4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2026-N-9550]

Advancing Development of Botanical Drug Products; Request for Information

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; request for information; establishment of a public docket.

SUMMARY: The Food and Drug Administration (FDA or Agency) is opening a public docket to solicit comments on FDA's efforts to advance development of botanical drug products (BDPs). FDA is publishing this request for information to better understand stakeholders' perspectives on the state of BDP development in the United States, challenges encountered, and potential solutions to gathering the information required by the Federal Food, Drug, and Cosmetic Act (FD&C Act).

DATES: Submit either electronic or written comments, data, or information by [INSERT DATE 60 DAYS AFTER PUBLICATION IN THE *FEDERAL REGISTER*].

ADDRESSES: You may submit comments, data, and information as follows. Please note that late, untimely filed comments will not be considered. The https://www.regulations.gov electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of [INSERT DATE 60 DAYS AFTER PUBLICATION IN THE *FEDERAL REGISTER*]. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are received on or before that date.

Electronic Submissions

Submit electronic comments in the following way:

- Federal eRulemaking Portal: https://www.regulations.gov. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to https://www.regulations.gov will be posted to the docket unchanged. Because your

comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on https://www.regulations.gov.

- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see "Written/Paper Submissions" and "Instructions").

Written/Paper Submissions

Submit written/paper submissions as follows:

- Mail/Hand delivery/Courier (for written/paper submissions): Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in "Instructions."

Instructions: All submissions received must include the Docket No. FDA-2026-N-9550 for "Advancing Development of Botanical Drug Products; Request for Information." Received comments, those filed in a timely manner (see ADDRESSES), will be placed in the docket and, except for those submitted as "Confidential Submissions," publicly viewable at https://www.regulations.gov or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, 240-402-7500.

- Confidential Submissions--To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper

submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states "THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION." The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on https://www.regulations.gov. Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as "confidential." Any information marked as "confidential" will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf.

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to https://www.regulations.gov and insert the docket number, found in brackets in the heading of this document, into the "Search" box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240-402-7500.

FOR FURTHER INFORMATION CONTACT: Caroline Huang, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6117, Silver Spring, MD 20993-0002, 855-543-3784, botanicaldrugproducts@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Background

There is broad public interest in botanical products among consumers, researchers, clinicians, industry, the U.S. Federal Government, and international regulators. Consumers

report widespread use of botanical products for self-treatment of a variety of conditions. In light of this, FDA seeks to facilitate additional research on botanicals, with the goal of accelerating drug product development and review of clinical treatments in this space.

In this notice, the terms "botanicals," "botanical drug products," and "BDPs" refer to drug products that include or may be derived from plant materials, algae, macroscopic fungi, or combinations thereof and that are intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in humans.[1] BDPs may be available as, but are not limited to, solutions (e.g., tea), powders, tablets, capsules, tinctures, topicals, or injections.

The inherent heterogeneity of botanicals creates unique challenges in research, product development, and regulatory review. In recognition of these unique considerations, FDA published the guidance for industry "Botanical Drug Development" on December 29, 2016 (81 FR 96018) (available at https://www.fda.gov/media/93113/download),[2] outlining recommendations related to characterization, quality control, clinical investigation, and regulatory considerations for BDPs. Despite increasing interest in plant-based medicines, researchers and developers of botanicals report a variety of challenges, such as clinical trial design and implementation, production quality and consistency, and other development considerations.

To date, four botanical products have been approved for marketing as prescription drugs under the new drug application (NDA) and biologics license application (BLA) pathways. The three NDAs include drug products containing the active ingredients sinecatechins, crofelemer, and birch triterpenes, respectively. The BLA contains the active ingredient anacaulase-bcdb.

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[1] See section 201(g)(1) of the FD&C Act (21 U.S.C. 321(g)(1)) for the definition of the term "drug". For more information on BDPs, see FDA's web page "What is a Botanical Drug?" at https://www.fda.gov/about-fda/cder-offices-and-divisions/what-botanical-drug.

[2] The draft guidance for industry "Botanical Drug Products" was issued in August 2000, finalized in June 2004, and later revised in August 2015, at which point the title was revised to "Botanical Drug Development." This revised draft guidance was finalized in December 2016. Available at https://www.fda.gov/media/93113/download.

Additionally, botanical active ingredients such as psyllium and witch hazel can be marketed under certain over-the-counter (OTC) monographs.[3]

Building on the lessons learned from these marketed products and the Agency's experience with other BDP development programs, FDA seeks to accelerate development of BDPs. As part of this effort, FDA recently collaborated on a roundtable to gather information on challenges and opportunities for development of BDPs.[4] External roundtable participants identified several potential opportunities to accelerate the development and review of BDPs, such as incorporating real-world evidence to inform fit-for-purpose BDP development programs, identifying and applying appropriate quality frameworks to address batch-to-batch variability and ensure reproducibility, and increasing education and outreach to align understanding across the development ecosystem.

II. Topics for Public Input

FDA seeks information and comments from researchers, clinicians, industry members, and other interested parties on the following questions:

1. **Research and BDP development experience**:
    a. What challenges, if any, have you encountered in botanical research or drug product development programs which you have led or to which you have contributed? For example, have you encountered specific challenges in studies in healthy volunteers compared to studies in patient populations, or vice versa? Provide detailed information and comments on the progress of and challenges for these programs.
    b. How are you using existing FDA resources to advance development of BDPs, if at all?

[3] OTC monograph drugs can be marketed without an approved drug application under section 505 of the FD&C Act (21 U.S.C. 355) if they meet the requirements of section 505G of the FD&C Act (21 U.S.C. 355h), including applicable conditions in an OTC monograph and other applicable requirements. An OTC monograph establishes conditions, such as active ingredients, uses (indications), doses, routes of administration, labeling, and testing, under which an OTC drug in a given therapeutic category is generally recognized as safe and effective for its intended use.
[4] For more information on this roundtable, see https://reaganudall.org/projects/botanical-drug-development-roundtable.

c. What systems, processes, and/or standard practices do you have in place as part of your drug product development program that facilitate gathering the information required by the FD&C Act and the implementing regulations in Title 21 of the Code of Federal Regulations (21 CFR)?

2. **General challenges**:

a. What challenges have you experienced or do you foresee for BDP development (e.g., scientific and economic)?

b. What are the challenges, regulatory or otherwise, in developing minimally purified or whole plant products versus highly purified or isolate products?

3. **General opportunities**:

a. What innovative approaches can FDA and/or industry take to support and accelerate BDP development?

b. What approaches have been successful in streamlining BDP development without impacting safety, efficacy, or quality of the BDP?

c. Which specific updates (e.g., to guidance or other materials) would provide clarity on FDA's approach to botanicals?

d. What opportunities exist for standards development (e.g., quality standards) outside of FDA to support advancements in BDP development and review?

e. What scientifically credible study designs are best suited for complex botanical mixtures, and how should those be assessed (e.g., with respect to safety, efficacy, and quality)?

f. How could information from botanicals with well-established use, generally accepted scientific knowledge, and/or real-world evidence be utilized to facilitate development?

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

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