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 **[INSERT 60 DAYS AFTER PUBLICATION IN THE FEDERAL REGISTER]**.

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, Pub. L. 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 89117-89117-8911	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	PO 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, PO Box 1848, University, MS 38677	Marihuana extract	7350	I
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.

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