

Controlled substance	Drug code	Schedule
Gamma Hydroxybutyric Acid ...	2010	I
Marihuana Extract .....	7350	I
Marihuana .....	7360	I

The company plans to import finished dosage unit products containing gamma-hydroxybutyric acid and cannabis extracts for clinical trial studies.

These cannabis extracts compounds are listed under drug code 7350. 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 FDA approved or non-approved finished dosage forms for commercial sale.

Dated: September 11, 2017.

**Demetra Ashley,**

*Acting Assistant Administrator.*

[FR Doc. 2017-19833 Filed 9-15-17; 8:45 am]

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**DEPARTMENT OF JUSTICE**

**Drug Enforcement Administration**

**[Docket No. DEA-392]**

**Bulk Manufacturer of Controlled Substances Application: Specgx LLC**

**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 November 17, 2017.

**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 August 9, 2017, Specgx 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
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.

Dated: September 13, 2017

**Demetra Ashley,**

*Acting Assistant Administrator.*

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**DEPARTMENT OF JUSTICE**

**Drug Enforcement Administration**

[Docket No. DEA-392]

**Importer of Controlled Substances Application: Specgx LLC**

**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 1301.34(a) on or before October 18, 2017. Such persons may also file a written request for a hearing on the application pursuant to 21 CFR 1301.43 on or before October 18, 2017.

**ADDRESSES:** Written comments should be sent to: Drug Enforcement Administration, Attention: DEA Federal Register Representative/DRW, 8701 Morrisette Drive, Springfield, Virginia 22152. All requests for hearing must be sent to: Drug Enforcement Administration, Attn: Administrator, 8701 Morrisette Drive, Springfield, Virginia 22152. All request for hearing should also be sent to: (1) Drug Enforcement Administration, Attn: Hearing Clerk/LJ, 8701 Morrisette Drive, Springfield, Virginia 22152; and (2) Drug Enforcement Administration, Attn: 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 1301.34(a), this is notice that on August 9, 2017, Specgx LLC, 3600 North Second Street, Saint Louis, Missouri 63147 applied to be registered as an importer of the following basic classes of controlled substances:

Controlled substance	Drug code	Schedule
Marihuana .....	7360	I
Phenylacetone .....	8501	II
Coca Leaves .....	9040	II
Opium, raw .....	9600	II
Poppy Straw Concentrate.	9670	II

The company plans to import the listed controlled substances to bulk manufacture into Active Pharmaceutical Ingredients for distribution to its customers. In reference to drug code 7360 (marihuana) the company plans to import a synthetic cannabidiol. No other activity for this drug code is authorized for this registration. Placement of these drug codes onto the company’s registration does not translate into automatic approval of subsequent permit applications to import controlled substances. 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 FDA approved or non-approved finished dosage forms for commercial sale.

Dated: September 11, 2017.

**Demetra Ashley,**

*Acting Assistant Administrator.*

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**DEPARTMENT OF JUSTICE**

**Drug Enforcement Administration**

[Docket No. DEA-392]

**Bulk Manufacturer of Controlled Substances Application: Halo Pharmaceutical, Inc.**

**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 November 17, 2017.

**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 July 11, 2017, Halo Pharmaceutical, Inc., 30 North Jefferson Road, Whippany, New Jersey 07981 applied to be registered as a bulk manufacturer the following basic classes of controlled substances:

Controlled substance	Drug code	Schedule
Dihydromorphine .....	9145	I
Hydromorphone .....	9150	II

The company plans to manufacture Hydromorphone (9150) for distribution to its customers. Dihydromorphine (9145) is an intermediate in the manufacture of Hydromorphone and is not for commercial distribution.

Dated: September 11, 2017.

**Demetra Ashley,**

*Acting Assistant Administrator.*

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**BILLING CODE P**

**DEPARTMENT OF JUSTICE**

**Drug Enforcement Administration**

[Docket No. DEA-392]

**Importer of Controlled Substances Application: Unither Manufacturing LLC**

**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 1301.34(a) on or before October 18, 2017. Such persons may also file a written request