



Drug Enforcement Administration

[Docket No. DEA-1280]

Bulk Manufacturer of Controlled Substances Application: Chattem Chemicals, Inc.

AGENCY: Drug Enforcement Administration, Justice.

ACTION: Notice of application.

SUMMARY: Chattem Chemicals, Inc., 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 [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER]. Such persons may also file a written request for a hearing on the application on or before [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

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 July 14, 2023, Chattem Chemicals, Inc. 3801 Saint Elmo Avenue,

Chattanooga, Tennessee 37409, applied to be registered as a bulk manufacturer of the

following basic class(es) of controlled substance(s):

Controlled Substance	Drug Code	Schedule
Gamma Hydroxybutyric Acid	2010	I
Marihuana	7360	I
Tetrahydrocannabinols	7370	I
4-Methoxyamphetamine	7411	I
Dihydromorphine	9145	I
Amphetamine	1100	II
Methamphetamine	1105	II
Lisdexamfetamine	1205	II
Methylphenidate	1724	II
Cocaine	9041	II
Codeine	9050	II
Dihydrocodeine	9120	II
Oxycodone	9143	II
Hydromorphone	9150	II
Ecgonine	9180	II
Hydrocodone	9193	II
Levorphanol	9220	II
Methadone	9250	II
Methadone intermediate	9254	II
Morphine	9300	II
Oripavine	9330	II
Thebaine	9333	II
Oxymorphone	9652	II
Noroxymorphone	9668	II
Alfentanil	9737	II
Remifentanil	9739	II
Sufentanil	9740	II
Tapentadol	9780	II
Fentanyl	9801	II

The company plans to bulk manufacture the listed controlled substances in bulk for distribution and sale to its customers. In reference to drug codes 7360 (Marihuana) and 7370 (Tetrahydrocannabinols), the company plans to bulk manufacture these drugs as a synthetic. 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 manufacturing of Food and Drug Administration-approved or non-approved finished dosage forms for commercial sale.

Claude Redd,

Acting Deputy Assistant Administrator.

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