DEPARTMENT OF JUSTICE

Drug Enforcement Administration

Manufacturer of Controlled Substances; Notice of Registration; Catalent Pharma Solutions, Inc.

By Notice dated April 17, 2012, and published in the Federal Register on April 26, 2012, 77 FR 24984, Catalent Pharma Solutions, Inc., 10381 Decatur Road, Philadelphia, Pennsylvania 19114, made application to the Drug Enforcement Administration (DEA) to be registered as an importer of Noroxymorphone (9668), a basic class of controlled substance listed in schedule II.

The company plans to import the listed controlled substance in finished dosage form for clinical trials.

The import of the above listed basic class of controlled substance would be granted only for analytical testing and clinical trials. This authorization does not extend to the import of a finished FDA approved or non-approved dosage form for commercial distribution in the United States.

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 Catalent Pharma Solutions, Inc. 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.

DEA has investigated Catalent Pharma Solutions, 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 class of controlled substance listed.


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Pursuant to § 1301.33(a), Title 21 of the Code of Federal Regulations (CFR), this is notice that on June 5, 2012, AMRI Rensselaer Inc., 33 Riverside Avenue, Rensselaer, New York 12144, made application by renewal to the Drug Enforcement Administration (DEA) to be registered as a bulk manufacturer of the following basic classes of controlled substances:

- Hydromorphone (9145)
- Lisdexamfetamine (1205)
- Meperidine (9230)
- Pentobarbital (2270)
- 4-Anilino-N-phenethyl-4-Piperidine (8333)
- Fentanyl (9801)

The company plans to manufacture bulk controlled substances for use in product development and for distribution to its customers.

In reference to drug code 7360 (Marihuana), the company plans to bulk manufacture cannabidiol as a synthetic intermediate, which will be further synthesized to bulk manufacture a synthetic THC (7370). No other activity for this drug code is authorized for this registration.

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).

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 Morrissette Drive, Springfield, Virginia 22152; and must be filed no later than October 9, 2012.

Dated: July 30, 2012.

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

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