



DEPARTMENT OF JUSTICE

Drug Enforcement Administration

Bulk Manufacturer of Controlled Substances Application: Mallinckrodt, LLC

[Docket No. DEA-392]

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 in accordance with 21 CFR 1301.33(a) 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 Morrisette 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 November 14, 2016, Mallinckrodt, LLC, 3600 North Second Street, Saint Louis, Missouri 63147 applied to be registered as a bulk manufacturer of the following basic classes of controlled substances:

Controlled Substance	Drug Code	Schedule
Gamma Hydroxybutyric Acid	2010	I
Tetrahydrocannabinols	7370	I
Codeine-N-oxide	9053	I
Dihydromorphine	9145	I
Difenoxin	9168	I
Morphine-N-oxide	9307	I
Normorphine	9313	I
Norlevorphanol	9634	I
Acetyl Fentanyl (N-(1-phenethylpiperidin-4-yl)-N-phenylacetamide)	9821	I
Butyryl Fentanyl	9822	I
Amphetamine	1100	II
Methamphetamine	1105	II
Lisdexamfetamine	1205	II
Methylphenidate	1724	II
Nabilone	7379	II
4-Anilino-N-phenethyl-4-piperidine (ANPP)	8333	II
Codeine	9050	II
Dihydrocodeine	9120	II
Oxycodone	9143	II
Hydromorphone	9150	II
Diphenoxylate	9170	II
Ecgonine	9180	II
Hydrocodone	9193	II
Levorphanol	9220	II
Meperidine	9230	II
Methadone	9250	II
Methadone intermediate	9254	II
Dextropropoxyphene, bulk (non-dosage forms)	9273	II
Morphine	9300	II
Oripavine	9330	II
Thebaine	9333	II
Opium tincture	9630	II
Opium, powdered	9639	II

Controlled Substance	Drug Code	Schedule
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 manufacture bulk active pharmaceutical ingredients (APIs) for distribution to its customers.

Louis J. Milione,
Assistant Administrator.
Billing Code 4410-09-P

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