

activity for this drug code is 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.

Matthew J. Strait,

Deputy Assistant Administrator.

[FR Doc. 2022-04806 Filed 3-7-22; 8:45 am]

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DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. DEA-961]

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 April 7, 2022. Such persons may also file a written request for a hearing on the application on or before April 7, 2022.

ADDRESSES: The DEA 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 January 6, 2022, ANI Pharmaceuticals Inc., 70 Lake Drive, East Windsor, New Jersey 08520, 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
Levorphanol	9220	II

The substance Levorphanol (9220) will be used to manufacture the Food and Drug Administration-approved dosage forms for distribution in the United States. The substance Psilocybin (7437) will be used to support formulation development and clinical trial research. No other activity 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 Drug Administration-approved or non-approved finished dosage forms for commercial sale.

Matthew J. Strait,

Deputy Assistant Administrator.

[FR Doc. 2022-04803 Filed 3-7-22; 8:45 am]

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DEPARTMENT OF JUSTICE

[OMB Number 1117-0006]

Agency Information Collection Activities; Proposed eCollection, eComments Requested; Extension Without Change of a Previously Approved Collection; Application for Individual Manufacturing Quota for a Basic Class of Controlled Substance and for Ephedrine, Pseudoephedrine, and Phenylpropanolamine; DEA Form 189

AGENCY: Drug Enforcement Administration, Department of Justice.

ACTION: 60-Day notice.

SUMMARY: The Department of Justice, Drug Enforcement Administration (DEA), will be submitting the following information collection request to the

Office of Management and Budget for review and approval in accordance with the Paperwork Reduction Act of 1995. This information collection is also associated with the proposed rulemaking "Management of Quotas for Controlled Substances and List I Chemicals." It is likely that the final rule will not be published before this information collection expires on June 30, 2022. If the final rule does publish prior to the expiration, it will be published as the 30-Day Notice.

DATES: Comments are encouraged and will be accepted for 60 days until May 9, 2022.

FOR FURTHER INFORMATION CONTACT: If you have comments, especially on the estimated public burden or associated response time, suggestions, or need a copy of the proposed information collection instrument with instructions or additional information, please contact Scott A. Brinks, Regulatory Drafting and Policy Support Section (DPW), Diversion Control Division, Drug Enforcement Administration; Mailing Address: 8701 Morrisette Drive, Springfield, Virginia 22152; Telephone: (571) 776-2265.

SUPPLEMENTARY INFORMATION: Written comments and suggestions from the public and affected agencies concerning the proposed collection of information are encouraged. Your comments should address one or more of the following four points:

- Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;
- Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;
- Evaluate whether and if so how the quality, utility, and clarity of the information proposed to be collected can be enhanced; and
- Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, e.g., permitting electronic submission of responses.

Overview of This Information Collection

1. *Type of Information Collection:* Extension of a currently approved collection.

2. *Title of the Form/Collection:* Application for Individual Manufacturing Quota for a Basic Class of Controlled Substance and for Ephedrine, Pseudoephedrine, and Phenylpropanolamine.

3. *The agency form number, if any, and the applicable component of the Department sponsoring the collection:* DEA Form 189. The applicable component within the Department of Justice is the Drug Enforcement Administration, Diversion Control Division.

4. *Affected public who will be asked or required to respond, as well as a brief abstract:*

Affected public (Primary): Business or other for-profit.

Affected public (Other): None.

Abstract: Pursuant to 21 U.S.C. 826(c) and 21 CFR 1303.22 and 1315.22, any person who is registered to manufacture any basic class of controlled substances listed in Schedule I or II, or the List I chemicals ephedrine, pseudoephedrine, or phenylpropanolamine, and who desires to manufacture a quantity of such class or such List I chemical, must apply on DEA Form 189 for a manufacturing quota for such quantity of such class or List I chemical.

5. *An estimate of the total number of respondents and the amount of time estimated for an average respondent to respond:* The DEA estimates 33 respondents complete 859 DEA Form 189 applications annually, and that each form takes 0.5 hours to complete.

6. *An estimate of the total public burden (in hours) associated with the proposed collection:* The DEA estimates this collection takes a total of 430 annual burden hours.

If additional information is required, please contact: Melody Braswell, Department Clearance Officer, United States Department of Justice, Justice Management Division, Policy and Planning Staff, Two Constitution Square, 145 N Street NE, Suite 3E.405B, Washington, DC 20530.

Dated: March 2, 2022.

Melody Braswell,

Department Clearance Officer for PRA, U.S. Department of Justice.

[FR Doc. 2022-04786 Filed 3-7-22; 8:45 am]

BILLING CODE 4410-09-P

DEPARTMENT OF JUSTICE

[OMB Number 1117-0008]

Agency Information Collection Activities; Proposed eCollection, eComments Requested; Extension Without Change of a Previously Approved Collection; Application for Procurement Quota for Controlled Substance and for Ephedrine, Pseudoephedrine, and Phenylpropanolamine; DEA Form 250

AGENCY: Drug Enforcement Administration, Department of Justice.

ACTION: 60-Day notice.

SUMMARY: The Department of Justice, Drug Enforcement Administration (DEA), will be submitting the following information collection request to the Office of Management and Budget for review and approval in accordance with the Paperwork Reduction Act of 1995. This information collection is also associated with the proposed rulemaking “Management of Quotas for Controlled Substances and List I Chemicals,” published in the **Federal Register**. It is likely that the final rule will not be published before this information collection expires on June 30, 2022. If the final rule does publish prior to the expiration, it will be published as the 30-Day Notice.

DATES: Comments are encouraged and will be accepted for 60 days until May 9, 2022.

FOR FURTHER INFORMATION CONTACT: If you have comments, especially on the estimated public burden or associated response time, suggestions, or need a copy of the proposed information collection instrument with instructions or additional information, please contact Scott A. Brinks, Regulatory Drafting and Policy Support Section (DPW), Diversion Control Division, Drug Enforcement Administration; Mailing Address: 8701 Morrisette Drive, Springfield, Virginia 22152; Telephone: (571) 776-2265.

SUPPLEMENTARY INFORMATION: Written comments and suggestions from the public and affected agencies concerning the proposed collection of information are encouraged. Your comments should address one or more of the following four points:

- Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;
- Evaluate the accuracy of the agency’s estimate of the burden of the proposed collection of information,

- including the validity of the methodology and assumptions used;
- Evaluate whether and if so how the quality, utility, and clarity of the information proposed to be collected can be enhanced; and
- Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, e.g., permitting electronic submission of responses.

Overview of This information Collection

1. *Type of Information Collection:* Extension of a currently approved collection.

2. *Title of the Form/Collection:* Application for Procurement Quota for Controlled Substance and for Ephedrine, Pseudoephedrine, and Phenylpropanolamine.

3. *The agency form number, if any, and the applicable component of the Department sponsoring the collection:* DEA Form 250. The applicable component within the Department of Justice is the Drug Enforcement Administration, Diversion Control Division.

4. *Affected public who will be asked or required to respond, as well as a brief abstract:*

Affected public (Primary): Business or other for-profit.

Affected public (Other): None.

Abstract: Pursuant to 21 U.S.C. 826 and 21 CFR 1303.12(b) and 1315.32, any person who desires to use, during the next calendar year, any basic class of controlled substances listed in schedules I or II, or the List I chemicals ephedrine, pseudoephedrine, or phenylpropanolamine for purposes of manufacturing must apply on DEA Form 250 for a procurement quota for such class or List I chemical.

5. *An estimate of the total number of respondents and the amount of time estimated for an average respondent to respond:* The DEA estimates 344 respondents complete 3,066 DEA Form 250 applications annually, and that each form requires 0.5 hours to complete.

6. *An estimate of the total public burden (in hours) associated with the proposed collection:* The DEA estimates this collection takes a total of 1,533 annual burden hours.

If additional information is required, please contact: Melody Braswell, Department Clearance Officer, United States Department of Justice, Justice Management Division, Policy and Planning Staff, Two Constitution