DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. DEA–392]

Bulk Manufacturer of Controlled Substances Application: Cedarburg Pharmaceuticals, Inc.

ACTION: Notice of application.

DATES: Registered bulk manufacturers of the affected basic class, 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 April 18, 2016.

ADDRESSES: Written comments should be sent to: Drug Enforcement Administration, Attention: DEA Federal Register Representative/ODW, 8701 Morrissette Drive, Springfield, Virginia 22152.

SUPPLEMENTARY INFORMATION: The Attorney General has delegated her 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 November 4, 2015, Cedarburg Pharmaceuticals, Inc., 870 Badger Circle, Grafton, Wisconsin 53024 applied to be registered as a bulk manufacturer of nabilone (7379), a basic class of controlled substance listed in schedule II.

The company plans to manufacturer bulk active pharmaceutical ingredients (API) for distribution to its customers.

Dated: February 10, 2016.

Louis J. Milione,

Deputy Assistant Administrator.

[FR Doc. 2016–03350 Filed 2–17–16; 8:45 am]

BILLING CODE 4410–09–P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. DEA–392]

Manufacturer of Controlled Substances Registration: Euticals, Inc.

ACTION: Notice of registration.

SUMMARY: Euticals, Inc. applied to be registered as a manufacturer of certain basic classes of controlled substances. The Drug Enforcement Administration (DEA) grants Euticals, Inc. registration as a manufacturer of those controlled substances.

SUPPLEMENTARY INFORMATION: By notice dated September 16, 2015, and published in the **Federal Register** on September 23, 2015, 80 FR 57391, Euticals, Inc., 2460 W. Bennett Street, Springfield, Missouri 65807–1229 applied to be registered as a manufacturer of certain basic classes of controlled substances. No comments or objections were submitted for this notice.

The DEA has considered the factors in 21 U.S.C. 823(a) and determined that the registration of Euticals, Inc. to manufacture the basic classes of controlled substances is consistent with the public interest and with United States obligations under international treaties, conventions, or protocols in effect on May 1, 1971. The DEA investigated the company's maintenance of effective controls against diversion by inspecting and testing the company's physical security systems, verifying the company's compliance with state and local laws, and reviewing the company's background and history.

Therefore, pursuant to 21 U.S.C. 823(a), and in accordance with 21 CFR 1301.33, the above-named company is granted registration as a bulk manufacturer of the following basic classes of controlled substances:

Controlled substance	Schedule
Gamma Hydroxybutyric Acid (2010).	I
Amphetamine (1100)	II
Lisdexamfetamine (1205)	II
Methylphenidate (1724)	II
Phenylacetone (8501)	II
Methadone (9250)	II
Methadone intermediate (9254)	II
Oripavine (9330)	II
Tapentadol (9780)	II

The company plans to manufacture the listed controlled substances in bulk for distribution and sale to its customers.

In reference to oripavine (9330), the company plans to acquire the listed controlled substance in bulk from a domestic source in order to manufacture other controlled substances in bulk for distribution to its customers.

Dated: February 10, 2016.

Louis J. Milione,

Deputy Assistant Administrator.

[FR Doc. 2016–03355 Filed 2–17–16; 8:45 am]

BILLING CODE 4410–09–P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. DEA–392]

Importer of Controlled Substances Registration: Catalent Pharma Solutions, LLC

ACTION: Notice of registration.

SUMMARY: Catalent Pharma Solutions, LLC applied to be registered as an importer of a certain basic class of controlled substance. The Drug Enforcement Administration (DEA) grants Catalent Pharma Solutions, LLC registration as an importer of this controlled substance.

SUPPLEMENTARY INFORMATION: By notice dated August 21, 2015, and published in the **Federal Register** on August 31, 2015, 80 FR 52510, Catalent Pharma Solutions, LLC, 3031 Red Lion Road, Philadelphia, Pennsylvania 19114 applied to be registered as an importer of a certain basic class of controlled substance. No comments or objections were submitted for this notice.

The DEA has considered the factors in 21 U.S.C. 823, 952(a) and 958(a) and determined that the registration of Catalent Pharma Solutions, LLC to import the basic class of controlled substance is consistent with the public interest and with United States obligations under international treaties, conventions, or protocols in effect on May 1, 1971. The DEA investigated the company's maintenance of effective controls against diversion by inspecting and testing the company's physical security systems, verifying the company's compliance with state and local laws, and reviewing the company's background and history.

Therefore, pursuant to 21 U.S.C. 952(a) and 958(a), and in accordance with 21 CFR 1301.34, the above-named company is granted registration as an importer of hydromorphone (9150), a basic class of controlled substance listed in schedule II.

The company plans to import the above listed controlled substance for a clinical trial study. Approval of permit applications will occur only when the

registrant's business activity is consistent with what is authorized under to 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: February 10, 2016.

Louis J. Milione,

Deputy Assistant Administrator.

[FR Doc. 2016–03358 Filed 2–17–16; 8:45 am]

BILLING CODE 4410–09–P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. DEA–392]

Importer of Controlled Substances Registration: Sigma Aldrich International GMBH-Sigma Aldrich Co. LLC

ACTION: Notice of registration.

SUMMARY: Sigma Aldrich International GMBH-Sigma Aldrich Co. LLC applied to be registered as an importer of a basic class of controlled substance. The Drug Enforcement Administration (DEA) grants Sigma Aldrich International GMBH-Sigma Aldrich Co. LLC registration as an importer of this controlled substance.

SUPPLEMENTARY INFORMATION: By notice dated October 13, 2015, and published in the **Federal Register** on October 21, 2015, 80 FR 63839, Sigma Aldrich International GMBH-Sigma Aldrich Co. LLC, 3500 Dekalb Street, Saint Louis, Missouri 63118 applied to be registered as an importer of a certain basic class of controlled substance. No comments or objections were submitted for this notice.

The DEA has considered the factors in 21 U.S.C. 823, 952(a) and 958(a) and determined that the registration of Sigma Aldrich International GMBH-Sigma Aldrich Co. LLC, to import the basic class of controlled substance is consistent with the public interest and with United States obligations under international treaties, conventions, or protocols in effect on May 1, 1971. The DEA investigated the company's maintenance of effective controls against diversion by inspecting and testing the company's physical security systems, verifying the company's compliance with state and local laws, and reviewing the company's background and history.

Therefore, pursuant to 21 U.S.C. 952(a) and 958(a), and in accordance with 21 CFR 1301.34, the above-named company is granted registration as an importer of butylone (7541), a basic class of controlled substance listed in schedule I.

The company plans to import the above listed controlled substance for analytical research and testing of equipment. This authorization does not extend to the import of a finished FDA approved or non-approved dosage form for commercial sale.

Dated: February 10, 2016.

Louis J. Milione,

Deputy Assistant Administrator.

[FR Doc. 2016–03353 Filed 2–17–16; 8:45 am]

BILLING CODE 4410–09–P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. 15–1]

Arvinder Singh, M.D.; Decision and Order

On October 16, 2014, the Deputy Assistant Administrator, Office of Diversion Control, issued an Order to Show Cause to Arvinder Singh, M.D. (Respondent), of Clifton Park, New York. ALJ Ex. 1. The Show Cause Order proposed the denial of Respondent's application for a DEA Certificate of Registration as a practitioner on three grounds.

First, the Show Cause Order alleged that on August 4, 2003, Respondent, following a jury trial, was convicted on 16 counts of health care fraud in violation of 18 U.S.C. 1347, one count of conspiracy to distribute controlled substances in violation of 21 U.S.C. 846, and 24 counts of unlawful distribution of controlled substances in violations of 21 U.S.C. 841(a)(1) and 18 U.S.C. 2. *Id.* at 1–2. (citing 21 U.S.C. 824(a)(2)).

Second, the Show Cause Order alleged that Respondent's convictions for violating the Controlled Substances Act ''were based on a scheme in which [he] left pre-signed but otherwise blank prescriptions for [his] nursing staff to fill in and issue Schedule II controlled substances prescriptions to patients when neither [he] nor any other physician saw the patient at the time such prescriptions were issued.'' *Id.* at 2. The Show Cause Order alleged that Respondent's scheme also violated 21 CFR 1306.04(a) and 1306.05(a), and that this conduct constituted acts inconsistent with the public interest. *Id.* (citing 21 U.S.C. 824(a)(4) and 823(f)).

Third, the Show Cause Order alleged that on May 8, 2004, the U.S. Department of Health and Human Services (HHS) excluded Respondent from participation in federal health care programs for a period of 15 years based on his convictions for Health Care Fraud and for violating the Controlled Substances Act. *Id.* The Government further alleged that because ''the amount of the financial loss'' was in excess of $5,000; the time period of Respondent's illegal activity exceeded more than one year; and Respondent had been convicted of the CSA violations; HHS imposed a 15-year exclusion, which was three times the minimum exclusion period. *Id.* (citing 21 U.S.C. 824(a)(5)).

Following service of the Show Cause Order, Respondent requested a hearing on the allegations. The matter was placed on the docket of the Office of Administrative Law Judges and assigned to Chief Administrative Law Judge (hereinafter, CALJ) John J. Mulrooney, II. Following pre-hearing procedures, the CALJ conducted a hearing at which both parties introduced documentary evidence and called witnesses to testify. Thereafter, both parties submitted briefs containing their proposed findings of fact, conclusions of law, and arguments regarding the ultimate disposition of this matter.

On February 10, 2015, the CALJ issued his Recommended Decision. Therein, the CALJ found that the Government had established a *prima facie* case to deny Respondent's application for registration as a practitioner on multiple grounds.[1] R.D. at 37.

These included that Respondent had been convicted of twenty-four counts of

[1] Pursuant to 21 U.S.C. 823(f), ''[t]he Attorney General may deny an application for [a practitioner's] registration . . . if [she] determines that the issuance of such registration . . . would be inconsistent with the public interest.'' In making this determination, section 823(f) directs the Agency to consider the following factors:

(1) The recommendation of the appropriate State licensing board or professional disciplinary authority.

(2) The applicant's experience in dispensing . . . controlled substances.

(3) The applicant's conviction record under Federal or State laws relating to the manufacture, distribution, or dispensing of controlled substances.

(4) Compliance with applicable State, Federal, or local laws relating to controlled substances.

(5) Such other conduct which may threaten the public health and safety.

Id. § 823(f).

''These factors are . . . considered in the disjunctive.'' *Robert A. Leslie, M.D.,* 68 FR 15227, 15230 (2003). I ''may rely on any one or a combination of factors[,] and may give each factor the weight [I] deem[ ] appropriate in determining whether a registration should be revoked. *Id.; see also MacKay* v. *DEA,* 664 F.3d 808, 816 (10th Cir. 2011); *Volkman* v. *DEA,* 567 F.3d 215, 222 (6th Cir. 2009); *Hoxie* v. *DEA,* 419 F.3d 477, 482 (6th Cir. 2005). Moreover, while I am required to consider each of the factors, I ''need not make explicit findings as to each one.'' *MacKay,* 664 F.3d at 816 (quoting *Volkman,* 567 F.3d at 222 (quoting *Hoxie,* 419 F.3d at 482)).