Controlled substance	Drug code	Schedule
AH-7921 (3,4-dichloro-N-[(1-dimethylamino)cyclohexylmethyl]benzamide))	9551	I
Acetylmethadol	9601	I
Allylprodine	9602	I
Alphacetylmethadol except levo-alphacetylmethadol	9603	I
Alphameprodine	9604	I
Alphamethadol	9605	I
Betacetylmethadol	9607	I
Betameprodine	9608	I
Betamethadol	9609	I
Betaprodine	9611	I
Dextromoramide	9613	I
Dipipanone	9622	I
Hydroxypethidine	9627	I
Noracymethadol	9633	I
Norlevorphanol	9634	I
Normethadone	9635	I
Racemoramide	9645	I
Trimeperidine	9646	I
1-Methyl-4-phenyl-4-propionoxypiperidine	9661	I
Tilidine	9750	I
Para-Fluorofentanyl	9812	I
3-Methylfentanyl	9813	I
Alpha-methylfentanyl	9814	I
Acetyl-alpha-methylfentanyl	9815	I
Beta-hydroxyfentanyl	9830	I
Beta-hydroxy-3-methylfentanyl	9831	I
Alpha-methylthiofentanyl	9832	I
3-Methylthiofentanyl	9833	I
Thiofentanyl	9835	I
Methamphetamine	1105	II
Methylphenidate	1724	II
Amobarbital	2125	II
Pentobarbital	2270	II
Secobarbital	2315	II
Glutethimide	2550	II
Nabilone	7379	II
1-Phenylcyclohexylamine	7460	II
Phencyclidine	7471	II
Phenylacetone	8501	II
1-Piperidinocyclohexanecarbonitrile	8603	II
Alphaprodine	9010	II
Dihydrocodeine	9120	II
Ecgonine	9180	II
Ethylmorphine	9190	II
Levomethorphan	9210	II
Levorphanol	9220	II
Meperidine	9230	II
Dextropropoxyphene, bulk (non-dosage forms)	9273	II
Levo-alphacetylmethadol	9648	II
Noroxymorphone	9668	II
Racemethorphan	9732	II
Alfentanil	9737	II
Remifentanil	9739	II
Sufentanil	9740	II
Carfentanil	9743	II
Tapentadol	9780	II

The company plans to import the listed controlled substances for the manufacture of analytical reference standards and distribution to their research and forensic customers. Approval of permit application will occur only when the registrant's 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: August 9, 2019.

Neil D. Doherty,

Acting Assistant Administrator.

[FR Doc. 2019–18455 Filed 8–26–19; 8:45 am]

BILLING CODE 4410–09–P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. DEA–392]

Bulk Manufacturer of Controlled Substances Applications: Bulk Manufacturers of Marihuana

ACTION: Notice of applications.

SUMMARY: The Drug Enforcement Administration (DEA) is providing

notice of certain applications it has received from entities applying to be registered to manufacture in bulk a basic class of controlled substances listed in schedule I. Prior to making decisions on these pending applications, DEA intends to promulgate regulations that govern the program of growing marihuana for scientific and medical research under DEA registration. In addition, this notice informs applicants that they may withdraw their applications if they no longer need to obtain a registration because of the recent amendments made by the Agriculture Improvement Act of 2018 to the definition of marihuana to no longer include ''hemp'' as defined by law.

DATES: Registered bulk manufacturers of the affected basic classes, and applicants therefor, may file written comments on or objections to the issuance of the proposed registration on or before October 28, 2019.

ADDRESSES: Written comments should be sent to: Drug Enforcement Administration, Attention: DEA Federal Register Representative/DPW, 8701 Morrissette Drive, Springfield, Virginia 22152–2639. To ensure proper handling of comments, please reference ''Docket No. DEA–392'' in all correspondence, including attachments.

SUPPLEMENTARY INFORMATION: The Controlled Substances Act (CSA) prohibits the cultivation and distribution of marihuana except by persons who are registered under the CSA to do so for lawful purposes. In accordance with the purposes specified in 21 CFR 1301.33(a), DEA is providing notice that the entities identified below have applied for registration as bulk manufacturers of schedule I controlled substances. In response, registered bulk manufacturers of the affected basic classes, and applicants therefor, may file written comments on or objections to the issuance of the requested registrations, as provided in this notice. This notice does not constitute any evaluation or determination of the merits of the applications submitted.

The applicants plan to manufacture bulk active pharmaceutical ingredients (APIs) for product development and distribution to DEA-registered researchers. If their applications for registration are granted, the registrants would not be authorized to conduct other activity under those registrations, aside from those coincident activities specifically authorized by DEA regulations. DEA will evaluate the applications for registration as bulk manufacturers for compliance with all applicable laws, treaties, and regulations and to ensure adequate safeguards against diversion are in place.

In particular, in accordance with the criteria specified in 21 U.S.C. 823(a), DEA is required, among other things, to maintain ''effective controls against diversion . . . by limiting the . . . bulk manufacture of such controlled substances to a number of establishments which can produce an adequate and uninterrupted supply of these substances under adequately competitive conditions for legitimate medical, scientific, research, and industrial purposes.'' 21 U.S.C. 823(a); *see* Lyle E. Craker;—Denial of Application, 74 FR 2101, 2118–23, 2127–33 (2009) (''[A]n applicant seeking to become registered to bulk manufacture a schedule I or II controlled substance bears the burden of demonstrating that the existing registered bulk manufacturers of a given schedule I or II controlled substance are unable to produce an adequate and uninterrupted supply of that substance under adequately competitive conditions.''), *pet. for rev. denied, Craker* v. *DEA,* 714 F.3d 17, 27–29 (1st Cir. 2013); *see also* Applications to Become Registered under the Controlled Substances Act to Manufacture Marijuana to Supply Researchers in the United States, 81 FR 53846, 53847 (Aug. 12, 2016) (''As subsection 823(a)(1) provides, DEA is obligated to register only the number of bulk manufacturers of a given schedule I or II controlled substance that is necessary to 'produce an adequate and uninterrupted supply of these substances under adequately competitive conditions for legitimate medical, scientific, research, and industrial purposes.' '').

Thus, in accordance with the criteria of section 823(a), DEA anticipates evaluating the applications and, of those applications that it finds are compliant with relevant laws, regulations, and treaties, granting the number that the agency determines is necessary to ensure an adequate and uninterrupted supply of the controlled substances at issue under adequately competitive conditions. By registering these additional growers in accordance with the criteria of section 823(a), DEA anticipates that additional strains of marihuana will be produced and made available to researchers. This should facilitate research, advance scientific understanding about the effects of marihuana, and potentially aid in the development of safe and effective drug products that may be approved for marketing by the Food and Drug Administration.

The applicants noticed below applied to become registered with DEA to grow marihuana as bulk manufacturers subsequent to a 2016 DEA policy statement that provided information on how it intended to expand the number of registrations, and described in general terms the way it would oversee those additional growers. Therein, DEA recognized the need to move past the single grower system and register additional growers. DEA has received 33 pending applications, as listed below; the most recent was filed in May 2019. Because the size of the applicant pool is unprecedented in DEA's experience, the Agency has determined that adjustments to its policies and practices with respect to the marihuana growers program are necessary to fairly evaluate the applicants under the 823(a) factors, including 823(a)(1).

In addition, since publication of the 2016 policy statement, the Department of Justice, in consultation with other federal agencies, has been engaged in a policy review process to ensure that the marihuana growers program is consistent with applicable laws and treaties. That review process remains ongoing; however, it has progressed to the point where DEA is able to issue Notices of Application. Over the course of this policy review process, the Department of Justice has also determined that adjustments to DEA's policies and practices related to the marihuana growers program may be necessary. Accordingly, before DEA completes this evaluation and registration process, DEA intends to propose regulations in the near future that would supersede the 2016 policy statement and govern persons seeking to become registered with DEA to grow marihuana as bulk manufacturers, consistent with applicable law.

DEA notes that, as the result of a recent amendment to federal law, certain forms of cannabis no longer require DEA registration to grow or manufacture. The Agriculture Improvement Act of 2018, Public Law 115–334, which was signed into law on December 20, 2018, changed the definition of marihuana under the CSA. As amended, the definition of marihuana no longer includes ''hemp,'' which is defined as ''the plant Cannabis sativa L. and any part of that plant, including the seeds thereof and all derivatives, extracts, cannabinoids, isomers, acids, salts, and salts of isomers, whether growing or not, with a delta-9 tetrahydrocannabinol concentration of not more than 0.3 percent on a dry weight basis.'' 7 U.S.C. 1639*o*(1). Pursuant to the amended definition, cannabis plant material which contains 0.3 percent or less delta-9 tetrahydrocannabinol (THC) on a dry

weight basis is not a controlled substance and does not require a DEA registration to grow. Accordingly, if any of the below-listed applicants have applied for a DEA registration exclusively for the purpose of growing cannabis that contains no more than 0.3 percent delta-9 THC on a dry weight basis, including cannabis that contains cannabidiol (CBD) and falls below the delta-9 THC threshold, the applicants no longer require DEA registration for that purpose. If desired, these applicants may respond in writing with a request to withdraw their applications. Upon receipt of a request to withdraw an application that is received no later than November 1, 2019, DEA will refund all related application fees paid by the applicant.

In addition, any listed applicants who no longer wish to obtain registration for any other reason may also request to withdraw their application in writing, and DEA will refund all related application fees paid by the applicant, provided the withdrawal is received no later than November 1, 2019. Applicants who wish to withdraw their application may do so by sending a letter to: Drug Enforcement Administration, Attn: Regulatory/DRG, 8701 Morrissette Drive, Springfield, VA 22152–2639.

List of Applications Received

In accordance with 21 CFR 1301.33(a), DEA is providing notice that on the following dates, the following entities applied to be registered as bulk manufacturers of the following basic classes of controlled substances:

Date	Applicant	Address	Controlled substance	Drug Code	Sch.
2/6/17	7218737 Delaware Inc	50 Otis Street, Westborough, MA 01581.	Marihuana	7360	I
5/11/17	A and C Laboratories	155 Federal Street, Suite 700, Boston, MA 02110.	Marihuana extract, Marihuana, Tetrahydrocannabinols.	7350, 7360, 7370	I
2/14/18	Abatin Cultivation Center	2146 Queens Chapel Rd., Washington, DC 20018.	Marihuana extract, Marihuana	7360	I
12/30/16.	Annac Medical Center LLC	5172 W Patrick Lane, Suite 100, Las Vegas, NV 89117–8911.	Marihuana extract, Marihuana	7350, 7360	I
1/4/18	Battelle Memorial Institute	1425 Plain City—Gorgesville Road, Bldg. JS–1–009, Powell, OH 43065–9647.	Marihuana, Tetrahydrocannabinols	7360, 7370	I
3/16/17	Biopharmaceutical Research Company, LLC.	11045 Commercial Parkway, Castroville, CA 95012–3209.	Marihuana extract	7350	I
11/2/16	Cannamed Pharmaceuticals, Inc	27120 Ocean Gateway, Salisbury, MD 21803.	Marihuana extract, Marihuana, Tetrahydrocannabinols.	7350, 7360, 7370	I
3/13/17	Columbia Care NY, LLC	Eastman Business Park, Bldg. 12, 4th Floor, 1669 Lake Ave., Rochester, NY 14615.	Marihuana extract	7350	I
5/3/18	Contract Pharmacal Corp	135 Adams Avenue, Hauppauge, NY 11788.	Marihuana extract, Marihuana, Tetrahydrocannabinols.	7350, 7360, 7370	I
8/2/17	Confederated Tribes of the Colville	P.O. Box 150, 21 Colville Street, Nespelem, WA 99155.	Marihuana,	7360	I
11/10/16.	Fraunhofer USA	Center for Molecular Biotechnology, 9 Innovation Way, Newark, DE 19711.	Marihuana extract	7350	I
7/31/14	Gary Gray DBA Complex Pharmacist Owner.	P.O. Box 2522, 1721 W Burrel Ave., Visalia, CA 93279–2522.	Marihuana, Tetrahydrocannabinols	7360, 7370	I
10/22/18.	GB Sciences, Inc. DBA GB Sciences Nevada, LLC.	3550 W Teco Ave., Las Vegas, NV 89118–6876.	Marihuana extract, Marihuana, Tetrahydrocannabinols.	7350, 7360, 7370	I
4/27/17	Green Leaf Inc	4614 Halibut Point Rd., Sitka, AK 99835.	Marihuana extract, Marihuana, Tetrahydrocannabinols.	7350, 7360, 7370	I
11/23/16.	Hawaii Agriculture Research Institute	94–340 Kunia Road, Kunia, HI 96759–0100.	Marihuana extract	7350	I
8/30/16	Hemp CBD LLC	190 Eagle Ford Dr., Pleasanton, TX 78064.	Marihuana, Tetrahydrocannabinols	7360, 7370	I
5/22/17	JT Medical, LLC	598 South Juniata St., Box 311, Lewistown, PA 17044–0311.	Marihuana extract, Marihuana	7350, 7360	I
5/5/17	Maridose LLC	23378 Barlake Dr., Boca Raton, FL 33433.	Marihuana, Tetrahydrocannabinols	7360, 7370	I
10/3/16	MCRGC LLC	811 Western Ave., Manchester, ME 04351.	Marihuana extract, Marihuana, Tetrahydrocannabinols.	7350, 7360, 7370	I
9/12/16	Medpharm Research, LLC	4880 Havana St., Denver, CO 80239.	Marihuana extract, Marihuana	7350, 7360	I
12/27/18.	MMJ Biopharma Cultivation	14930 Reflection Key Circle, Apt. 2511, Fort Myers, FL 33907.	Marihuana, Tetrahydrocannabinols	7360, 7370	I
1/17/17	Modern Pharmacy, LLC	123 Alton Rd., Miami Beach, FL 33139.	Marihuana extract, Marihuana	7350, 7360	I
4/5/17	National Center for Development of Natural Products.	The University of Mississippi, 135 Coy Waller Lab Complex, P.O. Box 1848, University, MS 38677.	Marihuana extract	7350	I

Date	Applicant	Address	Controlled substance	Drug Code	Sch.
5/2/19	Nuvue Pharma, LLC	4740 Dillion Drive, Pueblo, CO 81008–2112.	Marihuana	7360	I
3/31/17	Pharmacann LLC	1010 Lake St., 2nd Fl., Oak Park, IL 60301–1132.	Marihuana	7360	I
11/8/16	PS Patients Collective, Inc	36555 Bankside Drive, Cathedral City, CA 92234.	Marihuana, Tetrahydrocannabinols	7360, 7370	I
1/13/17	Scientific Botanical Pharmaceutical, Inc.	1225 W Deer Valley Rd., Phoenix, AZ 85027.	Marihuana extract, Marihuana, Tetrahydrocannabinols.	7350, 7360, 7370	I
11/29/16.	Scottsdale Research Institute	1225 W Deer Valley Rd., Phoenix, AZ 85027.	Marihuana extract	7350	I
10/3/16	The Giving Tree Wellness Center	21617 N 9th Avenue, Phoenix, AZ 85027.	Marihuana	7360	I
9/21/18	Trail Blazin' Productions	2005 Division St., Bellingham, WA 98226.	Marihuana	7360	I
2/21/17	Ultra Rich CBD	30 Rockcreek Rd., Orovada, NV 89425.	Marihuana extract	7350	I
11/1/17	University of California, Davis	One Shields Avenue, EH&S Hoagland Hall 276, Davis, CA 95616.	Marihuana	7360	I
2/22/17	University of Massachusetts	80 Campus Center Way, Amherst, MA 01003–9246.	Marihuana extract	7350	I

Dated: August 22, 2019.

Neil D. Doherty,

Acting Assistant Administrator, Deputy Assistant Administrator.

[FR Doc. 2019–18456 Filed 8–26–19; 8:45 am]

BILLING CODE 4410–09–P

DEPARTMENT OF LABOR

Office of the Secretary

Agency Information Collection Activities; Submission for OMB Review; Comment Request; National Medical Support Notice—Part B

ACTION: Notice of availability; request for comments.

SUMMARY: The Department of Labor (DOL) is submitting the Employee Benefits Security Administration (EBSA) sponsored information collection request (ICR) titled, ''National Medical Support Notice—Part B,'' to the Office of Management and Budget (OMB) for review and approval for continued use, without change, in accordance with the Paperwork Reduction Act of 1995 (PRA). Public comments on the ICR are invited.

DATES: The OMB will consider all written comments that agency receives on or before September 26, 2019.

ADDRESSES: A copy of this ICR with applicable supporting documentation; including a description of the likely respondents, proposed frequency of response, and estimated total burden may be obtained free of charge from the *RegInfo.gov* website at *http://www.reginfo.gov/public/do/PRAViewICR?ref_nbr=201907-1210-001* (this link will only become active on the day following publication of this notice) or by contacting Frederick Licari by telephone at 202–693–8073, TTY 202–693–8064, (these are not toll-free numbers) or by email at *DOL_PRA_PUBLIC@dol.gov.*

Submit comments about this request by mail to the Office of Information and Regulatory Affairs, Attn: OMB Desk Officer for DOL–EBSA, Office of Management and Budget, Room 10235, 725 17th Street NW, Washington, DC 20503; by Fax: 202–395–5806 (this is not a toll-free number); or by email: *OIRA_submission@omb.eop.gov.* Commenters are encouraged, but not required, to send a courtesy copy of any comments by mail or courier to the U.S. Department of Labor-OASAM, Office of the Chief Information Officer, Attn: Departmental Information Compliance Management Program, Room N1301, 200 Constitution Avenue NW, Washington, DC 20210; or by email: *DOL_PRA_PUBLIC@dol.gov.*

FOR FURTHER INFORMATION CONTACT: Frederick Licari by telephone at 202–693–8073, TTY 202–693–8064, (these are not toll-free numbers) or by email at *DOL_PRA_PUBLIC@dol.gov.*

SUPPLEMENTARY INFORMATION: This ICR seeks to extend PRA authority for the National Medical Support Notice—Part B information collection. Section 609 of the Employee Retirement Income Security Act (ERISA) and regulations at 29 CFR 2590.609–2 establish a National Medical Support Notice to provide group health benefits coverage pursuant to Qualified Medical Child Support Orders. Part B, Medical Support Notice to Plan Administrator, is a notice from an employer to a benefits plan administrator to implement coverage of children under ERISA covered group health plans. ERISA section 609(a) authorizes this information collection. *See* 29 U.S.C. 1169(a).

This information collection is subject to the PRA. A Federal agency generally cannot conduct or sponsor a collection of information, and the public is generally not required to respond to an information collection, unless the OMB under the PRA approves it and displays a currently valid OMB Control Number. In addition, notwithstanding any other provisions of law, no person shall generally be subject to penalty for failing to comply with a collection of information that does not display a valid Control Number. *See* 5 CFR 1320.5(a) and 1320.6. The DOL obtains OMB approval for this information collection under Control Number 1210–0113.

OMB authorization for an ICR cannot be for more than three (3) years without renewal, and the current approval for this collection is scheduled to expire on August 31, 2019. The DOL seeks to extend PRA authorization for this information collection for three (3) more years, without any change to existing requirements. The DOL notes that existing information collection requirements submitted to the OMB receive a month-to-month extension while they undergo review. For additional substantive information about this ICR, see the related notice published in the **Federal Register** on March 27, 2019 (84 FR 11573).

Interested parties are encouraged to send comments to the OMB, Office of