

119TH CONGRESS
2D SESSION

H. R. 7050

To amend the Federal Food, Drug, and Cosmetic Act with respect to homeopathic drug products, and for other purposes.

IN THE HOUSE OF REPRESENTATIVES

JANUARY 14, 2026

Mr. SESSIONS (for himself, Mr. KENNEDY of Utah, and Mr. JACKSON of Illinois) 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 with respect to homeopathic drug products, 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; TABLE OF CONTENTS.**

4 (a) SHORT TITLE.—This Act may be cited as the
5 “Homeopathic Drug Product Safety, Quality, and Trans-
6 parency Act”.

7 (b) TABLE OF CONTENTS.—The table of contents for
8 this Act is as follows:

Sec. 1. Short title; table of contents.

Sec. 2. Purpose; sense of Congress.

Sec. 3. Definitions.

Sec. 4. Safety, quality, and transparency requirements for homeopathic drug products.

Sec. 5. Conforming amendments.

Sec. 6. Withdrawal of guidance.

Sec. 7. Severability.

1 SEC. 2. PURPOSE; SENSE OF CONGRESS.

2 (a) PURPOSE.—The purpose of this Act is to address
3 consumer and practitioner needs for continued access to
4 homeopathic drug products that meet requirements for
5 safety, quality, and transparency.

6 (b) SENSE OF CONGRESS.—It is the sense of Con-
7 gress that—

8 (1) homeopathic medicines are important to
9 millions of American consumers, and continued con-
10 sumer access to safe homeopathic products is best
11 ensured by enacting a distinct statutory pathway for
12 the regulation of homeopathic drug products; and

13 (2) while the Federal Government should con-
14 tinue to take appropriate action against products
15 that are adulterated or misbranded, Federal agen-
16 cies should not impose regulatory barriers that un-
17 reasonably limit or prevent consumer and health
18 care provider access to safe products and accurate
19 information.

20 SEC. 3. DEFINITIONS.

21 Section 201 of the Federal Food, Drug, and Cosmetic
22 Act (21 U.S.C. 321) is amended—

1 (1) in paragraph (p), by striking “except a new
2 animal drug or an animal feed bearing or containing
3 a new animal drug” each place it appears and in-
4 serting “except a new animal drug, an animal feed
5 bearing or containing a new animal drug, or a home-
6 opathic drug product”;

7 (2) in paragraph (v), by inserting before the pe-
8 riod at the end the following: “, and that a homeo-
9 pathic drug product is not a new animal drug”; and

10 (3) by adding at the end the following:

11 “(tt) The term ‘homeopathic drug product’ means a
12 drug that—

13 “(1) contains 1 or more homeopathic ingredi-
14 ents; and

15 “(2) contains no other active ingredient.

16 “(uu) The term ‘homeopathic ingredient’ means an
17 ingredient—

18 “(1) listed in the Homeopathic Pharmacopoeia
19 of the United States or a State homeopathic for-
20 mulary; or

21 “(2) prepared pursuant to homeopathic safety
22 and quality standards described in—

23 “(A) the Homeopathic Pharmacopoeia of
24 the United States or any other officially recog-
25 nized homeopathic pharmacopoeia; or

1 “(B) any accredited voluntary consensus
 2 standard for homeopathic drug products, as de-
 3 termined by the Secretary in compliance with
 4 section 12(d) of the National Technology
 5 Transfer and Advancement Act of 1995.”.

6 **SEC. 4. SAFETY, QUALITY, AND TRANSPARENCY REQUIRE-**
 7 **MENTS FOR HOMEOPATHIC DRUG PROD-**
 8 **UCTS.**

9 Subchapter A of chapter V of the Federal Food,
 10 Drug, and Cosmetic Act (21 U.S.C. 351 et seq.) is amend-
 11 ed by inserting after section 503D (21 U.S.C. 353d) the
 12 following:

13 **“SEC. 503E. HOMEOPATHIC DRUG PRODUCTS.**

14 “(a) PROVISIONS APPLICABLE TO HOMEOPATHIC
 15 DRUG PRODUCTS.—

16 “(1) CHAPTER V PROVISIONS.—No section of
 17 this chapter shall apply to homeopathic drug prod-
 18 ucts except this section and sections 501, 502, and
 19 510.

20 “(2) REQUIREMENTS FOR ALL PROVISIONS.—
 21 No provision of law, a regulation, or a guidance doc-
 22 ument (including sections 501, 502, and 510 and
 23 any applicable provisions of this Act outside of this
 24 chapter) shall apply to homeopathic drug products
 25 unless such provision—

1 “(A) does not conflict with this section;
2 and

3 “(B) does not impose standards that are in
4 conflict with standards in the Homeopathic
5 Pharmacopoeia of the United States or in an
6 accredited voluntary consensus standard for ho-
7 meopathic drug products, as determined by the
8 Secretary in compliance with section 12(d) of
9 the National Technology Transfer and Advance-
10 ment Act of 1995.

11 “(b) ADULTERATION; GOOD MANUFACTURING PRAC-
12 TICE STANDARDS.—

13 “(1) ADULTERATION.—A homeopathic drug
14 product shall be deemed to be adulterated if it does
15 not comply with—

16 “(A) the safety and quality standards and
17 manufacturing practices described in—

18 “(i) the Homeopathic Pharmacopoeia
19 of the United States or any other officially
20 recognized homeopathic pharmacopoeia; or

21 “(ii) an accredited voluntary con-
22 sensus standard for homeopathic drug
23 products, as determined by the Secretary
24 in compliance with section 12(d) of the

1 National Technology Transfer and Ad-
2 vancement Act of 1995; or

3 “(B) in the case that no standard or man-
4 ufacturing practice described in subparagraph
5 (A) applies to such homeopathic drug product,
6 the regulations described in paragraph (2).

7 “(2) ALTERNATIVE REGULATIONS.—The regu-
8 lations described in this paragraph are the following:

9 “(A) Good manufacturing practice regula-
10 tions promulgated under section 501(a)(2) or
11 related guidance documents, provided that such
12 regulations or related guidance documents do
13 not conflict with any other provision of this sec-
14 tion.

15 “(B) In the case that no regulation de-
16 scribed in subparagraph (A) applies to the ho-
17 meopathic drug product, a new good manufac-
18 turing practice regulation, which shall be pro-
19 mulgated by the Secretary after notice and op-
20 portunity for public comment pursuant to chap-
21 ter 5 of title 5, United States Code—

22 “(i) that does not conflict with any
23 other provision of this section;

24 “(ii) that is specific to and appro-
25 priate for homeopathic drug products; and

1 “(iii) with respect to which the Sec-
2 retary has requested and received a favor-
3 able recommendation from the Homeo-
4 pathic Drug Product Advisory Committee.

5 “(3) PETITION FOR EXEMPTION, VARIANCE, OR
6 ALTERNATIVE STANDARD OR PRACTICE.—

7 “(A) PETITION.—A manufacturer of a ho-
8 meopathic drug product subject to a good man-
9 ufacturing practice regulation may submit to
10 the Secretary a petition for an exemption, vari-
11 ance, or alternative standard or practice with
12 respect to such product. The Secretary shall
13 refer such petition to the Homeopathic Drug
14 Product Advisory Committee, which shall report
15 its recommendation to the Secretary not later
16 than 60 days after receiving such petition.

17 “(B) DEADLINE FOR APPROVAL.—The
18 Secretary shall make a decision on a petition
19 submitted under subparagraph (A) not later
20 than 180 days after the submission of the peti-
21 tion. If the Secretary fails to make a decision
22 on such a petition within such 180-day period,
23 the petition shall be deemed approved and the
24 proposed exemption, variance, or alternative
25 standard or practice established.

1 “(C) STANDARD FOR APPROVAL.—The
2 Secretary may approve a petition submitted
3 under subparagraph (A) and establish the pro-
4 posed exemption, variance, or alternative stand-
5 ard or practice with respect to the homeopathic
6 drug product only if such exemption, variance,
7 or alternative standard or practice does not af-
8 fect the safety of the homeopathic drug prod-
9 uct.

10 “(D) JUDICIAL REVIEW.—For the pur-
11 poses of chapter 7 of title 5, United States
12 Code, a decision of the Secretary on a petition
13 submitted under subparagraph (A) shall be con-
14 sidered final agency action.

15 “(4) FINAL AND INTERMEDIATE PRODUCT
16 TESTING.—

17 “(A) FINAL PRODUCT TESTING.—A fin-
18 ished homeopathic drug product shall be exempt
19 from the requirement for a laboratory deter-
20 mination of identity and strength of each active
21 ingredient described in section 211.165(a) of
22 title 21, Code of Federal Regulations (or any
23 successor regulation), but shall continue to be
24 required to meet other final specifications, such

1 as testing for contaminants and defects of the
2 finished product, consistent with this section.

3 “(B) INTERMEDIATE TESTING FOR CER-
4 TAIN STARTING MATERIALS.—

5 “(i) IN GENERAL.—The manufacturer
6 of a homeopathic drug product made from
7 a starting material containing a substance
8 which may present a substantial risk of ill-
9 ness or injury in its undiluted form shall
10 ensure and document that the amount of
11 such substance in an intermediate level
12 preparation used to make all further at-
13 tenuations does not exceed a safe level, as
14 determined by the Secretary under this
15 subparagraph.

16 “(ii) SAFE LEVEL DEFINED.—In this
17 subparagraph, the term ‘safe level’
18 means—

19 “(I) a level set by nationally rec-
20 ognized standards for safety, includ-
21 ing the Homeopathic Pharmacopoeia
22 of the United States or an accredited
23 voluntary consensus standard for ho-
24 meopathic drug products, as deter-
25 mined by the Secretary in compliance

1 with section 12(d) of the National
2 Technology Transfer and Advance-
3 ment Act of 1995; or

4 “(II) in the absence of a stand-
5 ard described in subclause (I), a level
6 below an analytically detectable pres-
7 ence.

8 “(iii) PUBLICATION OF SAFE LEV-
9 ELS.—The Secretary may issue an order,
10 notice of which shall be published in the
11 Federal Register, establishing a safe level,
12 based on appropriate scientific and tech-
13 nical data, for a substance under clause
14 (i). Such notice shall include—

15 “(I) a statement of the basis for
16 the Secretary’s finding that there is a
17 reasonable probability that the sub-
18 stance may present a substantial risk
19 of illness or injury in its undiluted
20 form;

21 “(II) a statement of the basis for
22 the establishment of the safe level, in-
23 cluding any available methods to es-
24 tablish such level; and

1 “(III) a request for public com-
2 ments.

3 “(c) MISBRANDING.—

4 “(1) IN GENERAL.—A drug shall be deemed to
5 be misbranded if—

6 “(A) it is not a homeopathic drug product,
7 and its labeling bears the term ‘homeopathic’,
8 ‘homeopathy’, ‘homeopath’, or such similar
9 term as determined by the Secretary; or

10 “(B) it is a homeopathic drug product, and
11 its labeling does not comply with the require-
12 ments described in paragraph (2).

13 “(2) LABELING REQUIREMENTS.—With respect
14 to the labeling of a homeopathic drug product, the
15 requirements described in this paragraph are the re-
16 quirements for the labeling of a drug under this Act,
17 subject to the following:

18 “(A) The labeling need not adhere to any
19 requirement that does not apply to homeopathic
20 drug products under subsection (a).

21 “(B) The dosage units of the homeopathic
22 ingredients shall be expressed as attenuations
23 particular to homeopathic ingredients (such as
24 ‘3x’ or ‘6c’).

1 “(C) If the homeopathic drug product is
2 not intended for retail sale, the label of such
3 product need not contain a purpose or indica-
4 tion for use.

5 “(D) If the homeopathic drug product is
6 intended for retail sale, the label of such prod-
7 uct shall contain—

8 “(i) 1 or more purposes or indications
9 for use for self-limiting conditions that are
10 supported by—

11 “(I) the Homeopathic Pharma-
12 copoeia of the United States, an offi-
13 cial pharmacopeia of another country
14 where the practice of homeopathy is
15 licensed or certified, or an accredited
16 voluntary consensus standard for ho-
17 meopathic drug products, as deter-
18 mined by the Secretary in compliance
19 with section 12(d) of the National
20 Technology Transfer and Advance-
21 ment Act of 1995;

22 “(II) a traditional homeopathic
23 reference, including a homeopathic
24 Materia Medica in general use by li-
25 censed medical practitioners who prac-

1 tice homeopathy or certified homeo-
2 paths in the United States or another
3 country;

4 “(III) a peer-reviewed medical
5 journal, including any homeopathic
6 medical journal;

7 “(IV) citation to scientific evi-
8 dence, including clinical data or trials;

9 “(V) beneficial clinical usage doc-
10 umented by clinical reports from na-
11 tional or international organizations,
12 professionally recognized publications
13 of clinical indications and contra-
14 indications, national or international
15 instructional courses providing train-
16 ing in the use of homeopathic drug
17 products, or professional peer review
18 presentations of physicians’ usage re-
19 sults with homeopathic drug products
20 at local, county, State, national, or
21 international meetings; or

22 “(VI) quality real-world data that
23 provides sufficient evidence to support
24 such purposes or indications for use;
25 and

1 “(ii) adjacent to such purposes or in-
2 dications for use, the following statement:
3 ‘These indications have not been evaluated
4 by the Food and Drug Administration.
5 This product is intended for traditional ho-
6 meopathic uses.’.

7 “(E) The labeling shall not be considered
8 false or misleading for the purposes of section
9 502(a)(1) due to the inclusion of a purpose or
10 indication for use that is supported by any
11 source described in subclauses (I) through (VI)
12 of subparagraph (D)(i).

13 “(F)(i) Subject to clause (ii), the label
14 shall describe—

15 “(I) the source relied upon for each
16 purpose or indication for use under sub-
17 paragraph (D)(i); and

18 “(II) if applicable, the name and place
19 of business of any parent, subsidiary, or
20 affiliate company of the manufacturer of
21 the homeopathic drug product, if under
22 common ownership or control.

23 “(ii) If the label has insufficient space for
24 the information required by clause (i), in lieu of
25 such information the label may contain a quick

1 response code (commonly known as a ‘QR
2 code’) or similar mechanism that links to a pub-
3 licly accessible website containing such informa-
4 tion.

5 “(3) APPLICATION OF OTHER MISBRANDING-
6 RELATED PROVISIONS.—

7 “(A) FTC ACT.—Labeling or marketing
8 claims associated with a homeopathic drug
9 product that are in compliance with this sub-
10 section may not be considered a false advertise-
11 ment or an unfair or deceptive act or practice
12 in or affecting commerce for purposes of section
13 5 or 12 of the Federal Trade Commission Act.

14 “(B) OTHER PROVISIONS OF FEDERAL OR
15 STATE LAW.—If a homeopathic drug product’s
16 label, labeling, advertising, and marketing ma-
17 terials are in compliance with this subsection,
18 no other substantiation requirement in Federal
19 or State law shall apply to such product.

20 “(C) PRIVATE RIGHTS OF ACTION.—No
21 private right of action for false or deceptive ad-
22 vertising may be predicated on the lack of clin-
23 ical trials to substantiate indications for a ho-
24 meopathic drug product.

1 “(d) REGISTRATION AND LISTING.—For purposes of
2 drug establishment registration and drug listing under
3 section 510, the Secretary shall—

4 “(1) designate a homeopathic drug product es-
5 tablishment as a ‘homeopathic’ establishment; and

6 “(2) list a homeopathic drug product as ‘home-
7 opathic’, with no other designation.

8 “(e) NO PREMARKET APPROVAL.—The Secretary
9 may not require premarket approval of a homeopathic
10 drug product.

11 “(f) HOMEOPATHIC DRUG PRODUCT ADVISORY COM-
12 MITTEE.—

13 “(1) ESTABLISHMENT.—The Secretary shall es-
14 tablish a Homeopathic Drug Product Advisory Com-
15 mittee (in this subsection referred to as the ‘Com-
16 mittee’) to advise the Secretary on the regulation of
17 homeopathic drug products.

18 “(2) MEMBERSHIP.—

19 “(A) IN GENERAL.—Subject to subpara-
20 graph (B), the Committee shall be composed of
21 10 members, to be appointed by the Secretary,
22 as follows:

23 “(i) 1 representative from an organi-
24 zation of homeopathic product consumers
25 that has been operating for a minimum of

1 3 continuous years with a minimum of
2 10,000 members, who shall serve as the
3 Chair of the Committee.

4 “(ii) 1 representative from a domestic
5 homeopathic drug manufacturer that pro-
6 duces at least 50 distinct homeopathic
7 drug products and has no fewer than 50
8 employees.

9 “(iii) 1 representative from a domestic
10 homeopathic drug manufacturer that pro-
11 duces at least 50 distinct homeopathic
12 drug products and has no more than 50
13 employees.

14 “(iv) 1 representative from the Home-
15 opathic Pharmacopoeia Convention of the
16 United States.

17 “(v) 1 representative from an accred-
18 ited voluntary consensus standards body
19 for homeopathic drug products that has
20 been operating for a minimum of 3 contin-
21 uous years.

22 “(vi) 1 licensed medical doctor (M.D.)
23 or doctor of osteopathy (D.O.) who holds a
24 Diplomate, American Board of Homeo-
25 pathic Medicine (DABHM) or Diplomate,

1 Homeotherapeutics (DHt) and who main-
2 tains a homeopathic practice that has been
3 in operation for a minimum of 3 contin-
4 uous years.

5 “(vii) 1 licensed naturopathic doctor
6 (N.D.) who holds a Diplomate, American
7 Board of Homeopathic Medicine
8 (DABHM) or Diplomate, Homeopathic
9 Academy of Naturopathic Physicians
10 (DHANP) and who maintains a homeo-
11 pathic practice that has been in operation
12 for a minimum of 3 continuous years.

13 “(viii) 1 licensed pharmacist or chem-
14 ist actively engaged in the preparation of
15 homeopathic drug products for a minimum
16 of 3 continuous years.

17 “(ix) 1 licensed veterinarian certified
18 by the Academy of Veterinary Homeopathy
19 or accredited by a recognized homeopathy
20 institution who maintains a practice that
21 has been in operation for a minimum of 3
22 continuous years.

23 “(x) The Commissioner of Food and
24 Drugs.

1 “(B) ALTERNATIVE MEMBERS.—If the
2 Secretary is unable to find a suitable individual
3 to serve in the position of a representative de-
4 scribed in clauses (i) through (ix), the other
5 members of the Committee may appoint to such
6 position, by majority vote, such other expert in
7 the field of homeopathic drug products as the
8 Committee determines appropriate.

9 “(C) BALANCE OF MEMBERSHIP.—In mak-
10 ing appointments under subparagraph (A), the
11 Secretary shall ensure that the membership of
12 the Committee reflects a proper balance of per-
13 spectives from the homeopathic practitioner,
14 manufacturer, and consumer communities.

15 “(D) NO COMPENSATION.—The members
16 of the Committee shall serve without compensa-
17 tion.

18 “(3) FREQUENCY OF SESSIONS.—The Secretary
19 shall call the Committee into session at such times
20 and in such places as the Secretary determines ap-
21 propriate, but in no case less frequently than once
22 every 3 months.

23 “(4) INVESTIGATIONS.—The Committee may
24 investigate any report of a homeopathic drug prod-

1 uct to the FDA Adverse Event Reporting System to
2 assist in post-market surveillance.

3 “(5) TERMINATION.—Section 1013 of chapter
4 5, United States Code (relating to termination of ad-
5 visory committees), shall not apply to the Com-
6 mittee.

7 “(g) INSPECTORS.—All Federal inspectors whose du-
8 ties or authorities extend to homeopathic drug products
9 shall be familiar with the requirements of this section, in-
10 cluding the safety and quality manufacturing standards
11 in the Homeopathic Pharmacopoeia of the United States
12 or an accredited voluntary consensus standard for homeo-
13 pathic drug products.

14 “(h) NON-PREEMPTION OF STATE LAW ON PRAC-
15 TICE OF HOMEOPATHY.—Nothing in this section shall be
16 construed to preempt, limit, or interfere with State juris-
17 diction concerning the practice of homeopathy and related
18 activities within the scope of the health care professional-
19 patient relationship.

20 “(i) BURDEN OF PROOF.—The United States shall
21 bear the burden of proof to establish a violation of this
22 section. Any Federal court with jurisdiction shall decide
23 any matter under this section on a de novo basis.”.

1 **SEC. 5. CONFORMING AMENDMENTS.**

2 (a) PHARMACEUTICAL DISTRIBUTION SUPPLY
3 CHAIN.—Section 581(13) of the Federal Food, Drug, and
4 Cosmetic Act (21 U.S.C. 360eee(13)) is amended by strik-
5 ing “homeopathic drugs marketed in accordance with ap-
6 plicable guidance under this Act” and inserting “homeo-
7 pathic drug products marketed in accordance with this
8 Act”.

9 (b) SERIOUS ADVERSE EVENT REPORTING FOR NON-
10 PRESCRIPTION DRUGS.—Section 760(a)(2) of the Federal
11 Food, Drug, and Cosmetic Act (21 U.S.C. 379aa(a)(2))
12 is amended to read as follows:

13 “(2) NONPRESCRIPTION DRUG.—The term non-
14 prescription drug—

15 “(A) means a drug that is—

16 “(i) not subject to section 503(b); and

17 “(ii) not subject to approval in an ap-
18 plication submitted under section 505; and

19 “(B) includes a homeopathic drug prod-
20 uct.”.

21 (c) EXEMPTION FROM REGULATION OF BIOLOGICAL
22 PRODUCTS.—Section 351(i)(1) of the Public Health Serv-
23 ice Act (42 U.S.C. 262(i)(1)) is amended by adding at
24 the end the following: “Such term does not include a ho-
25 meopathic drug product (as defined in section 201 of the
26 Federal Food, Drug, and Cosmetic Act).”.

1 **SEC. 6. WITHDRAWAL OF GUIDANCE.**

2 The guidance of the Food and Drug Administration
3 titled “Homeopathic Drug Products; Guidance for Food
4 and Drug Administration Staff and Industry; Availability”
5 (87 Fed. Reg. 75054; published on December 7, 2022)
6 shall have no force or effect with respect to homeopathic
7 drug products (as defined in section 201 of the Federal
8 Food, Drug, and Cosmetic Act (21 U.S.C. 321), as
9 amended by section 3(3)).

10 **SEC. 7. SEVERABILITY.**

11 If any provision of this Act (including the amend-
12 ments made by this Act) is declared unconstitutional, or
13 the applicability of this Act (including the amendments
14 made by this Act) to any person or circumstance is held
15 invalid, the constitutionality of the remainder of this Act
16 (including the amendments made by this Act) and the ap-
17 plicability thereof to other persons and circumstances shall
18 not be affected.

○