

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. DEA-1116]

Importer of Controlled Substances Application: Noramco

AGENCY: Drug Enforcement Administration, Justice.

ACTION: Notice of application.

SUMMARY: Noramco has applied to be registered as an importer 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 February 21, 2023. Such persons may also file a written request for a hearing on the application on or before February 21, 2023.

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. All requests for a hearing must be sent to: (1) Drug Enforcement Administration, Attn: Hearing Clerk/OALJ, 8701 Morrisette Drive, Springfield, Virginia 22152; and (2) Drug Enforcement Administration, Attn: DEA Federal Register Representative/DPW, 8701 Morrisette Drive, Springfield, Virginia 22152. All requests for a hearing should also be sent to: Drug Enforcement Administration, Attn: Administrator, 8701 Morrisette Drive, Springfield, Virginia 22152.

SUPPLEMENTARY INFORMATION: In accordance with 21 CFR 1301.34(a), this is notice that on October 19, 2022, Noramco, 500 Swedes Landing Road, Wilmington, Delaware 19801-4417, applied to be registered as an importer 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
Nabilone	7379	II
Phenylacetone	8501	II
Opium, Raw	9600	II
Opium Extracts	9610	II
Opium Fluid Extract	9620	II
Opium Tincture	9630	II
Opium Powdered	9639	II
Opium Granulated	9640	II
Opium Poppy/Poppy Straw.	9650	II
Noroxymorphone	9668	II
Poppy Straw Concentrate.	9670	II
Tapentadol	9780	II

The company plans to import Phenylacetone (8501), and Poppy Straw Concentrate (9670) to bulk manufacture other controlled substances for distribution to its customers. The company plans to import an intermediate form of Tapentadol (9780) to bulk manufacture Tapentadol for distribution to its customers. In reference to drug codes 7360 (Marihuana) and 7370 (Tetrahydrocannabinols), the company plans to import a synthetic cannabidiol and a synthetic Tetrahydrocannabinol. No other activity for these drug codes is 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 import of Food and Drug Administration-approved or non-approved finished dosage forms for commercial sale.

Matthew Strait,

Deputy Assistant Administrator.

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DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. DEA-1127]

Bulk Manufacturer of Controlled Substances Application: Navinta LLC

AGENCY: Drug Enforcement Administration, Justice.

ACTION: Notice of application.

SUMMARY: Navinta LLC 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 March 21, 2023. Such persons may also file a written request for a hearing on the application on or before March 21, 2023.

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 October 6, 2022, Navinta LLC, 1499 Lower Ferry Road, Ewing, New Jersey 08618-1414, applied to be registered as a bulk manufacturer of the following basic class(es) of controlled substance(s):

Controlled substance	Drug code	Schedule
Pentobarbital	2270	II
Levomethorphan	9210	II
Levorphanol	9220	II
Remifentanil	9739	II

The company plans to bulk manufacture Active Pharmaceutical Ingredients (API) quantities of the listed controlled substances for validation purpose and the Food and Drug Administration approval. No other activities for these drug codes are authorized for this registration.

Matthew Strait,

Deputy Assistant Administrator.

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