BILLING CODE 4410-09-P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

Bulk Manufacturer of Controlled Substances Application: Navinta 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/ODW, 8701 Morrissette Drive, Springfield, Virginia 22152. Request for hearings should be sent to: Drug Enforcement Administration, Attention: Hearing Clerk/LJ, 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 Deputy Assistant Administrator of the DEA Office of Diversion

Control (“Deputy 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 September 5, 2014, Navinta LLC, 1499 Lower Ferry Road, Ewing, New Jersey 08618-1414, applied to be registered as a bulk manufacturer of the following basic classes of controlled substances:

Controlled Substance	Schedule
Pentobarbital (2270)	II
Remifentanil (9739)	II

The company plans to initially to manufacture API quantities of the listed controlled substances for validation purposes and FDA approval, then to produce commercial size batches for distribution to dosage form manufacturers upon FDA approval.

Dated: February 11, 2015.

Joseph T. Rannazzisi,
Deputy Assistant Administrator.

[FR Doc. 2015-03489 Filed 02/18/2015 at 8:45 am; Publication Date: 02/19/2015]