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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 marihuana, 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).[1]

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.

[1] Effective December 2, 2022, the Medical Marijuana and Cannabidiol Research Expansion Act, Pub. L. No. 117-215, 136 Stat. 2257 (2022) (Marijuana Research Amendments or MRA), amended the Controlled Substances Act (CSA) and other statutes; however, the relevant provision here, 21 U.S.C. 823(a), remained the same.

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, 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).[2]

[2] 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

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 **[INSERT DATE 30 DAYS FROM THE DATE OF PUBLICATION IN THE FEDERAL REGISTER]**.

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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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.