

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. DEA-869]

Bulk Manufacturer of Controlled Substances Application: AMPAC Fine Chemicals, LLC

AGENCY: Drug Enforcement Administration, Justice.

ACTION: Notice of application.

SUMMARY: AMPAC Fine Chemicals, 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 September 27, 2021. Such persons may also file a written request for a hearing on the application on or before September 27, 2021.

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 June 14, 2021, AMPAC Fine Chemicals, LLC., Highway 50 and Hazel Avenue, Rancho Cordova, California 95670, applied to be registered as a bulk manufacturer of the following basic class(es) of controlled substance(s):

Controlled substance	Drug code	Schedule
Norlevorphanol	9634	I
Methylphenidate	1724	II
Levomethorphan	9210	II
Levorphanol	9220	II
Thebaine	9333	II
Remifentanil	9739	II
Tapentadol	9780	II

The company plans to bulk manufacture the listed controlled substances for distribution to its customers.

Brian S. Besser,

Acting Assistant Administrator.

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DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. DEA-870]

Bulk Manufacturer of Controlled Substances Application: Bulk Manufacturer of Marijuana: Nusachi Labs, LLC.

AGENCY: Drug Enforcement Administration, Justice.

ACTION: Notice of application.

SUMMARY: The Drug Enforcement Administration (DEA) is providing notice of an application it has received from an entity applying to be registered to manufacture in bulk basic class(es) of controlled substances listed in schedule I. DEA intends to evaluate this and other pending applications according to its regulations governing the program of growing marijuana for scientific and medical research under DEA registration.

DATES: Registered bulk manufacturers of the affected basic class(es), and applicants therefor, may file written comments on or objections to the issuance of the proposed registration on or before September 27, 2021.

ADDRESSES: Written comments should be sent to: Drug Enforcement Administration, Attention: DEA Federal Register Representative/DPW 8701 Morrisette Drive, Springfield, Virginia 22152. To ensure proper handling of comments, please reference Docket No—DEA-870 in all correspondence, including attachments.

SUPPLEMENTARY INFORMATION: The Controlled Substances Act (CSA)

prohibits the cultivation and distribution of marijuana except by persons who are registered under the CSA to do so for lawful purposes. In accordance with the purposes specified in 21 CFR 1301.33(a), DEA is providing notice that the entity identified below has applied for registration as a bulk manufacturer of schedule I controlled substances. In response, registered bulk manufacturers of the affected basic class(es), and applicants therefor, may file written comments on or objections of the requested registration, as provided in this notice. This notice does not constitute any evaluation or determination of the merits of the application submitted.

The applicant plans to manufacture bulk active pharmaceutical ingredients (APIs) for product development and distribution to DEA-registered researchers. If the application for registration is granted, the registrant would not be authorized to conduct other activity under this registration aside from those coincident activities specifically authorized by DEA regulations. DEA will evaluate the application for registration as a bulk manufacturer for compliance with all applicable laws, treaties, and regulations and to ensure adequate safeguards against diversion are in place.

As this applicant has applied to become registered as a bulk manufacturer of marijuana, the application will be evaluated under the criteria of 21 U.S.C. 823(a). DEA will conduct this evaluation in the manner described in the rule published at 85 FR 82333 on December 18, 2020, and reflected in DEA regulations at 21 CFR part 1318.

In accordance with 21 CFR 1301.33(a), DEA is providing notice that on June 23, 2021, Nusachi Labs, LLC., 2909 Armory Drive, Nashville, Tennessee 37204, applied to be registered as a bulk manufacturer of the following basic class(es) of controlled substances:

Controlled substance	Drug code	Schedule
Marihuana	7360	I
Tetrahydrocannabinols	7370	I

Brian S. Besser,

Acting Assistant Administrator.

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