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

SUPPLEMENTARY INFORMATION: In accordance with 21 CFR 1301.34(a), this is notice that on July 11, 2025, Bright Green Corporation, 1033 George Hanosh Boulevard, Grants, New Mexico 87020, applied to be registered as an importer of the following basic class(es) of controlled substance(s):

Controlled substance	Drug code	Schedule
Opium, raw	9600	II
Poppy Straw	9650	II
Poppy Straw Concentrate.	9670	II

The company plans to import the listed controlled substances in bulk form to establish domestic manufacturing (growing) of poppies to supply other DEA-registered manufacturers to produce Active Pharmaceutical Ingredients. 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 W. Prevoznik,

Deputy Assistant Administrator.

[FR Doc. 2025–23468 Filed 12–18–25; 8:45 am]

BILLING CODE P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. DEA–1635]

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

AGENCY: Drug Enforcement Administration, Justice.

ACTION: Notice of application.

SUMMARY: Janssen 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 February 17, 2026. Such persons may also file a written request for a hearing on the application on or before February 17, 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 November 7, 2025, Janssen Pharmaceuticals, Inc., 1440 Olympic Drive, Buildings 1–5 and 7–14, Athens, Georgia 30601–1645, applied to be registered as a bulk manufacturer of the following basic class(es) of controlled substance(s):

Controlled substance	Drug code	Schedule
Methylphenidate	1724	II

The company plans to manufacture the listed controlled substance for sale to its customers. No other activity for this drug code is authorized for this registration.

Thomas Prevoznik,

Deputy Assistant Administrator.

[FR Doc. 2025–23467 Filed 12–18–25; 8:45 am]

BILLING CODE P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. DEA–1634]

Importer of Controlled Substances Application: Groff Health Inc.

AGENCY: Drug Enforcement Administration, Justice.

ACTION: Notice of application.

SUMMARY: Groff Health 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 January 20, 2026. Such persons may also file a written request for a hearing on the application on or before January 20, 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 Morrissette Drive, Springfield, Virginia 22152; and (2) Drug Enforcement Administration, Attn: DEA **Federal Register** Representative/DPW, 8701 Morrissette Drive, Springfield, Virginia 22152. All requests for a hearing should also be sent to: Drug Enforcement Administration, Attn: Administrator, 8701 Morrissette Drive, Springfield, Virginia 22152.

SUPPLEMENTARY INFORMATION: In accordance with 21 CFR 1301.34(a), this is notice that on November 7, 2025, Groff Health Inc., 2218 South Queen Street, York, Pennsylvania 17402, applied to be registered as an importer of the following basic class(es) of controlled substance(s):

Controlled substance	Drug code	Schedule
Psilocybin	7437	I
Psilocyn	7438	I

The company plans to import bulk substances to support internal research, clinical trials, analytical purposes, and distribution to their customers. 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. 2025–23466 Filed 12–18–25; 8:45 am]

BILLING CODE P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

Timothy Balisky, N.P.; Decision and Order

On July 28, 2025, the Drug Enforcement Administration (DEA or Government) issued an Order to Show Cause (OSC) to Timothy Balisky, N.P., of Huntersville, North Carolina (Registrant). Request for Final Agency Action (RFAA), Exhibit (RFAAX) 1 at 1, 4. The OSC proposed the revocation of Registrant's Certificate of Registration, No. MB7242352, alleging that Registrant's registration should be revoked because Registrant is ''currently without authority to prescribe, administer, dispense, or otherwise handle controlled substances in the State of North Carolina, the state in which [he is] registered with DEA.'' *Id.* at 2 (citing 21 U.S.C. 824(a)(3)).[1]

The OSC notified Registrant of his right to file a written request for hearing, and that if he failed to file such a request, he would be deemed to have waived his right to a hearing and be in default. *Id.* at 2–3 (citing 21 CFR 1301.43). Here, Registrant did not request a hearing, and the Agency finds him to be in default. RFAA, at 2–3.[2] ''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].'' 21 CFR 1301.43(e).

Further, ''[i]n the event that a registrant . . . 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). Here, the Government has requested final agency action based on Registrant's default pursuant to 21 CFR 1301.43(c), (f), 1301.46. RFAA, at 1; *see also* 21 CFR 1316.67.

Findings of Fact

The Agency finds that, in light of Registrant's default, the factual allegations in the OSC are deemed admitted. According to the OSC, effective May 13, 2025, the North Carolina State Board of Nursing issued an Order of Summary Suspension, suspending Registrant from the practice of nursing in North Carolina. RFAAX 1, at 2. According to North Carolina online records, of which the Agency takes official notice,[3] the current status of Registrant's North Carolina nurse practitioner license is ''No License due to Discipline.'' North Carolina Board of Nursing License Verification, *https://portal.ncbon.com/licenseverification/search.aspx* (last visited date of signature of this Order). Accordingly, the Agency finds that Registrant is not licensed as a nurse practitioner in North Carolina, the state in which he is registered with DEA.[4]

Discussion

Pursuant to 21 U.S.C. 824(a)(3), the Attorney General is authorized to suspend or revoke a registration issued under 21 U.S.C. 823 ''upon a finding that the registrant . . . has had his State license or registration suspended . . . [or] revoked . . . by competent State authority and is no longer authorized by State law to engage in the . . . dispensing of controlled substances.'' With respect to a practitioner, DEA has also long held that the possession of authority to dispense controlled substances under the laws of the state in which a practitioner engages in professional practice is a fundamental condition for obtaining and maintaining a practitioner's registration. *Gonzales* v. *Oregon,* 546 U.S. 243, 270 (2006) (''The Attorney General can register a physician to dispense controlled substances 'if the applicant is authorized to dispense . . . controlled substances under the laws of the State in which he practices.' . . . The very definition of a 'practitioner' eligible to prescribe includes physicians 'licensed, registered, or otherwise permitted, by the United States or the jurisdiction in which he practices' to dispense controlled substances. 802(21).''). The Agency has applied these principles consistently. *See, e.g., James L. Hooper, M.D.,* 76 FR 71371, 71372 (2011), *pet. for rev. denied,* 481 F. App'x 826 (4th Cir. 2012); *Frederick Marsh Blanton, M.D.,* 43 FR 27616, 27617 (1978).[5]

[1] According to the OSC and Agency records, Registrant's registration expired on July 31, 2025. RFAAX 1, at 2. The fact that a registrant allows his registration to expire during the pendency of an administrative enforcement proceeding does not impact the Agency's jurisdiction or prerogative under the Controlled Substances Act (CSA) to adjudicate the OSC to finality. *Jeffrey D. Olsen, M.D.,* 84 FR 68474, 68476–79 (2019).

[2] Based on the Government's submissions in its RFAA dated September 9, 2025, the Agency finds that service of the OSC on Registrant was adequate. Specifically, the Government's Declaration from a DEA Diversion Investigator (DI) indicates that on July 29, 2025, Registrant was personally served with a copy of the OSC. RFAAX 2, at 1; *see also id.* at 3 (Form-DEA 12 signed by Registrant, acknowledging receipt of the OSC).

[3] Under the Administrative Procedure Act, an agency ''may take official notice of facts at any stage in a proceeding—even in the final decision.'' United States Department of Justice, Attorney General's Manual on the Administrative Procedure Act 80 (1947) (Wm. W. Gaunt & Sons, Inc., Reprint 1979).

[4] Pursuant to 5 U.S.C. 556(e), ''[w]hen an agency decision rests on official notice of a material fact not appearing in the evidence in the record, a party is entitled, on timely request, to an opportunity to show the contrary.'' The material fact here is that Registrant, as of the date of this decision, is not licensed as a nurse practitioner in North Carolina. Accordingly, Registrant may dispute the Agency's finding by filing a properly supported motion for reconsideration of findings of fact within fifteen calendar days of the date of this Order. Any such motion and response shall be filed and served by email to the other party and to the DEA Office of the Administrator, Drug Enforcement Administration at *dea.addo.attorneys@dea.gov.*

[5] This rule derives from the text of two provisions of the CSA. First, Congress defined the term ''practitioner'' to mean ''a physician . . . or other person licensed, registered, or otherwise permitted, by . . . the jurisdiction in which he practices . . . , to distribute, dispense, . . . [or] administer . . . a controlled substance in the course of professional practice.'' 21 U.S.C. 802(21). Second, in setting the requirements for obtaining a practitioner's registration, Congress directed that ''[t]he Attorney General shall register practitioners . . . if the applicant is authorized to dispense . . . controlled substances under the laws of the State in which he practices.'' 21 U.S.C. 823(g)(1). Because Congress has clearly mandated that a practitioner possess state authority in order to be deemed a practitioner under the CSA, DEA has held repeatedly that revocation of a practitioner's registration is the