Billing Code 4410-09-M

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

Manufacturer of Controlled Substances

Notice of Application

Navinta, LLC

Pursuant to § 1301.33(a), Title 21 of the Code of Federal Regulations (CFR), this is notice that on February 13, 2013, Navinta, LLC., 1499 Lower Ferry Road, Ewing, New Jersey 08618-1414, made application to the Drug Enforcement Administration (DEA) to be registered as a bulk manufacturer of the basic classes of controlled substances:

Drug	Schedule
Pentobarbital (2270)	II
Remifentanil (9739)	II

The company plans 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.

Any other such applicant, and any person who is presently registered with DEA to manufacture such substance, may file comments or objections to the issuance of the proposed registration pursuant to 21 CFR § 1301.33(a).

Any such written comments or objections should be addressed, in quintuplicate, to the Drug Enforcement Administration, Office of Diversion Control, Federal Register Representative (ODL),8701 Morrissette Drive, Springfield, Virginia 22152; and must be filed no later than [INSERT DATE 60 DAYS FROM DATE OF PUBLICATION].

Joseph T. Rannazzisi
Deputy Assistant Administrator
Office of Diversion Control
Drug Enforcement Administration

DATED: April 10, 2013

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