Billing Code 4410-09-P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

Importer of Controlled Substances

Notice of Application

Catalent CTS, Inc.

Pursuant to 21 CFR 1301.34(a), this is notice that on September 23, 2013, Catalent CTS, Inc., 10245 Hickman Mills Drive, Kansas City, Missouri 64137, made application by renewal to the Drug Enforcement Administration (DEA)for registration as an importer of the following basic classes of controlled substances:

Drug	Schedule
Marihuana (7360)	I
Poppy Straw Concentrate (9670)	II

The company plans to import a finished pharmaceutical product containing cannabis extracts in dosage form for a clinical trial study.

In reference to drug code 7360, the company plans to import a synthetic cannabidiol. This compound is listed under drug

code 7360. No other activity for this drug code is authorized for this registration.

In addition, the company plans to import an ointment for the treatment of wounds which contain trace amounts of the controlled substances normally found in poppy straw concentrate for packaging and labeling to be used in clinical trials.

Comments and requests for any hearings on applications to import narcotic raw material are not appropriate. 72 FR 3417 (January 25, 2007).

Any bulk manufacturer who is presently, or is applying to be, registered with DEA to manufacture such basic classes of controlled substances listed in schedules 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. 958(i), 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 (ODW), 8701 Morrissette Drive, Springfield, Virginia 22152; and must be filed no later than [INSERT DATE 30 DAYS FROM DATE OF PUBLICATION].

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: January 15, 2014.

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

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