ORAL ARGUMENT NOT SCHEDULED
No.

IN THE

UNITED STATES COURT OF APPEALS

FOR THE DISTRICT OF COLUMBIA CIRCUIT

In Re MMJ BioPharma Cultivation Inc.

Petitioner

ON PETITION FOR A WRIT OF MANDAMUS TO MERRICK GARLAND, U.S. ATTORNEY GENERAL, ANN MILGRAM, ACTING ADMINISTRATOR OF THE U.S. DRUG ENFORCEMENT ADMINISTRATION, THOMAS COOK, INVESTIGATOR OF THE U.S. DRUG ENFORCEMENT ADMINISTRATION, THE U.S. DRUG ENFORCEMENT ADMINISTRATION, AND THE U.S. DEPARTMENT OF JUSTICE

Petition for a Writ of Mandamus

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GLOSSARY

APA…….Administrative Procedure Act

API ……..…….Active Pharmaceutical Ingredient

Catalent……..Catalent Pharma Solutions

CSA…….Controlled Substances Act

DEA……U.S. Drug Enforcement Administration

DOJ……...U.S. Department of Justice

FDA.…..….....….....….....U.S Food and Drug Administration

MCREA……..……..Marijuana and Cannabidiol Research Expansion Act

MMJ…….....MMJ BioPharma Cultivation Inc.

PRELIMINARY STATEMENT

The petitioner in this case, MMJ Biopharma Cultivation Inc. ("MMJ"), has exhausted every resource and avenue before reaching the point of necessity to file this action. MMJ was created in an effort to conduct groundbreaking research with the power to potentially change the lives of many for the better with the power of marihuana. However, due to exponential delays in the registration process, the DEA is hindering MMJ's ability to fulfill their mission.

MMJ is in the business of pharmaceutical development and seeks to produce a gel capsule which contains extracts from the marijuana plant. Without the approval of their registration, MMJ is unable to import and cultivate the specific marihuana plant genetics required for the pharmaceutical development and FDA protocols. These delays by the DEA create unnecessary barriers to this research and development of pharmaceutical drugs that could potentially ameliorate the symptoms of those suffering from chronic illnesses such as Multiple Sclerosis and Huntington's Disease. Despite beginning this process in November of 2017, MMJ has been unable to conduct the research that it was created to do. Further issues are created due to the fact that MMJ is similarly unable to fulfill their obligations to other parties connected to this pharmaceutical research and development because they have not yet been able

to obtain the proper registrations. None of these issues would have arisen if the DEA processed this application in a timely manner. The full details of the timeline and events from the beginning are set forth below.

On December 27, 2018, MMJ submitted DEA applications to import and manufacture Marihuana (drug codes 7350, 7360, and 7370) for the purpose of conducting FDA-approved clinical trials. MMJ received a 357 permit authorization from the DEA to import from Canada to the USA on November 12, 2019. Materials imported from Canada were received by a DEA schedule 1 registrant, Catalent, to start the required research to produce a soft gelatin capsule. The soft gelatin capsules are to be used in the MMJ pharmaceutical products.

As indicated above, MMJ applied to the DEA for an API Bulk Manufacturer (W18134021E) registration which will enable them to cultivate marijuana for their research and development of the above-mentioned pharmaceutical drug. This registration is essential to MMJ's ability to conduct FDA-sanctioned clinical trials because without the ability to cultivate their own marijuana, they are unable to produce the proper compound under their FDA IND approval. MMJ's research and development requires painstakingly careful control of all plant genetics in order to maintain compliance with FDA requirements regarding the consistent reproducibility of the compounds found in the pharmaceutical. See generally 21 CFR 330.10 and the "Botanical Drug

Development Guidance", published by the FDA in 2016.

On June 22, 2021, the DEA commenced their pre-registration 303 investigation process[1], and MMJ received the first visit by DEA Diversion personnel that day. The 303 investigation concluded when the final on-site visit took place on October 24, 2021. At the end of the visit, the diversion investigator informed MMJ that they would return to the DEA office, "write up" the report, and submit the report to their group supervisor who would then submit those findings to DEA Headquarters for a final determination. During the 303 investigation inspection, all DEA questions were satisfactorily answered, all security systems and protocols were reviewed, and MMJ demonstrated that all security and diversion conditions were in compliance with the regulations.

MMJ has not received any determination on the Bulk Manufacturing registration application. Despite numerous attempts to follow-up and check the status of the registration approval determinations for manufacturing, DEA personnel have expressed to MMJ that they have not yet made final determinations ***and they have no idea when that determination will be made***. DEA personnel responded "why do you want to know?" when MMJ inquired regarding the status of the registrations in April of 2022 and recently in June 2023, they said that "they'll get to it when they get to it."

[1] Named a "303" investigation after the legislative tracking number which established the investigatory process under the CSA.

The MCREA was signed into law on December 2, 2022, which - in theory - made the approval process for research faster and mandated DEA application responses within a 60-day period. The MCREA directs the DEA to follow procedures specified within the Act to expedite registrations for practitioners and institutions for the purpose of conducting research. As of this date, there has still been no determination on MMJ's registration. As such, the DEA has flagrantly ignored the deadlines put in place by the CSA and the MCREA, as well as ignored the requests of the sitting President of the United States.

It has been about five years since MMJ applied for the DEA registration and over a year since the DEA's last 303 Investigation. With this timeline being egregiously ignored, MMJ can no longer wait for the DEA to do nothing and with the CSA and MCREA in place, it should not have to. The DEA's action has been unlawfully withheld and absolutely unreasonably delayed. Recognizing that they were getting virtually nowhere with the DEA, on July 21, 2023 MMJ sent a demand letter to the DEA demanding that the DEA make a determination within 7 days or that MMJ would be forced to ask this Court for assistance. That notice period has long run its course. This demand letter was also sent to representatives for the State of Rhode Island, Rhode Island Senators, and Rhode Island's Secretary of Commerce, Gina Riamondo. Much

to their dismay, nothing came of these letters.

MMJ is turning to this Court because they have exhausted all avenues to try to redress this issue. MMJ's President, Duane Boise, has made several attempts to handle this matter amicably and efficiently without resorting to a lawsuit. The press has gotten involved and several delegates from Rhode Island have expressed their concern about this issue. The DEA's blatant disregard of the severity of this situation and lack of respect for the procedures and regulations in place have caused significant damage to MMJ. Countless patients affected by Multiple Sclerosis and Huntington's Disease are waiting on the potentially life-restoring treatments associated with the development of these pharmaceuticals.

The DEA, however, appears to be dragging their feet despite MMJ's constant and almost overbearing commitment to excellence which far exceeds mere compliance with the DEA's regulations and protocols. The DEA has found MMJ's security and diversion plans sufficient for the researcher registration, yet has been unable to make a determination for MMJ's manufacturing registration for some inexplicable reason which has not been articulated to MMJ. At this juncture, nothing short of a writ from this Court compelling the DEA to act will stop the ongoing harm by the DEA's unlawful and disrespectful delay.

RELIEF SOUGHT

MMJ seeks a writ of mandamus directing the Attorney General, DEA or its Acting Administrator to issue a final determination on all pending registration submitted by MMJ by 90 (ninety) days from the date of service of this petition or 15 (fifteen) after the writ issues, whichever is earlier. Additionally, MMJ requests this Court declare that the Attorney General, DEA, or its Acting Administrator's acts and omissions as alleged in this Petition violate the CSA and APA.

JURISDICTION STATEMENT

This petition for mandamus is brought under 28 U.S.C. § 1631 (the "Mandamus Act") which states that "[t]he district courts shall have original jurisdiction of any action in the nature of mandamus to compel . . . any agency . . . to perform a duty owed to the petitioner." This petition also arises under the Administrative Procedure Act ("APA"), 5 U.S.C. §§ 555(b), 702, and 706(1). DEA's failure to issue a notice of MMJ's application is agency action both unlawfully withheld and unreasonably delayed.

The Controlled Substances Act ("CSA") provides that the Courts of Appeals have direct review of all final determinations, findings, and conclusions of the Attorney General or agency decisions. 21 U.S.C. § 877. This action arises under the DEA's inaction and failure to make a determination for Petitioners'

registration. *Id.*

In addition, pursuant to the All Writs Act, this Court is permitted to issue writs of mandamus to cure unreasonable delays. *Telecomms. Research & Action Ctr. v. FCC,* 750 F.2d 70, 75 (D.C. Cir. 1984)("*TRAC*").

ISSUE PRESENTED

MMJ applied for a Bulk Manufacturer registration in an effort to be FDA compliant. The decision on this registration should have been issued within 90 days of the date of application. Instead of the prescribed 90-day period, nearly six years have passed since they started applying for these registrations, and the agency has still refused to make progress on the remaining Bulk Manufacturer registration.

This petition presents two issues:

(i) Has the DEA unlawfully withheld agency action under 21 U.S.C. § 823(i)(2)?

(ii) Should this Court issue a writ of mandamus under D.C. App. R. 26(c) to compel the agency to make a final determination on MMJ's Bulk Manufacturing registration application?

STATEMENT OF THE CASE

The CSA regulates the manufacturing, possession, and distribution of Controlled Substances. 21 U.S.C. § 801. The CSA classifies controlled substances into five schedules, with Schedule I being the most restricted class of drugs. 21 U.S.C. § 811(c). Marihuana is classified as a Schedule I drug. 21 U.S.C. § 812(c)(a). The CSA grants the authority to the U.S. Attorney General to promulgate regulations to enforce the CSA. 21 U.S.C. 811(a).

A. Processing applications.

The DEA may register an applicant for pharmaceutical research if it finds that the registration is in the public interest. 21 U.S.C. § 822(a). There has been increased interest in developing pharmaceutical drugs derived from Marihuana. The DEA has promulgated regulations for an entity to register for pharmaceutical research using Marihuana under 21 C.F.R. § 1301.13 and 21 C.F.R. § 1301.18.

For many years, the only registration which has been approved by the DEA has been the University of Mississippi. Despite this fact, amongst the research community it has been a long recognized fact that the Marihuana produced by the University of Mississippi was insufficient and of low quality for pharmaceutical research and development.

In 2015, Congress passed the "Improving Regulatory Transparency for New Medical Therapies Act", which was enacted on November 15, 2015. The Act amended the CSA to include a requirement that the Attorney General "issue a notice of application not later than 90 days after the application is accepted for filing. Not later than 90 days after the date on which the period for comment pursuant to such notice ends, the Attorney General shall register the applicant, or serve an order to show cause upon the applicant in accordance with section 824(c) of this title, unless the Attorney General has granted a hearing on the application under section 958(i) of this title." 21 U.S.C. § 823(i)(2)(a), emphasis added.

B. Congress expands research.

In 2016, in an effort to meet the growing demand for pharmaceutical research utilizing marihuana, the DEA announced an expansion of the registration program, stating that the DEA was"adopting a new policy . . . designed to increase the number of entities registered under the Controlled Substances Act to cultivate (manufacture) Marihuana to supply legitimate researchers in the United States." 81 Fed.Reg. 53846. The DEA also emphasized that this expansion was in an effort "[t]o facilitate research involving Marihuana and its chemical constituents." *Id.*

The process for registration is laid out in the DEA regulations, found at 21 C.F.R. § 1301. In addition, 21 C.F.R. § 1318 covers the registration for

manufacturing (including cultivation) of Marihuana. Without these deadlines in place, the DEA can delay processing applications for years with little to no recourse, which can have a severe detrimental impact on medical innovation and public health. In this, that was the exact outcome. The Belviq and Fycompa cases are perfect examples to illustrate this fact; both companies were not able to get FDA approval until the DEA had made a scheduling decision, and they lost significant advantages such as market exclusivity, due to this delay. See generally *Eisai, Inc. v. United States FDA*, 134 F. Supp. 3d 384, 390 (D.D.C. 2015)(chronicling the two companies' stories).

On December 2, 2022, the MCREA was enacted to ensure that the DEA followed specified procedures allowing more practitioners to conduct research and manufacturers to supply Marihuana for research purposes. Pub. L. 117-215. As illustrated by Eisai, Inc., the deadlines created by the CSA and MCREA were enacted to ensure that registrants are not unjustly injured by the lack of action by the DEA. *Eisai, Inc. v. United States FDA*, 134 F. Supp. 3d at 390.

SUMMARY OF THE ARGUMENT

The DEA's failure to make a determination on MMJ's Bulk Manufacturing registration application is unlawful, unreasonable, and a flagrant disregard for several laws and regulations. This inaction goes directly against that CSA,

significantly harms MMJ and ignores MMJ's efforts to help suffering individuals with Huntingson's Disease and Multiple Sclerosis through clinical research. All parties involved, including the DEA recognize that this work is important and should be able to continue. Unfortunately, however, the DEA has done nothing to support this belief and can easily remedy this situation.

This Court should issue a writ of mandamus because the DEA is bound to the above regulations and guidance, and their unnecessary delay is the remaining obstacle in MMJ's way to conduct the important and necessary work to change the lives of many.

STANDING

When a claim is made, specifically in this case, for an agency to process an application consistent with a congressional stipulation, the focus becomes whether the agency in question's lack of procedural action will cause a specific risk to a particularized and concrete interest of the party making said claim. *City of Dania Beach v. FAA*, 485 F.3d 1181, 1185 (D.C. Cir. 2007). If the plaintiff can demonstrate a causal relationship between the final agency action and the alleged injuries, the court will assume the causal relationship between the procedural defect and the final agency action. *Food & Water Watch v. United States Dep't. of Agric.*, 325 F. Supp. 3d 39, 55 (D.D.C 2018). The redressability requirement is

relaxed in cases involving procedural violations, such that the person who has been accorded a procedural right to protect his concrete interests can assert that right without meeting all the normal standards for redressability and immediacy. *Id.*

Petitioner has standing because it is suffering an injury that is directly connected to the DEA's inability to follow procedural demands, which would be remedied by the relief sought. Petitioner applied for the manufacturing registration, followed DEA regulations and paid the fee to ensure they would receive a determination. Under the plain language of section 823(i)(2), the CSA and the APA, Petitioner was entitled to have the DEA issue a determination regarding its ability to commence cultivation and manufacturing operations or not.

ARGUMENT

I. *Legal Standard.*

To bring a petition for mandamus, the petitioner must show: (1) the plaintiff has a clear right to relief; (2) the defendant has a clear duty to act; and (3) there is no other adequate remedy available to the plaintiff. *In re Nat'l Nurses United*, 47 F.4th 746, 752 (D.C. Cir. 2022). These three threshold requirements are jurisdictional: unless all are met, a court must dismiss the case for lack of jurisdiction. See *In re Medicare Reimbursement Litigation*, 414 F.3d 7, 10, 367 U.S. App. D.C. 116 (D.C. Cir. 2005). "Even when the legal requirements for

mandamus jurisdiction have been satisfied, however, a court may grant relief only when it finds compelling equitable grounds." *Id.* "The party seeking mandamus has the burden of showing that its right to issuance of the writ is clear and indisputable." *Power v. Barnhart,* 292 F.3d 781, 784 (D.C. Cir. 2002).

Mandamus claims that, such as the ones at present, target agency delays, turn on the egregiousness of the delay. *In re Core Communications, Inc.,* 531 F.3d 849, 855 (D.C. Cir. 2008). With cases like this, the courts look to the *TRAC* factors as a guideline, which are:

> "(1) the time agencies take to make decisions must be governed by a rule of reason; (2) where Congress has provided a timetable or other indication of the speed with which it expects the agency to proceed in the enabling statute, that statutory scheme may supply content for this rule of reason; (3) delays that might be reasonable in the sphere of economic regulation are less tolerable when human health and welfare are at stake; (4) the court should consider the effect of expediting delayed action on agency activities of a higher or competing priority; (5) the court should also take into account the nature and extent of the interests prejudiced by delay; and (6) the court need not find any impropriety lurking behind agency lassitude in order to hold that agency action is unreasonably delayed."

TRAC, 750 F.2d at 80.

When looking at these factors, there is a question of whether mandamus could or should be issued and where there is a statute that imposes deadlines and/or a clear duty, the factors may go to the equitable question of whether this *should* be issued. *AHA v. Burwell,* 812 F.3d 183, 190 (D.C. Cir. 2016). This equitable principle is directly applicable in the present case.

II. *The DEA Has Egregiously Failed to Comply with the Timeline Requirements under 21 U.S.C. § 823(i)(2).*

At all times, the DEA was aware that MMJ's applications for registration were for research purposes, as it was clearly outlined in MMJ's application materials and was stated multiple times to DEA officials. Problems began with the DEA's timely processing of MMJ's applications from the beginning. First, the DEA failed to issue the notice within the time frame required under the CSA. The CSA requires that for an applicant looking for registration for research purposes, the DEA must issue a notice of application no later than 90 days after the application is accepted for filing. See 21 U.S.C. § 823(i). MMJ 's application forAPI Bulk Manufacturing was submitted on December 27, 2018. The first Notice of Application regarding the API Bulk Manufacturing registration was not published to the Federal Register until August 27, 2019, eight months later. Then, an amended Notice of Application regarding the API Bulk Manufacturing registration was published to the Federal Register on October 11, 2019, ten months after the application was submitted.

According to the first Notice of Application regarding the API Bulk Manufacturing registration, the deadline for comment was October 28, 2019,

honoring the typical 60-day timeframe. The Amended Notice of Application regarding the API Bulk Manufacturing registration which was published on October 11, 2019 did not show a deadline for comment, but assuming the typical 60-day comment window, the deadline for comment would be December 10, 2019, nearly a year after the application was submitted.

In addition to the delay in publishing the notices within the required timeframe, the DEA has also grossly violated the CSA by failing to make a determination on MMJ's application within the 90-day timeframe required under the statute. Indeed, MMJ is still awaiting determination on its Bulk Manufacturing registration application nearly four years after the close of the application comment periods.

The CSA provides that "[n]ot later than 90 days after the date on which the period for comment pursuant to [the Notice of Application] ends, the Attorney General ***shall register the applicant, or serve an order to show cause upon the applicant in accordance with [21 U.S.C. § 824(c)].***" 21 U.S.C. § 823(i)(2), emphasis added.

The CSA provides clear guidance to the DEA showing that they have two options: either register the applicant; or deny the applicant with a statement of the basis for the denial pursuant to 21 U.S.C. § 824(c)(2)(A). The provision is patently clear about the timeframe in which the DEA must decide whether to register the

applicant or deny the application.

By those timelines, the DEA was required to come back with a final determination to MMJ by either January 26, 2020 (assuming the October 28, 2019 comment deadline for the Notice of Application regarding the API Bulk Manufacturing registration); or March 9, 2020 (assuming the December 10, 2019 comment deadline for the Amended Notice of Application regarding the API Bulk Manufacturing registration). It is plain to see that both of those windows have long passed.

In fact, nearly five years have elapsed since the API Bulk Manufacturing registration comment period closed with no sense of urgency on the part of the DEA. This is further evidenced by the fact that the DEA did not even commence their on-site investigation until June 22, 2021, over two years after the initial application was submitted. The investigation concluded after the final on-site visit which took place on October 24, 2021, nearly 3 years after the initial application was submitted.

At a minimum, DEA personnel should have been able to (and were in fact required to) make a determination within 90 days of the conclusion of the investigation, on or before January 22, 2022. Not surprisingly, that date has also come and gone and DEA appears to be no closer to a final determination. As such, it is MMJ's contention that something must be done to escalate this matter, hence

this Petition for Writ of Mandamus.

III. *Relief Is Proper Under the Administrative Procedures Act (APA)*.

Under the APA, 5 U.S.C. § 706(1), this Court is authorized to "compel agency action unlawfully withheld or unreasonably delayed." The court should then consider several factors under 5 U.S.C. § 706(1) and as laid out in *TRAC*, 750 F.2d at 80. First, the DEA is required to issue a determination within a certain timetable as stated in the CSA or MCREA as well as DEA internal policies which would constitute as "rule[s] of reason" under the *TRAC* factors. *Id.* Second, the statutes put in place by Congress for the DEA to follow, provide context and guidelines for which the speed of these determinations should be complete. *Id.* Third, the delay the DEA has caused is not only less tolerable than human health and welfare, but is the obstacle that delaying the betterment of human lives. *Id.* Due to the fact that this would take minimal time and resources for the DEA to make a final determination, the competing priority factor is a non issue. *Id.* Lastly, when looking at the "nature and extent of the interests prejudiced by the delay," the pain and suffering of human lives could be alleviated, if not eliminated, by expediting the DEA determination. *Id.* In this case, MMJ meets all the guidelines for relief under the APA.

(i) *Over Four Years Have Elapsed Since The DEA Came Under A Duty To Act And The DEA's Delay In Making A Final Determination On MMJ's Registrations Is Unreasonable.*

The present case surely encapsulates the definition of "unreasonably delay." 5 U.S.C. § 706(1). One of the more important factors the court should look to is the that the time require of agencies is governed by a rule of reason. In re Core Communications, Inc., 531 F.3d at 855. Here, the DEA first came under a duty to act when MMJ filed their applications with the DEA. Pursuant to *Controls To Enhance the Cultivation of Marihuana for Research in the United States*, 85 Fed. Reg. 82333, 82334 (December 18, 2020), and in accordance with 21 U.S.C. § 823(i), the DEA must issue a notice of application not later than 90 days after the application is accepted for filing.

According to the Federal Register, MMJ's applications were accepted on December 27, 2018. From that point, the DEA had 90 days to publish Notice of MMJ's applications on the Federal Register which is laid out by multiple statutes Congress has created. As noted above, the DEA did not post these notices until eight and ten months later, respectively. Further, 21 U.S.C. § 823(i)(2) provides that the DEA must make a final determination "[n]ot later than 90 days after the date on which the period for comment pursuant to [the Notice of Application] ends." The delays that have taken place since the public comment period ended

back in 2019 are the most egregious and unreasonable.

Here, the last comment period ended on December 10, 2019, which would mean the DEA was required to reach a final determination no later than March 9, 2020. Nearly four years later, MMJ is still awaiting a final determination on those applications. Under the regulations, the DEA would have a total of 240 days from the date of the acceptance of an application to make a final determination. This 240-day total includes the 90-day deadline to publish an applicant's Notice of Application in the Federal Register, the 60-day public comment period, and the 90-day period in which a final determination must be made after the close of the public comment period.

In the present case, as of the date of the filing of this Petition, approximately 1,218 days have elapsed since the DEA's acceptance of MMJ's application for the Bulk Manufacturing registration. This is, by all accounts, an unreasonable delay in the context of the statutory authority. See 21 U.S.C. 823(i)(2); *Controls To Enhance the Cultivation of Marihuana for Research in the United States*, 85 Fed. Reg. 82333, 82334 (December 18, 2020).

(ii) *The Consequences Of The DEA's Failure To Make A Final Determination on MMJ's Registrations Are Dire - To Both MMJ And Those Who Would Benefit From These Potentially Life-Changing Treatments.*

The consequences to both MMJ and the patients they seek to serve have

been drastic. As mentioned previously, MMJ's operations are currently at an impasse as a result of these delays. In this country alone, over 400,000 people are suffering from the debilitative effects of Multiple Sclerosis. Another 30,000 people in the United States are suffering from Huntington's Disease. MMJ has been actively pursuing the path to develop treatments to lessen the impact of these degenerative diseases. The years that have passed since submitting the initial applications could have been used toward more research and development, working the clinical trials, etc. Instead, however, this time has been used to fight for a determination that should have been made over four years ago under the regulations.

As a result of these delays, MMJ's business operations are at a standstill, which is not sustainable for any period of time, but certainly not sustainable after nearly six years of delays. This has resulted in significant and immeasurable harm to MMJ. Further, as outlined above, these delays have resulted in severe and immeasurable harm to the hundreds of thousands of people in the U.S. who are awaiting life-changing treatment to ameliorate the symptoms of these degenerative diseases.

(iii) *No Special Circumstances Involving Any Plea Of Administrative Error, Administrative Inconvenience, Practical Difficulty In Carrying Out A Legislative Mandate, Or Need To Prioritize In The Face Of Limited Resources Exist In This Case.*

There exist no special circumstances in this case which would prevent relief under the APA. Further, neither the DEA nor the Attorney General have discussed or alluded to any reasons involving administrative error, administrative inconvenience, practical difficulty, or need to prioritize limited resources which would prevent them from making a final determination on MMJ Cultivation's registration.

IV. *A Writ of Mandamus Is A Proper Vehicle For Relief Under These Circumstances*

Petitioners move for this writ of mandamus on the grounds that the DEA had a duty to Petitioners to timely process their applications pursuant to 21 U.S.C. § 823(i). It is well-established law that the decision to issue a writ of mandamus is one which is highly discretionary. *Citibank, NA. v. Fullam,* 580 F.2d 82, 90 (3d Cir. 1978). The writ is considered an extraordinary remedy and should be issued only in cases where the circumstances are exceptional. *Delgrosso v. Spang & Co.,* 903 F.2d 234, 237 (3rd Cir. 1990). As such, any party seeking a writ of mandamus has

the burden of proving that they have a clear and indisputable right to the writ. *Id.*

As stated prior, mandamus is proper when three elements are present: (1) the petitioner must show a clear right to the relief sought; (2) a plainly defined and peremptory duty on the part of the defendant to do the act in question; and (3) no other adequate remedy available. *In re Nat'l Nurses United*, 47 F.4th at 752. First, as discussed above, Petitioners have a clear right to the relief sought due through the DEA's noncompliance with their own regulations. Second, the DEA's duties to Petitioners to make a final determination within a fixed amount of time are clear under the statutory authorities, as outlined in great detail in the preceding sections. Finally, as discussed in the statement of facts above, Petitioners have exhausted any and all administrative remedies available to them, but to no avail. As such, in light of the foregoing elements being satisfied, a writ of mandamus is an appropriate vehicle for relief under this set of circumstances.

CONCLUSION

In light of the foregoing, Plaintiffs respectfully request this honorable Court to issue a writ of mandamus, grant the injunction, and issue a declaratory judgment directing the DEA to make a final determination on MMJ's outstanding application. If this Court chooses to grant the relief requested, it will be in the spirit of protecting Petitioners from further harm caused by this

undue delay in registration, and in an attempt to ameliorate the debilitating effects of Multiple Sclerosis and Huntington's Disease, will be a great service to society at large.

Dated: August 18, 2023

Respectfully Submitted,

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CERTIFICATE OF COMPLIANCE

This Petition complies with the Federal Rule of Appellate Procedure 21(d) because it contains 6,019 words, excluding the accompanying documents required by Rule 21(a)(2)(C).

I further certify that this Petition 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 Petition has been prepared in Georgia 14-point font using Google Documents.

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CERTIFICATE OF SERVICE

I, Megan E. Sheehan, hereby certify that on September 5, 2023, I caused this petition to be served via United States Postal Mail on the following respondents at the addresses listed below:

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