**DEP**

**Drug Enforcement Administration**

**[Docket No. DEA-1166]**

**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 Supplementary Information listed below for further drug information.

**DATES:** Registered bulk manufacturers of the affected basic class(es), and applicants therefore, may submit electronic 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:** The Drug Enforcement Administration requires that all comments be submitted electronically through the Federal eRulemaking Portal, which provides the ability to type short comments directly into the comment field on the Web page or attach a file for lengthier comments. Please go to https://www.regulations.gov and follow the online instructions at that site for submitting comments. Upon submission of your comment, you will receive a Comment Tracking Number. Please be aware that submitted comments are not instantaneously available for public view on https://www.regulations.gov. If you have received a Comment Tracking Number, your comment has been successfully submitted and there is no need to resubmit the same comment.

**SUPPLEMENTARY INFORMATION:** In accordance with 21 CFR 1301.33(a), this is notice that on February 1, 2023, Patheon Pharmaceuticals Inc., 2110 East Galbraith Road, Cincinnati, Ohio 45237, applied to be registered as a bulk manufacturer of the following basic class(es) of controlled substance(s)**:**

| 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.

**Matthew Strait,**

*Deputy Assistant Administrator.*

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