Advancing Development of Botanical Drug Products

Responses to the U.S. Food and Drug Administration's Request for Information

Dockets Management Staff (HFA-305)
Food and Drug Administration
5630 Fishers Lane Rm. 1061
Rockville, MD 20852



A COLLECTION OF COMMENTS FROM

THE PATIENT FIRST COALITION (PFC)
THE AMERICAN COUNCIL OF CANNABIS MEDICINE (ACCM)
AND INDIVIDUAL EXPERTS AND STAKEHOLDERS

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Patient First Coalition (PFC)

Dockets Management Staff (HFA-305)
Food and Drug Administration
5630 Fishers Lane Rm. 1061
Rockville, MD 20852

RE: Advancing Development of Botanical Drug Products; Request for Information

November 3, 2026

To whom it may concern,

The Patient First Coalition (PFC), a leading national voice for patient-centered healthcare, health freedom, and expanded access to innovative medical treatments, has established a **Blue Ribbon Medical Cannabis Committee consisting of more than 50 members serving across several specialized subcommittees**, bringing together patients, physicians, researchers, healthcare professionals, industry leaders, and policy experts to advance safe, effective, and accessible medical cannabis. On behalf of the Coalition and its Medical Cannabis Committee, we are submitting these comments in response to the Request for Information (RFI) issued by the Food and Drug Administration (FDA) on September 4, 2026. We wish to share our perspective on Botanical Drug Product (BDP) development in the United States, including some challenges encountered and potential solutions.

First, we want to applaud the U.S. Department of Health and Human Services (HHS) for acknowledging the broad public interest in botanical medicines among consumers, researchers, clinicians, industry stakeholders, and international regulators. We agree with FDA analysis that consumers report widespread use of botanical products for treatment of a variety of conditions, and as such, there is a need for additional research and where appropriate, acceleration of drug product development and review of clinical treatments.

In particular, we are most interested in the way cannabis fits into policy discussions about botanical medicines. As the transition is made from Schedule I to Schedule III classification, we wish to offer guidance to HHS and FDA staff while you contemplate the best manner to implement this significant and complex change. The following are some of our initial concerns, informed by the experience of medical cannabis patients, healthcare professionals, pharmacies, dispensaries, cultivators, and industry leaders represented within the Patient First Coalition's Medical Cannabis Committee. We offer these comments from both sides of the pharmacy counter: from patients who rely on botanical cannabis medicine, and from those responsible for producing it to state quality standards and dispensing it under professional oversight.

CONCERN: RESEARCH AND DEVELOPMENT

Utah’s medical cannabis program, which now serves more than 110,000 patients, already generates much of the fit-for-purpose information this RFI describes. Patient purchases are recorded in a state electronic verification system, inventory is tracked from plant to pharmacy, every batch carries an independent laboratory certificate of analysis, and pharmacists counsel patients on dosing and product selection. Yet state-licensed operators have no practical route to turn this information into the evidence FDA requires. A small, vertically integrated operator cannot fund an IND and multi-phase clinical trials on its own, academic partners face significant registration and secure-storage costs, and studies of isolated compounds in healthy volunteers rarely reflect how patients actually use cannabis. As advocates for patients, we want the products they rely on to be studied the way they are used. Will FDA establish a real-world evidence pathway that accepts de-identified state program data, such as dispensing records, certificates of analysis, and patient-reported outcomes, as supportive evidence under the 2016 Botanical Drug Development guidance, and allow state-licensed, DEA-registered operators to supply investigational material to qualified researchers?

CONCERN: WHOLE PLANT PREPARATIONS

Most patients do not use a single molecule. They use whole-plant and full-spectrum preparations whose effects reflect a combination of cannabinoids, terpenes, and other plant constituents. The cannabis-related drugs FDA has approved to date are a highly purified isolate (cannabidiol) and synthetic cannabinoids (dronabinol and nabilone), which leaves whole-plant developers without a clear precedent. Natural batch-

to-batch variation, the lack of reference standards for many minor cannabinoids and terpenes, and uncertainty over how to define the active constituents of a complex mixture make whole-plant programs costlier and riskier than isolate programs, even though the 2016 guidance contemplates complex botanical mixtures. Will FDA clarify, through updated guidance or a cannabis-specific supplement, that a whole-plant cannabis BDP may be characterized and controlled by a chemical fingerprint with defined ranges for major and minor constituents rather than by single-molecule potency alone? And will FDA confirm that approval of isolate products will not be used to narrow patient access to the whole-plant preparations already available through state programs?

CONCERN: INTEGRATION OF EXISTING STANDARDS

State programs have spent years building quality systems that overlap with what FDA expects of botanical raw materials and finished products. In Utah, cannabis must be tested by an independent, state-licensed laboratory for cannabinoid content, residual solvents, pesticides, heavy metals, microbial contaminants, and mycotoxins before it reaches a patient. However, roughly 40 state programs apply different methods, action limits, and labeling rules, and consensus bodies such as ASTM International (Committee D37 on Cannabis), AOAC International, and USP have developed cannabis methods and quality considerations that are not yet tied to any federal expectation. Operators who invested in these systems need to know which parts will carry forward. Will FDA work with states and these standards bodies to recognize harmonized cannabis testing methods and reference standards, and publish a phased roadmap from state manufacturing requirements to current Good Manufacturing Practice (21 CFR Parts 210 and 211), so compliant operators can build toward federal standards rather than start over? A Federal Cannabis Commission would be a natural forum for this coordination.

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The RFI rightly recognizes that BDPs take many forms, including teas, powders, tinctures, and topicals. Patients often rely on several forms at once: an inhaled product for fast relief, a tincture or capsule for steady daily dosing, and a topical for localized symptoms. In Utah, these forms are dispensed under pharmacist oversight with dosing guidance from a qualified medical provider. Our concern is that a development program built around a single approved product and dosage form could come to be treated as the only legitimate way to use cannabis medicine, putting the broader set of state-authorized applications at risk before any approved alternative exists. Development of approved botanical drugs should run in parallel with, not in place of, the state programs patients use today. Will FDA affirm a parallel-access framework in which approved cannabis BDPs and state-regulated medical cannabis coexist? How will FDA approach routes of administration, such as inhalation, that patients widely use but that have little precedent in botanical drug development? A moratorium on federal interference would preserve continuity of care while that evidence is built.

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The plant is the starting material for every cannabis BDP, and its genetic diversity is a public health resource. Cultivators maintain many distinct cultivars, including chemotypes rich in minor cannabinoids such as CBG and THCV that some patients depend on. Cultivar names are not reliable identifiers, since the same name can describe chemically different plants, and decades of prohibition left the United States without a well-documented public collection of drug-type cannabis germplasm. Pressure to standardize for drug development, combined with market consolidation, could narrow supply to a handful of clones and allow rare chemotypes to disappear before they are ever studied. Will FDA, in coordination with USDA's National Plant Germplasm System, which already maintains hemp accessions, support a public reference repository and chemotype-based identity standards for cannabis botanical raw material, so that diverse genetics are preserved, accurately identified, and available to researchers and developers of all sizes?

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Much of what is known about cannabis medicine was built over generations by patients, caregivers, cultivators, and small operators. As the botanical drug pathway opens to cannabis, the marketing exclusivities, orphan designations, and patents that reward drug sponsors could also let a first mover effectively control a cultivar, formulation, or indication that patients have long used under state law. The CBD experience showed that approval of a drug can change the legal status of the same ingredient in other products. Innovation deserves protection, but exclusivity for one approved product should not

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These are among our initial concerns as the FDA determines how to advance development of botanical medicines. The following simple, yet effective solutions would temporarily alleviate concerns while the process unfolds:

1. We request that the FDA develop and implement an agency-wide **moratorium on federal interference** in state-regulated cannabis programs. An estimated three to six million veterans, seniors and patients rely on the existing patchwork of state programs, both medical and non-medical, to provide botanical products that provide relief from complex and/or chronic health conditions that are sometimes terminal in nature. Please don't add barriers for ailing patients who obtain relief from botanical medicine.
2. Establishment of a **Federal Cannabis Commission** would help ensure that patients, caregivers and health care professionals are adequately represented in transparent discussions about how to best ensure medical cannabis remains a safe, viable, and accessible treatment for Americans who need and deserve the health benefits offered.

Comprehensive solutions and detailed policy recommendations are available upon request.

We look forward to participating in further discussions on botanical drug products.

Sincerely,

Shannon Burns

Shannon Burns
Director of Advocacy
Patient First Coalition (PFC)

Dan Rush

Dan Rush
Chairman
Medical Cannabis Committee
Patient First Coalition (PFC)

Patient First Coalition
15400 Pearl Rd #3
Strongsville, Ohio 44136
(800) 524-2910 ext. 326
www.1stcoalition.org

American Council of Cannabis Medicine (ACCM)

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RE: Advancing Development of Botanical Drug Products; Request for Information

November 3, 2026

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These are among our initial concerns as the FDA determines how to advance development of botanical medicines. The following simple, yet effective solutions would temporarily alleviate concerns while the process unfolds:

1. We request that the FDA develop and implement an agency-wide **moratorium on federal interference** in state-regulated cannabis programs. An estimated three to six million veterans, seniors and patients rely on the existing patchwork of state programs, both medical and non-medical, to provide botanical products that provide relief from complex and/or chronic health conditions that are sometimes terminal in nature. Please don't add barriers for ailing patients who obtain relief from botanical medicine.
2. Establishment of a **Federal Cannabis Commission** would help ensure that patients, caregivers and health care professionals are adequately represented in transparent discussions about how to best ensure medical cannabis remains a safe, viable, and accessible treatment for Americans who need and deserve the health benefits offered.

Comprehensive solutions and detailed policy recommendations are available upon request.

We look forward to participating in further discussions on botanical drug products.

Sincerely,



Doug Benns
Executive Committee Chairman
American Council of Cannabis Medicine (ACCM)

American Council of Cannabis Medicine
601 Pennsylvania Ave.
South Building, Suite 900
Washington, D.C. 20004
(202) 349-9650
www.accmforum.org

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Food and Drug Administration
5630 Fishers Lane Rm. 1061
Rockville, MD 20852

November 3, 2026

To whom it may concern,

I am writing in response to the Food and Drug Administration's (FDA) September 4, 2026 Request for Information (RFI) on Botanical Drug Product (BDP) development in the United States. I want to share the challenges I see in that pathway and some practical ways to address them.

I commend the U.S. Department of Health and Human Services (HHS) for recognizing how much consumers, researchers, clinicians, industry and international regulators care about botanical medicines. FDA is right that people use botanical products widely and for many conditions, and that this calls for more research and, where it is warranted, faster development and review of botanical treatments.

My particular interest is where cannabis fits in this conversation. As cannabis moves from Schedule I to Schedule III, I hope the following helps HHS and FDA staff as you work out how to carry out a significant and complex change. These concerns come from more than a decade of practicing cannabinoid medicine.

CONCERN: RESEARCH AND DEVELOPMENT
We already know a great deal. Decades of published research, clinical experience abroad, approved cannabinoid medicines and state medical programs serving millions of patients have built a substantial body of evidence, yet a sponsor today must largely start over to use it. In my practice the research gap is plain: most trials study an isolated cannabinoid at a fixed dose, often in healthy volunteers, while my patients use whole-plant preparations, titrated to their needs, alongside their other medications. Real-world data can close much of that gap if it captures product chemistry, dosing and concomitant medications, because CBD changes how the liver clears anticoagulants, some chemotherapy agents and transplant drugs, and it affects the metabolism of many other drugs as well. That data should also rest on patient consent, with patients in control of their own records. Will FDA publish criteria for when existing evidence and qualified real-world data can be relied on, so that new research goes to the questions that are still open?

CONCERN: WHOLE PLANT PREPARATIONS
My patients rarely use a single isolated cannabinoid. They use whole-plant and full-spectrum preparations, and the other constituents in those preparations can change how a product works. A preparation like this should be characterized by its full chemical profile, within an acceptable range of variability and including its genetic identity, and judged by its impairment potential at the labeled dose. That potential depends on the concentration of THC and its equivalents in the context of everything else in the product. Interactions among constituents are plausible but not yet fully established, which argues for targeted research, not for

assuming that a purified compound is the better medicine. Will FDA set characterization standards that let whole-plant preparations be evaluated as what they are, rather than as a collection of isolated compounds?

CONCERN: INTEGRATION OF EXISTING STANDARDS
FDA does not have to start from scratch. The American Herbal Pharmacopoeia's cannabis monograph and the published standards of ASTM Committee D37 on Cannabis already cover identity, cultivation, testing and quality, and state programs have years of experience applying them. Building on those standards and filling their gaps would be faster, and more trusted, than writing new ones in isolation. A Federal Cannabis Commission that brings clinicians, patients, producers and standards bodies to the same table is the right place to do that work.

CONCERN: PRESERVATION OF BOTANICAL APPLICATIONS
A drug pathway for cannabis should give patients another option, not take one away. Millions of Americans depend on botanical products from state-regulated programs, and many of them could not afford or obtain an FDA-approved product if that became the only lawful choice. If approval of one botanical drug were used to restrict the products patients already rely on, access would shrink instead of grow. A moratorium on federal interference in state-regulated programs during this transition would protect patients while the drug pathway develops alongside those programs.

CONCERN: SAFEGUARDING GENETIC DIVERSITY
Whole-plant medicine depends on genetic diversity, and genetics is often where enclosure starts. A botanical drug can be built on a patented cultivar, and whoever owns the cultivar then owns the medicine made from it. Landrace and long-cultivated genetics, developed by farmers and communities over generations, should stay in the public domain, and public seed and germplasm registries can document that record as prior art. Cultivation and genetics also belong under agricultural oversight, so FDA's raw-material requirements for drug development should not bring the plant's genetics under pharmaceutical control. How will FDA work with USDA and state agriculture departments to keep the drug pathway from reaching back into seeds and cultivation?

CONCERN: OWNERSHIP AND EXCLUSIVITY
The RFI is silent on exclusivity, patents and market protection, yet ownership may decide who benefits from a modernized pathway. A pathway that draws on decades of public use, published research and state program data could let the first sponsor turn that shared knowledge into an exclusive asset, leaving smaller producers and patients behind. Will FDA make clear that exclusivity for an approved botanical drug attaches only to that sponsor's specific product, never to a defined botanical class, a chemotype, or the prior human experience the application relied on? And will FDA publish reference standards for defined classes, so others can show comparability without needing a license?

These are some of my initial concerns as FDA decides how to advance botanical medicine development. In the meantime, two straightforward steps would ease them while the process moves forward:

1. I ask that FDA adopt an agency-wide **moratorium on federal interference** in state-regulated cannabis programs. An estimated three to six million veterans, seniors

and patients rely on today's patchwork of state programs, medical and non-medical alike, for botanical products that relieve complex or chronic conditions, some of them terminal. Please don’t put new barriers between these patients and the botanical medicine that helps them.

2. I recommend establishing a **Federal Cannabis Commission** so that patients, caregivers and health care professionals have a real voice in transparent discussions about keeping medical cannabis a safe, viable and accessible treatment for the Americans who need it.

I am glad to share more comprehensive solutions and detailed policy recommendations on request.
I look forward to taking part in further discussions on botanical drug products.

Sincerely,



Rachel Knox, MD, MBA
Physician and Cannabinoid Medicine Specialist; Co-Founder, Doctors Knox, Inc.
Member, Medical Cannabis Committee, Patient First Coalition

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In particular, I am most interested in the way cannabis fits into policy discussions about botanical medicines. As the transition is made from Schedule I to Schedule III classification, I wish to offer guidance to HHS and FDA staff while you contemplate the best manner to implement this significant and complex change. The following are some of my initial concerns as a medical cannabis patient of 6 years and as Chief Growth Officer of Dragonfly Wellness, Utah's first licensed medical cannabis pharmacy and a vertically integrated operator with licensed cultivation, processing, and pharmacy operations, where I have worked since 2019. I offer these comments from both sides of the pharmacy counter: as someone who relies on botanical cannabis medicine, and as someone responsible for producing it to state quality standards and dispensing it under pharmacist oversight.

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Medical Cannabis Patient since 2020
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Leadership Council, American Council of Cannabis Medicine
Co-Chair, Pharmacy/Dispensary Subcommittee, Medical Cannabis Committee, Patient First Coalition

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FDA

Dockets Management Staff (HFA-305)
Food and Drug Administration
5630 Fishers Lane Rm. 1061
Rockville, MD 20852

November 3, 2026

To whom it may concern,

I am writing in response to the Request for Information (RFI) issued by the Food and Drug Administration (FDA) on September 4, 2026. I wish to share my perspective on Botanical Drug Product (BDP) development in the United States, including some challenges encountered and potential solutions.

First, I want to applaud the U.S. Department of Health and Human Services (HHS) for acknowledging the broad public interest in botanical medicines among consumers, researchers, clinicians, industry stakeholders, and international regulators. We agree with FDA analysis that consumers report widespread use of botanical products for treatment of a variety of conditions, and as such, there is a need for additional research and where appropriate, acceleration of drug product development and review of clinical treatments.

In particular, I am most interested in the way cannabis fits into policy discussions about botanical medicines. As the transition is made from Schedule I to Schedule III classification, I wish to offer guidance to HHS and FDA staff while you contemplate the best manner to implement this significant and complex change. The following are some of my initial concerns as a caregiver of 15 years.

CONCERN: RESEARCH AND DEVELOPMENT

I encourage FDA to use the transition to Schedule III to support research that reflects how patients actually use cannabis, including whole-plant preparations, standardized extracts, medication interactions, and long-term outcomes. FDA's Botanical Drug Development framework and qualified real-world evidence from state medical programs could help identify priorities for further clinical study. How can FDA and HHS incorporate qualified state-based evidence so patient experience informs future botanical drug development?

CONCERN: WHOLE PLANT PREPARATIONS

As a caregiver, I am concerned that patients who benefit from whole-plant or full-spectrum preparations could lose options if the medical pathway focuses too narrowly on isolated cannabinoids or single-molecule products. FDA's botanical drug framework already recognizes that complex plant-derived medicines can be evaluated for consistency, safety, and clinical benefit. How will FDA and HHS ensure that standardized whole-plant and full-spectrum cannabis preparations retain a viable medical pathway as federal policy evolves?

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CONCERN: INTEGRATION OF EXISTING STANDARDS

A new federal framework should improve safety and consistency without unnecessarily disrupting patients who rely on state medical programs. Existing botanical standards in the U.S. and other countries address identity, traceability, cultivation, testing, and manufacturing and may provide a useful foundation for cannabis. How can FDA and HHS build on these standards while allowing an orderly transition that accounts for cannabis's genetic and chemical variation and protects patient access?

CONCERN: PRESERVATION OF BOTANICAL APPLICATIONS

A federal medical framework should preserve legitimate botanical forms of cannabis already in use while appropriate standards are developed. Whole-plant preparations, full-spectrum extracts, and FDA-reviewed cannabinoid medicines may each have a role within that framework. Would HHS and FDA consider a defined transition period, including appropriate protection from disruptive federal action, while standards for quality, consistency, clinical use, and patient access are established?

CONCERN: SAFEGUARDING GENETIC DIVERSITY

Future cannabis medicines may depend on genetic diversity that exists today. Breeders and preservationists have maintained cultivars for decades, including genetics that predate formal registries and may contain medically useful characteristics not yet studied. Could HHS and FDA work with USDA, DEA, and other appropriate agencies on a transition and preservation pathway for seeds, parental lines, tissue culture, rare cultivars, and other germplasm so potentially valuable genetics are not lost before their medical significance is understood?

CONCERN: OWNERSHIP AND EXCLUSIVITY

For cannabis, a cultivar may become part of the evidence supporting a botanical medicine, making its identity and provenance important for replication, follow-on research, and future treatments. Many cultivars predate the products developed from them and may already be relied upon by patients. As FDA considers botanical drug development and exclusivity, how will cultivar identity and provenance be treated so an approved product can be protected without unnecessarily limiting patient access, independent research, replication, or future medical development using the underlying cultivar?

These are among my initial concerns as FDA determines how to advance botanical medicines. Taken together, they support a careful transition that advances research and standards without unnecessarily disrupting patient access or narrowing future medical options. The following approaches could help while the process unfolds:

1. I encourage FDA and HHS to consider a **defined transition period**, including appropriate protection from disruptive federal action where necessary, while the federal framework is developed. This would allow time to address unresolved research, product standards, botanical access, and genetic preservation issues while maintaining continuity of patient access.
2. Establishment of a **Federal Cannabis Commission** or similar interagency forum would help ensure that patients, caregivers, health care professionals, researchers, regulators, and other relevant stakeholders are represented as federal medical cannabis policy evolves.

Comprehensive solutions and detailed policy recommendations are available upon request. I look forward to participating in further discussions on botanical drug products.

Sincerely,



Jennifer Alterwitz
Caregiver since 2011.
Member, American Council of Cannabis Medicine
Member, Medical Cannabis Committee, Patient First Coalition

DOCKET NO. FDA 2026-N-9550

Dockets Management Staff (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

October 28, 2026

RE: Response to Request for Information — Advancing Development of Botanical Drug Products

To Whom It May Concern:

I am writing in response to the Food and Drug Administration's (FDA) September 4, 2026, Request for Information (RFI) on advancing the development of botanical drug products. As a member of the American Council of Cannabis Medicine (ACCM) and the Patient First Coalition (PFC) Medical Cannabis Committee, I welcome the opportunity to offer recommendations that support patient access, scientific advancement, responsible regulation, and the preservation of the diverse botanical preparations that may have therapeutic value.

Cannabis is an important example of the opportunities and challenges associated with botanical medicines. Published research, approved cannabinoid medicines, international medical experience, and decades of use within state-regulated medical cannabis programs provide information that merits systematic evaluation. The objective should not be to presume that every cannabis product is safe and effective, but to determine what existing evidence establishes, identify genuine scientific gaps, and establish practical pathways for evaluating botanical preparations while maintaining rigorous standards for quality, safety, and effectiveness.

CONCERN: RESEARCH AND DEVELOPMENT

Research and development should begin with a systematic assessment of existing evidence rather than automatically requiring every botanical preparation to repeat the full conventional drug-development process. Evidence varies by indication, formulation, cannabinoid composition, route of administration, and study quality. FDA should clarify when existing clinical research, published literature, approved cannabinoid product data, and appropriately designed real-world evidence may support development decisions; when comparable products may rely on shared evidence; and when additional or bridging studies are necessary. A transparent, evidence-based framework would help direct resources toward unresolved scientific questions while avoiding unnecessary duplication.

CONCERN: WHOLE-PLANT PREPARATIONS

Botanical preparations may contain multiple constituents whose composition varies with genetics, cultivation, harvesting, processing, extraction, formulation, and storage. Evaluation should account for this complexity rather than assume that every botanical preparation must be reduced to a single isolated constituent. FDA should clarify how whole-plant preparations and multi-constituent botanical products can be characterized, standardized, compared, and evaluated

under the existing botanical drug-development framework. Appropriate chemical characterization, manufacturing controls, and product-specific evidence should preserve meaningful botanical differences while supporting reproducibility and reliable assessment of safety and effectiveness.

CONCERN: INTEGRATION OF EXISTING STANDARDS

Existing botanical monographs, recognized consensus standards, validated laboratory methods, and state regulatory controls may provide useful foundations for consistent product characterization and quality assessment. FDA should systematically evaluate relevant standards, including applicable American Herbal Pharmacopoeia and ASTM standards, identify where they adequately address federal regulatory objectives, and specify where additional validation or requirements are needed. The agency should also clarify expectations for analytical method validation, contaminant testing, stability, batch-to-batch consistency, and data traceability. Where appropriate, harmonizing existing standards could improve comparability across laboratories and developers without compromising product quality or patient safety.

CONCERN: PRESERVATION OF BOTANICAL APPLICATIONS

Modernizing botanical drug development should support scientific advancement without unnecessarily disrupting established patient-care systems or excluding botanical applications that may warrant further investigation. State medical cannabis programs have developed regulatory infrastructure involving licensed operators, testing, labeling, inventory tracking, physician participation, and patient access. FDA, working with relevant federal and state partners, should evaluate which elements of these systems can contribute to botanical product development and which additional safeguards are needed. A coordinated transition should preserve continuity of patient access while distinguishing the requirements for federally approved drug products from the separate legal and regulatory issues affecting existing state programs.

CONCERN: SAFEGUARDING GENETIC DIVERSITY

Genetic diversity is an important component of botanical identity, agricultural resilience, and the potential range of chemical profiles found across cannabis varieties. Standardization should not inadvertently eliminate meaningful botanical diversity by treating a single genetic line or chemical profile as the only acceptable model. FDA should clarify how genetic identity, chemotype, chemical fingerprints, cultivation conditions, and manufacturing controls can be considered together when defining botanical raw materials and assessing product consistency. Genetics alone should not establish therapeutic equivalence; rather, appropriate characterization should help distinguish meaningful differences, establish reproducible specifications, and determine when additional evidence is needed.

CONCERN: OWNERSHIP AND EXCLUSIVITY

The development of botanical medicines often builds upon longstanding public knowledge, published research, traditional applications, and evidence generated across multiple institutions and patient populations. Regulatory pathways should encourage investment in product development without unnecessarily restricting access to shared scientific knowledge or creating barriers for smaller developers. FDA should clarify how existing public evidence may be used to

support development, how product-specific regulatory exclusivity differs from patent rights, and how comparability may be demonstrated without assuming that a sponsor's approval establishes exclusive rights over an entire botanical class, chemotype, or body of prior human experience. Clear and transparent expectations would support innovation while respecting applicable intellectual property rights and encouraging continued research.

RECOMMENDED SOLUTIONS

The following actions would help address these concerns while federal agencies and stakeholders work toward a more consistent approach to botanical medicines:

1. Protect continuity of patient access during the federal transition. I encourage FDA to work with the Department of Health and Human Services, the Drug Enforcement Administration, and relevant state authorities to develop a coordinated approach that avoids unnecessary disruption to patients who rely on state-regulated medical cannabis programs. I further support consideration of an agency-wide moratorium on federal interference in state-regulated cannabis programs, within the respective agencies' legal authorities, while appropriate regulatory and policy issues are addressed. Patients should not face avoidable interruptions in access as federal standards evolve.

2. Establish a transparent federal coordination and stakeholder-engagement process. I support consideration of a Federal Cannabis Commission or comparable interagency working group that includes patients, caregivers, healthcare professionals, researchers, botanical experts, state regulators, and qualified industry representatives. Such a body should identify existing evidence, evaluate opportunities to integrate appropriate state regulatory controls, clarify standards for botanical characterization and comparability, and identify scientific and statutory barriers requiring further action. Its recommendations should be transparent, evidence-based, and focused on practical outcomes for patients and responsible development.

These recommendations are intended to support a constructive, science-driven dialogue about advancing botanical drug development. The central objective should be to distinguish genuine evidence gaps from avoidable regulatory inefficiencies, preserve meaningful botanical diversity, and establish clear expectations that enable responsible development without compromising patient safety.

I appreciate FDA's consideration of these comments and encourage the agency to continue engaging patients, researchers, clinicians, and industry stakeholders as it evaluates opportunities to improve botanical drug development in the United States.

Sincerely,

Dr. Elias B. Jackson Jr., PhD
Member, American Council of Cannabis Medicine
Member, Medical Cannabis Committee, Patient First Coalition

Dockets Management Staff (HFA-305) Food and Drug Administration 5630 Fishers Lane, Rm. 1061 Rockville, MD 20852

November 3, 2026

Re: Docket No. FDA-2026-N-9550, Advancing Development of Botanical Drug Products; Request for Information

To whom it may concern,

I am submitting this comment in response to FDA's September 4, 2026 Request for Information on advancing the development of botanical drug products. My perspective comes from the field: I have bred cannabis since the 1970s and have spent more than 20 years consulting growers on soil and plant health.

I appreciate HHS and FDA opening this docket. People across the country already rely on botanical medicines, and they deserve products that are studied carefully and held to sound standards of safety and consistency. I support that goal and want to help the agency reach it.

My focus is cannabis. As cannabis moves toward Schedule III, FDA will face questions that begin long before a product reaches a laboratory: in the soil, in the plant's genetics, and in how it is grown. The concerns below come from what I have seen in that work.

CONCERN: RESEARCH AND DEVELOPMENT

For more than 20 years my consulting practice has focused on managing soil minerals and the soil microbiome to improve how fully cannabis plants express their genetics. My practice also performs parts-per-billion contamination testing on soil and plant tissue. In the field, we have seen the same genotype show clearly different chemical profiles and therapeutic effect depending on how and where it was grown. Genetics alone does not guarantee a consistent medicine. How will FDA's botanical drug standards treat cultivation conditions, including soil minerals, the soil microbiome, and growing environment, as a variable when it judges batch-to-batch consistency and efficacy?

CONCERN: WHOLE PLANT PREPARATIONS

The patients and practitioners I work with report the strongest results from full-spectrum extracts, including among people living with cancer. We do not yet know which compounds, or which combinations of them, are responsible, and that uncertainty is the reason whole-plant preparations deserve rigorous study rather than reduction to single isolates. A full-spectrum extract keeps everything the plant contains: its beneficial compounds, and also any heavy metals, pesticide residues, or microbial contaminants it

took up from its soil and environment. Many of the patients who use these products have compromised immune systems. For that reason, safety testing needs to start with the soil and carry through to the finished plant material, at detection limits sensitive enough to protect this population. Will FDA's botanical drug framework include soil-to-product contamination testing, including parts-per-billion analysis, as part of characterizing whole-plant preparations?

CONCERN: INTEGRATION OF EXISTING STANDARDS

State-regulated cannabis programs, including California's, already require laboratory testing of finished products for contaminants such as heavy metals, pesticide residues, and microbial impurities. These programs hold years of testing data and working quality systems that FDA does not need to rebuild from scratch. At the same time, most of this testing begins at the finished product, after contamination has already entered the plant. Will FDA build on existing state testing standards and data, and extend them upstream to the soil, water, and inputs that determine what ends up in the medicine?

CONCERN: PRESERVATION OF BOTANICAL APPLICATIONS

The botanical medicine community welcomes the chance to study full-extract cannabis with the scientific method. My concern is that the only working model for supplying these medicines today is a nonprofit model run by small operators. These operators have the cultivation knowledge and the trust of patients, but they may not have the capital to get through a federal drug approval process. What path will keep medicine reaching patients while research goes on? A Federal Cannabis Commission that includes small growers and caregivers could help make sure that path exists.

CONCERN: SAFEGUARDING GENETIC DIVERSITY

I have been breeding cannabis since the 1970s. Much of the genetic diversity that exists today was developed and preserved by small breeders and citizen scientists working at their own expense over decades. Breeding is slow and costly: stabilizing a line takes many generations, and each generation needs testing to confirm what it produces. If legal breeding and analytical testing are open only to large, federally registered institutions, much of this diversity, and the knowledge behind it, could be lost. Will HHS and FDA support a clear, affordable legal pathway for citizen scientists and small breeders to breed cannabis and have their genetics tested?

CONCERN: OWNERSHIP AND EXCLUSIVITY

The genetics that may one day become approved botanical drugs often trace back to decades of work by small breeders. As sponsors pursue approvals and exclusivity, those who developed and preserved these lines risk being shut out of the very medicines their work made possible. A Federal Cannabis Commission could help ensure that ownership and exclusivity rules protect the contributions of small breeders and keep diverse genetics available for patients and future research.

These are among the initial concerns as the FDA determines how to advance development of botanical medicines. The following simple, yet effective solutions would temporarily alleviate concerns while the process unfolds:

I request that the FDA develop and implement an agency-wide moratorium on federal interference in state-regulated cannabis programs. An estimated three to six million veterans, seniors and patients rely on the existing patchwork of state programs, both medical and non-medical, to provide botanical products that provide relief from complex and/or chronic health conditions that are sometimes terminal in nature. Please don't add barriers for ailing patients who obtain relief from botanical medicine.

Establishment of a Federal Cannabis Commission would help ensure that patients, caregivers and health care professionals are adequately represented in transparent discussions about how to best ensure medical cannabis remains a safe, viable, and accessible treatment for Americans who need and deserve the health benefits offered.

Comprehensive solutions and detailed policy recommendations are available upon request.

I look forward to participating in further discussions on botanical drug products.

Sincerely,

David King Principal, Surprise Valley Agroecology LLC Cannabis breeder since the 1970s; soil and cultivation consultant for more than 20 years