



DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. DEA-652]

Importer of Controlled Substances Application: Catalent Pharma Solutions, LLC

ACTION: Notice of application.

DATES: Registered bulk manufacturers of the affected basic class(es), and applicants therefore, may file written comments on or objections to the issuance of the proposed registration 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 on or before [INSERT 30 DAYS AFTER PUBLICATION IN THE FEDERAL REGISTER].

ADDRESSES: Written comments should be sent to: Drug Enforcement Administration (DEA), Attention: DEA Federal Register Representative/DPW, 8701 Morrissette Drive, Springfield, Virginia 22152. All requests for a hearing must be sent to: Drug Enforcement Administration, Attn: Administrator, 8701 Morrissette Drive, Springfield, Virginia 22152. All requests for a hearing should also be sent to: (1) Drug Enforcement Administration, Attn: Hearing Clerk/OALJ, 8701 Morrissette Drive, Springfield, Virginia 22152; and (2) Drug Enforcement Administration, Attn: DEA Federal Register Representative/DPW, 8701 Morrissette Drive, Springfield, Virginia 22152.

SUPPLEMENTARY INFORMATION: In accordance with 21 CFR 1301.34(a), this is notice that on May 8, 2020, Catalent Pharma Solutions, LLC, 3031 Red Lion Road, Philadelphia, Pennsylvania 19114, applied to be registered as an importer of the following basic class(es) of controlled substance:

| Controlled Substance | Drug Code | Schedule |
|-----------------------------|------------------|-----------------|
| Gamma Hydroxybutyric Acid | 2010 | I |

The company plans to import finished dosage unit products containing Gamma Hydroxybutyric Acid for clinical trials, research, and analytical activities. No other activity for this drug code is authorized for this registration. Approval of permit applications will occur only when the registrant's business activity is consistent with what is authorized under 21 U.S.C. 952(a)(2). Authorization will not extend to the import of the Food and Drug Administration (FDA)-approved or non-approved finished dosage forms for commercial sale.

William T. McDermott,
Assistant Administrator.

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