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May 28, 2026

NOTICE OF INTENTION TO PARTICIPATE

VIA ELECTRONIC SUBMISSION (nprm@dea.gov)

Drug Enforcement Administration
Attn: Administrator Terry Cole
8701 Morrissette Drive
Springfield, Virginia 22152

Re: Schedules of Controlled Substances: Rescheduling of Marijuana (Docket No. DEA-1362; Attorney General Order No. 6753–2026), 91 Fed. Reg. 22777 (Apr. 28, 2026)

Dear Administrator Cole:

Pursuant to 21 U.S.C. § 811(a), 21 C.F.R. § 1308.44(b), and 21 C.F.R. § 1316.48, and in response to the Notice of Hearing on Proposed Rulemaking published at 91 Fed. Reg. 22777 (Apr. 28, 2026), MMJ International Holdings, Inc. ("MMJIH"), MMJ BioPharma Cultivation, Inc. ("MMJBC"), and MMJ BioPharma Labs, Inc. ("MMJBL") (collectively, "MMJ"), by and through undersigned counsel, hereby submit this Notice of Intention to Participate in the administrative hearing scheduled to commence on June 29, 2026, regarding the proposed rescheduling of marijuana from Schedule I to Schedule III of the Controlled Substances Act ("CSA").

MMJ is an "interested person" within the meaning of 21 C.F.R. § 1300.01(b), as a person adversely affected and aggrieved by the proposed rule issuable pursuant to 21 U.S.C. § 811. MMJ is also an aggrieved party entitled to seek judicial review under 21 U.S.C. § 877. As set forth below, MMJ states with particularity its interest in this proceeding, the objections and issues concerning which it desires to be heard, and its position regarding those objections and issues, as required by 21 C.F.R. §§ 1308.44(b) and 1316.48.

INTEREST OF MMJ IN THE PROCEEDING

MMJIH is a life sciences company incorporated in Delaware with its principal business address at 101425 Overseas Highway, Suite 170, Key Largo, Florida 33037. MMJIH was established for the purpose of developing pharmaceutical cannabinoid therapeutics under the FDA's botanical drug development framework, including the Botanical Drug

Development Guidance for Industry. MMJIH serves as the parent company of MMJBC and MMJBL, overseeing regulatory strategy, clinical development planning, chemistry, manufacturing, and controls preparation, and Investigational New Drug ("IND") submissions for cannabinoid-based treatments targeting Huntington's disease and multiple sclerosis.

MMJIH initiated formal regulatory engagement with the FDA's Center for Drug Evaluation and Research in August 2018 through submission of Pre-Investigational New Drug meeting requests for its cannabinoid drug candidates MMJ-001, intended for treatment of Huntington's disease, and MMJ-002, intended for treatment of multiple sclerosis. The FDA acknowledged these submissions and opened regulatory files, including IND file number 137754 associated with the Huntington's disease program and IND file number 140712 associated with the multiple sclerosis program. On January 29, 2019, the FDA's Office of Orphan Products Development granted Orphan Drug Designation for Δ9-tetrahydrocannabinol and cannabidiol for the "treatment of Huntington's disease" pursuant to Section 526 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. § 360bb).

MMJBC is a subsidiary of MMJIH incorporated in Delaware, formed to support the cultivation and production of pharmaceutical-grade cannabis plant material required for extraction and formulation of the active botanical drug substance used in MMJIH's IND programs. In December 2018, MMJBC submitted an application to the DEA for registration as a bulk manufacturer of marijuana active pharmaceutical ingredient for use in FDA-authorized clinical trials and drug development. MMJBC's cultivation facility in Westerly, Rhode Island was designed to employ state-of-the-art automated growth chambers capable of generating medical marijuana with exacting and repeatable secondary metabolite profiles at production levels consistent with federal research supply requirements. The DEA commenced its pre-registration Section 303 investigation on June 22, 2021, which concluded with a final on-site visit on October 24, 2021, during which all DEA questions were satisfactorily answered, all security systems and protocols were reviewed, and MMJBC demonstrated that all security and diversion conditions followed applicable regulations. MMJBC's bulk manufacturing registration application remains pending before the DEA Administrator.

MMJBL is a subsidiary of MMJIH incorporated in Delaware, established to perform analytical testing, formulation support, and regulatory-grade characterization of botanical extracts used in MMJIH's drug development program. MMJBL obtained a DEA Schedule I analytical laboratory registration following DEA inspection and approval of its facility's physical security systems, recordkeeping controls, and diversion-prevention safeguards. This Schedule I registration was approved for the same laboratory in Westerly, Rhode Island that MMJBC's pending bulk manufacturing registration application concerns.

Over the past approximately eight years, MMJ has invested over $10 million into advancing pharmaceutical cannabinoid therapeutics through the formal federal FDA botanical drug development pathway and the DEA controlled-substance registration framework. These investments include IND submissions and regulatory engagement with the FDA, orphan drug designation positioning for Huntington's disease, DEA registration activity (including the Schedule I analytical laboratory registration and the pending bulk manufacturing application), formulation development and stability studies conducted in collaboration with Catalent Pharma Solutions, analytical testing and chromatographic characterization, regulatory consulting engagements, a development summit and portfolio strategy engagement, FDA regulatory counsel services, and engagement of Seaport Global Securities LLC as lead financial advisor in connection with a proposed capital raise of approximately $45 million in debt and equity securities.

The rescheduling of marijuana to Schedule III will directly affect MMJ's pending DEA bulk manufacturing application, its existing DEA laboratory registration, the commercial viability of its FDA-pathway drug development programs, and its claims in the pending federal litigation.

OBJECTIONS AND ISSUES

MMJ desires to be heard on the following objections and issues:

1. Treaty Compliance and International Obligations.

MMJ objects to the proposed rescheduling to the extent that it fails to adequately address the United States' obligations under the 1961 Single Convention on Narcotic Drugs, as amended. Specifically, MMJ intends to address the apparent conflict between: (a) DEA's reliance upon international treaty obligations to regulate federally registered manufacturers; (b) the DEA's 2020 Marijuana Manufacturer Rule; (c) the continued expansion and recognition of state-licensed marijuana operations operating outside the federal registration system; and (d) the proposed rescheduling of marijuana to Schedule III, which may eliminate existing quota controls while treaty obligations remain in force. MMJ seeks clarification regarding how the DEA intends to satisfy its international treaty obligations while simultaneously permitting a regulatory framework that treats federally compliant applicants and state-licensed marijuana businesses under fundamentally different standards.

2. Impact on Pending DEA Manufacturer Registration Applications.

MMJ objects to the proposed rescheduling to the extent that it does not address the disposition of pending DEA registration applications for bulk manufacturers of marijuana submitted under the current Schedule I framework. MMJBC's bulk manufacturing registration application has been pending before the DEA Administrator since December 2018—a period of over seven years—including a completed Section 303 pre-registration investigation. MMJ desires to be heard

regarding the regulatory treatment of pending manufacturer applications upon rescheduling, including whether such applications will be expedited, converted, or otherwise resolved.

3. Competitive Injury and Administrative Fairness.

MMJ objects to the proposed rescheduling to the extent that it may confer substantial regulatory and economic benefits upon entities that have not complied with the same federal requirements imposed upon MMJ, thereby causing competitive injury. After more than eight years pursuing a lawful federal pharmaceutical pathway—including FDA IND applications, Orphan Drug Designation, DEA registration proceedings, and over $10 million in regulatory compliance investments—MMJ has a direct and substantial interest in ensuring that the rescheduling framework does not create a two-track regulatory system that advantages non-compliant entities at the expense of those who have pursued the established federal pathway.

4. Scheduling Criteria and Statutory Interpretation.

Pursuant to *Loper Bright Enterprises v. Raimondo*, 144 S. Ct. 2244 (2024), MMJ objects to any claim that DEA is entitled to judicial deference regarding the interpretation of "currently accepted medical use," scheduling criteria, or any other provisions of the Controlled Substances Act. MMJ desires to be heard regarding the proper application of the statutory scheduling factors under 21 U.S.C. § 812(b), including whether the evidentiary record supports the proposed transfer to Schedule III.

5. Article II Constitutional Objections.

MMJ maintains that DEA administrative proceedings continue to suffer from significant constitutional defects under Article II of the United States Constitution. The Department of Justice has acknowledged constitutional concerns regarding the protections afforded to Administrative Law Judges. Accordingly, MMJ reserves all rights under *Lucia v. SEC*, 585 U.S. 237 (2018), *Axon Enterprise, Inc. v. FTC*, 598 U.S. 175 (2023), *SEC v. Jarkesy*, 603 U.S. 109 (2024), and related precedent to challenge the validity of these proceedings in federal court.

6. Jurisdictional Objections.

MMJ does not concede that the DEA possesses lawful authority to adjudicate matters through an administrative process that is constitutionally defective. Participation in this hearing shall not constitute consent to jurisdiction nor a waiver of MMJ's right to seek declaratory, injunctive, or other relief in federal court.

POSITION OF MMJ REGARDING THE OBJECTIONS AND ISSUES

MMJ maintains that any rescheduling must: (1) adequately address the disposition of pending DEA manufacturer registration applications, including MMJBC's application that has been pending for over seven years; (2) satisfy the United States' obligations under the 1961 Single Convention on Narcotic Drugs; (3) ensure equitable treatment of entities that have pursued the established federal pharmaceutical regulatory pathway, including FDA IND authorization and DEA registration; and (4) comply with the statutory scheduling factors under 21 U.S.C. § 812(b) based on competent and substantial evidence in the record.

RESERVATION OF RIGHTS

This filing is made to preserve MMJ's standing, exhaust any purported administrative remedies, and protect MMJ's right to seek judicial review of any final agency action pursuant to 21 U.S.C. § 877 and 5 U.S.C. §§ 701–706. Participation in this proceeding shall not be construed as a waiver of any constitutional, statutory, treaty-based, or jurisdictional challenge. MMJ reserves the right to supplement this Notice, raise additional legal and factual objections, challenge any final agency action, and pursue all available remedies in federal court.

Respectfully submitted,

Patrick Kenneally

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