DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. DEA-392]

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

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 on or before [INSERT DATE 30 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 30 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:

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, dispensers, importers, and exporters of controlled substances (other than

final orders in connection with suspension, denial, or revocation of registration) has been redelegated to the Assistant Administrator of the DEA Diversion Control Division ("Assistant Administrator") pursuant to section 7 of 28 CFR part 0, appendix to subpart R.

In accordance with 21 CFR 1301.34(a), this is notice that on December 24, 2018, Patheon Pharmaceuticals, Inc., 2110 E Galbraith Road, Cincinnati, Ohio 45237, has re-applied to be registered as a bulk manufacturer of the Schedule I controlled substance Gamma Hydroxybutyric Acid (2010), a basic class of controlled substance.

The Gamma Hydroxybutyric Acid will be produced during the process of converting gamma-butyrolactone (GBL) 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: February 18, 2019.

John J. Martin,

Assistant Administrator.

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