ORAL ARGUMENT NOT SCHEDULED

No. 19-1120

IN THE

United States Court of Appeals

FOR THE DISTRICT OF COLUMBIA CIRCUIT

In re Scottsdale Research Institute, LLC,

Petitioner

_____

ON PETITION FOR A WRIT OF MANDAMUS TO WILLIAM P. BARR, U.S. ATTORNEY GENERAL, UTTAM DHILLON, ACTING ADMINISTRATOR OF THE U.S. DRUG ENFORCEMENT ADMINISTRATION, AND THE U.S. DRUG ENFORCEMENT ADMINISTRATION

Petitioner Scottsdale Research Institute, LLC's Reply in Support of Petition for a Writ of Mandamus

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GLOSSARY

CSA	Controlled Substances Act
DEA	U.S. Drug Enforcement Administration
Decl.	Declaration of Suzanne Sisley, M.D.
DOJ	U.S. Department of Justice
Ex.	Exhibit (Appendix/Supplemental Appendix)
FLRA	Federal Labor Relations Authority
FDA	U.S. Food and Drug Administration
NHTSA	National Highway Traffic Safety Administration
NIDA	National Institute on Drug Abuse
NIH	National Institutes of Health
OLC	Office of Legal Counsel
OMB	Office of Management and Budget
SRI	Scottsdale Research Institute, LLC

INTRODUCTION AND SUMMARY OF ARGUMENT

DEA does not dispute a single factual or legal point in SRI's Amended Petition. Instead, the agency argues that by publishing a document entitled "Bulk Manufacturer of Controlled Substances Applications: Bulk Manufacturers of Marihuana," the day before submitting its Response, it has rendered this case moot. Resp. 4-5, 7 (citing 84 Fed. Reg. 44,920 (Aug. 27, 2019) ("August 27th Notice")). But the August 27th Notice is not the relief SRI requested. In fact, it is not relief at all.

SRI requested an order compelling DEA to publish a notice of SRI's application to manufacture marijuana for use in clinical trials. Am. Pet. 4, 37-38. And it requested that relief for a reason. Congress established deadlines to govern DEA's processing of applications to manufacture Schedule I and II controlled substances for clinical trials. The notice of application SRI requested activates those deadlines, ensuring the promptness and transparency Congress intended.

The August 27th Notice, however, disclaims the triggering effect of a 21 U.S.C. § 823(i)(2) notice. Moreover, DEA embedded the supposed notice in a broader document that announces DEA's intent to delay further while it

creates new rules, thus ignoring its duty to make an up-or-down decision on SRI's application within the timeframe Congress intended.

In short, SRI sought an order compelling DEA to take a simple but important step to guarantee prompt processing of its application. What it got was more delay—the very delay that prompted the filing of this action. As a result, the controversy is more intense than ever. This case is not moot. Nor has DEA met its heavy burden under the voluntary cessation doctrine.

Finally, because DEA does not dispute SRI's *TRAC* analysis, this Court should retain jurisdiction to ensure the agency acts with dispatch and processes SRI's application promptly.

RELIEF SOUGHT

SRI continues to request a writ of mandamus directing the Attorney General, DEA, or its Acting Administrator to issue a notice of SRI's application to manufacture marijuana for clinical trials, commencing the registration process contemplated by section 823(i)(2) of the CSA, not later than 15 days after the writ issues.[1] SRI also requests this Court retain jurisdiction over this case.

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[1] *See* Am. Pet. 4 ("SRI seeks a writ of mandamus directing the Attorney General, DEA, or its Acting Administrator to issue a 'notice of application'"); *id.* 10-13 (explaining history of section 823(i)(2) and

ARGUMENT

I. The Case Is Not Moot.

A case is moot when "the issues presented are no longer live or the parties lack a legally cognizable interest in the outcome." *Cnty. of L.A. v. Davis*, 440 U.S. 625, 631 (1979) (quotes omitted). Here, because DEA bases its mootness argument on its own conduct in response to this action, it bears the "heavy burden" of demonstrating that "(1) there is no reasonable expectation that the conduct will recur and (2) interim relief or events have completely and irrevocably eradicated the effects of the alleged violation." *True the Vote, Inc. v. Internal Revenue Serv.*, 831 F.3d 551, 561 (D.C. Cir. 2016) (cites and quotes omitted).

DEA has not carried that burden. Contrary to its characterization, the August 27th Notice is not the relief SRI requested. And even if it were, far from demonstrating that there is no reasonable expectation that the conduct will recur, the August 27th Notice assures it will. Nor does the August 27th

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how "SRI falls within the class of researchers Congress sought to protect from delay"); *id.* 21 (citing section 823(i)(2) and arguing that SRI was entitled to a notice "to commence the process for determining whether Petitioner should be registered under the Act"); *id.* 24-25 (explaining DEA's duty to issue a notice); *id.* 30-32 (describing purpose of section 823(i)(2)); *id.* 37-38 (quoting section 823(i)(2) and explaining how requested notice would "allow the process contemplated by the statute to begin, not end").

Notice eradicate the effects of DEA's unlawful delays. Indeed, it compounds them.

a. DEA did not grant the relief SRI requested.

SRI requested an order compelling DEA to "issue a notice regarding *its* application in the Federal Register." Am. Pet. 21 (emph. added). While DEA claims to have fulfilled this request, it hasn't. The August 27th Notice differs from the relief SRI sought in form and substance.

SRI applied under section 823(i)(2) to manufacture marijuana for use in clinical trials. *See* Am Pet. 11-13, 16; Resp. 4. In contrast, the August 27th Notice never mentions clinical trials or section 823(i)(2). Also, instead of noticing SRI's application to manufacture *marijuana*, the August 27th Notice says SRI seeks to manufacture "marihuana extract." Ex. 24 at SA005 (84 Fed. Reg. at 44,921). SRI did not apply to manufacture "marihuana extract" and it did not request a notice of application to do so in its Amended Petition. *See* Ex. 1 at A004; Am. Pet. 16. Finally, SRI submitted its application on October 1, 2016. Ex. 1 at A003. DEA agrees. Resp. at 3. The August 27th Notice, however, says "11/29/2016." Ex. 24 at SA005 (84 Fed. Reg. at 44,921).

These discrepancies have consequences. DEA acknowledges that Congress singled out applications to manufacture Schedule I and II

controlled substances for clinical trials to receive expedited and transparent processing:

> If an applicant seeks to manufacture a schedule I or schedule II controlled substance "for use only in a clinical trial," the Administrator will "issue a notice of application not later than 90 days after the application is accepted for filing." 21 U.S.C. § 823(i)(2). The notice will allow for a comment period, and 90 days after the comment period ends, the Administrator will "register the applicant, or serve an order to show cause upon the applicant in accordance with" section 824(c). *Id.* If the Administrator issues a show cause order, then the Administrator will provide "a statement of the basis for the denial" of the application, will direct the applicant to appear at a hearing, and will notify the applicant "of the opportunity to submit a corrective action plan on or before" the hearing date. *Id.* § 824(c)(2).

Resp. 3. As DEA's description of this statutory timetable makes plain, a notice under section 823(i)(2) triggers the remaining statutory deadlines that guarantee an up-or-down decision on an application within months. *Id.* SRI relied on this triggering function when it requested a notice of its application. Am. Pet. 37-38. We all know this. Were it not for that triggering function, SRI's claim—that the harms it suffered from DEA's inaction could "be redressed by the relief requested"—would make little sense. Am. Pet. 21 (DEA's issuance of the requested notice would, "[u]nder the plain language of section 823(i)(2)," "commence the process for determining whether Petitioner should be registered"). DEA even acknowledges that SRI requested a notice under "21 U.S.C. § 823(i)(2)" to "'*commence the process*

for determining whether [Scottsdale] should be registered under the Act.'" Resp. 4 (quoting Am. Pet. 21) (emph. added).

Yet the August 27th Notice that DEA says provides SRI the relief it requested further undermines section 823(i)(2)'s deadlines and promises more indefinite delay. According to DEA, it needs more time to make new rules before it can make a decision to approve or deny SRI's application. Ex. 24 at SA003 (84 Fed. Reg. at 44,921); *see also* Ex. 25 (SA006) (Aug. 26, 2019 DEA letter to Dr. Sisley). These new rules are necessary, DEA says, because it has received an "unprecedented" number of applications. Ex. 24 at SA003 (84 Fed. Reg. at 44,921). But of course, that "unprecedented" backlog of 33 noticed-but-not-decided applications exists only because DEA inexplicably and unlawfully failed to process a single application to manufacture marijuana *for three years*. DEA can't use the consequences of its past egregious delays to justify even more unlawful delays going forward.

Boiled down, the August 27th Notice announces a plan to keep SRI's application in agency purgatory. That is *not* the relief SRI requested, and DEA's attempt to moot this case by doubling down on the unlawful conduct that prompted this action must be rejected.

b. Even if DEA had granted the relief SRI requested, the case still would not be moot.

Under the voluntary cessation doctrine, even if the August 27th Notice were the relief SRI requested, DEA has not carried its heavy burden to establish mootness. First, far from "completely and irrevocably eradicat[ing] the effects" of DEA's unlawful delays, the August 27th Notice compounds them. *True the Vote*, 831 F.3d at 561 (cites and quotes omitted). Second, instead of making it "absolutely clear that the allegedly wrongful behavior could not reasonably be expected to recur," *Friends of the Earth, Inc. v. Laidlaw Envtl. Servs., Inc.*, 528 U.S. 167, 190 (2000), the August 27th Notice all but guarantees the *same* unlawful conduct complained of will recur under the *same* statute in a matter of months.

In re Center for Auto Safety, 793 F.2d 1346 (D.C. Cir. 1986) ("*Auto Safety*") is instructive. The National Highway Traffic Safety Administration ("NHTSA") repeatedly missed a statutory deadline requiring it to promulgate fuel-economy standards for light trucks 18 months before the start of each model year. *Id.* at 1347-48. Petitioners asked this Court to compel the agency to promulgate standards. *See id.* While the petition was pending, NHTSA promulgated the 1987 model-year standards, and in response to this Court's request for timetables, the agency also issued the 1988 model-year

standards. *Id.* By the time this Court issued its opinion, the agency had also proposed 1989 model-year standards and assured this Court it would issue final standards timely. *Id.* at 1350. Like DEA here, NHTSA urged mootness, claiming it had granted the relief petitioners requested. But this Court rejected the plea, explaining that "petitioners have challenged a *pattern* of delay by the agency," *id.* at 1348 (emph. original), and the "pattern of missing deadlines remain[ed]," *id.* at 1352.

Nor did the agency's voluntary cessation moot the case. Despite NHTSA issuing standards more promptly in view of the pending lawsuit and assuring this Court it would act promptly going forward, this Court held the agency had not carried its burden of showing "no reasonable expectation" that it would not once again miss the statutory deadline. *Id.* at 1348. The Court emphasized the agency's history of delays and its refusal "to admit the illegality of its past conduct." *Id.* at 1352-53. These considerations increased the probability the agency would "once again fail to meet statutory deadlines in the future." *Id.*

For even stronger reasons, DEA has not carried its burden here.

First, DEA offers no assurances in the August 27th Notice, its Response, or anywhere else, that it will process SRI's application consistent with statutory mandate or in an otherwise timely manner. In fact, DEA promises

more of the same delay that inspired both section 823(i)(2) and this action. At the end of the Response, for example, DEA quotes SRI's Amended Petition, which acknowledges DEA's "discretion to deny or delay the application." Resp. 8 (quoting Am. Pet. 37). DEA takes SRI's statement out of context, however. SRI recognized DEA's discretion to delay but not beyond the confines of the timetable Congress established:

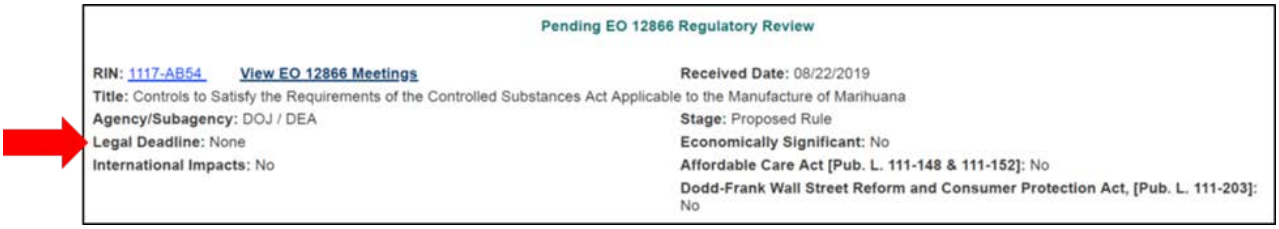
> Petitioner SRI respectfully requests this Court issue a writ of mandamus compelling the Attorney General, DEA, or its Acting Administrator to issue a "notice of application" by 90 days from the date of service of this petition or fifteen days after the writ issues, whichever is later. Notably, mandamus here will not divest the agency of its discretion. It simply allows the process contemplated by the statute to begin, not end. The agency still maintains discretion to deny or delay the application, *see, e.g.*, 21 U.S.C. § 823(i)(2) (". . . the Attorney General shall register the applicant, or serve an order to show cause upon the applicant in accordance with section 824(c) . . ."), should that continue to be its choice.

Am Pet. 37-38. DEA's confusion underscores exactly why this case is not moot, namely, because the agency plainly has no concrete deadlines going forward and has not recognized a duty to adhere to any timeline.

The August 27th Notice all but guarantees unlawful delay will persist. DEA isn't close to approving or denying SRI's application. Even if the proposed rulemaking process were well underway, it would be impossible for

the agency to promulgate new rules *and* apply them to decide SRI's application in such a short window of time.[2]

All other signs point to indefinite delay. The "policy review process" that DEA says must be completed before it can issue new rules "remains ongoing." Ex. 24 at SA003 (84 Fed. Reg. at 44,921). DEA will not be able to issue a notice of proposed rulemaking until the Office of Management and Budget ("OMB") completes its own review of the agency's proposal. Resp. 5. At the time of this writing, OMB's website reflects *no* progress on that review. Ex. 27 at SA015 (screenshot). Indeed, it provides little information at all, and as the screenshot below illustrates, what it *does* say is not reassuring—"**Legal Deadline**: None":



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[2] *See, e.g.*, Congressional Research Serv., *Agency Delay: Congressional and Judicial Means to Expedite Agency Rulemaking* at 5 and nn.37, 41 (Oct. 5, 2018), *available at* https://fas.org/sgp/crs/misc/R45336.pdf (noting average administrative rulemaking takes between one and two years but many take "41 months or longer").

Second, DEA's refusal to acknowledge its obligation to process applications promptly—even in the face of a statute designed to cure opaqueness and delay—demonstrates it will likely continue to ignore deadlines. Two days before filing the Response, DEA, the Acting Administrator, DOJ, and the Attorney General all went on record touting DEA's plan to promulgate new rules to facilitate marijuana research. Ex. 26 (SA010) (Aug. 26, 2019 press releases). Nobody acknowledged an obligation to process any applications promptly. Nor did DEA say anything about the unlawfulness or unreasonableness of its refusal to process applications that have been pending for years. As this Court explained *Auto Safety*, a "refusal to admit the illegality of its past conduct heightens the probability that the agency will once again fail to meet statutory deadlines in the future." 793 F.2d at 1353.

The cases DEA relies on are not persuasive. Most stand for the unremarkable proposition that, as a general matter, a mandamus action becomes moot when the government takes the action requested in the petition. *See, e.g.*, Resp. 7-8 & n.2. Consider *In re American Federation of Government Employees, AFL-CIO*, 837 F.2d 503, 505 (D.C. Cir. 1988)

("*American Federation*"), one of the two cases DEA chiefly relies on.[3] It undercuts DEA's argument. DEA correctly notes that this Court held a mandamus action that sought to compel the Federal Labor Relations Authority ("FLRA") to decide certain appeals within thirty days was moot because "all the negotiability appeals listed in the petition ha[d] been decided." Resp. 7 (citing *American Federation*, 83 F.2d at 505). But there, the request for prompt resolution of the appeals at issue was an end in itself. *American Federation*, 837 F.2d at 504-05. Once FLRA disposed of the appeals, petitioners had received all the relief they requested. Here, in contrast, SRI's request for a notice of application was a means to end DEA's unlawful delay. Am. Pet. 37 ("[M]andamus here will . . . simply allow[] the process contemplated by the statute to begin, not end."). But by embedding the August 27th Notice in a broader document that disclaims the effectiveness of the notice of SRI's application to activate section 823(i)(2)'s remaining deadlines, DEA stripped the notice of the power that motivated SRI to request it in the first place.

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[3] The other is *Gordon v. Gray*, 193 F.2d 367 (D.C. Cir. 1951), a two-paragraph per curiam opinion that is also distinguishable. Unlike this case, the "substantive objectives which could be served by a writ of mandamus" in *Gordon* "ha[d] been served." *Id.* at 367. Not so here where DEA intends to continue its unlawful delays.

Furthermore, in *American Federation*, this Court concluded that the request for an order requiring FLRA to process all future negotiability appeals within six months was *not moot*. 837 F.2d at 507. Although FLRA was apologetic—promising to act more promptly in the future and implementing internal improvements to facilitate faster resolution of appeals—this Court held that the agency still had not shown the unlawful delays were unlikely to recur. *Id*. Here, in contrast, DEA has never acknowledged its unlawful conduct and offers no assurance it will change its ways in the future.

More important, DEA's cases do not involve an agency's attempt to manufacture mootness by doubling down on the same unlawful conduct that triggered the filing of the action. This Court has held that an agency cannot establish mootness when it equivocates about its intent to refrain from unlawful conduct going forward. *See, e.g.*, *True the Vote*, 831 F.3d at 563 (D.C. Cir. 2016) (holding agency's statement that it had merely *suspended* unlawful activity was insufficient to demonstrate "no reasonable expectation of resumption"). For even stronger reasons, DEA cannot establish mootness while promising to continue its unlawful delays.

II. The Court Should Retain Jurisdiction Over This Case.

Even in cases where this Court has declined to issue a writ of mandamus, it has retained jurisdiction to ensure the agency acts with appropriate dispatch going forward. The writ should issue, for the reasons stated above and in the Amended Petition. But in any case, the Court should retain jurisdiction.

Auto Safety is, once again, instructive. Even after NHTSA took the requested action, this Court retained jurisdiction because of the agency's history of chronic delay, the effect the delay had on the statutory scheme, and the agency's refusal to admit the illegality of its past conduct. 793 F.2d at 1354. In *TRAC*, although this Court declined to compel agency action via mandamus, it retained jurisdiction until final disposition by the agency to ensure the agency kept its promise of expeditious treatment of petitioners' claim. *Telecomms. Research & Action Ctr. v. F.C.C.*, 750 F.2d 70, 81 (D.C. Cir. 1984). The Court also required periodic updates from the agency, and stated that "[p]rior to final agency orders, any party may petition this court to take additional appropriate action as may be warranted." *Id.*; *see also In re Monroe Commc'ns Corp.*, 840 F.2d 942, 947 (D.C. Cir. 1988) ("[T]he unusual circumstance of an unrebutted allegation of bad faith leads us to retain jurisdiction over the case until the license is awarded to ensure the kind of progress promised at oral argument."); *In re Bluewater Network*, 234 F.3d 1305, 1316 (D.C. Cir. 2000) (similar).

More recently, in *In re United Mine Workers of Am. Int'l Union*, the Court declined to issue a writ of mandamus, but retained jurisdiction where the agency had violated a ninety-day deadline for rulemaking under the Mine Safety and Health Act of 1977, 30 U.S.C. § 811(a)(4) ("Mine Act"). 190 F.3d 545, 549-50 (D.C. Cir. 1999). The parties agreed the rulemaking had great significance to the health and safety of miners. While the agency contended it had discretion to defer the deadline, this Court disagreed, concluding that the deadline put a "closure date" on the process. *Id.* at 550-51. Faced with a transparent violation of the statutory deadline, this Court declined to issue mandamus relief which would have interfered with the agency's internal processes and damaged the interests petitioner sought to protect with the writ. *Id.* at 551, 556. At the same time, however, in view of the agency's briefs, which contained "no hint of a schedule for coming into compliance with the Mine Act," this Court accepted the alternative suggestion to retain jurisdiction. *Id.* at 554, 556.

The circumstances here justify similar relief. They are as concerning, if not more concerning, than those in the cases cited above. DEA does not justify its unlawful delay in publishing a two-page notice, but instead, proposes to stall on SRI's application while the agency makes new rules. DEA disputes *none* of SRI's analysis under *TRAC*. In particular, it does not dispute that good science using medical grade cannabis is an urgent national priority that implicates the health and welfare of our nation's veterans and everyone

else that uses medicinal cannabis. If, as the agency maintains, marijuana has "no currently accepted medical use in in treatment the United States" because of a lack of adequate and well controlled studies proving efficacy, *see* Am. Pet. 6-7 (citing Ex. 16), then robust FDA approved clinical trials involving true medical-grade cannabis are needed as soon as possible. Indeed, the very same day DEA published the August 27th Notice, FDA and the National Institutes of Health ("NIH") explained exactly what Dr. Sisley declared, Decl. ¶¶ 20-29—that the NIDA monopoly stifles robust cannabis-based clinical trials:

> There are a variety of barriers to conducting research on cannabis and cannabanoids. First, through a contract with University of Mississippi, which is the only entity registered with the Drug Enforcement Agency (DEA) to cultivate marijuana for research purposes, NIDA is the only source of marijuana permitted for use in research, thereby limiting the diversity products and formulations available to researchers and slowing the development of cannabis-based medications. *Although the University of Mississippi supplies cannabis for clinical trials, it does not have the capacity to manufacture a broad array of cannabis-derived formulations for research or to supply these cannabis products for commercial development*.

Ex. 28 at SA019 (Aug. 27, 2019 FDA/NIH Ltr. to Sen. Schatz) (emph. added).

For three years, DEA and DOJ shirked congressional inquiries about this important program essential to facilitating robust clinical trials. Am. Pet. at 18-19. Even today, neither explains—to Congress, the public, or even to this Court—why more than three years lapsed before the agency *announced* the supposed need for new rules, or more fundamentally, why special rules for manufacturing *marijuana*, as opposed to other controlled substances, are

necessary at all. And over three years, only one event ever triggered any visible agency action: this Court ordering DEA to respond to SRI's Amended Petition, which it basically did not do.[4]

DEA's non-response makes it impossible to gauge the purity of its motives. But at the very least, the facts and circumstances of this case justify this Court maintaining jurisdiction.

CONCLUSION

It is time for the "administrative keep-away" game to end. *In re Am. Rivers & Idaho Rivers United*, 372 F.3d 413, 420 (D.C. Cir. 2004). The Court should issue the writ, and in any case, retain jurisdiction to ensure the agency acts with dispatch going forward.

[4] SRI suspects (although it cannot be certain) that DEA's non-response in this case and its refusal to allow applications to manufacture marijuana to mature into reviewable final agency action share a common root: a desire to shield from judicial scrutiny an undisclosed Office of Legal Counsel ("OLC") interpretation of the Single Convention on Narcotic Drugs of 1961, contrary to the view DEA took in August 2016. *See* Ex. 16 at A159 ("Treaty Considerations"); Ex. 20 at A176 (Sept. 2018 Wall St. Journal article explaining OLC concluded growers program violated 1961 Treaty); *see also* Ex. 24 at SA003 (DOJ, in consultation with other federal agencies, has been engaged in "policy review process to ensure that the marihuana growers program is consistent with applicable law *and treaties*") (emph. added).

Dated September 11, 2019

Respectfully Submitted,

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CERTIFICATE OF COMPLIANCE

This Reply complies with this Court's July 29, 2019 Order because it contains 3,852 words.

I further certify that this Reply complies with the typeface requirements of Federal Rule of Appellate Procedure 32(a)(5) and the type style requirements of Federal Rule of Appellate Procedure 32(a)(6) because the Reply has been prepared in Georgia 14-point font for text and footnotes using Microsoft Word.

Dated September 11, 2019

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CERTIFICATE OF SERVICE

I certify that on September 11, 2019, I electronically filed this document with the Clerk of the Court for the United States Court of Appeals for the District of Columbia Circuit by using the appellate CM/ECF system. Participants in the case are registered CM/ECF users, and service will be accomplished by the appellate CM/ECF system.

/s/ *Shane Pennington*
Shane Pennington

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EXHIBIT 24

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

EXHIBIT 25

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

www.dea.gov

Scottsdale Research Institute
1225 W. Deer Valley Road
Phoenix, Arizona 85027

AUG 2 6 2019

Dear Suzanne Sisley:

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."[1] 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[2], 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.[3] Upon receipt of such a request on or before November 1, 2019, DEA will refund any applicable application fees.[4] 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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[1] 7 U.S.C. § 1639*o*(1); 21 U.S.C. § 802(16)(B)(i).
[2] 21 C.F.R. § 1301.33.
[3] 21 C.F.R. § 1301.16.
[4] 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 Morrissette Drive
Springfield, Virginia 22152

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

EXHIBIT 26

[redacted]

Department of Justice

Office of Public Affairs

FOR IMMEDIATE RELEASE Monday, August 26, 2019

DEA Announces Steps Necessary to Improve Access to Marijuana Research

The Drug Enforcement Administration today announced that it is moving forward to facilitate and expand scientific and medical research for marijuana in the United States. The DEA is providing notice of pending applications from entities applying to be registered to manufacture marijuana for researchers. DEA anticipates that registering additional qualified marijuana growers will increase the variety of marijuana available for these purposes.

Over the last two years, the total number of individuals registered by DEA to conduct research with marijuana, marijuana extracts, derivatives and delta-9-tetrahydrocannabinol (THC) has increased by more than 40 percent from 384 in January 2017 to 542 in January 2019. Similarly, in the last two years, DEA has more than doubled the production quota for marijuana each year based on increased usage projections for federally approved research projects.

“I am pleased that DEA is moving forward with its review of applications for those who seek to grow marijuana legally to support research,” said Attorney General William P. Barr. “The Department of Justice will continue to work with our colleagues at the Department of Health and Human Services and across the Administration to improve research opportunities wherever we can.”

“DEA is making progress in the program to register additional marijuana growers for federally authorized research, and will work with other relevant federal agencies to expedite the necessary next steps,” said DEA Acting Administrator Uttam Dhillon. “We support additional research into marijuana and its components, and we believe registering more growers will result in researchers having access to a wider variety for study.”

This notice also announces 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, which was signed into law on Dec. 20, 2018, changed the definition of marijuana to exclude “hemp”—plant material that contains 0.3 percent or less delta-9 THC on a dry weight basis. Accordingly, hemp, including hemp plants and cannabidiol (CBD) preparations at or below the 0.3 percent delta-9 THC threshold, is not a controlled substance, and a DEA registration is not required to grow or research it.

Before making decisions on these pending applications, DEA intends to propose new regulations that will govern the marijuana growers program for scientific and medical research. The new rules will help ensure DEA can evaluate the applications under the applicable legal standard and conform the program to relevant laws. To ensure transparency and public participation, this process will provide applicants and the general public with an opportunity to comment on the regulations that should govern the program of growing marijuana for scientific and medical research.

The Notice of Application is available here: https://www.federalregister.gov/documents/2019/08/27/2019-18456/bulk-manufacturer-of-controlled-substances-applications-bulk-manufacturers-of-marihuana.

Component(s):
Drug Enforcement Administration (DEA)
Office of the Attorney General

Press Release Number:
19-895

Drug Enforcement Administration

DEA Headquarters
@DEAHQ

August 26, 2019
Contact: National Media Affairs Office
Phone Number: (202) 307-7977
FOR IMMEDIATE RELEASE

DEA announces steps necessary to improve access to marijuana research

WASHINGTON – The Drug Enforcement Administration today announced that it is moving forward to facilitate and expand scientific and medical research for marijuana in the United States. The DEA is providing notice of pending applications from entities applying to be registered to manufacture marijuana for researchers. DEA anticipates that registering additional qualified marijuana growers will increase the variety of marijuana available for these purposes.

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hemp, including hemp plants and cannabidiol (CBD) preparations at or below the 0.3 percent delta-9 THC threshold, is not a controlled substance, and a DEA registration is not required to grow or research it.

Before making decisions on these pending applications, DEA intends to propose new regulations that will govern the marijuana growers program for scientific and medical research. The new rules will help ensure DEA can evaluate the applications under the applicable legal standard and conform the program to relevant laws. To ensure transparency and public participation, this process will provide applicants and the general public with an opportunity to comment on the regulations that should govern the program of growing marijuana for scientific and medical research.

Notice of Application.

Who We Are+
What We Do+
Resources+
Doing Business with the DEA+
Policies+

EXHIBIT 27

Pending EO 12866 Regulatory Review

RIN: 1117-AB54 **View EO 12866 Meetings**
Received Date: 08/22/2019
Title: Controls to Satisfy the Requirements of the Controlled Substances Act Applicable to the Manufacture of Marihuana
Agency/Subagency: DOJ / DEA
Stage: Proposed Rule
Legal Deadline: None
Economically Significant: No
International Impacts: No
Affordable Care Act [Pub. L. 111-148 & 111-152]: No
Dodd-Frank Wall Street Reform and Consumer Protection Act, [Pub. L. 111-203]: No

EXHIBIT 28

August 27, 2019

The Honorable Brian Schatz
United States Senate
Washington, DC 20510-1105

Dear Senator Schatz:

Thank you for your March 20 letter requesting information on research and regulatory issues related to the therapeutic use of cannabis and cannabinoid compounds. The National Institutes of Health (NIH) and the Food and Drug Administration (FDA) are committed to advancing research on the risks and potential benefits of cannabis for therapeutic uses, and we are pleased to share the following information about this important area of inquiry with you.

NIH's research portfolio includes epidemiologic, basic, and applied research on cannabis, its constituent compounds, and the endocannabinoid system through which cannabinoids act. Much of the current evidence on cannabis and health was synthesized in a National Academy of Sciences report, "The Health Effects of Cannabis and Cannabinoids: The Current State of Evidence and Recommendations for Research,"[1] which was sponsored by the National Institute on Drug Abuse (NIDA), the National Cancer Institute (NCI), the Centers for Disease Control and Prevention, FDA, and other stakeholders. The report summarizes the evidence on the efficacy of cannabis or cannabinoids for chronic pain, as anti-emetics, and for improving patient-reported spasticity symptoms in multiple sclerosis, as well as evidence on the risks cannabis poses to respiratory health, brain development, and impaired driving.

Several NIH Institutes and Centers, including NIDA, the National Center for Complementary and Integrative Health (NCCIH), the National Institute of Neurological Disorders and Stroke, NCI, the National Institute on Alcohol Abuse and Alcoholism (NIAAA), the National Institute of Arthritis and Musculoskeletal and Skin Diseases, and the National Institute of Diabetes and Digestive and Kidney Diseases fund studies on the therapeutic potential of cannabis and cannabinoids as relevant to their respective missions. In fiscal year 2018, NIH estimates to have spent $148 million on cannabinoid research, broadly, and $38 million on therapeutics, specifically. NIH funds studies on delta-9-tetrahydrocannabinol (THC) and cannabidiol (CBD), two of the cannabinoid components of the cannabis plant, for the treatment of pain, including chronic pain, back pain, and neuropathic pain caused by HIV. Several studies are also examining the endogenous signaling system that cannabinoids influence as a potential target for new pain and addiction therapies, including difficult-to-treat issues such as pain caused by sickle

[1] National Academies of Sciences, Engineering, and Medicine. 2017. The health effects of cannabis and cannabinoids: Current state of evidence and recommendations for research. Washington, DC: The National Academies Press.

cell disease or diabetic neuropathy. As part of these efforts, NIH recently reissued a funding opportunity announcement (FOA) titled "Developing the Therapeutic Potential of the Endocannabinoid System for Pain Treatment," signaling its continued interest in this area. NIH supports research on the development of novel CBD therapies to further understanding of the therapeutic potential of CBD. NIH's research portfolio on cannabinoids has already helped to facilitate important therapeutic advances, providing some of the early basic and preclinical work on CBD as an epilepsy therapy. FDA's June 2018 approval of Epidiolex (cannabidiol oral solution for the treatment of seizures associated with Lennox-Gastaut syndrome or Dravet syndrome) demonstrates the potential for CBD drug development.

FDA also has demonstrated extensive support for drug development with cannabis and plant-derived cannabinoids. The Epidiolex development program received a fast track designation in FDA's Center for Drug Evaluation and Research. The new drug application for Epidiolex had been given a priority review and was approved in its first review cycle under the shortened review period for priority review of a new molecular entity. In addition, FDA has granted fast track designation for other cannabis-derived investigational new drug programs. FDA will continue to support development of drugs from the cannabis plant, and will continue to leverage its expedited programs (e.g., fast track, breakthrough therapy designation, etc.) to facilitate this drug development whenever the relevant standards are met.[2] This support includes the development of guidance for formulating and developing botanical drugs, and engagement with companies in formal industry meetings to discuss their planned or ongoing drug development programs for drugs derived from cannabis or containing cannabinoids.

NIH is also interested in disentangling the distinct therapeutic benefits and potential health risks of different component compounds within cannabis. Several studies across NIH are examining whether THC, CBD, and other cannabis components might have distinct profiles of risk and benefit. To further facilitate such research, in early 2019, NCCIH released an FOA titled "Exploring the Mechanisms Underlying Analgesic Properties of Minor Cannabinoids and Terpenes," which focused on soliciting applications to study the therapeutic potential of non-THC/CBD components of cannabis as it relates to pain and nociception.

NIH also supports policy research on cannabis, including how it affects the use of other drugs. In 2017, NIAAA, NIDA, and NCI issued a program announcement for research on "Public Policy Effects on Alcohol-, Marijuana-, and Other Substance-Related Behaviors and Outcomes," which invites grant applications (through 2020) to study how changes in policy affect substance use. One project funded under this FOA is examining how local policies around both cannabis and opioids contribute to the use of both retail marijuana and prescription opioids within a particular jurisdiction. NIH is also supporting research to determine whether individuals in states with legalized medical marijuana transition to using cannabis as a replacement for prescribed controlled substances like opioids.

NIH and FDA strongly support the need for additional research on cannabis and its constituent

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[2] For example, a drug may be granted breakthrough therapy designation "if the drug is intended, alone or in combination with one or more other drugs, to treat a serious or life-threatening disease or condition and preliminary clinical evidence indicates that the drug may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints" (21 U.S.C. 356(a)(1)).

compounds. A larger body of rigorous research, including on cannabis and cannabinoid products that are already in use or that could be developed into FDA-approved medications, is key to furthering our understanding of their potential medical benefits and risks. Research on cannabis as an alternative or adjunctive to opioids for treating pain conditions is ongoing; however, the study of cannabis as a treatment for opioid use disorder (OUD) is a gap area, with the exception of some work using CBD. At present, there are no clinical data showing that cannabis is effective for treating OUD (though there are other FDA-approved medications with established safety and efficacy that are underutilized),[3] and the current evidence on the use of cannabis to replace or reduce opioid use for pain is inconclusive. These are important areas for further research.

There are a variety of barriers to conducting research on cannabis and cannabinoids. First, through a contract with the University of Mississippi, which is the only entity registered with the Drug Enforcement Administration (DEA) to cultivate marijuana for research purposes, NIDA is the only source of marijuana permitted for use in research, thereby limiting the diversity of products and formulations available to researchers and slowing the development of cannabis-based medications.[4] Although the University of Mississippi supplies cannabis for clinical trials, it does not have the capacity to manufacture a broad array of cannabis-derived formulations for research or to supply these cannabis products for commercial development. It is not clear how entities seeking to develop these products for commercial purposes would demonstrate equivalency between the University of Mississippi cannabis used in clinical trials and the drug product that would ultimately be approved by the FDA for eventual marketing and sale. With this in mind, NIH and FDA support licensing additional entities to supply cannabis, including extracts and derivatives, to legitimate researchers and drug product developers in the United States.

Second, another barrier to advancing cannabis research is that, under federal law, researchers are unable to purchase strains of marijuana or products containing marijuana from state dispensaries (even with non-federal funds), resulting in a significant gap in our understanding of these products and their impact on health. Licensing additional entities to supply marijuana may improve the diversity of research products that more closely reflect what is currently consumed. In addition, NIH and FDA support enabling researchers holding Schedule I licenses for marijuana to obtain products from state authorized dispensaries. Such products could be used for basic or clinical research, provided such materials to be used in clinical studies also comply with FDA chemistry, manufacturing, and control requirements for materials to be used in research conducted under an investigational new drug application.

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[3] National Academies of Sciences, Engineering, and Medicine. 2019. Medications for opioid use disorder save lives. Washington, DC: The National Academies Press. doi: https://doi.org/10.17226/25310 .

[4] Marijuana is defined under the Controlled Substances Act as "all parts of the plant Cannabis sativa L., whether growing or not; the seeds thereof; the resin extracted from any part of such plant; and every compound, manufacture, salt, derivative, mixture, or preparation of such plant, its seeds or resin. Such term does not include hemp or the mature stalks of such plant, fiber produced from such stalks, oil or cake made from the seeds of such plant, any other compound, manufacture, salt, derivative, mixture, or preparation of such mature stalks (except the resin extracted therefrom), fiber, oil, or cake, or the sterilized seed of such plant which is incapable of germination." 21 U.S.C. § 802(16).

The continued placement of marijuana in Schedule I of the Controlled Substances Act creates significant administrative and cost challenges that slow this research and may deter scientists from pursuing cannabis research altogether. For example, researchers have reported that the registration process can take more than a year to complete, that the process of adding different cannabinoids (e.g., THC, and individual *cannabimimetics*) to a researcher's Schedule I registration is time consuming, and that differing interpretations of the Schedule I registration process among local DEA field offices as well as distinct federal and state registration requirements greatly complicate the process. To address these challenges, NIH and FDA recommend streamlining the process for conducting research with cannabis and other Schedule I substances.

Thank you again for your inquiry on cannabis and cannabinoid research and for soliciting our input on the barriers to conducting this research and how they could be addressed. Please do not hesitate to contact us if we can provide you with additional information on the role of NIH or FDA in advancing this important area of science.

Sincerely yours,

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