

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

Importer of Controlled Substances; Notice of Application; Clinical Supplies Management, Inc.

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 November 13, 2011, Clinical Supplies Management, Inc., 342 42nd Street South, Fargo, North Dakota 58103, made application by renewal to the Drug Enforcement Administration (DEA) to be registered as an importer of Sufentanil (9740), a basic class of controlled substance listed in schedule II.

The company plans to import the listed controlled substance with the sole purpose of packaging, labeling, and distributing to customers which are qualified clinical sites conducting clinical trials under the auspices of an FDA-approved clinical study.

Any bulk manufacturer who is presently, or is 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 May 29, 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 43745-46, 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: April 17, 2012.

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

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DEPARTMENT OF JUSTICE

Drug Enforcement Administration

Importer of Controlled Substances; Notice of Application; Catalent Pharma Solutions, Inc.

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) 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 January 5, 2012, 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.

Any bulk manufacturer who is presently, or is 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 May 29, 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 43745-46, all applicants for registration to import a basic class of any controlled substance in schedules 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: April 17, 2012.

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

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DEPARTMENT OF JUSTICE

Drug Enforcement Administration

Importer of Controlled Substances; Notice of Application; Rhodes Technologies

This is notice that on February 24, 2011, Rhodes Technologies, 498 Washington Street, Coventry, Rhode Island 02816, made application by renewal to the Drug Enforcement Administration (DEA) for registration as an importer of the following basic classes of controlled substances in schedule II:

Drug	Schedule
Opium, Raw (9600)	II
Poppy Straw Concentrate (9670)	II

The company plans to import the listed controlled substances in order to bulk manufacture controlled substances in Active Pharmaceutical Ingredient (API) form. The company distributes the manufactured APIs in bulk form to its customers.

Comments and requests for hearings on applications to import narcotic raw material are not appropriate. 72 FR 3417 (2007).

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