

119TH CONGRESS
2D SESSION

H. R. 10150

To amend the Federal Food, Drug, and Cosmetic Act to provide a period of market exclusivity for botanical drugs, and for other purposes.

IN THE HOUSE OF REPRESENTATIVES

AUGUST 27, 2026

Ms. BOEBERT (for herself and Mr. VAN ORDEN) introduced the following bill;
which was referred to the Committee on Energy and Commerce

A BILL

To amend the Federal Food, Drug, and Cosmetic Act to provide a period of market exclusivity for botanical drugs, and for other purposes.

1 *Be it enacted by the Senate and House of Representa-*
2 *tives of the United States of America in Congress assembled,*

3 **SECTION 1. SHORT TITLE.**

4 This Act may be cited as the “Advancing Botanical
5 Drug Development Act of 2026”.

6 **SEC. 2. FINDINGS.**

7 Congress finds the following:

8 (1) Chronic and age-related diseases are among
9 the leading causes of disability, impaired quality of
10 life, and health care spending in the United States.

1 (2) Many chronic and age-related diseases in-
2 volve multiple biological pathways and complex
3 pathophysiology, yet most currently approved thera-
4 pies are designed to target a single molecular path-
5 way.

6 (3) Botanical drugs regulated by the Food and
7 Drug Administration (in this section referred to as
8 the “FDA”) under section 505 of the Federal Food,
9 Drug, and Cosmetic Act (21 U.S.C. 355) may con-
10 tain multiple naturally occurring active constituents
11 capable of acting on multiple biological pathways si-
12 multaneously and safely.

13 (4) Since the FDA established a regulatory
14 pathway for botanical drugs in 2004, only a limited
15 number of botanical drugs have received approval,
16 despite significant scientific and therapeutic poten-
17 tial and the growing interest of patients in evidence-
18 based, FDA-approved treatment options derived
19 from natural products.

20 (5) In addition to the costs associated with the
21 clinical development of conventional synthetic drugs,
22 botanical drugs present unique scientific and manu-
23 facturing challenges arising from the natural varia-
24 bility of plant-derived raw materials, including the
25 need for extensive sourcing controls, batch consist-

1 ency testing, constituent characterization, and stand-
2 ardization processes to ensure safety, quality, and
3 effectiveness. These additional development burdens
4 may increase costs and commercial uncertainty for
5 sponsors seeking to bring innovative botanical thera-
6 pies to market.

7 (6) As a result of these unique scientific, manu-
8 facturing, and regulatory challenges, existing intel-
9 lectual property and regulatory exclusivity frame-
10 works may not provide sufficient incentives to sup-
11 port private investment in the research and develop-
12 ment of innovative botanical drugs.

13 (7) Congress has previously recognized that cer-
14 tain categories of complex medical products require
15 tailored periods of regulatory exclusivity to encour-
16 age innovation and facilitate long-term investment in
17 research and development.

18 (8) Expanding incentives for the development of
19 safe and effective botanical drugs may increase
20 multi-target treatment options for patients suffering
21 from multi-pathway, chronic and age-related dis-
22 eases while promoting biomedical innovation and
23 economic growth in the United States.

24 (9) Advances in computational biology, artificial
25 intelligence, and systems pharmacology have created

1 new opportunities to identify and develop innovative
2 botanical drug combinations capable of addressing
3 complex diseases through multi-pathway mechanisms
4 of action.

5 (10) It is in the public interest to encourage the
6 development and approval of multi-target, evidence-
7 based, FDA-regulated botanical drugs subject to the
8 same standards of safety and effectiveness applicable
9 to other drugs regulated by the FDA.

10 **SEC. 3. PERIOD OF MARKET EXCLUSIVITY FOR BOTANICAL**
11 **DRUGS.**

12 Section 505(c)(3)(E) of the Federal Food, Drug, and
13 Cosmetic Act (21 U.S.C. 355(c)(3)(E)) is amended by
14 adding at the end the following:

15 “(vi)(I) A botanical drug approved under subsection
16 (b)(1) pursuant to an application submitted after the date
17 of enactment of this clause shall be entitled to a 12-year
18 period during which no application submitted under sub-
19 section (b)(2) or (j) that references or relies upon such
20 drug may become effective.

21 “(II) In this clause, the term ‘botanical drug’ means
22 a botanical drug subject to subsection (a), as determined
23 by the Secretary by regulation.”.

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