

Controlled substance	Drug code	Schedule
Diphenoxylate .....	9170	II
Levomethorphan .....	9210	II
Levorphanol .....	9220	II
Meperidine .....	9230	II
Dextropropoxyphene, bulk (non-dosage forms) .....	9273	II
Thebaine .....	9333	II
Oxymorphone .....	9652	II
Noroxymorphone .....	9668	II
Alfentanil .....	9737	II
Sufentanil .....	9740	II

The company plans to import the bulk control substances for distribution as analytical reference standards to its customers for analytical testing of raw materials. 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.

**Matthew Strait,**  
Deputy Assistant Administrator.  
[FR Doc. 2023-11166 Filed 5-24-23; 8:45 am]  
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**DEPARTMENT OF JUSTICE**

**Drug Enforcement Administration**

[Docket No. DEA-1198]

**Importer of Controlled Substances Application: Almac Clinical Services Incorp. (ACSI)**

**AGENCY:** Drug Enforcement Administration, Justice.

**ACTION:** Notice of application.

**SUMMARY:** Almac Clinical Services Incorp (ACSI) 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 26, 2023. Such persons may also file a written request for a hearing on the application on or before June 26, 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 May 1, 2023, Almac Clinical Services Incorp (ACSI), 25 Fretz Road, Souderton, Pennsylvania 18964, 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
Oxycodone .....	9143	II
Hydromorphone .....	9150	II
Morphine .....	9300	II
Tapentadol .....	9780	II
Fentanyl .....	9801	II

The company plans to import the listed controlled substances as finished dosage form units for clinical trials purposes only. 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.

**Matthew Strait,**  
Deputy Assistant Administrator.  
[FR Doc. 2023-11173 Filed 5-24-23; 8:45 am]  
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**DEPARTMENT OF JUSTICE**

**Drug Enforcement Administration**

[Docket No. 22-11]

**Gary Gray d/b/a Complex; Decision and Order**

On November 22, 2021, the Drug Enforcement Administration (DEA or the Agency) issued an Order to Show Cause (OSC) to Gary Gray d/b/a Complex (hereinafter, the Respondent) seeking to deny Respondent's application for a DEA Certificate of Registration to manufacture marijuana, Control No. W14063382E. OSC, at 1.

After a hearing, the Chief Administrative Law Judge (Chief ALJ) issued his Recommended Rulings, Findings of Law, and Decision of the Administrative Law Judge (Recommended Decision or RD), which recommended Respondent's application for a manufacturing registration be denied because "the plain language of the controlling regulations compels the denial of the present application as a matter of law." RD, at 2, 11. The Agency agrees with the Chief ALJ's recommendation, and, for the reasons explained below, denies Respondent's application as inconsistent with the public interest under 21 U.S.C. 823(a).<sup>1</sup>

<sup>1</sup> Effective December 2, 2022, the Medical Marijuana and Cannabidiol Research Expansion Act, Public Law 117-215, 136 Stat. 2257 (2022) (Marijuana Research Amendments or MRA), amended the Controlled Substances Act (CSA) and

## I. Findings of Fact

On July 30, 2014, Respondent filed an application with DEA to bulk manufacture Schedule I controlled substances. Government Exhibit (GX) 1. According to Respondent, he is seeking to obtain DEA registration as a bulk manufacturer of marihuana “so that he may cultivate, harvest, and package the particular strains of marihuana required for his research and product development purposes.” Resp Posthearing, at 4; Tr. 30. Respondent hopes to ultimately produce products that will treat Alzheimer’s and other degenerative diseases. Tr. 30, 49.

Respondent is a pharmacist and has possessed, and operated under, pharmacy controlled substance registrations, as well as having held multiple state pharmacy licenses for over 50 years. Tr. 58–61. It is undisputed, however, that Respondent does not currently hold any type of DEA controlled substance registration, and at the onset of the hearing, a certification of Respondent’s lack of DEA registration as a schedule 1 researcher was admitted into the record without objection. Tr. 18; GX 1, at 2.

## II. Discussion

The Controlled Substances Act (CSA) states that the Agency shall register an applicant to manufacture controlled substances in schedule I or II if such registration is determined to be “consistent with the public interest and with United States obligations under international treaties, conventions, or protocols in effect on May 1, 1971.” 21 U.S.C. 823(a). The CSA provides six factors DEA must consider in determining the public interest. *Id.* 21 CFR 1318.05, which implements the requirements of § 823(a) for marihuana growers and manufacturers, further provides that the Agency shall place “particular emphasis” on certain enumerated criteria in determining the public interest.

In situations, such as here, where “an applicant seeks registration to grow cannabis for its own research or product development” one of the criteria of “particular emphasis” is that “the applicant *must possess* registration as a schedule I researcher with respect to marihuana under § 1301.31 of this chapter.” 21 CFR 1318.05(b)(3)(ii) (emphasis added). It is undisputed that Respondent does not possess a DEA schedule I researcher registration under § 1301.31. Tr. 19; Respondent’s Exceptions, at 3. Accordingly, under the plain language of the regulation,

other statutes; however, the relevant provision here, 21 U.S.C. 823(a), remained the same.

Respondent does not meet the criteria to receive the manufacturer registration for which he has applied, and the Agency finds that granting his application for a registration would not be consistent with the public interest under § 823(a).<sup>2</sup>

### Order

Pursuant to 28 CFR 0.100(b) and the authority vested in me by 21 U.S.C. 823(a), I hereby deny DEA registration application No. W14063382E submitted by Gary Gray d/b/a/Complex. This Order is effective June 26, 2023.

### Signing Authority

This document of the Drug Enforcement Administration was signed on May 16, 2023, by Administrator Anne Milgram. That document with the original signature and date is maintained by DEA. For administrative purposes only, and in compliance with requirements of the Office of the Federal Register, the undersigned DEA Federal Register Liaison Officer has been authorized to sign and submit the document in electronic format for publication, as an official document of DEA. This administrative process in no way alters the legal effect of this document upon publication in the **Federal Register**.

#### Heather Achbach,

*Federal Register Liaison Officer, Drug Enforcement Administration.*

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<sup>2</sup> Respondent filed Exceptions to the Chief ALJ’s Recommended Decision arguing that he is eligible for a manufacturer registration because he applied for the requisite researcher registration in June 2022 and that application is pending with DEA. Respondent’s Exceptions, at 4. Respondent’s argument is unpersuasive as the regulations clearly state that an applicant must *currently* possess a researcher registration, not just have submitted an application for one. (Respondent’s application for a researcher registration is also not in the record under consideration for this matter as, based on a declaration from Respondent’s counsel, it was submitted after the Chief ALJ had transferred the certified record for this matter to the DEA Administrator). Respondent requests, in the alternative, that any action on the instant application be stayed pending action on his application for registration as a schedule 1 researcher. *Id.* at 6–7. Respondent’s request is denied. Respondent may submit a new application for a manufacturer registration and that application will be evaluated on its merits.

## DEPARTMENT OF LABOR

### Agency Information Collection Activities; Submission for OMB Review; Comment Request; Request for State or Federal Workers’ Compensation Information

**ACTION:** Notice of availability; request for comments.

**SUMMARY:** The Department of Labor (DOL) is submitting this Office of Workers’ Compensation Programs (OWCP)-sponsored information collection request (ICR) to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act of 1995 (PRA). Public comments on the ICR are invited.

**DATES:** The OMB will consider all written comments that the agency receives on or before June 26, 2023.

**ADDRESSES:** Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to [www.reginfo.gov/public/do/PRAMain](http://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.

*Comments are invited on:* (1) whether the collection of information is necessary for the proper performance of the functions of the Department, including whether the information will have practical utility; (2) the accuracy of the agency’s estimates of the burden and cost of the collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility and clarity of the information collection; and (4) ways to minimize the burden of the collection of information on those who are to respond, including the use of automated collection techniques or other forms of information technology.

**FOR FURTHER INFORMATION CONTACT:** Nicole Bouchet by telephone at 202–693–0213, or by email at [DOL\\_PRA\\_PUBLIC@dol.gov](mailto:DOL_PRA_PUBLIC@dol.gov).

**SUPPLEMENTARY INFORMATION:** The OWCP Form CM–981 is completed by a school official to verify whether a Black Lung beneficiary’s dependent, aged 18 to 23, qualifies as a full-time student. For additional substantive information about this ICR, see the related notice published in the **Federal Register** on January 31, 2022 (88 FR 6314).

This information collection is subject to the PRA. A Federal agency generally cannot conduct or sponsor a collection of information, and the public is