Billing Code 4410-09-P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. DEA-392]

Bulk Manufacturer of Controlled Substances Application: Cedarburg Pharmaceuticals

ACTION: Notice of application.

DATES: Registered bulk manufacturers of the affected basic classes, and applicants therefore, may file written comments on or objections to the issuance of the proposed registration on or before [INSERT 60 DAYS AFTER PUBLICATION IN THE FEDERAL REGISTER].

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

SUPPLEMENTARY INFORMATION: The Attorney General has delegated his authority under the Controlled Substances Act to the Administrator of the Drug Enforcement Administration (DEA), 28 CFR 0.100(b). Authority to exercise all necessary functions with respect to the promulgation and implementation of 21 CFR part 1301, incident to the registration of manufacturers, distributors, dispensers, importers, and exporters of controlled substances (other than final orders in connection with suspension, denial, or revocation of registration) has been redelegated to the Assistant Administrator of the DEA Diversion Control Division ("Assistant Administrator") pursuant to section 7 of 28 CFR part 0, appendix to subpart R.

In accordance with 21 CFR 1301.33(a), this is notice that on August 29, 2017, Cedarburg Pharmaceuticals, Inc., A Division of Albany Molecular Research Inc. (AMRI), 870 Badger Circle, Grafton, Wisconsin 53024 applied to be registered as a bulk manufacturer the following basic classes of controlled substances:

Controlled Substance	Drug Code	Schedule
Marihuana	7360	I
Tetrahydrocannabinols	7370	I
Lisdexamfetamine	1205	II
Pentobarbital	2270	II
Nabilone	7379	II
4-Anilino-N-phenethyl-4-piperidine (ANPP)	8333	II
Remifentanil	9739	II
Fentanyl	9801	II

The company plans to manufacture the above listed controlled substances in bulk for distribution to its customers. In reference to drug codes 7360 marihuana, the company plans to bulk manufacture cannabidiol as a synthetic intermediate. The company plans to manufacture bulk active pharmaceutical ingredients (API) for distribution to its customers. This controlled substance will be further synthesized to bulk manufacture a synthetic tetrahydrocannabinols 7370. No other activity for this drug code is authorized for this registration.

Dated: January 30, 2018

Susan A. Gibson,

Deputy Assistant Administrator.

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