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(Original Signature of Member)

119TH CONGRESS
2D SESSION

H. R.

To amend the Federal Food, Drug, and Cosmetic Act to provide for the regulation of cannabinoid hemp products, and for other purposes.

IN THE HOUSE OF REPRESENTATIVES

Mr. GRIFFITH introduced the following bill; which was referred to the Committee on _____

A BILL

To amend the Federal Food, Drug, and Cosmetic Act to provide for the regulation of cannabinoid hemp 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.**

4 This Act may be cited as the “Hemp Enforcement,
5 Modernization, and Protection Act”.

6 **SEC. 2. TABLE OF CONTENTS.**

7 The table of contents of this Act is as follows:

Sec. 1. Short title.

Sec. 2. Table of contents.

Sec. 3. Definitions.

Sec. 4. Cannabinoid hemp product regulation.

“CHAPTER X—CANNABINOID HEMP PRODUCTS

“Sec. 1001. Definitions.

“Sec. 1002. Adulterated cannabinoid hemp products.

“Sec. 1003. Misbranded cannabinoid hemp products.

“Sec. 1004. Standards for oral cannabinoid hemp products.

“Sec. 1005. Standards for inhalable cannabinoid hemp products.

“Sec. 1006. Standards for topical cannabinoid hemp products.

“Sec. 1007. Minimum age of sale.

“Sec. 1008. Manufacturing and testing.

“Sec. 1009. Facility registration and product listing.

“Sec. 1010. Inspection of foreign cannabinoid hemp facilities.

“Sec. 1011. Mandatory recall authority.

“Sec. 1012. Applicable thresholds for cannabinoid content.

“Sec. 1013. Cannabinoid hemp products advisory committee.

Sec. 5. Enforcement.

Sec. 6. Rules of construction.

1 **SEC. 3. DEFINITIONS.**

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

4 (1) in paragraph (ff)(1), by striking “(other
5 than tobacco)” and inserting “(other than a
6 cannabinoid hemp product or tobacco)”;

7 (2) in paragraph (rr)(2), by striking “or a com-
8 bination product described in section 503(g)” and
9 inserting “a combination product described in sec-
10 tion 503(g), or a cannabinoid hemp product under
11 paragraph (uu)”;

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

13 “(tt)(1) The term ‘cannabinoid’ means a chemical,
14 regardless of its source, that meets one or more of the
15 following criteria:

1 “(A) A chemical belonging to any of the fol-
2 lowing chemical subclasses, including any acid, ace-
3 tate, salt, ester, ether, derivative, or isomer thereof:

4 “(i) Cannabigerol.

5 “(ii) Cannabichromene.

6 “(iii) Cannabidiol.

7 “(iv) Delta-9 tetrahydrocannabinol.

8 “(v) Delta-8 tetrahydrocannabinol.

9 “(vi) Cannabicyclol.

10 “(vii) Cannabielsoin.

11 “(viii) Cannabinol.

12 “(ix) Cannabinodiol.

13 “(x) Cannabitriol.

14 “(xi) Any cannabinoid that is naturally
15 found in, or produced by, the plant *Cannabis*
16 *sativa L.* but is of a different chemical subclass
17 than the subclasses listed in subclauses (i)
18 through (x).

19 “(xii) Any cannabinoid that is not natu-
20 rally found in or produced by the plant *Can-*
21 *nabis sativa L.* and can only be created through
22 synthetic means, such as hexahydrocannabinol
23 or tetrahydrocannabinol acetate.

24 “(B) Any chemical, regardless of origin or
25 method of production, that—

1 “(i) is equivalent in chemical structure to
2 a chemical referred to in clause (A); or

3 “(ii) has both a similar terpenophenolic
4 chemical structure and pharmacological effect
5 to a chemical referred to in clause (A).

6 “(C) Any chemical derived from a plant of the
7 genus *Cannabis* that is a CB-1 or CB-2 receptor
8 agonist or partial agonist.

9 “(D) Any chemical that the Secretary by regu-
10 lation deems to meet the criteria specified in clause
11 (A), (B), or (C).

12 “(2) The Secretary shall—

13 “(A) maintain, and periodically update through
14 publication on the website of the Department of
15 Health and Human Services, a list of cannabinoid
16 compounds that the Secretary has determined meet
17 the definition of cannabinoid as set forth in subpara-
18 graph (1); and

19 “(B) not later than 1 year after the date of the
20 enactment of this paragraph, publish the initial list
21 under clause (A).

22 “(uu)(1) The term ‘cannabinoid hemp product’
23 means, except as provided in subparagraph (2), any arti-
24 cle, including its components or parts, that contains or
25 purports to contain one or more cannabinoids on the list

1 maintained by the Secretary under paragraph (tt)(2) that
2 is intended for use in or on the body of humans or ani-
3 mals.

4 “(2) The term ‘cannabinoid hemp product’ does not
5 include the following:

6 “(A) A drug that is the subject of an applica-
7 tion approved under subsection (e) or (j) of section
8 505 or sections 512 or 571, or is an indexed drug
9 under 572.

10 “(B) A drug that is the subject of an applica-
11 tion that has been authorized for investigation pur-
12 suant to section 505(i) only to the extent it is being
13 used for such investigation, or a drug intended solely
14 for investigational use that conforms to the terms of
15 an exemption in effect under section 512(j) only to
16 the extent it is being used for such investigation.

17 “(C) A drug that may lawfully be marketed
18 pursuant to section 505G.

19 “(D) A biological product that is subject to an
20 approved biologics license application under section
21 351 of the Public Health Service Act or licensed
22 under the virus, serum, toxin, and analogous prod-
23 ucts provisions of the Act of Congress approved
24 March 4, 1913 (21 U.S.C. 151).

1 “(E) A device that may lawfully be marketed
2 pursuant to section 510(k), 513, or 515.

3 “(F) A food additive for which there is in effect
4 a regulation issued under section 409 prescribing
5 the conditions under which such additive may be
6 safely used, if the additive’s use or intended use is
7 in conformity with such regulation.

8 “(G) Any cannabis plant actively under cultiva-
9 tion that is being cultivated in accordance with the
10 requirements of subtitle G of the Agricultural Mar-
11 keting Act of 1946 (7 U.S.C. 1639o et seq.).

12 “(vv)(1) The term ‘inhalable cannabinoid hemp prod-
13 uct’ means a cannabinoid hemp product intended to be
14 delivered to the respiratory tract by oral inhalation, such
15 as by smoking, combusting, or aerosolizing, and regardless
16 of whether done through the use of a device, including de-
17 vices such as vaporizers.

18 “(2) Such term includes any component, part, or ac-
19 cessory thereof.

20 “(ww)(1) The term ‘oral cannabinoid hemp product’
21 means a cannabinoid hemp product intended for oral con-
22 sumption through ingestion, sublingual absorption, or
23 buccal absorption.

1 “(2) Such term includes an edible product, a bev-
2 erage, a tincture, an oil, a tablet, a capsule, an oral pouch,
3 a softgel, and a gelcap.

4 “(3) Such term does not include a topical product
5 or product for inhalation.

6 “(xx)(1) The term ‘prohibited cannabinoid product’
7 means, except as provided in subparagraph (2), any prod-
8 uct for human or animal use that meets one or more of
9 the following criteria:

10 “(A) In the case of an oral cannabinoid hemp
11 product, the product contains or purports to contain
12 an amount per serving of total intoxicating
13 cannabinoid content that exceeds the applicable
14 threshold specified under section 1012.

15 “(B) In the case of an oral cannabinoid hemp
16 product, the product contains or purports to contain
17 an amount per package or container of total intoxi-
18 cating cannabinoid content that exceeds the applica-
19 ble threshold specified under section 1012.

20 “(C) In the case of a cannabinoid hemp product
21 for inhalation, the material to be inhaled in the
22 product contains or purports to contain more than
23 0.3 percent on a weight basis of total intoxicating
24 cannabinoid content in the product form for its in-
25 tended use.

1 “(D) In the case of a cannabinoid hemp prod-
2 uct for inhalation that is required under section
3 1005(e) to utilize a prefilled, nonrefillable cartridge,
4 the cartridge contains or purports to contain an
5 amount of total cannabinoid content that exceeds
6 the applicable threshold specified under section
7 1012.

8 “(E) In the case of a topical cannabinoid hemp
9 product, the product is, or is intended to be, system-
10 ically absorbed through the skin.

11 “(F) In the case of a topical cannabinoid hemp
12 product, the product contains or purports to contain
13 more than 0.3 percent on a weight basis.

14 “(G) The product contains, or purports to con-
15 tain, a cannabinoid of the type referred to in para-
16 graph (tt)(1)(A)(xii), or another cannabinoid that is
17 not naturally occurring in the plant *Cannabis sativa*
18 *L.* or is produced by the plant *Cannabis sativa L.*
19 only through genetic engineering or other manipula-
20 tion of the plant.

21 “(H) The product is a cannabinoid hemp prod-
22 uct that does not meet the definition of an oral
23 cannabinoid hemp product, inhalable cannabinoid
24 hemp product, or topical cannabinoid hemp product.

1 “(I) The product is a cannabinoid hemp prod-
2 uct intended for, used in or on, food-producing ani-
3 mals.

4 “(2) The term ‘prohibited cannabinoid product’ does
5 not include—

6 “(A) any product specified in clauses (A)
7 through (G) of paragraph (uu)(2); and

8 “(B) marijuana as defined in section 102(16) of
9 the Controlled Substances Act.

10 “(yy) The term ‘topical cannabinoid hemp product’
11 means a cannabinoid hemp product intended to be applied
12 externally to the body or any part thereof.

13 “(zz) The term ‘total intoxicating cannabinoid con-
14 tent’ means the total amount of all chemicals present in
15 a cannabinoid hemp product that satisfy any of the fol-
16 lowing:

17 “(1) The chemicals meet the criteria of sub-
18 clause (iv) or (v) of paragraph (tt)(1)(A).

19 “(2) The chemicals are deemed by the Sec-
20 retary under paragraph (tt)(1)(D) as meeting the
21 criteria specified in paragraph (tt)(1)(B) by ref-
22 erence to—

23 “(A) chemicals meeting the criteria of sub-
24 clause (iv) or (v) of paragraph (tt)(1)(A); or

1 “(B) hexahydrocannabinols or
2 tetrahydrocannabinols meeting the criteria spec-
3 ified in paragraph (tt)(1)(A)(xii).

4 “(3) Any other chemical that—

5 “(A) the Secretary has deemed to be a
6 cannabinoid under paragraph (tt)(1)(D); and

7 “(B) has, or is marketed to have, a phar-
8 macological effect that is similar to—

9 “(i) chemicals meeting the criteria of
10 subclause (iv) or (v) of paragraph
11 (tt)(1)(A); or

12 “(ii) hexahydrocannabinols or
13 tetrahydrocannabinols meeting the criteria
14 specified in paragraph (tt)(1)(A)(xii).”.

15 **SEC. 4. CANNABINOID HEMP PRODUCT REGULATION.**

16 (a) IN GENERAL.—The Federal Food, Drug, and
17 Cosmetic Act (21 U.S.C. 301 et seq.) is amended—

18 (1) by redesignating chapter X as chapter XI;

19 (2) by redesignating sections 1001 through
20 1014 as sections 1101 through 1114;

21 (3) in section 505(n)(2), by striking “section
22 1004” and inserting “section 1104”;

23 (4) in section 516(a), in the matter following
24 paragraph (2), by striking “section 1006” and in-
25 serting “section 1106”;

1 (5) in section 704(g)(13), by striking “section
2 1003(g)” and inserting “section 1103(g)”;

3 (6) in subsection (a)(5)(A) of section 1109 (as
4 redesignated by paragraph (2)), by striking “section
5 1008” and inserting “section 1108”; and

6 (7) by inserting after chapter IX the following:

7 **“CHAPTER X—CANNABINOID HEMP**
8 **PRODUCTS**

9 **“SEC. 1001. DEFINITIONS.**

10 “For the purposes of this chapter:

11 “(1) ADVERSE EVENT.—The term ‘adverse
12 event’ means any health-related event associated
13 with a cannabinoid hemp product that is adverse.

14 “(2) DERIVATIVE.—The term ‘derivative’ in-
15 cludes chemical modifications of substances, includ-
16 ing chemical modifications of substances obtained
17 from cannabis.

18 “(3) FACILITY.—The term ‘facility’ includes
19 any establishment (including an establishment of an
20 importer) that manufactures, processes, labels, or
21 imports cannabinoid hemp products.

22 “(4) RESPONSIBLE PERSON.—The term ‘re-
23 sponsible person’ means the manufacturer, packer,
24 or distributor of a cannabinoid hemp product whose
25 name appears on the label of such product.

1 “(5) SERIOUS ADVERSE EVENT.—The term ‘se-
2 rious adverse event’ means an adverse event that re-
3 sults in—

4 “(A) death;

5 “(B) a life-threatening adverse event;

6 “(C) inpatient hospitalization or prolonga-
7 tion of existing hospitalization;

8 “(D) a persistent or significant disability
9 or incapacity;

10 “(E) a congenital anomaly or birth defect;

11 “(F) a serious medical event that requires,
12 based on reasonable medical judgment, a med-
13 ical or surgical intervention to prevent an out-
14 come described in subparagraphs (A) through
15 (E).

16 **“SEC. 1002. ADULTERATED CANNABINOID HEMP PROD-**
17 **UCTS.**

18 “A cannabinoid hemp product shall be deemed to be
19 adulterated if—

20 “(1) it consists in whole or in part of any filthy,
21 putrid, or decomposed substance, or is otherwise
22 contaminated by any added poisonous or added dele-
23 terious substance that may render the product inju-
24 rious to health;

1 “(2) it has been prepared, packed, or held
2 under insanitary conditions whereby it may have
3 been contaminated with filth, or whereby it may
4 have been rendered injurious to health;

5 “(3) its package is composed, in whole or in
6 part, of any poisonous or deleterious substance
7 which may render the contents injurious to health;

8 “(4) its content of total cannabinoids exceeds
9 any limit set forth in section 201(xx);

10 “(5) it is a cannabinoid hemp product intended
11 for, or to be used in or on, food producing animals;

12 “(6) it contains any added substance, such as
13 alcohol, caffeine, tobacco, nicotine, or melatonin, or
14 another substance with effects that could interact
15 with cannabinoids or enhance or alter their effects
16 as determined by the Secretary by order;

17 “(7) it is an oral cannabinoid hemp product
18 and it bears or contains any food additive that is un-
19 safe within the meaning of section 409;

20 “(8) it is intended for use in animals and—

21 “(A) is also intended for use by humans;

22 “(B) is an inhalable cannabinoid hemp
23 product; or

24 “(C) is sold in a place or in a manner such
25 that a member of the general public under cus-

1 tomary conditions of purchase would believe it
2 will be used by humans;

3 “(9) it has been manufactured, processed,
4 packed, or held in any factory, warehouse, or estab-
5 lishment and the owner, operator, or agent of such
6 factory, warehouse, or establishment delays, denies,
7 or limits an inspection, or refuses to permit entry or
8 inspection;

9 “(10) in the case of an oral cannabinoid hemp
10 product, it fails to comply with the requirements of
11 subsection (a) or (c) of section 1004; or

12 “(11) in the case of an inhalable cannabinoid
13 hemp product, it fails to comply with the require-
14 ments of subsection (a), (b), (c), (d), (e), (g), or (h)
15 of section 1005;

16 “(12) in the case of a topical cannabinoid hemp
17 product, it fails to comply with the requirements of
18 section 1006.

19 **“SEC. 1003. MISBRANDED CANNABINOID HEMP PRODUCTS.**

20 “A cannabinoid hemp product shall be deemed mis-
21 branded if—

22 “(1) its labeling is false or misleading in any
23 particular;

24 “(2) its advertising or promotion is false or
25 misleading in any particular;

1 “(3) it is in package form unless it bears a
2 label containing—

3 “(A) the name, place of business, and con-
4 tact information of the manufacturer, packer,
5 or distributor;

6 “(B) an accurate statement of the quantity
7 of the contents in terms of weight, measure,
8 and numerical count;

9 “(C) a statement on the front of the prod-
10 uct packaging indicating that the product is a
11 cannabinoid hemp product;

12 “(D) in the case of an oral cannabinoid
13 hemp product—

14 “(i) the serving size; and

15 “(ii) the number of servings per con-
16 tainer;

17 “(E) the ingredients;

18 “(F) the content per serving and per pack-
19 age of—

20 “(i) cannabidiol, even if absent; and

21 “(ii) total naturally occurring intoxi-
22 cating cannabinoid content, even if absent;

23 “(G) the content of all cannabinoids other
24 than those specified in clause (F), if present

1 above a specified level, per serving and per
2 package;

3 “(H) for products intended for human use,
4 a disclaimer of the presence in the product of
5 any major food allergen, processing aid, or com-
6 pound, which the Secretary may, by order, re-
7 quire to be disclosed;

8 “(I) a disclaimer of known risks to special
9 populations, including children, those who are
10 pregnant or breastfeeding, and those taking
11 drugs known to interact with the product;

12 “(J) a quick response (QR) code, any
13 other scannable mechanism, or internet address
14 that leads to a webpage with testing results for
15 the cannabinoid hemp product in the form of a
16 certificate of analysis;

17 “(K) clear instructions of use, if applica-
18 ble; and

19 “(L) information about how to report ad-
20 verse events;

21 “(4) it is in package form unless it bears a
22 label formatted in such manner as the Secretary
23 may prescribe by order;

24 “(5) it exceeds dose limits or otherwise does not
25 meet the standards specified in section 1004;

1 “(6) the Secretary has issued orders requiring
2 that its labeling bear adequate directions for use, or
3 adequate warnings against use by children, that are
4 necessary for the protection of users, unless its la-
5 beling conforms in all respects to such orders;

6 “(7) any word, statement, or other information
7 required by or under authority of this Act to appear
8 on the label or labeling is not prominently placed
9 thereon with such conspicuousness (as compared
10 with other words, statements, designs, or devices, in
11 the labeling) and in such terms as to render it likely
12 to be read and understood by the general public
13 under customary conditions of purchase and use;

14 “(8) its labeling does not include a disclaimer
15 of risks posed by the specific cannabinoid contained
16 or purported to be contained in the product, includ-
17 ing the risk of drug test failure;

18 “(9) its labeling does not include a disclaimer
19 that the Food and Drug Administration has not de-
20 termined the product to be safe or effective for
21 treating any condition;

22 “(10) its labeling does not include a statement
23 that the product is not required to meet standards
24 for foods or dietary supplements;

1 “(11) its labeling makes a claim regarding the
2 product’s effect (or lack thereof) on the structure or
3 any function of the body of humans or other ani-
4 mals;

5 “(12) it is in package form and the product
6 packaging does not meet the requirements of section
7 1700.15 of title 16, Code of Federal Regulations (or
8 any successor regulations);

9 “(13) it is in package form containing multiple
10 servings that are not in prepacked servings unless
11 such packaging includes one or more indicators or
12 barriers to entry which, if breached or missing, can
13 reasonably be expected to provide visible evidence to
14 consumers that tampering has occurred;

15 “(14) it is in package form intended for use by
16 humans, and it contains product packaging features
17 imitating images popularly used to advertise to chil-
18 dren or otherwise market to anyone under 21 years
19 of age, including—

20 “(A) labeling depicting or in the shape of
21 characters (real or imaginary), animals, vehi-
22 cles, cartoons, candy, or fruit; and

23 “(B) brightly colored products and pack-
24 aging;

1 “(15) it is in package form intended for use in
2 animals, and its label and labeling do not contain
3 prominently placed, conspicuous—

4 “(A) warnings that the product should not
5 be used by humans; and

6 “(B) statements that the product is in-
7 tended for use in animals, including any such
8 statements specifying the intended species;

9 “(16)(A) it was manufactured, processed,
10 packed, labeled, imported, or held by or in an estab-
11 lishment not duly registered under section 1009(a);

12 “(B) it was not included in a list required by
13 section 1009(b); or

14 “(C) it was manufactured, processed, packed,
15 labeled, imported, or held by or in an establishment
16 for which the registration was suspended under sec-
17 tion 1009(d) and the registration has not been rein-
18 stated;

19 “(17) there was a failure or refusal to furnish
20 any material or information required by section
21 1008;

22 “(18) it is labeled as a dietary supplement, or
23 otherwise purports to be a dietary supplement;

1 “(19) in the case of an oral cannabinoid hemp
2 product, it fails to comply with the requirements of
3 section 1004(b);

4 “(20) in the case of an inhalable cannabinoid
5 hemp product, it fails to comply with the require-
6 ments of section 1005(f) ;

7 “(21) in the case of a topical cannabinoid hemp
8 product, it fails to comply with the requirements of
9 section 1006; or

10 “(22) any word, statement, or other informa-
11 tion required by or under this Act to appear on the
12 label or labeling is not in compliance with any for-
13 matting requirements as the Secretary may specify
14 by order.

15 **“SEC. 1004. STANDARDS FOR ORAL CANNABINOID HEMP**
16 **PRODUCTS.**

17 “(a) **ADDITIONAL REQUIREMENTS.**—An oral
18 cannabinoid hemp product shall be subject to the require-
19 ments of this section, in addition to any other require-
20 ments of this Act applicable to cannabinoid hemp prod-
21 ucts.

22 “(b) **SERVING SIZE AND CONTENT LIMITS.**—

23 “(1) **ORAL CANNABINOID HEMP PRODUCTS.**—
24 An oral cannabinoid hemp product shall contain no
25 more than the amount of total cannabinoids or of

1 specified individual cannabinoids per serving and per
2 package as the Secretary may specify by regulation
3 under section 1012.

4 “(2) PACKAGE CONTAINING MULTIPLE
5 SERVINGS OF ORAL CANNABINOID HEMP PROD-
6 UCTS.—If a package contains multiple servings of
7 oral cannabinoid hemp products, the contents shall
8 be divided and separated from each other into por-
9 tions equivalent to one serving.

10 “(3) LIQUID CONTAINERS.—Liquid containers
11 of oral cannabinoid hemp products shall—

12 “(A) contain only one serving; or

13 “(B) include with such container a conven-
14 ient device for measuring servings, such as a
15 dropper or measuring cup.

16 “(c) LABELING STANDARDS FOR ORAL
17 CANNABINOID HEMP PRODUCTS.—

18 “(1) FRONT-OF-PACKAGE LABELING.—An oral
19 cannabinoid hemp product shall include prominent
20 labeling on the front of the product packaging clear-
21 ly indicating that it is a cannabinoid hemp product.

22 “(2) STANDARDIZED INFORMATION PANEL.—
23 The Secretary may prescribe by order a standard-
24 ized format, label panel, or identifying symbols

1 under which label information required under this
2 subsection and section 1003 shall be displayed.

3 “(d) TAMPER-EVIDENT AND CHILD SAFETY PACK-
4 AGING.—The Secretary may issue orders to establish re-
5 quirements for tamper-evident and child safety packaging
6 for oral cannabinoid hemp products.

7 **“SEC. 1005. STANDARDS FOR INHALABLE CANNABINOID**
8 **HEMP PRODUCTS.**

9 “(a) ADDITIONAL REQUIREMENTS.—An inhalable
10 cannabinoid hemp product shall be subject to the require-
11 ments of this section, in addition to any other require-
12 ments of this Act applicable to cannabinoid hemp prod-
13 ucts.

14 “(b) SOURCING.—An inhalable cannabinoid hemp
15 product shall not contain, nor shall any ingredient or sub-
16 stance used in an inhalable cannabinoid hemp product
17 contain, a pesticide chemical residue that is at a level
18 greater than is specified by any tolerance under this Act
19 or under the Federal Insecticide, Fungicide, and
20 Rodenticide Act.

21 “(c) INGREDIENTS AND ADDITIVES.—An inhalable
22 cannabinoid hemp product shall not include any of the fol-
23 lowing:

1 “(1) Any added terpene or flavoring agent un-
2 less such terpene or flavoring agent is designated by
3 the Secretary by order as being both—

4 “(A) naturally occurring in the plant *Can-*
5 *nabis sativa L.*; and

6 “(B) not posing an unreasonable risk to
7 the public health.

8 “(2) Any amount of total or specific naturally
9 occurring terpene or flavoring agent that exceeds the
10 concentration limits as set forth by the Secretary by
11 order.

12 “(3) Any ingredient that is not a cannabinoid,
13 or is not derived from the plant *Cannabis sativa L.*,
14 unless—

15 “(A) the Secretary has, by order, estab-
16 lished a level at which such ingredient may per-
17 missibly be added to inhalable cannabinoid
18 hemp products without posing an unreasonable
19 risk to the public health; and

20 “(B) the ingredient is added in accordance
21 with such order.

22 “(d) SOLVENTS AND EXTRACTION METHODS USED
23 IN MANUFACTURING.—An inhalable cannabinoid hemp
24 product shall not be manufactured using any solvent, ex-
25 traction method, or other means of production unless the

1 Secretary has designated by order that such solvent, ex-
2 traction method, or other means of production is permis-
3 sible because it poses no unreasonable risk to the public
4 health. With respect to any solvent so permitted to be used
5 in the manufacturing process, the Secretary may, by
6 order, limit the amount of residual solvent.

7 “(e) COMPONENTS, PARTS, AND ACCESSORIES.—A
8 component, part, or accessory of an inhalable cannabinoid
9 hemp product shall—

10 “(1) not present an unreasonable risk to the
11 public health;

12 “(2) meet each of the standards established by
13 the Secretary by order, including standards regard-
14 ing—

15 “(A) the types of materials determined to
16 be permissible for use as a component, part, or
17 accessory of such a product;

18 “(B) the permissible level of one or more
19 leachable substances from such a component,
20 part, or accessory;

21 “(C) specifications related to the heating,
22 burning, or combusting of any such materials;
23 or

24 “(D) specifications for temperature con-
25 trols; or

1 “(3) meet any standard (or a portion of such
2 standard) established by a third-party, standard-set-
3 ting entity for which the Secretary publishes an
4 order adopting such standard (or portion).

5 “(f) PREFILLED AND NONREFILLABLE CARTRIDGES
6 OR DEVICES.—

7 “(1) IN GENERAL.—Except for an inhalable
8 cannabinoid hemp product described in paragraph
9 (2), any inhalable cannabinoid hemp product, includ-
10 ing an oil, concentrate, or extract (such as a res-
11 inous extract or secretion of the plant *Cannabis*
12 *sativa L.*), that is marketed or intended for use via
13 aerosolization shall be sold in a cartridge or device
14 that is prefilled and nonrefillable.

15 “(2) EXCEPTION.—Paragraph (1) shall not
16 apply with respect to an inhalable cannabinoid hemp
17 product that consists of whole cannabis inflorescence
18 processed only through trimming, drying, curing, or
19 grinding, or a combination of such methods.

20 “(g) LABELING STANDARDS FOR INHALABLE
21 CANNABINOID HEMP PRODUCTS.—

22 “(1) IN GENERAL.—The label of an inhalable
23 cannabinoid hemp product shall prominently display
24 in boldface type, a warning statement determined
25 appropriate by the Secretary.

1 “(2) PREFILLED, NONREFILLABLE CARTRIDGES
2 OR DEVICES.—Any cartridge or device described in
3 subsection (f)(1) shall, in addition to the statement
4 described in paragraph (1), bear a standardized
5 mark or symbol (in such manner as may be specified
6 by the Secretary by order) on the label identifying
7 the cartridge or device as containing cannabinoids.

8 “(h) ADDITIONAL CONTENT LIMITS.—In addition to
9 any other applicable content limits, a cartridge or device
10 described in subsection (f)(1) shall contain not more total
11 cannabinoid content than the applicable threshold speci-
12 fied under section 1012.

13 “(i) PRE-MARKET NOTIFICATION.—

14 “(1) NEW PRODUCTS.—Except as specified in
15 paragraph (2), not later than 90 days before intro-
16 ducing or delivering for introduction into interstate
17 commerce an inhalable cannabinoid hemp product, a
18 person seeking to so introduce or deliver such prod-
19 uct and who is required to register under section
20 1009 shall report to the Secretary (in such form and
21 manner as the Secretary shall prescribe) the prod-
22 uct’s formulation and labeling.

23 “(2) EXISTING PRODUCTS.—In the case of a
24 person described in paragraph (1) who is the respon-
25 sible person with respect to an inhalable cannabinoid

1 hemp product that, as of the date of the enactment
2 of the Hemp Enforcement, Modernization, and Pro-
3 tection Act, has been introduced or delivered for in-
4 troduction into interstate commerce, such person
5 shall report to the Secretary (in such form and man-
6 ner as the Secretary shall prescribe), the product’s
7 formulation and labeling not later than 60 days
8 after such date of enactment.

9 “(j) LABELING STANDARDS FOR INHALABLE
10 CANNABINOID HEMP PRODUCTS.—

11 “(1) FRONT-OF-PACKAGE LABELING.—An
12 inhalable cannabinoid hemp product shall include
13 prominent labeling on the front of the product pack-
14 aging clearly indicating that it is a cannabinoid
15 hemp product.

16 “(2) STANDARDIZED INFORMATION PANEL.—
17 The Secretary may prescribe by order a standard-
18 ized format, label panel, or identifying symbols
19 under which label information required under this
20 subsection and section 1003 shall be displayed.

21 “(k) TAMPER-EVIDENT AND CHILD SAFETY PACK-
22 AGING.—The Secretary may issue orders to establish re-
23 quirements for tamper-evident and child safety packaging
24 for inhalable cannabinoid hemp products.

1 **“SEC. 1006. STANDARDS FOR TOPICAL CANNABINOID HEMP**
2 **PRODUCTS.**

3 “(a) **ADDITIONAL REQUIREMENTS.**—A topical
4 cannabinoid hemp product shall be subject to the require-
5 ments of this section, in addition to any other require-
6 ments of this Act applicable to cannabinoid hemp prod-
7 ucts.

8 “(b) **CONTENT LIMITS FOR TOPICAL CANNABINOID**
9 **HEMP PRODUCTS.**—A topical cannabinoid hemp product
10 shall contain not more than the amount of total
11 cannabinoids per package, or such other amount of total
12 cannabinoids, or of specified individual cannabinoids per
13 package, as the Secretary may specify under section 1012.

14 “(c) **LABELING STANDARDS FOR TOPICAL**
15 **CANNABINOID HEMP PRODUCTS.**—

16 “(1) **FRONT-OF-PACKAGE LABELING.**—A topical
17 cannabinoid hemp product shall include prominent
18 labeling on the front of the product packaging clear-
19 ly indicating that it is a cannabinoid hemp product.

20 “(2) **STANDARDIZED INFORMATION PANEL.**—
21 The Secretary may prescribe by order a standard-
22 ized format, label panel, or identifying symbols
23 under which label information required under this
24 subsection and section 1003 shall be displayed.

25 “(d) **TAMPER-EVIDENT AND CHILD SAFETY PACK-**
26 **AGING.**—The Secretary may issue orders to establish re-

1 requirements for tamper-evident and child safety packaging
2 for topical cannabinoid hemp products.

3 **“SEC. 1007. MINIMUM AGE OF SALE.**

4 “It shall be unlawful for any retailer to sell a
5 cannabinoid hemp product to any person younger than 21
6 years of age.

7 **“SEC. 1008. MANUFACTURING AND TESTING.**

8 “(a) UNIFORM REQUIREMENTS.—Cannabinoid hemp
9 products shall be subject to uniform manufacturing and
10 testing requirements established by order by the Secretary
11 that shall include—

12 “(1) specifications for key components, poten-
13 tial contaminants, and cannabinoid content; and

14 “(2) any other manufacturing and testing
15 standards the Secretary determines necessary.

16 “(b) STANDARDS DEVELOPED BY APPROPRIATE
17 STANDARD-SETTING BODIES.—In establishing require-
18 ments under subsection (a), the Secretary may recognize
19 and rely upon standards developed by appropriate stand-
20 ard-setting bodies that have relevant expertise and are
21 subject to third-party auditing.

22 “(c) INSPECTION OF RECORDS.—The Secretary may
23 inspect records as necessary to demonstrate compliance
24 with manufacturing and testing requirements under this
25 section.

1 **“SEC. 1009. FACILITY REGISTRATION AND PRODUCT LIST-**
2 **ING.**

3 “(a) REGISTRATION.—

4 “(1) IN GENERAL.—Any facility engaged in
5 manufacturing, processing, packing, importing, la-
6 beling, or holding cannabinoid hemp products for
7 consumption in the United States shall be registered
8 with the Secretary. To be registered—

9 “(A) in the case of a domestic facility, the
10 owner, operator, or agent in charge of the facil-
11 ity shall submit a registration to the Secretary;
12 and

13 “(B) in the case of a foreign facility, the
14 owner, operator, or agent in charge of the facil-
15 ity shall—

16 “(i) submit a registration to the Sec-
17 retary; and

18 “(ii) include with the registration the
19 name of the United States agent for the
20 facility.

21 “(2) REGISTRATION.—

22 “(A) CONTENTS.—An entity (referred to
23 in this section as the ‘registrant’) shall submit
24 a registration under paragraph (1) to the Sec-
25 retary containing—

1 “(i) information necessary to notify
2 the Secretary of the name, address, and
3 telephone number of each facility at which,
4 and all trade names under which, the reg-
5 istrant conducts business;

6 “(ii) the email address and telephone
7 number for the contact person of the facil-
8 ity or, in the case of a foreign facility, the
9 United States agent for the facility;

10 “(iii) the general activities conducted,
11 including with respect to each cannabinoid
12 hemp product category manufactured,
13 processed, packed, or held at such facility;

14 “(iv) the facility registration number,
15 if any, previously assigned by the Sec-
16 retary;

17 “(v) all brand names under which
18 products manufactured, processed, or
19 packaged in the facility are sold; and

20 “(vi) such other information as the
21 Secretary may require.

22 “(B) INSPECTION.—A registration under
23 paragraph (1) shall contain an assurance that
24 the Secretary will be permitted to inspect the

1 facility at the times and in the manner per-
2 mitted by this Act.

3 “(C) TIME AND MANNER OF SUBMIS-
4 SION.—A registration under paragraph (1) shall
5 be submitted at such time and in such manner
6 as the Secretary may prescribe.

7 “(3) INITIAL REGISTRATION.—

8 “(A) EXISTING FACILITIES.—Every person
9 that, on the date of the enactment of the Hemp
10 Enforcement, Modernization, and Protection
11 Act, owns or operates a facility that engages in
12 the manufacturing, processing, packing, import-
13 ing, labeling, or holding of a cannabinoid hemp
14 product for distribution in the United States
15 shall register such facility with the Secretary
16 not later than 1 year after such date of enact-
17 ment.

18 “(B) NEW FACILITIES.—Every person that
19 owns or operates a facility that engages in the
20 manufacturing, processing, packing, or holding
21 of a cannabinoid hemp product for distribution
22 in the United States shall register with the Sec-
23 retary such facility within 60 days of first en-
24 gaging in such activity or 60 days after the

1 deadline for registration under subparagraph
2 (A), whichever is later.

3 “(4) BIENNIAL REGISTRATION RENEWAL.—A
4 person required to register a facility under para-
5 graph (1) shall renew such registrations with the
6 Secretary biennially.

7 “(5) PROCEDURE.—At the time of the initial
8 registration of any facility under paragraph (3), the
9 Secretary shall assign a facility registration number
10 to the facility. Upon receipt of a completed registra-
11 tion described in paragraph (1), the Secretary shall
12 notify the registrant of the receipt of such registra-
13 tion.

14 “(6) UP-TO-DATE LIST.—The Secretary shall
15 compile and maintain an up-to-date list of facilities
16 that are registered under this section. Such list and
17 any registration documents submitted pursuant to
18 this subsection shall not be subject to disclosure
19 under section 552 of title 5, United States Code. In-
20 formation derived from such list or registration doc-
21 uments shall not be subject to disclosure under sec-
22 tion 552 of title 5, United States Code, to the extent
23 that such information discloses the identity or loca-
24 tion of a specific registered person.

25 “(b) CANNABINOID HEMP PRODUCT LISTING.—

1 “(1) IN GENERAL.—For each cannabinoid hemp
2 product, the responsible person shall submit to the
3 Secretary a cannabinoid hemp product listing, or en-
4 sure that such submission is made, at such time and
5 in such manner as the Secretary may prescribe.

6 “(2) LISTING.—

7 “(A) IN GENERAL.—Not later than 120
8 days after the first day on which a cannabinoid
9 hemp product (other than an inhalable
10 cannabinoid hemp product) is marketed, the re-
11 sponsible person for such product shall submit
12 to the Secretary a cannabinoid hemp product
13 listing for such product, except as provided in
14 subparagraph (B).

15 “(B) CURRENTLY MARKETED PROD-
16 UCTS.—In the case of a cannabinoid hemp
17 product (other than an inhalable cannabinoid
18 hemp product), that was marketed before the
19 date of the enactment of the Hemp Enforce-
20 ment, Modernization, and Protection Act, or
21 that is first marketed within 245 days after
22 such date of enactment, the responsible person
23 shall submit to the Secretary a cannabinoid
24 hemp product listing not later than 1 year after
25 such date of enactment.

1 “(C) INHALABLE CANNABINOID HEMP
2 PRODUCTS.—

3 “(i) IN GENERAL.—Not later than 90
4 days after the first day on which an
5 inhalable cannabinoid hemp product is
6 marketed, the responsible person for such
7 product shall submit to the Secretary a
8 cannabinoid hemp product listing for such
9 product, except as provided in clause (ii).

10 “(ii) CURRENTLY MARKETED
11 INHALABLE CANNABINOID HEMP PROD-
12 UCTS.—In the case of an inhalable
13 cannabinoid hemp product that was mar-
14 keted before the date of the enactment of
15 the Hemp Enforcement, Modernization,
16 and Protection Act, or that is first mar-
17 keted within 455 days after such date of
18 enactment, the responsible person shall
19 submit to the Secretary a cannabinoid
20 hemp product listing not later than 1 year
21 after such date of enactment.

22 “(D) UPDATES.—A responsible person for
23 a cannabinoid hemp product shall, beginning
24 one year after the date on which such
25 cannabinoid hemp product is first listed under

1 subparagraph (A), (B), or (C), submit to the
2 Secretary an update of such listing on an an-
3 nual basis.

4 “(3) CONTENTS OF LISTING.—

5 “(A) IN GENERAL.—Each listing under
6 paragraph (1) shall include—

7 “(i) the facility registration number of
8 each facility where the cannabinoid hemp
9 product is manufactured or processed;

10 “(ii) the name and contact number of
11 the responsible person;

12 “(iii) the name of the cannabinoid
13 hemp product, as such name appears on
14 the label;

15 “(iv) the name and contact number of
16 the person submitting the listing;

17 “(v) an electronic copy of the label,
18 and an electronic copy of the package in-
19 sert, if any;

20 “(vi) a list of ingredients, and the
21 amount of cannabinoids, in the
22 cannabinoid hemp product;

23 “(vii) the product listing number, if
24 any, previously assigned by the Secretary;

1 “(viii) whether the product is an oral
2 cannabinoid hemp product, inhalable
3 cannabinoid hemp product, or topical
4 cannabinoid hemp product; and

5 “(ix) any other information as the
6 Secretary may by order require.

7 “(B) FLEXIBLE LISTINGS.—A single list-
8 ing submission under paragraph (1) for a
9 cannabinoid hemp product may include multiple
10 cannabinoid hemp products with identical for-
11 mulations, or formulations that differ only with
12 respect to flavors or quantity of contents.

13 “(C) UPDATES.—A responsible person that
14 is required to submit a cannabinoid hemp prod-
15 uct listing under paragraph (1) shall submit
16 any updates to such listing annually.

17 “(D) OPTIONAL INCLUSION IN FACILITY
18 REGISTRATION.—A responsible person may sub-
19 mit a listing required by paragraph (1) as part
20 of a facility registration or separately.

21 “(e) FACILITY REGISTRATION AND PRODUCT LIST-
22 ING NUMBERS.—At the time of the initial registration of
23 any facility or initial listing of any cannabinoid hemp
24 product, the Secretary shall assign—

1 “(1) a facility registration number to the facil-
2 ity; and

3 “(2) product listing numbers for the listed
4 products.

5 “(d) SUSPENSIONS.—

6 “(1) SUSPENSION OF REGISTRATION OF A FA-
7 CILITY.—The Secretary may suspend the registra-
8 tion of a facility under this section if the Sec-
9 retary—

10 “(A) determines that a cannabinoid hemp
11 product manufactured, processed, packed, or
12 held by such facility and distributed in the
13 United States has a reasonable probability of
14 causing serious adverse health consequences or
15 death to humans or other animals; and

16 “(B) has a reasonable belief that other
17 products manufactured, processed, packed, or
18 held by such facility may be similarly affected
19 because of a failure that—

20 “(i) cannot be isolated to a product or
21 products; or

22 “(ii) is sufficiently pervasive to raise
23 concerns about other products manufac-
24 tured, processed, packed, or held in the fa-
25 cility.

1 “(2) NOTICE OF SUSPENSION.—Before sus-
2 pending a facility registration under this section, the
3 Secretary shall provide—

4 “(A) notice to the registrant or other re-
5 sponsible person, as appropriate, of the intent
6 to suspend the facility registration, which notice
7 shall specify the basis of the determination by
8 the Secretary that the facility registration
9 should be suspended; and

10 “(B) an opportunity, within 5 business
11 days of providing the notice under subpara-
12 graph (A), for the responsible person to provide
13 a plan for addressing the reasons for possible
14 suspension of the facility registration.

15 “(3) HEARING OF SUSPENSION.—The Secretary
16 shall—

17 “(A) provide the registrant subject to a no-
18 tice of suspension under paragraph (2) with an
19 opportunity for an informal hearing, to be held
20 as soon as possible but not later than 5 busi-
21 ness days after the issuance of the notice, or
22 such other time period agreed upon by the Sec-
23 retary and the registrant, on the actions re-
24 quired for reinstatement of registration and

1 why the registration that is subject to the sus-
2 pension should be reinstated; and

3 “(B) reinstate the registration if the Sec-
4 retary determines, based on evidence presented,
5 that adequate grounds do not exist to continue
6 the suspension of the registration.

7 “(4) POST-HEARING CORRECTIVE ACTION
8 PLAN.—If, after providing opportunity for an infor-
9 mal hearing, the Secretary determines that the sus-
10 pension of registration remains necessary, the Sec-
11 retary shall—

12 “(A) require the registrant to submit a
13 corrective action plan to demonstrate how the
14 registrant plans to correct the conditions found
15 by the Secretary; and

16 “(B) review such plan not later than 14
17 business days after the submission of the plan
18 or such other time period as determined by the
19 Secretary, in consultation with the registrant.

20 “(5) VACATING OF ORDER; REINSTATEMENT.—
21 Upon a determination by the Secretary that ade-
22 quate grounds do not exist to continue the suspen-
23 sion of a facility’s registration under this subsection,
24 the Secretary shall promptly vacate the suspension
25 and reinstate the registration of the facility.

1 “(6) EFFECT OF SUSPENSION.—If the registra-
2 tion of the facility is suspended under this section,
3 no person shall—

4 “(A) export or import cannabinoid hemp
5 products into the United States from such facil-
6 ity;

7 “(B) offer to export or import cannabinoid
8 hemp products into the United States from
9 such facility; or

10 “(C) otherwise introduce or deliver for in-
11 troduction into interstate commerce
12 cannabinoid hemp products from such facility.

13 **“SEC. 1010. INSPECTION OF FOREIGN CANNABINOID HEMP**
14 **FACILITIES.**

15 “(a) INSPECTION.—The Secretary—

16 “(1) may enter into arrangements and agree-
17 ments with foreign governments to facilitate the in-
18 spection of foreign facilities registered under section
19 1009; and

20 “(2) shall direct resources to inspections of for-
21 eign facilities, suppliers, and cannabinoid hemp
22 products, especially such facilities, suppliers, and
23 cannabinoid hemp products that present a high risk
24 (as identified by the Secretary), to help ensure the

1 safety and security of the supply of such products in
2 the United States.

3 “(b) EFFECT OF INABILITY TO INSPECT.—Notwith-
4 standing any other provision of law, a cannabinoid hemp
5 product shall be refused admission into the United States
6 if it is from a foreign factory, warehouse, or other estab-
7 lishment of which the owner, operator, or agent in charge,
8 or the government of the foreign country, refuses to per-
9 mit entry of United States inspectors or other individuals
10 duly designated by the Secretary, upon request, to inspect
11 such factory, warehouse, or other establishment. For pur-
12 poses of this subsection, such an owner, operator, or agent
13 in charge shall be considered to have refused an inspection
14 if such owner, operator, or agent in charge does not permit
15 an inspection of a factory, warehouse, or other establish-
16 ment during the 24-hour period after such request is sub-
17 mitted, or after such other time period, as agreed upon
18 by the Secretary and the foreign factory, warehouse, or
19 other establishment.

20 **“SEC. 1011. MANDATORY RECALL AUTHORITY.**

21 “(a) IN GENERAL.—If the Secretary determines that
22 there is a reasonable probability that a cannabinoid hemp
23 product is adulterated under section 1002 or misbranded
24 under section 1003 and the use of or exposure to such
25 cannabinoid hemp product will cause serious adverse

1 health consequences or death, the Secretary shall provide
2 the responsible person with an opportunity to voluntarily
3 cease distribution and recall such article. If the responsible
4 person refuses to or does not voluntarily cease distribution
5 or recall such cannabinoid hemp product within the time
6 and manner prescribed by the Secretary (if so prescribed),
7 the Secretary may, by order, require, as the Secretary de-
8 termines necessary, such person to immediately cease dis-
9 tribution of such article.

10 “(b) HEARING.—The Secretary shall provide the re-
11 sponsible person who is subject to an order under sub-
12 section (a) with an opportunity for an informal hearing,
13 to be held not later than 10 days after the date of issuance
14 of the order, on whether adequate evidence exists to justify
15 the order.

16 “(c) ORDER RESOLUTION.—After an order is issued
17 according to the process under subsections (a) and (b),
18 the Secretary shall, except as provided in subsection (d)—

19 “(1) vacate the order, if the Secretary deter-
20 mines that inadequate grounds exist to support the
21 actions required by the order;

22 “(2) continue the order ceasing distribution of
23 the cannabinoid hemp product until a date specified
24 in such order; or

1 “(3) amend the order to require a recall of the
2 cannabinoid hemp product, including any require-
3 ments to notify appropriate persons, a timetable for
4 the recall to occur, and a schedule for updates to be
5 provided to the Secretary regarding such recall.

6 “(d) ACTION FOLLOWING ORDER.—Any person who
7 is subject to an order pursuant to paragraph (2) or (3)
8 of subsection (c) shall immediately cease distribution of
9 or recall, as applicable, the cannabinoid hemp product and
10 provide notification as required by such order.

11 “(e) NOTICE TO PERSONS AFFECTED.—If the Sec-
12 retary determines necessary, the Secretary may require
13 the person subject to an order pursuant to subsection (a)
14 or an amended order pursuant to paragraph (2) or (3)
15 of subsection (c) to provide either a notice of a recall order
16 for, or an order to cease distribution of, such cannabinoid
17 hemp product, as applicable, under this section to appro-
18 priate persons, including persons who manufacture, dis-
19 tribute, import, or offer for sale such product that is the
20 subject of an order and to the public.

21 “(f) PUBLIC NOTIFICATION.—In conducting a recall
22 under this section, the Secretary shall—

23 “(1) ensure that a press release is published re-
24 garding the recall, and that alerts and public notices

1 are issued, as appropriate, in order to provide notifi-
2 cation—

3 “(A) of the recall to consumers and retail-
4 ers to whom such cannabinoid hemp product
5 was, or may have been, distributed; and

6 “(B) that includes, at a minimum—

7 “(i) the name of the cannabinoid
8 hemp product subject to the recall;

9 “(ii) a description of the risk associ-
10 ated with such article; and

11 “(iii) to the extent practicable, infor-
12 mation for consumers about similar
13 cannabinoid hemp products that are not
14 affected by the recall; and

15 “(2) ensure publication, as appropriate, on the
16 website of the Food and Drug Administration of an
17 image of the cannabinoid hemp product that is the
18 subject of the press release described in paragraph
19 (1), if available.

20 “(g) DELEGATION.—The authority conferred by this
21 section to order a recall or vacate a recall order shall not
22 be delegated to any officer or employee other than the
23 Commissioner, or an individual at or above the level of
24 individuals empowered to approve a drug (such as division

1 directors within the Center for Drug Evaluation and Re-
2 search).

3 “(h) EFFECT.—Nothing in this section shall affect
4 the authority of the Secretary to request or participate
5 in a voluntary recall, or to issue an order to cease distribu-
6 tion or to recall under any other provision of this chapter.

7 **“SEC. 1012. APPLICABLE THRESHOLDS FOR CANNABINOID**
8 **CONTENT.**

9 “(a) IN GENERAL.—The Secretary shall issue a rule
10 specifying—

11 “(1) the applicable thresholds for the content
12 limits of total cannabinoid content in inhalable
13 cannabinoid hemp products, oral cannabinoid hemp
14 products, and topical cannabinoid hemp products for
15 such products; and

16 “(2) the applicable thresholds for the content
17 limits of total intoxicating cannabinoid content in
18 oral cannabinoid hemp products.

19 “(b) TIMING.—The Secretary shall—

20 “(1) not later than 60 days after the date of
21 the enactment of the Hemp Enforcement, Mod-
22 ernization, and Protection Act, publish in the Fed-
23 eral Register a notice of proposed rulemaking with
24 respect to the content limits referred to in sub-
25 section (a); and

1 “(2) not later than 3 years after such date of
2 enactment, finalize the rule specified in such sub-
3 section.

4 “(c) FAILURE TO TIMELY FINALIZE FINAL RULE.—
5 If the Secretary fails to finalize the rule specified in sub-
6 section (a) within the 3-year period specified in subsection
7 (b)(2), the applicable threshold specified in this section
8 shall be the following:

9 “(1) With respect to section 1004(b), 10 milli-
10 grams per serving, and 50 milligrams per package.

11 “(2) With respect to section 1005(h), 100 milli-
12 grams per serving, and 500 milligrams per package.

13 “(3) With respect to section 1006(b), 100 milli-
14 grams per serving, and 500 milligrams per package.

15 “(4) With respect to subparagraph (A) of sec-
16 tion 201(xx)(1), 5 milligrams per serving, and with
17 respect to subparagraph (B) of such section, 30 mil-
18 ligrams per package or container.

19 **“SEC. 1013. CANNABINOID HEMP PRODUCTS ADVISORY**
20 **COMMITTEE.**

21 “(a) ESTABLISHMENT.—The Secretary shall estab-
22 lish an advisory committee, to be known as the
23 Cannabinoid Hemp Products Advisory Committee (in this
24 section referred to as the ‘Advisory Committee’).

25 “(b) MEMBERSHIP.—

1 “(1) IN GENERAL.—

2 “(A) MEMBERS.—The Secretary shall ap-
3 point as members of the Advisory Committee
4 individuals who—

5 “(i) are technically qualified by train-
6 ing and experience in medicine, medical
7 ethics, science, or technology involving the
8 manufacture, evaluation, or use of
9 cannabinoid hemp products; and

10 “(ii) are of appropriately diversified
11 professional backgrounds.

12 “(B) COMPOSITION.—The membership of
13 the Advisory Committee shall be composed of
14 16 individuals, represented as follows:

15 “(i) 3 individuals representing the
16 Food and Drug Administration.

17 “(ii) 7 individuals who are physicians,
18 scientists, or health care professionals
19 practicing in the area of oncology,
20 pulmonology, cardiology, toxicology, phar-
21 macology, addiction, or any other relevant
22 specialty.

23 “(iii) 1 individual who is an officer or
24 employee of a State or local government or
25 of the Federal Government.

1 “(iv) 1 individual as a representative
2 of the general public.

3 “(v) 1 individual with experience as a
4 State regulator for *cannabis sativa L.*.

5 “(vi) 1 individual as a representative
6 of the interests of the *cannabis sativa L.*
7 manufacturing industry.

8 “(vii) 1 individual as a representative
9 of the interests of the small business
10 cannabinoid hemp product manufacturing
11 industry, which position may be filled on a
12 rotating, sequential basis by representa-
13 tives of different small business
14 cannabinoid hemp product manufacturers
15 based on areas of expertise relevant to the
16 topics being considered by the Advisory
17 Committee.

18 “(viii) 1 individual as a representative
19 of the interests of the *cannabis sativa L.*
20 growers.

21 “(C) NONVOTING MEMBERS.—The mem-
22 bers of the Advisory Committee described in
23 clauses (vi), (vii), and (viii) of subparagraph
24 (B) shall serve as consultants to those described

1 in clauses (i) through (iv) of subparagraph (B)
2 and shall be nonvoting representatives.

3 “(D) CONFLICTS OF INTEREST.—No mem-
4 bers of the Advisory Committee, other than
5 members described in clauses (vi), (vii), and
6 (viii) of subparagraph (B) shall, during the
7 member’s tenure on the committee or for the
8 18-month period prior to becoming such a
9 member, receive any salary, grants, or other
10 payments or support from any business that
11 manufactures, distributes, markets, or sells
12 cigarettes or other tobacco products.

13 “(2) CHAIRPERSON.—The Secretary shall des-
14 ignate 1 of the members described in clauses (ii),
15 (iii), (iv), and (v) of paragraph (1)(B) to serve as
16 chairperson.

17 “(c) DUTIES.—The Cannabinoid Products Advisory
18 Committee shall provide advice, information, and rec-
19 ommendations to the Secretary—

20 “(1) as provided in this chapter;

21 “(2) on the limits (in milligrams) of total
22 cannabinoid content allowed in cannabinoid hemp
23 products, and categories thereof; and

24 “(3) on the limits (in milligrams) of total in-
25 toxicating cannabinoid content allowed in

1 cannabinoid hemp products, and categories thereof,
2 to be established pursuant to section 1012.

3 “(d) COMPENSATION; SUPPORT; CHAPTER 10 OF
4 TITLE 5.—

5 “(1) COMPENSATION AND TRAVEL.—Members
6 of the Advisory Committee who are not officers or
7 employees of the United States, while attending con-
8 ferences or meetings of the committee or otherwise
9 engaged in its business, shall be entitled to receive
10 compensation at rates to be fixed by the Secretary,
11 which may not exceed the daily equivalent of the
12 rate in effect under the Senior Executive Schedule
13 under section 5382 of title 5, for each day (including
14 travel time) they are so engaged; and while so serv-
15 ing away from their homes or regular places of busi-
16 ness each member may be allowed travel expenses,
17 including per diem in lieu of subsistence, as author-
18 ized by section 5703 of title 5 for persons in the
19 Government service employed intermittently.

20 “(2) ADMINISTRATIVE SUPPORT.—The Sec-
21 retary shall furnish the Advisory Committee clerical
22 and other assistance.

23 “(3) NONAPPLICATION OF CHAPTER 10 OF
24 TITLE 5.—Section 1013 of title 5 does not apply to
25 the Advisory Committee.

1 “(e) PROCEEDINGS OF ADVISORY COMMITTEES.—
2 The Advisory Committee shall make and maintain a tran-
3 script of any proceeding of the. Each such committee shall
4 delete from any transcript made under this subsection in-
5 formation which is exempt from disclosure under section
6 552(b) of title 5.

7 “(f) REPORT TO CONGRESS.—The Advisory Com-
8 mittee shall report to Congress annually on—

9 “(1) any changes to the limits under section
10 1012 the Advisory Committee recommends; and

11 “(2) any other information the Advisory Com-
12 mittee determines necessary to carry out this chap-
13 ter.”.

14 (b) EFFECTIVE DATE.—This section and the amend-
15 ments made by this section shall apply with respect to
16 cannabinoid hemp products introduced or delivered for in-
17 troduction into interstate commerce on or after the date
18 of the enactment of this Act.

19 **SEC. 5. ENFORCEMENT.**

20 (a) PROHIBITED ACTS.—Section 301 of the Federal
21 Food, Drug, and Cosmetic Act (21 U.S.C. 331) is amend-
22 ed—

23 (1) in paragraphs (a), (b), (c), (g), (h), and (k)
24 by inserting “cannabinoid hemp product,” before “or
25 cosmetic” each place such term appears;

1 (2) in paragraph (e), by striking “or 920” and
2 inserting “920, or 1011”;

3 (3) in paragraph (ll)—

4 (A) in the matter preceding subparagraph
5 (1), by striking “or a drug or a biological prod-
6 uct for which substantial clinical investigations
7 have been instituted and for which the existence
8 of such investigations has been made public”
9 and inserting “a drug or a biological product
10 for which substantial clinical investigations have
11 been instituted and for which the existence of
12 such investigations has been made public, or a
13 cannabinoid hemp product”;

14 (B) in subparagraph (3)(E), by striking
15 “or” at the end;

16 (C) in subparagraph (4), by striking the
17 period at the end and inserting “; or”; and

18 (D) by adding at the end the following:

19 “(5) the finished product is a cannabinoid hemp
20 product that conforms with the requirements of this
21 Act.”; and

22 (4) by adding at the end the following:

23 “(jjj)(1) The introduction or delivery for introduction
24 into interstate commerce of a prohibited cannabinoid prod-
25 uct;

1 “(2) the receipt in interstate commerce of a prohib-
2 ited cannabinoid product, and the delivery or proffered de-
3 livery thereof for pay or otherwise;

4 “(3) the doing of any act with respect to an article,
5 if such act is done while such article is held for sale
6 (whether or not the first sale) after shipment in interstate
7 commerce and results in such article being a prohibited
8 cannabinoid product;

9 “(4) the holding for sale or distribution in interstate
10 commerce of a prohibited cannabinoid product;

11 “(5) the sale by a retailer of a cannabinoid hemp
12 product to any person younger than 21 years of age in
13 violation of section 1007; or

14 “(6) the failure to adhere to uniform manufacturing
15 and testing requirements in accordance with section 1008.

16 “(kkk) The refusal or failure to follow an order under
17 section 1011.”.

18 (b) ENHANCED CRIMINAL PENALTIES.—Section
19 303(b) of the Federal Food, Drug, and Cosmetic Act (21
20 U.S.C. 333(b)) is amended by adding at the end the fol-
21 lowing:

22 “(9) ENHANCED CRIMINAL PENALTIES.—Notwith-
23 standing subsection (a), any person who knowingly vio-
24 lates section 301(jjj) shall be imprisoned for not more

1 than 10 years or fined in accordance with title 18, United
2 States Code, or both.”.

3 (c) SEIZURE.—Section 304 of the Federal Food,
4 Drug, and Cosmetic Act (21 U.S.C. 334) is amended—

5 (1) in subsection (a)(2)—

6 (A) by striking “and (H)” and inserting
7 “(H)”; and

8 (B) by inserting before the period at the
9 end the following: “, (I) Any adulterated or
10 misbranded cannabinoid hemp product, and (J)
11 Any prohibited cannabinoid product”;

12 (2) in subsection (d)(1)—

13 (A) by inserting “cannabinoid hemp prod-
14 uct,” before “or cosmetic”; and

15 (B) in the last sentence, by inserting “an
16 article in violation of section 301(jjj) or” after
17 “by reason of its being”; and

18 (3) in subsection (g)—

19 (A) in paragraph (1)—

20 (i) by striking the first sentence and
21 inserting the following: “If during an in-
22 spection conducted under section 704 of a
23 facility or a vehicle, a device, cannabinoid
24 hemp product, or tobacco product, which
25 the officer or employee making the inspec-

1 tion has reason to believe is adulterated or
2 misbranded is found in such facility or ve-
3 hicle, or the officer or employee making
4 the inspection has reason to believe the
5 product is a prohibited cannabinoid prod-
6 uct, such officer or employee may order the
7 device, cannabinoid hemp product, prohib-
8 ited cannabinoid hemp product, or tobacco
9 product detained (in accordance with regu-
10 lations prescribed by the Secretary) for a
11 reasonable period which may not exceed
12 twenty days unless the Secretary deter-
13 mines that a period of detention greater
14 than twenty days is required to institute
15 an action under subsection (a) or section
16 302, in which case he may authorize a de-
17 tention period of not to exceed thirty
18 days.”; and

19 (ii) in each of the second, third, and
20 fourth sentences, by striking “device or to-
21 bacco product” each place it appears and
22 inserting “device, cannabinoid hemp prod-
23 uct, prohibited cannabinoid product, or to-
24 bacco product”; and

1 (B) in paragraph (2)(A), in the matter
2 preceding clause (i), by striking “device or to-
3 bacco product” and inserting “device,
4 cannabinoid hemp product, prohibited
5 cannabinoid product, or tobacco product”.

6 (d) **FOOD ADDITIVES.**—Section 409(a) of the Fed-
7 eral Food, Drug, and Cosmetic Act (21 U.S.C. 348(a))
8 is amended by adding at the end of the matter following
9 paragraph (3) the following: “A food bearing or containing
10 a cannabinoid hemp product that meets the requirements
11 of chapter X shall not, by reason of bearing or containing
12 such a cannabinoid hemp product, be considered adulter-
13 ated under section 402(a)(1).”.

14 **SEC. 6. RULES OF CONSTRUCTION.**

15 Except as expressly provided in this Act (or the
16 amendments made by this Act), nothing in this Act (or
17 such amendments) shall be construed as modifying or lim-
18 iting—

19 (1) any applicable provision of the Federal
20 Food, Drug, and Cosmetic Act (21 U.S.C. 301 et
21 seq.) or the Public Health Service Act (42 U.S.C.
22 201 et seq.); or

23 (2) the authority of the Secretary of Health and
24 Human Services or the Commissioner of Food and
25 Drugs under such Acts.