



U. S. Department of Justice  
Drug Enforcement Administration  
8701 Morrisette Drive  
Springfield, Virginia 22152

[www.dea.gov](http://www.dea.gov)

Biopharmaceutical Research Company, LLC  
BRC 27 Laurel Street  
Atherton, California 94027

AUG 26 2019  
 **COPY**

Dear George B. Hodgin:

On August 12, 2016, the Drug Enforcement Administration (DEA) published a policy statement in the Federal Register (81 FR 53846) ("2016 Policy Statement"). The 2016 Policy Statement concerned applications by persons seeking to become registered under the Controlled Substances Act (CSA) to grow (manufacture) marijuana in order to supply DEA-registered researchers in the United States. You are receiving this letter because you submitted such an application.

DEA supports research into the effects of marijuana and the potential medical utility of its chemical constituents. Under the CSA, DEA is responsible for registering growers to produce an adequate and uninterrupted supply of marijuana under adequately competitive conditions for such research. Since publication of the 2016 Policy Statement, the Department of Justice, of which DEA is a component, has determined that adjustments to DEA's policies and practices may be necessary. This letter serves two main purposes. First, we wish to inform you of DEA's intent to issue a Notice of Proposed Rulemaking (NPRM) that, if finalized, would supersede the 2016 Policy Statement. This rulemaking process will provide applicants and other interested parties an opportunity to comment on the regulations that should govern the program of growing marijuana for scientific and medical research under DEA registration consistent with applicable law. Second, this letter provides you with instructions on how to withdraw your application if you no longer wish to have your application considered by DEA, or if you no longer seek registration because of recent changes in federal law with respect to "hemp" under the Agricultural Improvement Act of 2018.

*Notice of Proposed Rulemaking*

Applications for registration to manufacture controlled substances in schedule I or II are governed by 21 U.S.C. § 823(a). Under section 823(a), the DEA Administrator (through a delegation from the Attorney General) may register such an applicant only if the Administrator determines that the registration is consistent with the public interest and with applicable laws and treaties. DEA intends to propose regulations that govern the program of growing marijuana for scientific and medical research under DEA registration, consistent with applicable law.

The 2016 policy statement 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; the most recent was filed in May 2019.



Because the size of the applicant pool is unprecedented in DEA's experience, DEA has determined that adjustments to its policies and practices with respect to the marijuana 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 marijuana 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 a notice of applications. 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 marijuana 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 marijuana as bulk manufacturers, consistent with applicable law.



#### *Recent Amendment to the CSA Regarding Hemp*

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, which was signed into law on December 20, 2018, changed the definition of marijuana under the CSA. As amended, the definition of marijuana 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 [THC] concentration of not more than 0.3 percent on a dry weight basis."<sup>1</sup> Pursuant to the amended definition, cannabis plant material that contains 0.3 percent or less delta-9 THC on a dry weight basis is not a controlled substance and does not require a DEA registration to grow. Accordingly, if you 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 and falls below the delta-9 THC threshold, you no longer need to register with DEA for that purpose.

#### *Next Steps*

In accordance with DEA regulations<sup>2</sup>, a notice of applications will be published in the Federal Register shortly. However, if, as a result of the Agriculture Improvement Act or for any other reason, you no longer wish to have your application considered by DEA, please submit a written statement indicating your desire to withdraw your application.<sup>3</sup> Upon receipt of such a request on or before November 1, 2019, DEA will refund any applicable application fees.<sup>4</sup> If you still wish to seek registration, no further action is required as of this time. DEA will provide additional information through the forthcoming NPRM and future letters to applicants, as needed.

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<sup>1</sup> 7 U.S.C. § 1639o(1); 21 U.S.C. § 802(16)(B)(i).

<sup>2</sup> 21 C.F.R. § 1301.33.

<sup>3</sup> 21 C.F.R. § 1301.16.

<sup>4</sup> DEA is granting a temporary exception to 21 C.F.R. § 1301.13(e) in order to issue refunds to those applicants who wish to withdraw their application as a bulk marijuana manufacturer.

*Contact Information*

Please submit your written correspondence regarding any of the above matters to the following address:

Drug Enforcement Administration  
Diversion Regulatory Section (DRG)  
Attn: Charlotte D. Barron, Section Chief  
8701 Morrisette Drive  
Springfield, Virginia 22152



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If you have any questions about this letter, please contact Deputy Assistant Administrator Donetta Spears at (202) 307-7165.

Sincerely,

Neil D. Doherty  
Acting Assistant Administrator  
DEA Diversion Control Division