

collection: The estimated annual public burden associated with this collection is 540 hours, which is equal to 300 (# of respondents) * 1 (# of responses per respondents) * 1.8 (1 hour and 48 minutes).

If additional information is required 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, 3E.405A, Washington, DC 20530.

Dated: October 6, 2020.

Melody Braswell,

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

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DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. DEA-720]

Bulk Manufacturer of Controlled Substances Application: Purisys, LLC

AGENCY: Drug Enforcement Administration, Justice.

ACTION: Notice of application.

SUMMARY: Purisys, LLC has applied to be registered as a bulk manufacturer of basic class(es) of controlled substance(s). Refer to Supplemental Information listed below for further drug information.

DATES: Registered bulk manufacturers of the affected basic class(es), and applicants therefore, may file written comments on or objections to the issuance of the proposed registration on or before December 8, 2020. Such persons may also file a written request for a hearing on the application on or before December 8, 2020.

ADDRESSES: Written comments should be sent to: Drug Enforcement Administration, Attention: DEA Federal Register Representative/DPW, 8701 Morrisette Drive, Springfield, Virginia 22152.

SUPPLEMENTARY INFORMATION: In accordance with 21 CFR 1301.33(a), this is notice that on August 27, 2020, Purisys, LLC, 1550 Olympic Drive, Athens, Georgia 30601-1602, applied to be registered as an bulk manufacturer of the following basic class(es) of controlled substances:

Controlled substance	Drug code	Schedule
5-Methoxy-N-N-dimethyltryptamine.	7431	I
Norlevorphanol	9634	I

The company plans to manufacture the above-listed controlled substances as clinical trial and starting materials to make compounds for distribution to its customers. No other activity for these drug codes is authorized for this registration.

William T. McDermott,

Assistant Administrator.

[FR Doc. 2020-22442 Filed 10-8-20; 8:45 am]

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DEPARTMENT OF JUSTICE

Drug Enforcement Administration

Steven A. Holper, M.D.; Decision and Order

On October 22, 2019, the Acting Assistant Administrator, Diversion Control Division, Drug Enforcement Administration (hereinafter, Government or DEA), issued an Order to Show Cause (hereinafter, OSC) to Steven A. Holper, M.D., (hereinafter, Registrant), of Las Vegas, Nevada. Government's Request for Final Agency Action Exhibit (hereinafter, RFAAX) 5 (OSC), at 1. The OSC proposed the revocation of Registrant's Certificate of Registration No. BH2498106. It alleged that Registrant is without "authority to handle controlled substances in Nevada, the state in which [Registrant is] registered with the DEA." *Id.* (citing 21 U.S.C. 823(f) and 824(a)(3)).

Specifically, the OSC alleged that Registrant's state controlled substance license expired on October 21, 2018. *Id.* at 1-2. The OSC also alleged that Registrant's state medical license was revoked by the Board of Medical Examiners of the State of Nevada on September 6, 2019. *Id.* at 2. The OSC further alleged that Registrant is not eligible to obtain or retain a DEA registration because he lacks state authority to handle controlled substances in the state of Nevada. *Id.*

The OSC notified Registrant of the right to either request a hearing on the allegations or submit a written statement in lieu of exercising the right to a hearing, the procedures for electing each option, and the consequences for failing to elect either option. *Id.* (citing 21 CFR 1301.43). The OSC also notified Registrant of the opportunity to submit

a corrective action plan. *Id.* at 3 (citing 21 U.S.C. 824(c)(2)(C)).

A DEA Diversion Investigator personally served Registrant with the OSC on December 16, 2019. RFAAX 12, at 2-3 (Declaration of Diversion Investigator One). I find that more than thirty days have now passed since the Government accomplished service of the OSC. Further, based on the Government's written representations, I find that neither Registrant, nor anyone purporting to represent Registrant, requested a hearing, submitted a written statement while waiving Registrant's right to a hearing, or submitted a corrective action plan. RFAAX 11, at 3-4 (Declaration of Diversion Investigator Two). Accordingly, I find that Registrant has waived the right to a hearing and the right to submit a written statement and corrective action plan. 21 CFR 1301.43(d) and 21 U.S.C. 824(c)(2)(C). I, therefore, issue this Decision and Order based on the record submitted by the Government, which constitutes the entire record before me. 21 CFR 1301.46.

Findings of Fact

Registrant's DEA Registration

Registrant is the holder of DEA Certificate of Registration No. BH2498106 at the registered address of 3233 W. Charleston Blvd. 202, Las Vegas, NV 89102. RFAAX 1 (Registrant's DEA Certificate of Registration). Pursuant to this registration, Registrant is authorized to dispense controlled substances in schedules II through V as a practitioner. *Id.* Registrant's registration will expire on its own terms on October 31, 2020. *Id.*

DEA Investigation and the Status of Registrant's State Licenses

On July 22, 2019, Registrant was sentenced in the United States District Court for the District of Nevada on a matter related to his conviction on one count of unlawful distribution of a controlled substance. RFAAX 11, at 2. On August 12, 2019, a DEA Diversion Investigator (hereinafter, DI Two) asked Registrant, through his legal counsel, to voluntarily surrender his DEA registration. *Id.* Registrant declined. *Id.* The General Counsel for the Nevada State Board of Pharmacy (hereinafter, Pharmacy Board) sent DI Two a letter dated September 17, 2019, stating that Registrant did not renew his Nevada controlled substance license and did not hold an active controlled substance license with the Pharmacy Board. RFAAX 4. According to the online records of the Pharmacy Board, Registrant's controlled substance