



Billing Code 4410-09-P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

Bulk Manufacturer of Controlled Substances Application: Patheon

Pharmaceuticals, Inc.

[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 1301.33(a) 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/DRW, 8701 Morrisette 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 Deputy Assistant Administrator of the DEA Office of Diversion Control (“Deputy Assistant Administrator”) pursuant to section 7 of 28 CFR part 0, appendix to subpart R.

In accordance with 21 CFR 1301.33(a), this is notice that on December 11, 2017, Patheon Pharmaceuticals, Inc., 2110 E Galbraith Road, Cincinnati, OH 45237 applied for renewal of their registration as a bulk manufacturer of the Schedule I control substance Gamma Hydroxybutyric Acid (2010) the basic class of controlled substances.

The Gama 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: January 30, 2018

Susan A. Gibson,
Deputy Assistant Administrator

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