

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. DEA-1266]

Importer of Controlled Substances Application: Benuvia Operations, LLC

AGENCY: Drug Enforcement Administration, Justice.

ACTION: Notice of application.

SUMMARY: Benuvia Operations, LLC 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 October 16, 2023. Such persons may also file a written request for a hearing on the application on or before October 16, 2023.

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 August 10, 2023, Benuvia Operations, LLC, 3950 North Mays Street, Round Rock, Texas 78665-2729, applied to be registered as an importer of the following basic class(es) of controlled substance(s):

Controlled substance	Drug code	Schedule
Ibogaine	7260	I
Tetrahydrocannabinols	7370	I
Mescaline	7381	I
3,4-Methylenedioxyamphetamine	7400	I
3,4-Methylenedioxymethamphetamine	7405	I
5-Methoxy-N,N-dimethyltryptamine	7431	I
Dimethyltryptamine	7435	I
Psilocybin	7437	I
Psilocyn	7438	I
5-Methoxy-N,N-diisopropyltryptamine	7439	I
Dronabinol in an oral solution in a drug product approved for marketing by the U.S. Food and Drug Administration	7365	II

The company plans to import the listed controlled substances for clinical trial manufacturing and analytical 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.

Claude Redd,

Acting Deputy Assistant Administrator.
[FR Doc. 2023-19998 Filed 9-14-23; 8:45 am]

BILLING CODE P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. DEA-1248]

Bulk Manufacturer of Controlled Substances Application: PCI Synthesis

AGENCY: Drug Enforcement Administration, Justice.

ACTION: Notice of application.

SUMMARY: PCI Synthesis 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 November 14, 2023. Such persons may also file a written request for a hearing on the application on or before November 14, 2023.

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 March 30, 2023, PCI Synthesis, 9 Opportunity Way, Newburyport, Massachusetts 01950-0195, applied to be registered as a bulk manufacturer of the following basic class(es) of controlled substance(s):

Controlled substance	Drug code	Schedule
Amphetamine	1100	II

Controlled substance	Drug code	Schedule
Methamphetamine	1105	II

The company plans to develop manufacturing processes, conduct analytical method validation and conduct bulk product stability studies. No other activities for these drug codes are authorized for this registration.

Claude Redd,

Acting Deputy Assistant Administrator.

[FR Doc. 2023–19989 Filed 9–14–23; 8:45 am]

BILLING CODE P

DEPARTMENT OF JUSTICE

[OMB Number 1140–0017]

Agency Information Collection Activities; Proposed eCollection eComments Requested; Annual Firearms Manufacturing and Exportation Report (AFMER)

AGENCY: Bureau of Alcohol, Tobacco, Firearms and Explosives, Department of Justice.

ACTION: 30-Day notice.

SUMMARY: The Bureau of Alcohol, Tobacco, Firearms and Explosives (ATF), Department of Justice (DOJ), will be submitting the following information collection request to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act of 1995. The proposed information collection was previously published in the **Federal Register**, on July 6, 2023, allowing a 60-day comment period.

DATES: Comments are encouraged and will be accepted for 30 days until October 16, 2023.

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: Leslie Anderson, by email at Leslie.anderson@atf.gov, or by telephone at 301–616–4634.

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;
- Enhance the quality, utility, and clarity of the information to be collected; and/or
- 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.

Written comments and recommendations for this information collection should be submitted within 30 days of the publication of this notice on the following website www.reginfo.gov/public/do/PRAMain. Find this particular information collection by selecting “Currently under 30-day Review—Open for Public Comments” or by using the search function and entering either the title of the information collection or the OMB Control Number 1140–0017. This information collection request may be viewed at www.reginfo.gov. Follow the instructions to view Department of Justice, information collections currently under review by OMB.

DOJ seeks PRA authorization for this information collection for three (3) years. OMB authorization for an ICR cannot be for more than three (3) years without renewal. The DOJ notes that information collection requirements submitted to the OMB for existing ICRs receive a month-to-month extension while they undergo review.

Overview of This Information Collection

1. *Type of Information Collection:* Revision of a previously approved collection.

2. *Title of the Form/Collection:* Annual Firearms Manufacturing and Exportation Report (AFMER).

3. *Agency form number, if any, and the applicable component of the Department of Justice sponsoring the collection:* ATF Form 5300.11.

Component: Bureau of Alcohol, Tobacco, Firearms and Explosives, U.S. Department of Justice.

4. *Affected public who will be asked or required to respond, as well as a brief abstract:* Private Sector—Businesses or other for-profit.

Abstract: The information collected is used to compile statistics on the

manufacture and exportation of firearms. The furnishing of this information is mandatory under 18 U.S.C. 923(g)(5)(A). This form must be submitted annually for every Type 07 and Type 10 Federal Firearms Licensees (FFLs), even if no firearms were exported or distributed into commerce. The information collection (IC) OMB #1140–0017 is being revised due to material and non-material changes to the form, such as added instructions, definitions, formatting changes (to adjust form length), bolded lines (to fillable boxes), grammatical changes (sentence rephrasing/statement modification), and instruction clarification.

5. *Obligation to Respond:* Mandatory. The statutory requirements are implemented under 18 U.S.C. chapter 44.

6. *Total Estimated Number of Respondents:* 19,200 respondents.

7. *Estimated Time per Respondent:* 20 minutes.

8. *Frequency:* Once annually.

9. *Total Estimated Annual Time Burden:* 6,400 hours.

10. *Total Estimated Annual Other Costs Burden:* No new cost is associated with this collection. All respondents can electronically submit the AFMER to ATF free of charge, however, it is estimated that half the respondents submit the form to the Federal Firearms Licensing Center by mail. The annual cost has increased due to a change in the postal rate from \$0.55 during the last renewal in 2020, to \$0.63 in 2023. Consequently, the new public cost burden will be reported as \$6,048.00, which is equal to \$0.63 (mailing cost per respondent) * 19,200 (# of respondents) * 50% (percentage of responses submitted by mail).

If additional information is required, contact: Darwin Arceo, Department Clearance Officer, Policy and Planning Staff, Justice Management Division, United States Department of Justice, Two Constitution Square, 145 N Street NE, 4W–218 Washington, DC 20530.

Dated: September 11, 2023.

Darwin Arceo,

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

[FR Doc. 2023–19941 Filed 9–14–23; 8:45 am]

BILLING CODE 4410–14–P