DEPARTMENT OF JUSTICE
Drug Enforcement Administration

[Docket No. DEA–1215]

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 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 August 7, 2023. Such persons may also file a written request for a hearing on the application on or before August 7, 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 April 13, 2023, AMPAC Fine Chemicals, LLC, Highway 50 & Hazel Avenue, Rancho Cordova, California 95670, applied to be registered as a bulk manufacturer of the following basic class(es) of controlled substance(s):

<table>
<thead>
<tr>
<th>Controlled substance</th>
<th>Drug code</th>
<th>Schedule</th>
</tr>
</thead>
<tbody>
<tr>
<td>Norlevorphanol</td>
<td>9634</td>
<td>I</td>
</tr>
<tr>
<td>Methylphenidate</td>
<td>1724</td>
<td>II</td>
</tr>
<tr>
<td>Levorphanol</td>
<td>9210</td>
<td>II</td>
</tr>
<tr>
<td>Thebaine</td>
<td>9333</td>
<td>II</td>
</tr>
<tr>
<td>Remifentanil</td>
<td>9739</td>
<td>II</td>
</tr>
<tr>
<td>Tapentadol</td>
<td>9780</td>
<td>II</td>
</tr>
</tbody>
</table>

The company plans to bulk manufacture the listed controlled substances for distribution to its customers. No other activities for these drug codes are authorized for this registration.

Matthew Strait,
Deputy Assistant Administrator.

THE company’s procedures with respect to filings.

In accordance with §§ 201.16(c) and 207.3 of the rules, each document filed by a party to the review must be served on all other parties to the review (as identified by either the public or BPI service list), and a certificate of service must be timely filed. The Secretary will not accept a document for filing without a certificate of service.

Determination.—The Commission has determined this review is extraordinarily complicated and therefore has determined to exercise its authority to extend the review period by up to 90 days pursuant to 19 U.S.C. 1675(c)(5)(B).

Authority: This review is being conducted under authority of title VII of the Tariff Act of 1930; this notice is published pursuant to § 207.62 of the Commission’s rules.

By order of the Commission.
Issued: June 2, 2023.
Lisa Barton,
Secretary to the Commission.

INFORMATION listed below for further drug information.

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The company plans to import the listed controlled substance for the development of bulk dosage formulations for research and clinical studies. No other activities for this drug code 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.

Lysergic Acid Diethylamide 7315 I