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Drug Enforcement Administration

[Docket No. DEA-802]

Bulk Manufacturer of Controlled Substances Application: Patheon Pharmaceuticals

Inc

AGENCY: Drug Enforcement Administration, Justice.

ACTION: Notice of application.

SUMMARY: Patheon Pharmaceuticals Inc has applied to be registered as a bulk manufacturer of basic class(es) of controlled substance(s). Refer to Supplemental Information listed below for further drug information.

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 DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER]. Such persons may also file a written request for a hearing on the application on or before [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

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

SUPPLEMENTARY INFORMATION: In accordance with 21 CFR 1301.33(a), this is notice that on February 2, 2021, Patheon Pharmaceuticals Inc, 2110 East Galbraith Road, Cincinnati, Ohio 45237-1625, applied to be registered as a bulk manufacturer of the following basic class of controlled substance:

Controlled Substance	Drug Code	Schedule
Gamma Hydroxybutyric Acid	2010	I

The company plans to manufacture the above-listed controlled substance as Active Pharmaceutical Ingredient (API) that will be further synthesized into Food and Drug Administration-approved dosage forms. No other activities for this drug code are authorized for this registration.

William T. McDermott,
Assistant Administrator.

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