DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. DEA-585]

Bulk Manufacturer of Controlled Substances Application: Patheon Pharmaceuticals, Inc.

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 60 DAYS AFTER 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 December 23, 2019, Patheon Pharmaceuticals, Inc., 2100 E Galbraith Road, Cincinnati, Ohio 45237-1625 applied to be registered as a bulk manufacturer of the following basic class(es) of controlled substance:

Controlled Substance	Drug Code	Schedule
Gamma Hydroxybutyric Acid	2010	I

The Gamma Hydroxbutyric Acid will be produced during the process of converting gamma-butyrolactone into a new product for development. The company plans to manufacture the above-listed controlled substance as Active Pharmaceutical Ingredient (API)

that will be further synthesized into dosage forms of a new product. No other activities for this drug code are authorized for this registration.

Dated: January 31, 2020.

William T. McDermott,
Assistant Administrator.

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