

Issued: April 30, 2026.

Lisa Barton,
Secretary to the Commission.

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DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. DEA-1708]

Importer of Controlled Substances Application: ANI Pharmaceuticals Inc.

AGENCY: Drug Enforcement Administration, Justice.

ACTION: Notice of application.

SUMMARY: ANI Pharmaceuticals Inc. has applied to be registered as an importer 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 June 3, 2026. Such persons may also file a written request for a hearing on the application on or before June 3, 2026.

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. All requests for a hearing must be sent to: (1) Drug Enforcement Administration, Attn: Hearing Clerk/OALJ, 8701 Morrisette Drive, Springfield, Virginia 22152; and (2) Drug Enforcement Administration, Attn: DEA Federal Register Representative/DPW, 8701 Morrisette Drive, Springfield, Virginia 22152. All requests for a hearing should also be sent to: Drug Enforcement Administration, Attn: Administrator, 8701 Morrisette Drive, Springfield, Virginia 22152.

SUPPLEMENTARY INFORMATION: In accordance with 21 CFR 1301.34(a), this is notice that on April 15, 2026, ANI Pharmaceuticals Inc., 70 Lake Drive, East Windsor, New Jersey 08520-5321, applied to be registered as an importer of the following basic class(es) of controlled substance(s):

Controlled substance	Drug code	Schedule
Levorphanol	9220	II
Tapentadol	9780	II

Levorphanol (9220) will be imported for distribution to customers. Tapentadol (9780) will only be used to import small quantities for internal research and reference standards purposes. No other activities for these drug codes are authorized for this registration.

Approval of permit applications will occur only when the registrant's business activity is consistent with what is authorized under 21 U.S.C. 952(a)(2). Authorization will not extend to the import of Food and Drug Administration-approved or non-approved finished dosage forms for commercial sale.

Thomas Prevoznik,
Deputy Assistant Administrator.
[FR Doc. 2026-08587 Filed 5-1-26; 8:45 am]
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DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. DEA-1710]

Bulk Manufacturer of Controlled Substances Application: Patheon API Inc.

AGENCY: Drug Enforcement Administration, Justice.

ACTION: Notice of application.

SUMMARY: Patheon API 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 July 6, 2026. Such persons may also file a written request for a hearing on the application on or before July 6, 2026.

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 9, 2026, Patheon API Inc., 6173 East Old Marion Highway, Florence, South Carolina 29506, applied to be registered as a bulk manufacturer of the following basic class(es) of controlled substance(s):

Controlled substance	Drug code	Schedule
Dimethyltryptamine	7435	I
Psilocybin	7437	I
Psilocyn	7438	I

The company plans to bulk manufacture the listed controlled substances for research and clinical trials. No other activities for these drug codes are authorized for this registration.

Thomas Prevoznik,
Deputy Assistant Administrator.
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DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. DEA-1711]

Bulk Manufacturer of Controlled Substances Application: ANI Pharmaceuticals Inc.

AGENCY: Drug Enforcement Administration, Justice.

ACTION: Notice of application.

SUMMARY: ANI 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