Persons filing written submissions must file the original document electronically on or before the deadlines stated above pursuant to 19 CFR 210.4(f). Submissions should refer to the investigation number (''Inv. No. 337–TA–1419'') in a prominent place on the cover page and/or the first page. (*See* Handbook for Electronic Filing Procedures, *https://www.usitc.gov/documents/handbook_on_filing_procedures.pdf*). Persons with questions regarding filing should contact the Secretary, (202) 205–2000.

Any person desiring to submit a document to the Commission in confidence must request confidential treatment by marking each document with a header indicating that the document contains confidential information. This marking will be deemed to satisfy the request procedure set forth in Rules 201.6(b) and 210.5(e)(2) (19 CFR 201.6(b) & 210.5(e)(2)). Documents for which confidential treatment by the Commission is properly sought will be treated accordingly. Any non-party wishing to submit comments containing confidential information must serve those comments on the parties to the investigation pursuant to the applicable Administrative Protective Order. A redacted non-confidential version of the document must also be filed with the Commission and served on any parties to the investigation within two business days of any confidential filing. All information, including confidential business information and documents for which confidential treatment is properly sought, submitted to the Commission for purposes of this investigation may be disclosed to and used: (i) by the Commission, its employees and Offices, and contract personnel (a) for developing or maintaining the records of this or a related proceeding, or (b) in internal investigations, audits, reviews, and evaluations relating to the programs, personnel, and operations of the Commission including under 5 U.S.C. appendix 3; or (ii) by U.S. Government employees and contract personnel, solely for cybersecurity purposes. All contract personnel will sign appropriate nondisclosure agreements. All nonconfidential written submissions will be available for public inspection on EDIS.

The Commission vote for this determination took place on May 30, 2025.

The authority for the Commission's determination is contained in section 337 of the Tariff Act of 1930, as amended (19 U.S.C. 1337), and in part 210 of the Commission's Rules of Practice and Procedure (19 CFR part 210).

By order of the Commission.
Issued: May 30, 2025.

Lisa Barton,

Secretary to the Commission.

[FR Doc. 2025–10184 Filed 6–4–25; 8:45 am]

BILLING CODE 7020–02–P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. DEA–1552]

Bulk Manufacturer of Controlled Substances Application: Usona Institute, Inc

AGENCY: Drug Enforcement Administration, Justice.

ACTION: Notice of application.

SUMMARY: Usona Institute, 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 August 4, 2025. Such persons may also file a written request for a hearing on the application on or before August 4, 2025.

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 May 5, 2025, Usona Institute, Inc, 2780 Woods Hollow Road, Room 2413, Fitchburg, Wisconsin 53711, applied to be registered as a bulk manufacturer of the following basic class(es) of controlled substance(s):

Controlled substance	Drug code	Schedule
5-Methoxy-N-N-dimethyltryptamine.	7431	I
Psilocybin	7437	I
Psilocyn	7438	I

The company plans to bulk manufacture the listed controlled substances for use in chemical process development as well as pre-clinical and clinical research. No other activities for these drug codes are authorized for this registration.

Matthew Strait,

Deputy Assistant Administrator.

[FR Doc. 2025–10234 Filed 6–4–25; 8:45 am]

BILLING CODE P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. DEA–1547]

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 on or before August 4, 2025. Such persons may also file a written request for a hearing on the application on or before August 4, 2025.

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 April 21, 2025, ANI Pharmaceuticals Inc., 70 Lake Drive, East Windsor, New Jersey 08520, applied to be registered as a bulk manufacturer of the following basic class(es) of controlled substance(s):

Controlled substance	Drug code	Schedule
Levorphanol	9220	II

The company plans to bulk manufacture the listed controlled substance for development and eventual use in a commercial drug product. No other activity for this drug code is authorized for this registration.

Matthew Strait,

Deputy Assistant Administrator.

[FR Doc. 2025–10230 Filed 6–4–25; 8:45 am]

BILLING CODE P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

Lee S. Altman, M.D.; Decision and Order

I. Introduction

On September 6, 2024, the Drug Enforcement Administration (DEA or Government) issued an Order to Show Cause and Immediate Suspension of Registration (OSC/ISO) to Lee S. Altman, M.D., of Stoughton, Massachusetts (Respondent). Request for Final Agency Action (RFAA), Exhibit (RFAAX) 1, at 1. The OSC/ISO informed Respondent of the immediate suspension of his DEA Certificate of Registration, No. BA4429684, pursuant to 21 U.S.C. 824(d), alleging that Respondent's continued registration constitutes ''an imminent danger to the public health or safety.'' RFAAX, at 1 (quoting 21 U.S.C. 824(d)). The OSC/ISO also proposes the revocation of Respondent's registration, No. BA4429684, pursuant to 21 U.S.C. 824(a)(1) and (a)(4), and 823(g)(1), alleging that Respondent materially falsified an application for renewal of his registration and his continued registration is inconsistent with the public interest. RFAAX 1, at 1.

The OSC/ISO notified Respondent of his right to file with DEA a written request for a hearing. RFAAX 1, at 11 (citing 21 CFR 1301.43). The OSC/ISO also notified Respondent that if he failed to file such a request or file an answer, he would be deemed to have waived his right to a hearing and be in default. *Id.* On September 10, 2024, Respondent timely requested a hearing in this matter. RFAAX 3.[1] The matter was placed on the docket of DEA Administrative Law Judge Teresa Wallbaum (ALJ).

Then on October 4, 2024, Respondent, through his attorney, submitted a letter stating that he was withdrawing his request for a hearing and that he would ''not contest the suspension of his DEA registration.'' [2] RFAAX 4, at 3–5. On October 7, 2024, Respondent filed a motion to terminate proceedings based on his voluntary withdrawal of the request for a hearing. RFAAX 4, at 1. On the same day, the ALJ granted the motion to terminate proceedings and canceled the hearing. RFAAX 5. After the ALJ terminated the proceedings, the Government requested final agency action based on Respondent's default pursuant to 21 CFR 1301.43(c), (f). RFAA, at 1–10.

Pursuant to 21 CFR 3101.43(e), ''[a] default, unless excused, shall be deemed to constitute a waiver of the registrant's/applicant's right to a hearing and an admission of the factual allegations of the [OSC].'' Further, ''[i]n the event that a [registrant/applicant] . . . is deemed to be in default . . . DEA may then file a request for final agency action with the Administrator, along with a record to support its request. In such circumstances, the Administrator may enter a default final order pursuant to [21 CFR] § 1316.67.'' *Id.* 1301.43(f)(1). In this case, the Agency finds that Respondent's voluntary withdrawal of the request for a hearing constitutes a default.[3] *See Salman Akbar, M.D.,* 89 FR 82259 (2024) (finding that a voluntary withdrawal of a hearing request displayed a failure to defend one's case and therefore the respondent was deemed to be in default). Accordingly, in light of Respondent's default, the Agency finds that the factual allegations in the OSC/ISO are deemed admitted.

II. Applicable Law

The OSC/ISO alleges that Respondent violated multiple provisions of the Controlled Substances Act (CSA) and its implementing regulations. As the Supreme Court stated in *Gonzales* v. *Raich,* the ''main objectives of the CSA were to conquer drug abuse and to control the legitimate and illegitimate traffic in controlled substances. Congress was particularly concerned with the need to prevent the diversion of drugs from legitimate to illicit channels.'' 545 U.S. 1, at 12–13 (2005). The Supreme Court further explained that, to accomplish its objectives, ''Congress devised a closed regulatory system making it unlawful to . . . dispense[ ] or possess any controlled substance except in a manner authorized by the CSA.'' *Id.* at 13. Accordingly, the Supreme Court stated, the ''CSA and its implementing regulations set forth strict requirements regarding registration, . . . drug security, and recordkeeping.'' *Id.* at 14.

The OSC/ISO's allegations concern the CSA's ''statutory and regulatory provisions . . . mandating . . . compliance with . . . prescription requirements'' and, therefore, go to the heart of the CSA's ''closed regulatory system'' specifically designed ''to conquer drug abuse and to control the legitimate and illegitimate traffic in controlled substances,'' and ''to prevent the diversion of drugs from legitimate to illicit channels.'' *Id.* at 12–14, 27.

A. The Allegation That Respondent Materially Falsified His DEA Application

The OSC/ISO alleges that Respondent materially falsified his May 6, 2022, application to renew his DEA registration. RFAAX 1, at 4. Pursuant to the CSA, the Attorney General is authorized to suspend or revoke a registration ''upon a finding that the registrant . . . has materially falsified any application filed pursuant to or required by this subchapter.'' 21 U.S.C. 824(a)(1); *see* RFAAX 1, at 4.

B. The Allegation That Respondent Issued Prescriptions Outside the Usual Course of Professional Practice

The OSC/ISO also alleges that Respondent improperly issued controlled substance prescriptions to an undercover law enforcement officer and

[1] Based on the Government's submissions in its RFAA, the Agency finds that service of the OSC/ISO on Respondent was adequate. According to the Notice of Service of Order to Show Cause and Immediate Suspension Order, Respondent was personally served with the OSC/ISO on September 10, 2024. RFAAX 2, at 1.

[2] In the letter, Respondent asserted that on September 11, 2024, he submitted an Answer ''with a categorical denial of the factual allegations contained in the OSC/ISO'' and that he ''st[ood] by his earlier denial of the factual allegations.'' RFAAX 4, at 3–4. However, DEA's rules do not permit ''categorical denials.'' 21 CFR 1301.37(d)(3). Instead, ''[f]or each factual allegation in the order to show cause, the answer shall specifically admit, deny, or state that the party does not have and it unable to obtain sufficient information to admit or deny the allegation in the ISO/OSC.'' *Id.* Respondent admitted that he did not specifically address the allegations in the OSC/ISO, and therefore, Respondent's purported ''Answer'' was not an answer filed in compliance with the rules. *See* RFAAX 4, at 3–4; 21 CFR 1301.37 (d)(3).

[3] Respondent stated that he wished to ''waiv[e] his right to a hearing[] without any admission of guilt.'' RFAAX 4, at 4. While Respondent's waiver does not result in an admission that he is ''guilty'' of violating the Controlled Substances Act, it does result in ''an admission of the factual allegations of the order to show cause.'' 21 CFR 1301.43(e).