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IN THE UNITED STATES DEPARTMENT OF JUSTICE DRUG ENFORCEMENT ADMINISTRATION

In the matter of

Schedules of Controlled Substances: Proposed Rescheduling of Marijuana

DEA Docket No. 1362

Hearing Docket No. 24-44

Submitted by: Jason K. Castro, Esq. Individually and as In-House Counsel The Doc App, Inc., d.b.a. My Florida Green 4055 1st Ave SW Naples, FL 34119 Phone: (833) 665-3279

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Nicholas Garulay Individually and as President and CEO The Doc App, Inc., d.b.a. My Florida Green 4055 1st Ave SW

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To: Chief Administrative Law Judge John J. Mulrooney, II Office of Administrative Law Judges Drug Enforcement Administration 8701 Morrissette Drive Springfield, VA 22152 Email: <u>ECF-DEA@dea.gov</u> Subject: Joint Response to the DEA's Preliminary Order dated October 31, 2024; Notice of Intention to Participate in DEA Hearing on Proposed Rescheduling of Marijuana (Docket No. DEA–1362) individually and on behalf of The Doc App, Inc., and Notice of Appearance as Counsel as attorney for Nicholas Garulay, and The Doc App, Inc.

Dear Chief Judge Mulrooney,

This Notice of Intention to Participate is submitted by Jason K. Castro, Esq., as In-House Counsel for The Doc App, Inc., and Nicholas Garulay, President and CEO of The Doc App, Inc., in response to the DEA's Preliminary Order dated October 31, 2024. Both individuals seek to participate in the DEA hearing on the proposed rescheduling of marijuana from Schedule I to Schedule III of the Controlled Substances Act, and both individuals will appear and testify as directed.

1. Name, Address, Phone Number, and General Nature of Business:

- Name: Jason K. Castro, Esq.
- For: Individually and on behalf of The Doc App, Inc.
- Address: 625 Quincy Ln, Wexford, PA 15090
- **Direct Phone:** (718)702-5540
- Email: <u>JasonCastro@MyFloridaGreen.com</u>
- Name: Nicholas Garulay, President and CEO
- For: The Doc App, Inc.
- Business Address: 4055 1st Ave SW, Naples, FL 34119
- Business Phone: (833) 665-3279
- Email: Nick@TheDocApp.net
- General Nature of Business:

Jason K. Castro, Esq., licensed attorney in Florida, will represent both Mr. Garulay and The Doc App, Inc., a company that supports over 43,000 medical marijuana patients in Florida. Mr. Garulay will serve as a key witness. The Doc App, Inc. provides a HIPAAcompliant platform offering real-time analytics, data-driven insights, and treatment support for medical marijuana patients. As a bridge between patients, physicians, dispensaries, and regulatory bodies, The Doc App is dedicated to promoting patient safety, access, and treatment efficacy, particularly for veterans and individuals with chronic conditions. The Doc App's platform addresses the critical regulatory and patient-centered needs within the medical marijuana space, ensuring responsible use, privacy protection, and support for a self-treatment model that aligns with the DEA's goals. The platform's operations emphasize patient autonomy, transparent access, and a commitment to regulatory compliance, aligning closely with the proposed rescheduling of marijuana.

2. Notice of Appearance:

Jason K. Castro, Esq., shall participate in this action individually and as attorney for Nicholas Garulay and The Doc App, Inc., a technology company operating in the medical marijuana sector. As an attorney licensed in Florida (Fla. Bar No. 118604), an Army veteran, and a former law enforcement officer, I bring a unique perspective on regulatory needs for medical marijuana, with a particular focus on veterans' healthcare, patient safety, and market accessibility. As counsel, I will address the legal and regulatory implications surrounding the proposed rescheduling and will provide an overview of compliance, patient protections, and structural recommendations. Mr. Garulay, in his role as CEO, will testify directly on the patient experience, drawing from his years of interaction with patients and firsthand knowledge of their challenges.

3. Date of Request for Hearing/Participation Filed with DEA:

The initial Notice of Intention to Participate was filed with the DEA on behalf of Nicholas Garulay, Jason K. Castro, Esq., & The Doc App, Inc., on September 24, 2024, per the NPRM and General Notice of Hearing.

4. How We Are Adversely Affected or Aggrieved

While rescheduling marijuana to Schedule III is a positive step, several critical issues must be addressed to ensure a fair, accessible, and patient-centered medical marijuana framework. Marijuana, under Schedule III, will occupy a unique position as a substance that continues to support a self-treatment model. The framework must preserve patient autonomy while promoting responsible, informed use for healthier outcomes.

- Preserving the Self-Treatment Model with Physician Guidance and Real-Time Analytics: Medical marijuana is highly individualized, with no single strain, dosage, or method that works universally. To support safe and effective self-treatment, patients need the flexibility to select what best meets their needs, guided by real-time data on strain options, effects, and availability. Platforms like The Doc App provide these data-driven tools, equipping patients to make informed decisions at dispensaries and promoting safe self-treatment practices. With guidance, patients often learn to use medical marijuana more effectively, sometimes reducing overall usage or shifting to healthier methods.
- Licensing Affordability and Accessibility: A successful federal medical marijuana framework requires affordable licensing fees to allow small and mid-sized businesses to participate alongside large players. Licensing should be accessible for growers, sellers, and testing labs, preventing monopolization and promoting competition. This competitive market is essential for offering patients a variety of providers, products, and dispensaries, ensuring a safe and dynamic marketplace.
- Addressing Vertical Integration and Keeping Medical and Recreational Markets Separate: Vertical integration, where a single entity controls cultivation, processing, and retail, limits competition and can prioritize profit over patient care. Additionally, it is essential that medical dispensaries remain distinct from recreational ones. Amendment 3's failure demonstrated the concerns for merging these two markets, as it would compromise

the quality and accessibility of medical care by placing it within a profit-driven recreational framework. A regulatory model that separates cultivation, processing, and retail, and keeps medical and recreational dispensaries separate, would ensure a market that focuses on patient care and avoids the monopolistic practices that can harm patient access to quality treatment.

- **Distinguishing Medical Marijuana in Federal Healthcare Programs**: Rescheduling marijuana opens the possibility of inclusion in federal healthcare programs such as the VA and Medicare, particularly for veterans and patients managing chronic or complex conditions. Including medical marijuana in federal healthcare coverage would expand equitable access, allowing it to become a mainstream, accessible treatment option for those who need it most.
- Federal Research Mandates to Develop Evidence-Based Standards: To ensure a safe and effective medical marijuana market, rescheduling should come with federally funded research mandates focused on strain efficacy, dosing, and delivery methods. Collaborating with licensed dispensaries and platforms like The Doc App, the federal government can create reliable, data-driven guidelines that support patients and providers in making informed choices.
- Ensuring Patient Safety through Physician-Guided Education Programs: Federally licensed dispensaries should provide education on strain selection, dosages, and administration methods, especially in partnership with platforms like The Doc App, which collaborates with physicians to deliver patient-centered information. Education programs would promote responsible, informed use, helping patients understand how to use medical marijuana effectively, often reducing the need for higher doses or frequent use over time.

5. Position on the Rescheduling Action

While we support rescheduling marijuana to Schedule III, we urge the DEA to consider the following measures to preserve a fare, accessible, safety focused, and patient-centered framework, recognizing marijuana's unique role under the self-treatment model within Schedule III:

- **Preserve the Self-Treatment Model with Physician Support and Real-Time Data:** Federal regulations should reinforce the self-treatment model, backed by platforms like The Doc App that provide real-time data on strain efficacy, dosage, and administration options. This model, guided by physician support, empowers patients to use medical marijuana effectively, helping them optimize treatment and reduce usage over time for healthier outcomes.
- Set Affordable and Accessible Licensing Standards: Licensing fees for dispensaries, growers, and testing labs should remain affordable to prevent market monopolization. A fair licensing structure will support a competitive, diverse marketplace, enhancing patient choice and ensuring a patient-centered environment.
- **Prohibit Vertical Integration and Keep Medical and Recreational Markets Separate**: To prevent monopolistic practices and preserve quality patient care, a regulatory structure should separate cultivation, processing, and retail roles. Additionally, medical and recreational dispensaries must remain distinct. The failure of Amendment 3 highlighted the

dangers of merging these markets, which risks prioritizing profit-driven recreational sales over dedicated patient care in the medical sector.

- **Distinguish Medical Marijuana within Federal Healthcare Programs**: Including medical marijuana in federal healthcare programs like Medicare and the VA would make it accessible to veterans and low-income patients. This step would expand equitable access and support a monitored, patient-focused approach.
- Federal Research Mandates for Evidence-Based Standards: Establish federal research initiatives focused on developing standards for safe dosing, strain efficacy, and treatment protocols. By leveraging data and insights from platforms like The Doc App, this approach will create evidence-based guidelines that support safe, effective treatment practices.
- **Require Patient Education Programs in Federally Approved Dispensaries**: Federally approved dispensaries should implement education programs, partnering with platforms like The Doc App to provide information on strain selection, dosing, and administration methods. This ensures patients engage in safe self-treatment and make informed decisions under physician-guided education.
- **Implement a Digital Benefits Card to Complement the Self-Treatment Model**: A digital benefits card accessible through a secure app would provide veterans and Medicaid recipients with seamless access to their medical marijuana prescriptions, dosage limits, and exemptions. This card would enhance the self-treatment model by allowing patients to manage their treatment responsibly, ensuring they receive the appropriate care under federal oversight.
- Collaborate with Federal Agencies to Establish a Model for State Programs: The Doc App, Inc. is prepared to work closely with the VA, Medicaid, and the DEA to deliver patient-focused services and establish best practices for medical marijuana treatment at the federal level. By developing an effective model through these collaborations, we aim to set a high standard that can serve as a blueprint for state-run medical marijuana programs, supporting accessible, responsible, and safe treatment for patients across the country.

6. Known Conflicts of Interest:

We have no known conflicts of interest with DEA or DOJ personnel.

Sincerely,

/s/ Jason K. Castro, Esq.

Jason K. Castro Fla. Bar.: 118604

<u>/s/ Nicholas Garulay</u> President and CEO The Doc App, Inc., d/b/a, My Florida Green

Certificate of Service

It is hereby certified that a true and correct copy of this document has been sent by email to the address listed on this 11th day of November, 2024:

voegtlin@theiacp.org; ECF-DEA@dea.gov; James.J.Schwartz@dea.gov: DEA.Registration.Litigation@dea.gov; spennington@porterwright.com; aaron@thecannabisindustry.org; michelle@thecannabisindustry.org; wchill@aahpm.org; ir@cbih.net; robert@bluecordfarms.com; Erin.Kirk@ct.gov; ellen@greenpathtraining.com; info@veteransinitiative22.com: jasoncastro@myfloridagreen.com; nick@thedocapp.net kag@platinumadvisors.com; mslade@cannabispublicpolicyconsulting.com; jomcguire@ndasa.com; pphilbin@torridonlaw.com; roneetlev@gmail.com; thinkon908@aol.com; kfinn@springsrehab.net; ExecutiveSecretariat@ntsb.gov; correspondence@ntsb.gov; phillipdrum@comcast.net; zachary.viglianco@nebraska.gov; marshallfisher@rocketmail.com; occumedix@comcast.net; craig@acoem.org; cdoarn@cadca.org; kim.litman@tbi.tn.gov; sheriffskinner@collincountytx.gov; ykaraman@sheriffs.org