Billing Code 4410-09-P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

Importer of Controlled Substances Application: CATALENT CTS, LLC

[Docket No. DEA-392]

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 1301.34(a) on or before [INSERT 30 DAYS AFTER PUBLICATION IN THE FEDERAL REGISTER]. Such persons may also file a written request for a hearing on the application pursuant to 21 CFR 1301.43 on or before [INSERT 30 DAYS AFTER PUBLICATION IN THE FEDERAL REGISTER].

ADDRESS: Written comments should be sent to: Drug Enforcement Administration, Attention: DEA Federal Register Representative/ODW, 8701 Morrissette Drive, Springfield, Virginia 22152.

SUPPLEMENTARY INFORMATION:

The Attorney General has delegated his 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, and dispensers 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 sec. 7(g) of 28 CFR pt. 0, subpt. R, App.

In accordance with 21 CFR 1301.34(a), this is notice that on May 7, 2014, Catalent CTS, LLC, 10245 Hickman Mills Drive, Kansas City, Missouri 64137, applied to be registered as an importer of the following basic classes of controlled substances:

Controlled Substance	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 hearings on applications to import narcotic raw material are not appropriate. 72 FR 3417 (January 25, 2007).

Dated: June 10, 2014.

Joseph T. Rannazzisi,
Deputy Assistant Administrator.

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