Chief Information Officer, Attn: Departmental Information Compliance Management Program, Room N1301, 200 Constitution Avenue NW.,

Washington, DC 20210; or by email: [DOL\\_PRA\\_PUBLIC@dol.gov](mailto:DOL_PRA_PUBLIC@dol.gov).

#### FOR FURTHER INFORMATION CONTACT:

Michel Smyth by telephone at 202-693-4129, TTY 202-693-8064, (these are not toll-free numbers) or by email at [DOL\\_PRA\\_PUBLIC@dol.gov](mailto:DOL_PRA_PUBLIC@dol.gov).

**Authority:** 44 U.S.C. 3507(a)(1)(D).

**SUPPLEMENTARY INFORMATION:** This ICR seeks to extend PRA authority for the Hazardous Waste Operations and Emergency Response (HAZWOPER) Standard information collection. The HAZWOPER Standard specifies a number of information collection requirements. Employers can use the information collected under the HAZWOPER rule to develop the various programs the Standard requires and to ensure that their workers are trained properly about the safety and health hazards associated with hazardous waste operations and emergency response to hazardous waste releases. The OSHA uses the records developed in response to this Standard to determine adequate compliance with the Standard's safety and health provisions. An employer's failure to collect and distribute information required in this standard will significantly affect OSHA efforts to control and reduce injuries and fatalities. Such failure would also be contrary to the direction Congress provided in the Superfund Amendments and Reauthorization Act. Occupational Safety and Health Act of 1970 sections 2(b)(9), 6, and 8(c) authorize this information collection. See 29 U.S.C. 651(b)(9), 655, and 657(c).

This information collection is subject to the PRA. A Federal agency generally cannot conduct or sponsor a collection of information, and the public is generally not required to respond to an information collection, unless it is approved by the OMB under the PRA and displays a currently valid OMB Control Number. In addition, notwithstanding any other provisions of law, no person shall generally be subject to penalty for failing to comply with a collection of information that does not display a valid Control Number. See 5 CFR 1320.5(a) and 1320.6. The DOL obtains OMB approval for this information collection under Control Number 1218-0202.

OMB authorization for an ICR cannot be for more than three (3) years without renewal. The DOL seeks to extend PRA authorization for this information collection for three (3) more years, without any change to existing requirements. The DOL notes that existing information collection requirements submitted to the OMB

receive a month-to-month extension while they undergo review. For additional substantive information about this ICR, see the related notice published in the **Federal Register** on May 21, 2015 (80 FR 29344).

Interested parties are encouraged to send comments to the OMB, Office of Information and Regulatory Affairs at the address shown in the **ADDRESSES** section within thirty (30) days of publication of this notice in the **Federal Register**. In order to help ensure appropriate consideration, comments should mention OMB Control Number 1218-0202. The OMB is particularly interested in comments that:

- Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;
- Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;
- Enhance the quality, utility, and clarity of the information to be collected; and
- Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, e.g., permitting electronic submission of responses.

*Agency:* DOL-OSHA.

*Title of Collection:* Hazardous Waste Operations and Emergency Response Standard.

*OMB Control Number:* 1218-0202.

*Affected Public:* Private Sector—businesses or other for-profit.

*Total Estimated Number of Respondents:* 30,052.

*Total Estimated Number of Responses:* 1,440,759.

*Total Estimated Annual Time Burden:* 261,551 hours.

*Total Estimated Annual Other Costs Burden:* \$3,124,960.

Dated: November 27, 2015.

**Michel Smyth,**

*Departmental Clearance Officer.*

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