

115TH CONGRESS
1ST SESSION

S. _____

To amend the Federal Food, Drug, and Cosmetic Act to ensure the safety
of cosmetics.

IN THE SENATE OF THE UNITED STATES

_____ introduced the following bill; which was read twice
and referred to the Committee on _____

A BILL

To amend the Federal Food, Drug, and Cosmetic Act to
ensure the safety of cosmetics.

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 “Personal Care Products Safety Act”.

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

Sec. 1. Short title; table of contents.

TITLE I—COSMETIC SAFETY

Sec. 101. Registration of cosmetics facilities and cosmetic ingredient state-
ments.

- Sec. 102. Review of ingredients and non-functional constituents; safety of finished products.
- Sec. 103. Good manufacturing practices for cosmetics.
- Sec. 104. Adverse event reports.
- Sec. 105. Records inspection; mandatory recall authority.
- Sec. 106. Labeling.
- Sec. 107. Coal tar chemicals.
- Sec. 108. Animal testing alternatives.
- Sec. 109. Preemption.
- Sec. 110. Reporting.
- Sec. 111. Small businesses.
- Sec. 112. Applicability with respect to certain cosmetics.
- Sec. 113. Enforcement.
- Sec. 114. Consumer information.

TITLE II—FEES RELATED TO COSMETIC SAFETY

- Sec. 201. Findings.
- Sec. 202. Authority to assess and use cosmetic safety fees.
- Sec. 203. Direct hiring authority to support activities related to cosmetics.

1 **TITLE I—COSMETIC SAFETY**

2 **SEC. 101. REGISTRATION OF COSMETICS FACILITIES AND** 3 **COSMETIC INGREDIENT STATEMENTS.**

4 (a) AMENDMENTS.—Chapter VI of the Federal Food,
 5 Drug, and Cosmetic Act (21 U.S.C. 361 et seq.) is amend-
 6 ed by adding at the end the following:

7 **“SEC. 604. DEFINITIONS.**

8 “In this chapter:

9 “(1) COSMETIC FORMULATION.—The term ‘cos-
 10 metic formulation’ means a preparation of cosmetic
 11 raw materials with a qualitatively and quantitatively
 12 set composition.

13 “(2) COSMETIC PRODUCT.—The term ‘cosmetic
 14 product’ means a cosmetic comprised of a specified
 15 set of ingredients, which may come in a range of

1 possible amounts for each ingredient and which may
2 include a variety of fragrances, flavors, and colors.

3 “(3) FACILITY.—The term ‘facility’ includes
4 any factory, warehouse, or establishment (including
5 a factory, warehouse, or establishment of an im-
6 porter) that manufactures, processes, packs, or holds
7 cosmetic products or cosmetic formulations, or any
8 other entity whose name and address appear on the
9 label of a cosmetic product. Such term does not in-
10 clude—

11 “(A) beauty shops and salons that do not
12 otherwise manufacture, process, or package cos-
13 metics at that location;

14 “(B) cosmetic product retailers, including
15 individual sales representatives, retail distribu-
16 tion facilities, and pharmacies, that do not oth-
17 erwise manufacture, process, or package cos-
18 metics at that location;

19 “(C) hospitals, physicians’ offices, and
20 health care clinics;

21 “(D) public health agencies and other non-
22 profit entities that provide cosmetics directly to
23 the consumer;

24 “(E) hotels and other entities that provide
25 complimentary cosmetics to guests;

1 “(F) trade shows and other venues where
2 cosmetic product samples are provided free of
3 charge; or

4 “(G) a factory, warehouse, or establish-
5 ment of—

6 “(i) domestic manufacturers with less
7 than \$500,000 in average gross annual
8 sales of cosmetic products in the United
9 States for the previous 3-year period, or
10 less than \$1,000,000 in such sales of cos-
11 metic products produced in a private resi-
12 dence; or

13 “(ii) entities that manufacture or
14 compound cosmetic products solely for use
15 in research, teaching, or pilot plant pro-
16 duction and not for sale.

17 “(4) FOREIGN FACILITY.—The term ‘foreign fa-
18 cility’ means a facility that manufactures, processes,
19 packs, or holds, a cosmetic formulation or cosmetic
20 product that is exported to the United States with-
21 out further processing or packaging inside the
22 United States. A cosmetic is not considered to have
23 undergone further processing or packaging for pur-
24 poses of this definition solely on the basis that label-
25 ing was added or that any similar activity of a de

1 minimis nature was carried out with respect to the
2 cosmetic.

3 “(5) NON-FUNCTIONAL CONSTITUENT.—The
4 term ‘non-functional constituent’ means any sub-
5 stance that is an incidental component of an ingre-
6 dient, a breakdown product of an ingredient or a by-
7 product of the manufacturing process that has not
8 been intentionally added as a separate substance and
9 serves no technical function in the cosmetic.

10 “(6) RESPONSIBLE PERSON.—The term ‘re-
11 sponsible person’ means—

12 “(A) the brand owner who is the domestic
13 or foreign manufacturer, packer, or entity
14 whose name appears on a cosmetic product
15 label of a cosmetic product distributed in the
16 United States, except for entities described in
17 subparagraphs (A) through (G) of paragraph
18 (3); or

19 “(B) a contract manufacturer who provides
20 cosmetic products to the entities described in
21 subparagraphs (A) through (G) of paragraph
22 (3).”.

23 **“SEC. 605. REGISTRATION OF COSMETIC FACILITIES.**

24 “(a) REGISTRATION AND FEES FOR EXISTING MAN-
25 UFACTURING OR PROCESSING OF COSMETICS.—

1 “(1) REGISTRATION, IN GENERAL.—Not later
2 than December 1, 2017, and at a similar time in
3 each subsequent year, as determined by the Food
4 and Drug Administration, each responsible person
5 engaged in manufacturing or processing a cosmetic
6 product or a cosmetic formulation distributed in the
7 United States shall register all of the responsible
8 person’s facilities with the Food and Drug Adminis-
9 tration.

10 “(2) FEES.—If the average gross annual sales
11 in the United States of cosmetic products of all of
12 the responsible person’s facilities registered under
13 paragraph (1) for the previous 3-year period is
14 greater than \$2,000,000, a registration shall not be
15 complete under this subsection until the responsible
16 person has paid any registration fee required under
17 section 744L.

18 “(b) REGISTRATION FOR EXISTING PACKING OR
19 HOLDING OF COSMETICS.—Not later than December 1,
20 2017, and at a similar time once every 3 years thereafter,
21 as determined by the Food and Drug Administration, each
22 person who owns or operates a cosmetic facility or facili-
23 ties engaged in packing or holding a cosmetic product dis-
24 tributed in the United States shall register each such facil-
25 ity with the Food and Drug Administration.

1 “(c) REGISTRATION BY NEW FACILITIES.—Any facil-
2 ity first engaging after the date of enactment of the Per-
3 sonal Care Products Safety Act in an activity that would
4 require it to register under subsection (a) or (b) shall reg-
5 ister with the Food and Drug Administration within 60
6 days of first engaging in such activity, and thereafter in
7 accordance with subsection (a) or (b).

8 “(d) CHANGES TO INFORMATION.—A registrant who
9 has submitted a registration under this section shall notify
10 the Food and Drug Administration of any change to the
11 information required under subsection (a) or (b) not later
12 than 60 days after the date of such change, unless other-
13 wise specified by the Food and Drug Administration.

14 “(e) FORMAT; CONTENTS.—

15 “(1) ELECTRONIC FORMAT.—Each registration
16 shall be submitted using an electronic format, as
17 specified in a registration form provided by the Food
18 and Drug Administration.

19 “(2) CONTENTS.—

20 “(A) IN GENERAL.—The registration shall
21 contain the following information:

22 “(i) Each facility’s name and full ad-
23 dress, identifying the precise physical loca-
24 tion of the facility.

1 “(ii) The identity of the facility, in-
2 cluding the unique facility identifier, if
3 any, previously assigned by the Food and
4 Drug Administration to the facility under
5 subsection (g).

6 “(iii) All business trading names used
7 by the facility.

8 “(iv) The product category or cat-
9 egories of each cosmetic product or cos-
10 metic formulation manufactured, proc-
11 essed, packed, or held at the facility or on
12 whose label the facility’s name and address
13 appear.

14 “(v) The type of activity conducted at
15 the facility (such as manufacturing, proc-
16 essing, packing, or holding).

17 “(vi) The name, title, street address,
18 telephone number, and electronic contact
19 information of the emergency contact for
20 the facility.

21 “(vii) In the case of a foreign facility,
22 the name, street address, telephone num-
23 ber, emergency contact information for the
24 facility, the name of the United States
25 agent for the facility, and, if available, the

1 electronic contact information of the
2 United States agent.

3 “(viii) The name, title, street address,
4 telephone number, and electronic contact
5 information of the individual submitting
6 the registration.

7 “(ix) An assurance that the Food and
8 Drug Administration will be permitted to
9 inspect such facility at the times and in
10 the manner permitted by this Act.

11 “(x) Additional information pertaining
12 to the facility or to the cosmetic products
13 or cosmetic formulations manufactured,
14 processed, packed, or held at the facility,
15 or on whose label the facility’s name and
16 address appear, including all brand names
17 known to consumers, as the Food and
18 Drug Administration may require by regu-
19 lation.

20 “(B) SMALL BUSINESSES.—

21 “(i) REQUIREMENTS.—In the case of
22 a registrant described in clause (ii), the
23 registration shall contain the following in-
24 formation:

1 “(I) Each facility’s name and full
2 address, identifying the precise phys-
3 ical location of the facility.

4 “(II) The name, title, street ad-
5 dress, telephone number, and elec-
6 tronic contact information of the
7 emergency contact for the facility.

8 “(III) The consumer product cat-
9 egory or categories of each cosmetic
10 product or cosmetic formulation man-
11 ufactured, processed, packed, or held
12 at the facility or on whose label the
13 facility’s name and address appear.

14 “(ii) SMALL BUSINESS REG-
15 ISTRANTS.—A registrant described in this
16 clause is a domestic registrant—

17 “(I) whose average gross annual
18 sales in the United States of cosmetic
19 products for the previous 3-year pe-
20 riod is between \$500,000 and
21 \$2,000,000 (or between \$1,000,000
22 and \$2,000,000 in the case of sales of
23 cosmetic products produced in a pri-
24 vate residence); and

25 “(II) who does not produce—

1 “(aa) products that are in-
2 tended to go on the eye area;

3 “(bb) lip products with
4 color;

5 “(cc) products that are in-
6 jected;

7 “(dd) products that are in-
8 tended for internal use; and

9 “(ee) products that are
10 meant to alter appearance for
11 more than 24 hours.

12 “(3) ABBREVIATED REGISTRATION.—The Food
13 and Drug Administration shall provide for an abbrevi-
14 ated registration renewal process for any registrant
15 that has not had any changes to the required infor-
16 mation with respect to the facility or facilities in-
17 volved since the registrant submitted the preceding
18 registration.

19 “(f) INCOMPLETE OR INACCURATE REGISTRATION.—

20 “(1) IN GENERAL.—Not earlier than 10 days
21 after providing notice of the intent to cancel a reg-
22 istration and the basis for such cancellation, the
23 Food and Drug Administration may cancel a reg-
24 istration under this section if the Food and Drug
25 Administration has reasonable grounds to believe

1 that the registration was not properly completed or
2 updated in accordance with this section or otherwise
3 contains false, incomplete, or inaccurate information.

4 “(2) TIMELY UPDATE OR CORRECTION.—If, not
5 later than 7 days after receipt of a notice of intent
6 to cancel, the sponsor corrects the registration in ac-
7 cordance with the basis for the cancellation, and the
8 required registration fee, if any, is paid, the Food
9 and Drug Administration shall not cancel such reg-
10 istration.

11 “(g) UNIQUE IDENTIFIER.—At the time of the initial
12 registration of any cosmetic facility under this section, the
13 Food and Drug Administration shall assign a unique iden-
14 tifier to the facility.

15 “(h) REGISTRY OF FACILITIES.—

16 “(1) IN GENERAL.—The Food and Drug Ad-
17 ministration shall compile, maintain, and update a
18 registry of facilities that are registered under this
19 section, and shall remove from such registry the
20 name of any facility whose registration under this
21 section is cancelled. The registry shall be publicly
22 available.

23 “(2) PUBLIC AVAILABILITY EXCEPTIONS.—In-
24 formation derived from the registry or registration
25 documents that discloses the residential address of a

1 registrant or that discloses specific facilities where
2 specific cosmetic products are manufactured or proc-
3 essed shall not be subject to disclosure under section
4 552 of title 5, United States Code.

5 **“SEC. 606. COSMETIC INGREDIENT STATEMENTS.**

6 “(a) IN GENERAL.—For each cosmetic product, the
7 responsible person shall submit to the Food and Drug Ad-
8 ministration a cosmetic ingredient statement, at such time
9 and in such manner as the Food and Drug Administration
10 may prescribe. The cosmetic ingredient statement shall
11 not become effective until the responsible person pays any
12 applicable fee required under section 744L.

13 “(b) SUBMISSION OF A COSMETIC INGREDIENT
14 STATEMENT.—

15 “(1) EXISTING COSMETIC PRODUCTS.—In the
16 case of a cosmetic product that is marketed on the
17 date of enactment of the Personal Care Products
18 Safety Act, the responsible person shall submit a
19 cosmetic ingredient statement not later than Decem-
20 ber 1, 2017. The responsible person shall submit to
21 the Food and Drug Administration a renewal of
22 such statement on a yearly basis.

23 “(2) COSMETIC INGREDIENT STATEMENT FOR
24 NEW COSMETIC PRODUCTS.—

1 “(A) IN GENERAL.—Except as provided
2 under subparagraph (B), in the case of a cos-
3 metic product that is first marketed after the
4 date of enactment of the Personal Care Prod-
5 ucts Safety Act or a cosmetic product that is
6 reformulated after such date of enactment, the
7 responsible person shall submit a cosmetic in-
8 gredient statement to the Food and Drug Ad-
9 ministration within 60 days of first marketing
10 the new cosmetic product or the reformulated
11 cosmetic product, and annually thereafter.

12 “(B) SMALL BUSINESSES.—The Food and
13 Drug Administration shall allow a responsible
14 person that is a business that meets the appli-
15 cable industry-based small business size stand-
16 ard established by the Administrator of the
17 Small Business Administration under section 3
18 of the Small Business Act to have a period
19 longer than 60 days to submit an initial new
20 cosmetic ingredient statement under subpara-
21 graph (A). Such responsible person shall submit
22 a cosmetic ingredient statement annually there-
23 after.

24 “(C) DEFINITION.—A cosmetic product
25 shall not be considered first marketed or refor-

1 “(i) each facility where the cosmetic
2 product is manufactured, processed,
3 packed, or held; and

4 “(ii) the facility whose name and ad-
5 dress appear on the label, unless the state-
6 ment is filed by a contract manufacturer,
7 described in section 604(6)(B).

8 “(B) The brand name and the full name
9 for the cosmetic product as it appears on the
10 label.

11 “(C) The cosmetic product listing number,
12 if any, previously assigned by the Food and
13 Drug Administration under subsection (f) to
14 the cosmetic product.

15 “(D) The applicable cosmetic category for
16 the cosmetic product.

17 “(E) A list of ingredients in the cosmetic
18 product, including a range of possible amounts
19 of each ingredient, and with each ingredient
20 identified by the name adopted in regulations
21 promulgated by the Food and Drug Adminis-
22 tration, if any, or by the common or usual
23 name of the ingredient. The cosmetic ingredient
24 statement shall contain—

1 “(i) a list of fragrances, flavors, and
2 colors that may be included in the product,
3 interchangeably, with ranges of possible
4 amounts, which shall include—

5 “(I) in the case of fragrances
6 that are purchased from a fragrance
7 supplier, identification of the fra-
8 grances by the name or code provided
9 by the supplier, including the name
10 and contact information for the fra-
11 grance supplier; and

12 “(II) in the case of flavors that
13 are purchased from a flavor supplier,
14 identification of the flavors by the
15 name or code provided by the sup-
16 plier, including the name and contact
17 information for the flavor supplier;
18 and

19 “(ii) other appropriate interchange-
20 able ingredients as the Food and Drug Ad-
21 ministration may specify in regulations or
22 guidance that may be included in the prod-
23 uct, with ranges of possible amounts.

24 “(F) The title and full contact information
25 of each individual submitting the statement.

1 “(G) If applicable, information on the la-
2 beling required under section 614.

3 “(H) Such additional information per-
4 taining to the cosmetic product as the Food and
5 Drug Administration may require.

6 “(3) ADDITIONAL INFORMATION.—In the case
7 of a cosmetic ingredient statement that includes a
8 list of fragrances or flavors that are purchased from
9 a fragrance or flavor supplier as described in para-
10 graph (2)(E)(i), upon request by the Food and Drug
11 Administration, the fragrance or flavor supplier shall
12 submit to the Food and Drug Administration the
13 complete list of ingredients in specific fragrances, or
14 flavors not later than 30 days after receiving such
15 request.

16 “(d) INCOMPLETE OR INACCURATE COSMETIC IN-
17 GREDIENT STATEMENT.—

18 “(1) IN GENERAL.—Not earlier than 10 days
19 after providing notice to the responsible person of
20 the intent to cancel the cosmetic ingredient state-
21 ment and the basis for such cancellation, the Food
22 and Drug Administration may nullify a cosmetic in-
23 gredient statement filed under this section if the
24 Food and Drug Administration has reasonable
25 grounds to believe that the cosmetic ingredient state-

1 ment was not completed or updated in accordance
2 with this section or otherwise contains false, incom-
3 plete, or inaccurate information.

4 “(2) TIMELY UPDATE OR CORRECTION.—If the
5 cosmetic ingredient statement is appropriately up-
6 dated or corrected not later than 7 days after notice
7 is provided under paragraph (1), the Food and Drug
8 Administration shall not nullify such cosmetic ingre-
9 dient statement.

10 “(e) ADDITIONAL REQUIREMENTS.—

11 “(1) SAFETY REQUIREMENTS.—In filing each
12 cosmetic ingredient statement cosmetic product, the
13 responsible person shall include an attestation that
14 the safety of the product, including the individual in-
15 gredients of such product and the product as a
16 whole, has been substantiated in accordance with
17 section 609. In the case of a cosmetic ingredient
18 statement that includes a range of possible amounts
19 (as described in subsection (c)(2)(E)), the respon-
20 sible person shall include an attestation that such
21 person has substantiated the safety of the product
22 and its ingredients in accordance with the require-
23 ments of section 609.

24 “(2) ABBREVIATED FILING.—The Food and
25 Drug Administration shall provide for an abbre-

1 viated renewal process for any such filing with re-
2 spect to which there has been no change since the
3 responsible person submitted the previous filing.

4 “(3) CHANGES TO INFORMATION.—

5 “(A) IN GENERAL.—Except as provided in
6 subparagraph (B), the responsible person shall
7 notify the Food and Drug Administration with-
8 in 60 days of any change to the information re-
9 quired to be in a cosmetic ingredient statement,
10 including discontinuation of the manufacture of
11 a cosmetic product, except that notification
12 under this paragraph is not required for a
13 change in—

14 “(i) the amount of an existing ingre-
15 dient if it is within the range previously re-
16 ported under subsection (c)(2)(E); or

17 “(ii) the addition or subtraction of a
18 fragrance, flavor or color, or such other
19 interchangeable ingredients specified by
20 the Food and Drug Administration in reg-
21 ulations or guidance, previously reported
22 as a potential ingredient under subsection
23 (c)(2)(E), if, in the case of an addition of
24 such an ingredient, the amount is within
25 the range previously reported.

1 “(B) EXCEPTIONS.—

2 “(i) SMALL BUSINESSES.—The Food
3 and Drug Administration shall allow a re-
4 sponsible person that is a business that
5 meets the applicable industry-based small
6 business size standard established by the
7 Administrator of the Small Business Ad-
8 ministration under section 3 of the Small
9 Business Act to have a period longer than
10 60 days, but not longer than the next an-
11 nual registration deadline under section
12 605(a)(1), to submit any change to the in-
13 formation required to be in a cosmetic in-
14 gredient statement as described in sub-
15 paragraph (A).

16 “(ii) OTHER BUSINESSES.—Any busi-
17 ness that has an average of not more than
18 \$2,000,000 in annual domestic cosmetic
19 sales over the previous 3 years is not re-
20 quired to report the discontinuation of the
21 manufacture of a cosmetic product or cos-
22 metic product category as described in sub-
23 paragraph (A) until the next annual reg-
24 istration period under section 605.

1 “(f) COSMETIC PRODUCTS LIST.—At the time of the
2 initial submission of any cosmetic ingredient statement
3 under this section, the Food and Drug Administration
4 shall assign a unique cosmetic product listing number to
5 the cosmetic ingredient statement. Based on such cosmetic
6 ingredient statements, the Food and Drug Administration
7 shall compile and maintain a list of cosmetic products dis-
8 tributed in the United States, including the ingredients
9 of each such product, and shall make available such list
10 to any State, upon request. Information disclosed to a
11 State that is exempt from disclosure under section
12 552(b)(4) of title 5, United States Code, shall be treated
13 as a trade secret and confidential information by the
14 State.

15 **“SEC. 607. SUSPENSION OF REGISTRATION OR COSMETIC**
16 **INGREDIENT STATEMENT.**

17 “(a) SUSPENSION OF REGISTRATION OF A FACIL-
18 ITY.—If the Food and Drug Administration determines
19 that a cosmetic formulation or cosmetic product manufac-
20 tured, processed, packed, or held by a registered facility
21 and distributed in the United States has a reasonable
22 probability of causing serious adverse health consequences
23 or death to humans, and the Food and Drug Administra-
24 tion has a reasonable belief that other products manufac-
25 tured or processed by the facility may be similarly affected

1 because of a failure that cannot be isolated to a single
2 product or products or is sufficiently pervasive to raise
3 concerns about other products manufactured in the facil-
4 ity, the Food and Drug Administration may suspend the
5 registration of a facility.

6 “(b) SUSPENSION OF COSMETIC INGREDIENT STATE-
7 MENT.—If the Food and Drug Administration determines
8 that a cosmetic product manufactured in a registered fa-
9 cility has a reasonable probability of causing serious ad-
10 verse health consequences or death to humans, the Food
11 and Drug Administration may suspend the cosmetic ingre-
12 dient statement of that product.

13 “(c) NOTICE OF SUSPENSION.—Before suspending a
14 facility registration or a cosmetic ingredient statement
15 under this section, the Food and Drug Administration
16 shall provide—

17 “(1) notice to the facility registrant of the cos-
18 metic product or formulation or other responsible
19 person, as appropriate, of the intent to suspend the
20 facility registration or the cosmetic ingredient state-
21 ment, which shall specify the basis of the determina-
22 tion by the Food and Drug Administration that the
23 facility or the cosmetic ingredient should be sus-
24 pended and recommendations for specific actions to
25 avoid suspension; and

1 “(2) an opportunity, within 2 business days of
2 the notice provided under paragraph (1), for the re-
3 sponsible person to address the reasons for possible
4 suspension of the facility registration or cosmetic in-
5 gredient statement.

6 “(d) REINSTATEMENT.—Upon a determination by
7 the Food and Drug Administration that adequate grounds
8 do not exist to continue the suspension actions, the Food
9 and Drug Administration shall promptly vacate the sus-
10 pension and reinstate the registration of the facility or the
11 cosmetic ingredient statement.

12 “(e) EFFECT OF SUSPENSION.—

13 “(1) REGISTRATION.—If the registration of a
14 facility is suspended under this section, no person
15 shall introduce or deliver for introduction into inter-
16 state commerce cosmetics or cosmetic products from
17 such facility.

18 “(2) COSMETIC INGREDIENT STATEMENT.—If
19 the cosmetic ingredient statement for a cosmetic
20 product is suspended under this section, no person
21 shall introduce or deliver for introduction into inter-
22 state commerce any cosmetic product that is the
23 subject of such statement.

24 “(f) NO DELEGATION.—The authority conferred by
25 this section to issue an order to suspend a registration

1 or vacate an order of suspension shall not be delegated
2 to any officer or employee other than the Commissioner.”.

3 **SEC. 102. REVIEW OF INGREDIENTS AND NON-FUNCTIONAL**
4 **CONSTITUENTS; SAFETY OF FINISHED PROD-**
5 **UCTS.**

6 (a) AMENDMENTS.—Chapter VI of the Federal Food,
7 Drug, and Cosmetic Act (21 U.S.C. 361 et seq.), as
8 amended by section 101, is further amended by adding
9 at the end the following:

10 **“SEC. 608. REVIEW OF INGREDIENTS AND NON-FUNC-**
11 **TIONAL CONSTITUENTS.**

12 “(a) INGREDIENTS AND NON-FUNCTIONAL CON-
13 STITUENTS SUBJECT TO REVIEW.—

14 “(1) IN GENERAL.—Beginning in fiscal year
15 2018, the Food and Drug Administration shall re-
16 view the safety of the cosmetic ingredients and non-
17 functional constituents under paragraph (3), as
18 modified under subsection (c), if applicable, and
19 issue an order under subsection (d) with respect to
20 the use of each such ingredient and presence of each
21 such non-functional constituent.

22 “(2) PUBLIC NOTICE AND COMMENT.—At the
23 initiation of the review of each cosmetic ingredient
24 or non-functional constituent, the Food and Drug
25 Administration shall open a docket for the submis-

1 sion of public comment and additional data relevant
2 to the safety of the ingredient or non-functional con-
3 stituent. The Food and Drug Administration shall
4 provide 60 days for public comment.

5 “(3) COSMETIC INGREDIENTS.—

6 “(A) INGREDIENTS TO BE CONSIDERED IN
7 FIRST YEAR.—During fiscal year 2018, the
8 Food and Drug Administration shall initiate the
9 review for safety of the following cosmetic in-
10 gredients:

11 “(i) Diazolidinyl urea.

12 “(ii) Lead acetate.

13 “(iii) Methylene glycol/methanediol/
14 formaldehyde.

15 “(iv) Propyl paraben.

16 “(v) Quaternium-15.

17 “(B) INGREDIENTS TO BE CONSIDERED IN
18 SUBSEQUENT YEARS.—

19 “(i) IN GENERAL.—Beginning in fis-
20 cal year 2019, the Food and Drug Admin-
21 istration shall annually select and complete
22 a review of at least 5 cosmetic ingredients
23 or non-functional constituents that were
24 not reviewed in the prior 3 years from a
25 list determined in consultation with indus-

1 try and consumer groups for review of
2 safety. The Food and Drug Administration
3 may combine selected cosmetics ingredients
4 or nonfunctional constituents into cat-
5 egories for purposes of such review. The
6 Food and Drug Administration may mod-
7 ify such list under subsection (c).

8 “(ii) CONSIDERATIONS.—The deter-
9 mination of which ingredients or functional
10 ingredients will be reviewed in a given year
11 shall be publicized in annual reports to
12 Congress and the public, in accordance
13 with section 618, and subject to consulta-
14 tion as provided for in clause (iii). The re-
15 view of any cosmetic ingredient or non-
16 functional constituent shall commence with
17 a public announcement by the Food and
18 Drug Administration and the opening of a
19 docket as required under paragraph (2).

20 “(iii) CONSULTATION.—The Food and
21 Drug Administration shall establish a Cos-
22 metics Safety Advisory Committee, which
23 shall include equal numbers of individuals
24 from the cosmetics industry and consumer
25 groups, and other individuals, as the Food

1 and Drug Administration determines ap-
2 propriate, including medical practitioners.
3 Such advisory committee shall advise the
4 Food and Drug Administration on cos-
5 metic ingredients and non-functional con-
6 stituents to be considered for review, sum-
7 marize public comments received pursuant
8 to paragraph (4), and recommend 5 cos-
9 metic ingredients or non-functional con-
10 stituents to be reviewed for safety each
11 year, as described in clause (i). The Food
12 and Drug Administration may consult with
13 the Cosmetics Safety Advisory Committee
14 on other matters pertaining to cosmetic
15 safety.

16 “(4) COMMENT PERIOD.—As part of the annual
17 reporting to Congress and the public under section
18 618, the Food and Drug Administration shall solicit
19 public comment on which cosmetic ingredients or
20 non-functional constituents on the list are of great-
21 est interest to be reviewed next for early review and
22 which additional cosmetic ingredients or non-func-
23 tional constituents should be added to the list. The
24 public may submit comments to the Food and Drug
25 Administration at any time during the year regard-

1 ing which cosmetic ingredients or non-functional
2 constituents of interest the Food and Drug Adminis-
3 tration may consider during that year or subsequent
4 years.

5 “(b) LIST.—The Food and Drug Administration
6 shall maintain a list, posted on the Internet website of the
7 Food and Drug Administration, of the cosmetic ingredi-
8 ents and non-functional constituents for which final orders
9 have been issued under subsection (d)(3), the finding
10 made for each such ingredient or non-functional con-
11 stituent under subsection (d)(4), as modified by any order
12 under subsection (f), if applicable, and, if applicable, com-
13 pliance dates that are the subject of a final order under
14 subsection (e).

15 “(c) INITIATIVE OF THE FDA.—The Food and Drug
16 Administration may at any time, after consultation with
17 the Cosmetics Safety Advisory Committee, propose the
18 issuance of an order on the safety of a cosmetic ingredient
19 or non-functional constituent that was not previously list-
20 ed in subsection (a) or under section 618(a)(3). The Food
21 and Drug Administration shall follow the same procedures
22 and policies for review of any cosmetic ingredient or non-
23 functional constituent so proposed as for the ingredients
24 and constituents reviewed pursuant to subsection (a).

25 “(d) DETERMINATION ON SAFETY.—

1 “(1) INITIAL PROPOSED ADMINISTRATIVE
2 ORDER.—Following consideration of data and com-
3 ments to the public docket and any other informa-
4 tion before the Food and Drug Administration, the
5 Food and Drug Administration shall determine
6 whether there is adequate evidence to make an ini-
7 tial finding on the safety of the ingredient or non-
8 functional constituent. If the Food and Drug Ad-
9 ministration determines that there is adequate evi-
10 dence, the Food and Drug Administration shall issue
11 a proposed administrative order and shall post such
12 order on the Internet website of the Food and Drug
13 Administration, notwithstanding subchapter II of
14 chapter 5 of title 5, United States Code.

15 “(2) PUBLIC COMMENT.—Upon publication of
16 the proposed administrative order described in para-
17 graph (1), the Food and Drug Administration shall
18 open a docket for the submission of public comment.
19 The Food and Drug Administration shall provide 30
20 days for public comment following publication of the
21 proposed administrative order.

22 “(3) FINAL ADMINISTRATIVE ORDER.—Fol-
23 lowing the public comment period described in para-
24 graph (2) and consideration of comments to the pub-
25 lic docket and any other information before the Food

1 and Drug Administration, the Food and Drug Ad-
2 ministration shall determine whether there is ade-
3 quate evidence to make a final finding on the safety
4 of the ingredient or non-functional constituent. If
5 the Food and Drug Administration determines that
6 there is adequate evidence, the Food and Drug Ad-
7 ministration shall issue a final administrative order
8 and shall post such order on the Internet website of
9 the Food and Drug Administration, notwithstanding
10 subchapter II of chapter 5 of title 5, United States
11 Code.

12 “(4) DETERMINATIONS.—In the proposed ad-
13 ministrative order or the final administrative order,
14 as applicable, the Food and Drug Administration
15 shall make a determination that the ingredient or
16 non-functional constituent is—

17 “(A) safe in cosmetic products under speci-
18 fied conditions of use or tolerances;

19 “(B) safe in cosmetic products without the
20 need for specified conditions of use or toler-
21 ances; or

22 “(C) not safe in cosmetic products.

23 “(5) CONDITIONS OF USE AND TOLERANCES.—
24 An order under paragraph (4)(A) shall include such
25 conditions on the use of an ingredient or such toler-

1 ances on the presence of a non-functional con-
2 stituent as are necessary for the safety of cosmetic
3 products containing such ingredient or non-func-
4 tional constituent, including—

5 “(A) limits on the amount or concentration
6 of the ingredient or non-functional constituent
7 that may be present in a cosmetic product, in-
8 cluding limits in products intended for children
9 and other vulnerable populations, and limits on
10 use near the eye or mucosal membranes;

11 “(B) warnings that are necessary or appro-
12 priate under section 614, including warnings re-
13 lated to use by children, pregnant women, popu-
14 lations with high exposure to the ingredient
15 (such as workers who are exposed through pro-
16 duction practices or handling of final products),
17 or other vulnerable populations, to help ensure
18 safe use of cosmetic products containing the in-
19 gredient or non-functional constituent; and

20 “(C) such other conditions as are nec-
21 essary for the safety of cosmetic products con-
22 taining such ingredient or non-functional con-
23 stituent.

24 “(6) PUBLIC NOTICE.—A final order under this
25 subsection shall set forth the determination of the

1 Food and Drug Administration on safety, any condi-
2 tions of use or tolerances under subparagraph (A) or
3 (B) of paragraph (4) and a summary of the valid
4 scientific evidence supporting the finding. The order
5 shall be effective upon its publication on the Internet
6 website of the Food and Drug Administration and
7 shall be considered final agency action.

8 “(e) ORDER.—

9 “(1) IN GENERAL.—If the Food and Drug Ad-
10 ministration issues a final administrative order
11 under subparagraph (A) or (C) of subsection (d)(4),
12 the Food and Drug Administration shall, at the
13 same time as publication of the notice under sub-
14 section (d)(6), publish a proposed order identifying
15 dates by which use of the ingredient or non-func-
16 tional constituent in cosmetic products shall comply
17 with the final administrative order, and provide 60
18 days for public comment, including comment on
19 whether compliance is feasible within the proposed
20 dates. After considering comments on the proposed
21 order, the Food and Drug Administration shall pub-
22 lish in the Federal Register a final order.

23 “(2) CONTENT.—The public notice information
24 regarding the final order under paragraph (1) shall
25 include a summary that is written in plain and un-

1 derstandable language that is comprehensible and
2 meaningful for consumers. The summary shall in-
3 clude information on any conditions of use or warn-
4 ings required under section 614, including the appli-
5 cation to vulnerable populations, the types of safety
6 studies evaluated, and any additional relevant infor-
7 mation that was part of the review process.

8 “(f) MODIFICATION OF AN ORDER.—An order issued
9 under subsection (d) or (e) may be modified or revoked
10 by the Food and Drug Administration on the initiative of
11 the Food and Drug Administration or in response to a
12 petition.

13 “(g) INADEQUATE EVIDENCE.—

14 “(1) NOTICE; EXTENSION.—If the Food and
15 Drug Administration determines that the available
16 data and information are not adequate to make a
17 proposed or final determination regarding safety
18 under subsection (d)(4), with respect to a cosmetic
19 ingredient or non-functional constituent, the Food
20 and Drug Administration shall—

21 “(A) publish such finding on the Internet
22 website of the Food and Drug Administration
23 not later than 90 days after the close of the rel-
24 evant comment period for the ingredient or
25 non-functional constituent under subsection

1 (a)(2), in the case of a proposed order, or sub-
2 section (d)(2), in the case of a final order; and

3 “(B)(i) include a notice providing inter-
4 ested persons an additional 30 days from the
5 notice date to provide additional data and infor-
6 mation; and

7 “(ii) if, after the 30-day period under
8 clause (i), the Food and Drug Administration
9 determines that additional safety substantiation
10 with respect to such ingredient or non-func-
11 tional constituent is necessary to make a safety
12 determination—

13 “(I) include a notice specifying an ad-
14 ditional time period, not to exceed 18
15 months from the notice date, during which
16 time the determination made by a respon-
17 sible person under subsection (a) or (b) of
18 section 609 with respect to the safety of
19 such cosmetic ingredient or non-functional
20 constituent shall be deemed to be in com-
21 pliance with the requirements of this Act,
22 but shall not affect final determinations of
23 safety under subsection (d); and

24 “(II) plan to obtain such data and in-
25 formation.

1 “(2) DETERMINATION; ORDER.—

2 “(A) INADEQUATE DATA AND INFORMA-
3 TION.—If the Food and Drug Administration
4 determines, after considering any additional
5 data and information submitted under para-
6 graph (1)(B), that the available data and infor-
7 mation still are not adequate to make a deter-
8 mination regarding safety under subsection
9 (d)(4), the Food and Drug Administration
10 shall, within 90 days of the close of the addi-
11 tional time period provided under paragraph
12 (1)(B), issue a proposed order or a final admin-
13 istrative order—

14 “(i) making a determination that the
15 ingredient or non-functional constituent
16 has not been shown to be safe in cosmetic
17 products; and

18 “(ii) explaining why the available data
19 and information are not adequate to assess
20 the safety of the ingredient or non-func-
21 tional constituent.

22 “(B) ADEQUATE DATA AND INFORMA-
23 TION.—If the Food and Drug Administration
24 determines, after considering any additional
25 data and information submitted under para-

1 graph (1)(B), that the available data and infor-
2 mation are adequate to make a determination
3 regarding safety under subsection (d)(4), the
4 Food and Drug Administration shall, within
5 180 days of the close of the comment period,
6 issue a proposed order, followed by a final
7 order, on such cosmetic ingredient or non-func-
8 tional constituent, in accordance with such sub-
9 section.

10 “(h) SAFETY ASSESSMENT.—

11 “(1) IN GENERAL.—In assessing the safety of
12 an ingredient or non-functional constituent, the
13 Food and Drug Administration shall consider wheth-
14 er there is adequate evidence to support a reasonable
15 certainty among competent scientists that the ingre-
16 dient is not harmful under the recommended or sug-
17 gested conditions of use or customary or usual use,
18 or that a non-functional constituent is not harmful
19 under the recommended or suggested tolerance levels
20 or the level at which it is customarily or usually
21 present. The Food and Drug Administration may
22 not consider an ingredient or non-functional con-
23 stituent harmful solely because it can cause minor
24 adverse health reactions, such as minor transient al-

1 lergic reactions or minor transient skin irritations,
2 in some users.

3 “(2) FACTORS.—In assessing the safety of an
4 ingredient or non-functional constituent, the Food
5 and Drug Administration shall consider, among
6 other relevant factors, the following:

7 “(A) The probable human exposure to the
8 ingredient or non-functional constituent from
9 expected use in cosmetics.

10 “(B) The probable cumulative and aggre-
11 gate effect in humans of relevant exposure to
12 the ingredient or non-functional constituent or
13 to any chemically or pharmacologically related
14 substances from use in cosmetics or other prod-
15 ucts with similar routes of exposure under rec-
16 ommended or suggested conditions of use or
17 their customary use, to the extent adequate
18 data is available for analysis. In appropriate
19 cases, the Food and Drug Administration may
20 consider available information on the total expo-
21 sure to an ingredient or non-functional con-
22 stituent from all sources.

23 “(C) Whether warnings or recommenda-
24 tions in a product label required under section
25 614, as part of any conditions of use or toler-

1 ances imposed by the Food and Drug Adminis-
2 tration, would be necessary and appropriate to
3 help ensure the safety of the ingredient or non-
4 functional constituent.

5 “(3) DATA AND INFORMATION.—

6 “(A) REQUIRED INFORMATION.—A deter-
7 mination that an ingredient or non-functional
8 constituent is safe in cosmetics shall be based
9 upon adequate evidence submitted or otherwise
10 known to the Food and Drug Administration,
11 which shall include full reports of all available
12 studies, published or unpublished, that are ade-
13 quately designed to show whether the ingredient
14 or non-functional constituent is safe. Such stud-
15 ies may include in vitro and in silico studies
16 and epidemiological studies, biomonitoring stud-
17 ies, and studies focused on various points dur-
18 ing the lifespan of the subject, that use scientif-
19 ically valid methodology.

20 “(B) ADDITIONAL RELEVANT INFORMA-
21 TION.—The Food and Drug Administration
22 shall consider any other relevant information
23 related to the safety of the ingredient or non-
24 functional constituent, including—

25 “(i) adverse event reports;

1 “(ii) findings and information from
2 State, Federal, national, and international
3 entities and other bodies composed of sci-
4 entific and medical experts;

5 “(iii) if the ingredient or non-func-
6 tional constituent is lawfully used or
7 present in other products regulated by the
8 Food and Drug Administration, the sci-
9 entific basis for such use; and

10 “(iv) experience with the ingredient or
11 non-functional constituent in products that
12 are distributed in the United States or in
13 other countries, if such experience is well-
14 documented and has resulted in substantial
15 human exposure to the ingredient or non-
16 functional constituent over time.”.

17 **“SEC. 609. SAFETY OF FINISHED COSMETIC PRODUCTS.**

18 “(a) DETERMINATION.—

19 “(1) IN GENERAL.—Each responsible person
20 for a finished cosmetic product, before first intro-
21 ducing or delivering for introduction into interstate
22 commerce, or, in the case of such a product in inter-
23 state commerce on the date of enactment of the Per-
24 sonal Care Products Safety Act, not later than the
25 date on which registration is first required under

1 subsection 605(b), shall make a written determina-
2 tion that the product is safe under the conditions of
3 use recommended in the labeling of the product.
4 Such determination shall be based on adequate evi-
5 dence that each ingredient in the finished product is
6 safe for the use recommended or suggested in the la-
7 beling of the product and that the finished product
8 is safe.

9 “(2) NEW INFORMATION.—If new information
10 relevant to the determination becomes available, the
11 responsible person shall promptly update the deter-
12 mination to address that information.

13 “(3) SAFETY WITH RESPECT TO RANGES OF
14 POSSIBLE AMOUNTS.—In the case of a cosmetic
15 product for which there is a range of possible
16 amounts of cosmetic ingredients included in the cos-
17 metic ingredient statement, as described in section
18 606(c)(2)(E), the safety determination under para-
19 graph (1) shall include substantiation of the safety
20 of the full range in the finished product.

21 “(4) SMALL BUSINESSES.—A small business
22 registrant (as defined in section 605(e)(2)(B)(ii))
23 may satisfy the requirements of this section by using
24 the ingredients in concentrations recommended by
25 available medical or scientific guidelines, or cosmetic

1 manufacturing reference, and following any other
2 specific instructions for use recommended by the in-
3 gredient manufacturer.

4 “(b) PRESUMPTION OF ADEQUATE EVIDENCE.—

5 “(1) IN GENERAL.—Except as provided in sub-
6 section (c), a determination made under subsection
7 (a) shall be presumed to be based on adequate evi-
8 dence if it is supported by—

9 “(A) with respect to each ingredient in the
10 finished product—

11 “(i) references to an official statement
12 by one or more expert medical or scientific
13 bodies that the ingredient is safe under the
14 conditions of use recommended or sug-
15 gested in the product’s labeling; or

16 “(ii) appropriate safety testing of the
17 ingredient; and

18 “(B) appropriate safety substantiation of
19 the finished product beyond the safety substan-
20 tiation of individual ingredients and consider-
21 ation of the combination of ingredients.

22 “(2) STATEMENT OF AN EXPERT MEDICAL OR
23 SCIENTIFIC BODY.—For purposes of this section, a
24 statement of an expert medical or scientific body is
25 an official statement of that body, if—

1 “(A) the medical or scientific body is a
2 Federal, State, national, or international entity
3 with recognized expertise in chemical or cos-
4 metic safety, or other similarly recognized body
5 composed of scientific and medical experts;

6 “(B) the statement is based upon adequate
7 data to support the finding of safety, and such
8 data are available to the Food and Drug Ad-
9 ministration; and

10 “(C) the statement is published and en-
11 dorsed by the medical or scientific body and is
12 not a statement of an employee of such body
13 made in the individual capacity of the employee.

14 “(c) REBUTTAL OF PRESUMPTION.—Notwith-
15 standing subsection (b), a determination under subsection
16 (a) will not be presumed to be based on adequate evidence
17 if—

18 “(1) the Food and Drug Administration issues
19 an order under section 608 that an ingredient or
20 non-functional constituent in the finished product is
21 not safe under the product’s conditions of use or
22 customary or usual use; or

23 “(2) the Food and Drug Administration has
24 provided the manufacturer with notice that—

1 “(A) the manufacturer has not met the cri-
2 teria for a presumption of adequate information
3 under subsection (b); or

4 “(B) the Food and Drug Administration
5 has information that raises significant questions
6 about the safety of the product or any of its in-
7 gredients.

8 “(d) **TIMELY UPDATE.**—Upon notice of inadequate
9 evidence under subsection (c), the responsible person shall
10 have 10 days to submit additional evidence to the Food
11 and Drug Administration regarding the safety of an ingre-
12 dient, non-functional constituent, or the entire cosmetic
13 product, and the Food and Drug Administration shall
14 have 30 days from the date of receipt of such additional
15 evidence to provide the responsible person with notice that
16 the criteria under subsection (b) have been met or not met.

17 “(e) **RECORDS MAINTENANCE.**—The responsible per-
18 son shall maintain records documenting the determination
19 required under this section and the information on which
20 such determination is based until 5 years after the fin-
21 ished product is no longer marketed, except that a respon-
22 sible person for a domestic company whose sales are under
23 \$2,000,000 per year shall maintain such records for at
24 least 2 years after the finished product is no longer mar-
25 keted.

1 “(f) SUBMISSION OF RECORDS.—

2 “(1) IN GENERAL.—The records required under
3 subsection (e) shall, upon the written request of the
4 Food and Drug Administration to the responsible
5 person, be provided to the Food and Drug Adminis-
6 tration within a reasonable timeframe not to exceed
7 60 days, in either electronic or paper form.

8 “(2) CRITERIA.—The Food and Drug Adminis-
9 tration may require records under paragraph (1)
10 if—

11 “(A) the Food and Drug Administration
12 has a reasonable belief, described in written no-
13 tice, that—

14 “(i) the finished product may be
15 harmful based on adverse event reports or
16 other scientific information;

17 “(ii) scientific information raises cred-
18 ible and relevant questions about the safe-
19 ty of the product or any of its ingredients;

20 “(iii) the responsible person has not
21 made the determination required under
22 subsection (a), or such determination is
23 not supported by adequate evidence; or

24 “(iv) one or more of the criteria to es-
25 tablish a presumption of adequate evidence

1 of safety in subsection (b) has not been
2 satisfied;

3 “(B) the Food and Drug Administration,
4 an expert regulatory body, or an expert body
5 composed of scientific and medical experts finds
6 an ingredient in the product to be unsafe under
7 the conditions of use of the product; or

8 “(C) the Food and Drug Administration
9 concludes that submission of the records will
10 serve the public health or otherwise enable the
11 Food and Drug Administration to fulfill the
12 cosmetic safety purposes of this section.

13 “(g) GUIDANCE AND REGULATIONS.—

14 “(1) IN GENERAL.—The Food and Drug Ad-
15 ministration shall issue guidance describing the evi-
16 dence necessary to support a determination under
17 subsection (a), and may, by regulation, establish ex-
18 emptions to the requirements of this section, if the
19 Food and Drug Administration determines that such
20 exemptions are supported by adequate evidence and
21 would have no adverse effect on public health.

22 “(2) SMALL BUSINESSES.—The Food and Drug
23 Administration shall, after consultation with the
24 Small Business Administration and small businesses
25 that manufacture cosmetics, provide additional guid-

1 ance for small businesses on compliance with the re-
2 quirements of this section that would apply to small
3 business registrants. Such guidance shall include
4 specific examples of options for compliance that do
5 not place an undue burden on small businesses.”.

6 (b) EFFECTIVE DATE.—Section 609 of the Federal
7 Food, Drug, and Cosmetic Act, as added by subsection
8 (a), shall take effect 180 days after the date of enactment
9 of this Act.

10 **SEC. 103. GOOD MANUFACTURING PRACTICES FOR COS-**
11 **METICS.**

12 (a) IN GENERAL.—Chapter VI of the Federal Food,
13 Drug, and Cosmetic Act (21 U.S.C. 361 et seq.), as
14 amended by section 102, is further amended by adding
15 at the end the following:

16 **“SEC. 610. GOOD MANUFACTURING PRACTICES FOR COS-**
17 **METICS.**

18 “(a) IN GENERAL.—The Food and Drug Administra-
19 tion shall review national and international standards for
20 cosmetic good manufacturing practices that are in exist-
21 ence on the date of enactment of the Personal Care Prod-
22 ucts Safety Act and shall develop and implement, through
23 regulations, standards consistent, to the extent the Food
24 and Drug Administration determines practicable and ap-
25 propriate, with such national and international standards

1 for cosmetic good manufacturing practices to ensure that
2 requirements of this chapter with respect to the manufac-
3 ture of cosmetic products are in harmony.

4 “(b) CONSULTATION.—The standards under sub-
5 section (a) shall include simplified good manufacturing
6 practices for small businesses that take into account the
7 size and scope of the business, developed in consultation
8 with the Small Business Administration.

9 “(c) TIMEFRAME.—The Food and Drug Administra-
10 tion shall publish a proposed rule described in subsection
11 (a) not later than 18 months after the date of enactment
12 of the Personal Care Products Safety Act and shall pub-
13 lish a final such rule not later than 3 years after such
14 date of enactment.”.

15 (b) EFFECTIVE DATE FOR COSMETIC MANUFACTUR-
16 ERS.—

17 (1) LARGE BUSINESSES.—For businesses of a
18 size greater than the Small Business Administra-
19 tion’s standard for a small business, section 610 of
20 the Federal Food, Drug, and Cosmetic Act (as
21 added by subsection (a)) shall take effect beginning
22 180 days after the date on which the Food and
23 Drug Administration makes effective cosmetic good
24 manufacturing practices.

1 (2) **SMALL BUSINESSES.**—For businesses of a
2 size that meets the Small Business Administration’s
3 standard for a small business, section 610 of the
4 Federal Food, Drug, and Cosmetic Act (as added by
5 subsection (a)) shall take effect beginning 2 years
6 after the date the Food and Drug Administration
7 makes effective cosmetic good manufacturing prac-
8 tices.

9 **SEC. 104. ADVERSE EVENT REPORTS.**

10 Chapter VI of the Federal Food, Drug, and Cosmetic
11 Act (21 U.S.C. 361 et seq.), as amended by section
12 103(a), is further amended by adding at the end the fol-
13 lowing:

14 **“SEC. 611. ADVERSE EVENT REPORTING FOR COSMETICS.**

15 “(a) **IN GENERAL.**—With respect to any cosmetic
16 product distributed in the United States, the responsible
17 person shall submit to the Food and Drug Administration
18 a report of any serious adverse event associated with such
19 cosmetic product, when used in the United States, accom-
20 panied by a copy of the label on or with the retail pack-
21 aging of the cosmetic, any new medical information, re-
22 lated to a submitted serious adverse event report that is
23 received by the responsible person, and an annual report
24 for all adverse events received by the responsible person.

25 “(b) **DEFINITIONS.**—In this section:

1 “(1) An ‘adverse event’ for a cosmetic product
2 is a health-related event associated with the use of
3 this product that is adverse.

4 “(2) A ‘serious adverse event’ for a cosmetic
5 product is an adverse event that—

6 “(A) results in—

7 “(i) death;

8 “(ii) a life-threatening experience;

9 “(iii) inpatient hospitalization;

10 “(iv) a persistent or significant dis-
11 ability or incapacity;

12 “(v) congenital anomaly or birth de-
13 fect; or

14 “(vi) significant disfigurement, includ-
15 ing serious and persistent rashes or infec-
16 tions and significant hair loss; or

17 “(B) requires, based on appropriate med-
18 ical judgment, a medical or surgical interven-
19 tion to prevent an outcome described in sub-
20 paragraph (A).

21 “(c) SUBMISSION OF REPORTS.—

22 “(1) SERIOUS ADVERSE EVENT REPORTS.—Ex-
23 cept as provided in paragraph (2), with respect to a
24 cosmetic product distributed in the United States,
25 the responsible person shall submit a serious adverse

1 event report to the Food and Drug Administration
2 not later than 15 business days after information
3 concerning the adverse event is received. If a serious
4 adverse event report for a cosmetic with drug prop-
5 erties is filed using Form FDA 3500A (or any suc-
6 cessor form developed for such purpose) or its elec-
7 tronic equivalent for over-the-counter drugs, the re-
8 sponsible person shall not have to submit a duplica-
9 tive serious adverse event report under this section.

10 “(2) NEW MEDICAL INFORMATION.—The re-
11 sponsible person shall submit to the Food and Drug
12 Administration any new medical information, related
13 to a submitted serious adverse event report that is
14 received by the responsible person within 1 year of
15 the initial report, and shall submit such information
16 not later than 15 business days after the new infor-
17 mation is received by the responsible person.

18 “(3) ANNUAL REPORT.—

19 “(A) IN GENERAL.—Not later than March
20 1 of each year, except as provided under sub-
21 paragraph (C), the responsible person shall sub-
22 mit an electronic report for the prior calendar
23 year for each cosmetic product marketed during
24 that year.

1 “(B) CONTENTS.—Each report under this
2 paragraph shall contain a summary of all ad-
3 verse events received during the reporting pe-
4 riod, a complete list of individual reports, and
5 an estimate of the total number of product
6 units estimated to have been distributed to con-
7 sumers during such period. The report shall not
8 include consumer complaints that are solely re-
9 garding efficacy and do not contain any infor-
10 mation about an adverse event. The Food and
11 Drug Administration shall further specify the
12 contents of the annual electronic report by reg-
13 ulation or guidance.

14 “(C) SMALL BUSINESS EXCEPTION.—In
15 the case of a domestic facility for which the av-
16 erage gross annual sales in cosmetic products in
17 the United States over the previous 3-year pe-
18 riod is not more than \$2,000,000, the respon-
19 sible person is not required to submit an annual
20 report under this paragraph.

21 “(4) EXEMPTION.—The Food and Drug Ad-
22 ministration may establish by regulation an exemp-
23 tion to any of the requirements under this sub-
24 section if the Food and Drug Administration deter-
25 mines that such exemption is supported by adequate

1 evidence and would have no adverse effect on public
2 health.

3 “(d) REQUIREMENTS.—

4 “(1) IN GENERAL.—Each serious adverse event
5 report under this section shall be submitted to the
6 Food and Drug Administration using an electronic
7 system of the Food and Drug Administration. The
8 Food and Drug Administration shall make such elec-
9 tronic system available not later than 1 year after
10 the date of enactment of the Personal Care Products
11 Safety Act.

12 “(2) MODIFICATION.—The format of the re-
13 porting system may be modified by the Food and
14 Drug Administration and the reports may include
15 additional information. The Food and Drug Admin-
16 istration may, in guidance, further specify the for-
17 mat and contents of required reports.

18 “(3) SCOPE OF SERIOUS ADVERSE EVENT RE-
19 PORT.—A serious adverse event report (including all
20 information submitted in the initial report or added
21 later) submitted to the Food and Drug Administra-
22 tion under subsection (a) includes—

23 “(A) a report under section 756 with re-
24 spect to safety and related to a specific cos-
25 metic product;

1 “(B) a record about an individual who suf-
2 fered the serious adverse event under section
3 552a of title 5, United States Code;

4 “(C) a medical or similar file documenting
5 the serious adverse event, the disclosure of
6 which would constitute a violation of section
7 552(b)(6) of such title 5, and shall not be pub-
8 licly disclosed unless all personally identifiable
9 information is redacted; and

10 “(D) contact information for the individual
11 reporting the serious adverse event.

12 “(4) RESPONSIBILITY TO GATHER INFORMA-
13 TION.—After an individual initiates the reporting of
14 a serious adverse event, the responsible person for
15 the cosmetic product shall actively gather all of the
16 information to complete and file the report with the
17 Food and Drug Administration.

18 “(5) NO ADVERSE EVENTS TO REPORT.—The
19 Food and Drug Administration shall provide an op-
20 tion as part of the electronic registration process for
21 the responsible person to indicate if such responsible
22 person had no adverse events to report over the pre-
23 vious year. With respect to a responsible person who
24 received no adverse event reports for a year, the an-
25 nual adverse event report requirement may be met

1 by indicating no such events on the annual registra-
2 tion form.

3 “(e) LIMITATION WITH RESPECT TO ADVERSE
4 EVENT REPORTS.—The submission of an adverse event
5 report in compliance with subsection (a) shall not con-
6 stitute an admission that the cosmetic involved caused or
7 contributed to the adverse event.

8 “(f) CONTACT INFORMATION.—The label of a cos-
9 metic shall bear the domestic telephone number or elec-
10 tronic contact information, and it is encouraged that the
11 label include both the telephone number and electronic
12 contact information, through which the responsible person
13 may receive a report of an adverse event.

14 “(g) MAINTENANCE OF RECORDS.—The responsible
15 person shall maintain records related to each report of an
16 adverse event received by the responsible person for a pe-
17 riod of 6 years.

18 “(h) AVAILABILITY TO STATES.—The Food and
19 Drug Administration shall make available records sub-
20 mitted under this section to any State, upon request. In-
21 formation disclosed to a State that is exempt from disclo-
22 sure under section 552(b)(4) of title 5, United States
23 Code, shall be treated as a trade secret and confidential
24 information by the State.

1 “(i) EFFECTIVE DATE OF REQUIREMENT WITH RE-
2 SPECT TO SERIOUS ADVERSE EVENTS.—The requirement
3 under this section to report serious adverse events shall
4 become effective on the date that the Food and Drug Ad-
5 ministration publicizes the availability of the electronic
6 system described in subsection (d)(1).”.

7 **SEC. 105. RECORDS INSPECTION; MANDATORY RECALL AU-**
8 **THORITY.**

9 Chapter VI of the Federal Food, Drug, and Cosmetic
10 Act (21 U.S.C. 361 et seq.), as amended by section 104,
11 is further amended by adding at the end the following:

12 **“SEC. 612. INSPECTION OF COSMETIC RECORDS.**

13 “(a) INSPECTION OF RECORDS.—Each manufac-
14 turer, processor, packer, or holder of a cosmetic shall, at
15 the request of an officer or employee duly designated by
16 the Food and Drug Administration, permit such officer
17 or employee, upon presentation of appropriate credentials
18 and written notice to such person, at reasonable times and
19 within reasonable limits and in a reasonable manner, to
20 have access to and copy—

21 “(1) all records maintained under section 611
22 and in accordance with the rules promulgated by the
23 Food and Drug Administration under section 610,
24 as applicable; and

1 “(2) except as provided in subsection (b), all
2 other records, if the Food and Drug Administra-
3 tion—

4 “(A) has a reasonable belief that the cos-
5 metic—

6 “(i) is adulterated;

7 “(ii) has caused a reportable serious
8 adverse event; or

9 “(iii) contains an ingredient that sub-
10 stantial new scientific information shows
11 may be unsafe when present in a cosmetic;
12 and

13 “(B) provides written notice of the basis
14 for the Food and Drug Administration’s rea-
15 sonable belief described in subparagraph (A).

16 “(b) EXCLUSIONS.—No inspection authorized by this
17 section shall extend to financial data, pricing data, per-
18 sonnel data (other than data as to qualification of tech-
19 nical and professional personnel performing functions sub-
20 ject to this Act), research data (other than safety data),
21 or sales data other than shipment data.

22 “(c) SCOPE.—The requirements under subsection (a)
23 apply to records maintained by or on behalf of such person
24 in any format (including paper and electronic formats)
25 and at any location.

1 “(d) PROTECTION OF SENSITIVE INFORMATION.—
2 The Food and Drug Administration shall take appropriate
3 measures to ensure that there are effective procedures to
4 prevent the unauthorized disclosure of any trade secret or
5 confidential information that is obtained by the Food and
6 Drug Administration pursuant to this section. Information
7 disclosed to a State that is exempt from disclosure under
8 section 552(b)(4) of title 5, United States Code, shall be
9 treated as a trade secret and confidential information by
10 the State.

11 “(e) LIMITATIONS.—This section shall not be con-
12 strued—

13 “(1) to limit the authority of the Food and
14 Drug Administration to inspect records or to require
15 establishment and maintenance of records under any
16 other provision of this Act; or

17 “(2) to have any legal effect on section 552 of
18 title 5, United States Code, or section 1905 of title
19 18, United States Code.”.

20 **“SEC. 613. MANDATORY RECALL AUTHORITY.**

21 “(a) VOLUNTARY PROCEDURES.—If the Food and
22 Drug Administration determines that there is a reasonable
23 probability that a cosmetic is adulterated under section
24 601 or misbranded under section 602 and the use of or
25 exposure to such cosmetic is likely to cause serious adverse

1 health consequences or death, the Food and Drug Admin-
2 istration shall provide the responsible person with an op-
3 portunity to voluntarily cease distribution and recall such
4 article.

5 “(b) PREHEARING ORDER TO MANDATORILY CEASE
6 DISTRIBUTION AND GIVE NOTICE.—

7 “(1) IN GENERAL.—If the responsible person
8 refuses to or does not voluntarily cease distribution
9 or recall such cosmetic within the time and in the
10 manner prescribed by the Food and Drug Adminis-
11 tration, the Food and Drug Administration may
12 order such person to—

13 “(A) immediately cease distribution of
14 such cosmetic; and

15 “(B) as applicable, immediately notify all
16 persons—

17 “(i) manufacturing, processing, pack-
18 ing, transporting, holding, receiving, dis-
19 tributing, or importing and selling such
20 cosmetic; and

21 “(ii) to which such cosmetic has been
22 distributed, transported, or sold,
23 to immediately cease distribution of such cos-
24 metic.

25 “(2) REQUIRED ADDITIONAL INFORMATION.—

1 “(A) IN GENERAL.—If a cosmetic covered
2 by a recall order issued under paragraph (1)(B)
3 has been distributed to a warehouse-based third
4 party logistics provider without providing such
5 provider sufficient information to know or rea-
6 sonably determine the precise identity of such
7 cosmetic covered by a recall order that is in its
8 possession, the notice provided by the respon-
9 sible person subject to the order issued under
10 paragraph (1)(B) shall include such information
11 as is necessary for the warehouse-based third
12 party logistics provider to identify the cosmetic.

13 “(B) RULES OF CONSTRUCTION.—Nothing
14 in this paragraph shall be construed—

15 “(i) to exempt a warehouse-based
16 third party logistics provider from the re-
17 quirements of this chapter, including the
18 requirements of this section and section
19 612; or

20 “(ii) to exempt a warehouse-based
21 third party logistics provider from being
22 the subject of a mandatory recall order.

23 “(3) DETERMINATION TO LIMIT AREAS AF-
24 FECTED.—If the Food and Drug Administration re-
25 quires a responsible person to cease distribution

1 under paragraph (1)(A) of a cosmetic, the Food and
2 Drug Administration may limit the size of the geo-
3 graphic area and the markets affected by such ces-
4 sation if such limitation would not compromise the
5 public health.

6 “(c) HEARING ON ORDER.—The Food and Drug Ad-
7 ministration shall provide the responsible party subject to
8 an order under subsection (b) with an opportunity for an
9 informal hearing, to be held as soon as possible, but not
10 later than 2 days after the issuance of the order, on the
11 actions required by the order and on why the cosmetic that
12 is the subject of the order should not be recalled.

13 “(d) POST-HEARING RECALL ORDER AND MODIFICA-
14 TION OF ORDER.—

15 “(1) AMENDMENT OF ORDER.—If, after pro-
16 viding opportunity for an informal hearing under
17 subsection (c), the Food and Drug Administration
18 determines that removal of the cosmetic from com-
19 merce is necessary, the Food and Drug Administra-
20 tion shall, as appropriate—

21 “(A) amend the order to require recall of
22 such cosmetic or other appropriate action;

23 “(B) specify a timetable in which the recall
24 shall occur;

1 “(C) require periodic reports to the Food
2 and Drug Administration describing the
3 progress of the recall; and

4 “(D) provide notice to consumers to whom
5 such cosmetic was, or may have been, distrib-
6 uted.

7 “(2) VACATING OF ORDER.—If, after such hear-
8 ing, the Food and Drug Administration determines
9 that adequate grounds do not exist to continue the
10 actions required by the order, or that such actions
11 should be modified, the Food and Drug Administra-
12 tion shall vacate the order or modify the order.

13 “(e) COOPERATION AND CONSULTATION.—The Food
14 and Drug Administration shall work with State and local
15 public health officials in carrying out this section, as ap-
16 propriate.

17 “(f) PUBLIC NOTIFICATION.—In conducting a recall
18 under this section, the Food and Drug Administration
19 shall—

20 “(1) ensure that a press release is published re-
21 garding the recall, and that alerts and public notices
22 are issued, as appropriate, in order to provide notifi-
23 cation—

1 “(A) of the recall to consumers and retail-
2 ers to whom such cosmetic was, or may have
3 been, distributed; and

4 “(B) that includes, at a minimum—

5 “(i) the name of the cosmetic subject
6 to the recall;

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

9 “(iii) to the extent practicable, infor-
10 mation for consumers about similar cos-
11 metics that are not affected by the recall;
12 and

13 “(2) ensure publication on the Internet website
14 of the Food and Drug Administration an image of
15 the cosmetic that is the subject of the press release
16 described in paragraph (1), if available.

17 “(g) NO DELEGATION.—The authority conferred by
18 this section to order a recall or vacate a recall order shall
19 not be delegated to any officer or employee other than the
20 Commissioner.

21 “(h) EFFECT.—Nothing in this section shall affect
22 the authority of the Food and Drug Administration to re-
23 quest or participate in a voluntary recall, or to issue an
24 order to cease distribution or to recall under any other

1 provision of this chapter or under the Public Health Serv-
2 ice Act.”.

3 **SEC. 106. LABELING.**

4 (a) IN GENERAL.—Chapter VI of the Federal Food,
5 Drug, and Cosmetic Act (21 U.S.C. 361 et seq.), as
6 amended by section 105, is further amended by adding
7 at the end the following:

8 **“SEC. 614. LABELING.**

9 “(a) SAFETY REVIEW AND LABELING.—Following a
10 review of cosmetic ingredients that determines that warn-
11 ings are required to help ensure safe use of cosmetic prod-
12 ucts under section 608(d)(5), the Food and Drug Admin-
13 istration shall require labeling of cosmetics that are not
14 appropriate for use in the entire population, including
15 warnings that vulnerable populations, such as children or
16 pregnant women, should limit or avoid using the product.

17 “(b) COSMETIC PRODUCTS FOR PROFESSIONAL
18 USE.—

19 “(1) DEFINITION OF PROFESSIONAL.—With re-
20 spect to cosmetics, the term ‘professional’ means an
21 individual who—

22 “(A) is licensed by an official State author-
23 ity to practice in the field of cosmetology, nail
24 care, barbering, or esthetics;

1 “(B) has complied with all requirements
2 set forth by the State for such licensing; and

3 “(C) has been granted a license by a State
4 board or legal agency or legal authority.

5 “(2) LISTING OF INGREDIENTS.—Cosmetic
6 products used and sold by professionals shall list all
7 ingredients and warnings, as required for other cos-
8 metic products under this chapter.

9 “(3) PROFESSIONAL USE LABELING.—In the
10 case of a cosmetic product intended to be used only
11 by a professional on account of a specific ingredient
12 or increased concentration of an ingredient that re-
13 quires safe handling by trained professionals, the
14 product shall bear a statement as follows: ‘To be Ad-
15 ministered Only by Licensed Professionals’.

16 “(c) REQUIREMENTS.—

17 “(1) DISPLAY.—A warning required under sub-
18 section (a) and a statement required under sub-
19 section (b)(3) shall be prominently displayed—

20 “(A) in the primary language used on the
21 label; and

22 “(B) in conspicuous and legible type in
23 contrast by typography, layout, or color with
24 other material printed or displayed on the label.

1 “(2) MINIMUM WARNING REQUIREMENTS.—A
2 responsible person may include on the labeling any
3 additional warnings in addition to the minimum
4 warnings required under subsection (a).

5 “(d) INTERNET SALES.—In the case of Internet sales
6 of cosmetics, each Internet website offering a cosmetic
7 product for sale to consumers shall provide the same infor-
8 mation that is included on the packaging of the cosmetic
9 product as regularly available through in-person sales, ex-
10 cept information that is unique to a single cosmetic prod-
11 uct sold in a retail facility, such as a lot number or expira-
12 tion date, and the warnings and statements described in
13 subsection (c) shall be prominently and conspicuously dis-
14 played on the website.

15 “(e) CONTACT INFORMATION.—The label on each
16 cosmetic shall bear the domestic telephone number or elec-
17 tronic contact information, and it is encouraged that the
18 label include both the telephone number and electronic
19 contact information, that consumers may use to contact
20 the responsible person with respect to adverse events. The
21 contact number shall provide a means for consumers to
22 obtain additional information about ingredients in a cos-
23 metic, including the ability to ask if a specific ingredient
24 may be present that is not listed on the label, including
25 whether a specific ingredient may be contained in the fra-

1 grance or flavor used in the cosmetic. The manufacturer
2 of the cosmetic is responsible for providing such informa-
3 tion, including obtaining the information from suppliers
4 if it is not readily available. Suppliers are required to re-
5 lease such information upon request of the cosmetic manu-
6 facturer.”.

7 (b) EFFECTIVE DATE.—Section 614 of the Federal
8 Food, Drug, and Cosmetic Act, as added by subsection
9 (a), shall take effect on the date that is 1 year after the
10 date of enactment of this Act.

11 **SEC. 107. COAL TAR CHEMICALS.**

12 Chapter VI of the Federal Food, Drug, and Cosmetic
13 Act (21 U.S.C. 361 et seq.), as amended by section 106,
14 is further amended by adding at the end the following:

15 **“SEC. 615. COAL TAR CHEMICALS.**

16 “Specific chemicals in coal tar hair dyes may be se-
17 lected and reviewed under section 608.”.

18 **SEC. 108. ANIMAL TESTING ALTERNATIVES.**

19 Chapter VI of the Federal Food, Drug, and Cosmetic
20 Act (21 U.S.C. 361 et seq.), as amended by section 107,
21 is further amended by adding the following:

22 **“SEC. 616. ANIMAL TESTING ALTERNATIVES.**

23 “(a) IN GENERAL.—To minimize the use of animal
24 testing for safety of cosmetic ingredients, non-functional

1 constituents, and finished cosmetic products, the Food
2 and Drug Administration shall—

3 “(1) encourage the use of alternative testing
4 methods that provide information that is equivalent
5 or superior in scientific quality to the animal testing
6 method to—

7 “(A) not involve the use of an animal to
8 test a chemical substance for safe use in cos-
9 metics; or

10 “(B) use fewer animals than conventional
11 animal-based tests for safe use in cosmetics
12 when nonanimal methods are impracticable; and

13 “(2) encourage—

14 “(A) the sharing of data across companies
15 and organizations that are testing for safety in
16 cosmetics, so as to avoid duplication of animal
17 tests; and

18 “(B) funding for research and validation of
19 alternative testing methods.

20 “(b) GUIDANCE.—Not later than 3 years after the
21 date of enactment of the Personal Care Products Safety
22 Act, the Food and Drug Administration shall issue guid-
23 ance on the acceptability of scientifically reliable and rel-
24 evant alternatives to animal testing for the safety of cos-
25 metic ingredients, non-functional constituents, and fin-

1 ished cosmetic products, and encouraging the use of such
2 methods. The Food and Drug Administration shall update
3 such guidance on an annual basis.

4 “(c) RESOURCES REGARDING ANIMAL TESTING AL-
5 TERNATIVES.—Not later than 180 days after the date of
6 enactment of the Personal Care Products Safety Act, the
7 Food and Drug Administration shall provide information
8 on the Internet website of the Food and Drug Administra-
9 tion regarding resources available for information about
10 non-animal methods, and methods that reduce animal
11 usage, in testing for the safety of cosmetic ingredients,
12 non-functional constituents, and finished cosmetic prod-
13 ucts.”.

14 **SEC. 109. PREEMPTION.**

15 Chapter VI of the Federal Food, Drug, and Cosmetic
16 Act (21 U.S.C. 361 et seq.), as amended by section 108,
17 is further amended by adding the following:

18 **“SEC. 617. PREEMPTION.**

19 “(a) IN GENERAL.—No State or political subdivision
20 of a State may establish or continue in effect any require-
21 ment for cosmetics, other than a requirement that is in
22 full effect and implemented on the date of enactment of
23 the Personal Care Products Safety Act—

1 “(1) with respect to registration, good manufac-
2 turing practices, mandatory recalls, or adverse event
3 reporting; or

4 “(2) with respect to the safety of a cosmetic in-
5 gredient or non-functional constituent that is the
6 subject of a final order on a determination of safety
7 under this chapter, unless the requirement of the
8 State or political subdivision is more restrictive than
9 the final order under section 608(d)(3).

10 “(b) SAFETY OF COSMETIC INGREDIENTS AND NON-
11 FUNCTIONAL CONSTITUENTS.—

12 “(1) DELAYED EFFECT OF NEW STATE RE-
13 QUIREMENTS.—

14 “(A) IN GENERAL.—From the date that
15 the Food and Drug Administration has made
16 public the final selection of a cosmetic ingre-
17 dient or non-functional constituent to be re-
18 viewed in the coming year under section
19 608(a)(3)(B) and opened the public comment
20 period under section 608(a)(2), until the date
21 that is one year after the Food and Drug Ad-
22 ministration has made public such selection, no
23 State or political subdivision of a State may es-
24 tablish any new requirement related to such

1 cosmetic ingredient or non-functional con-
2 stituent.

3 “(B) INITIAL REVIEW.—With respect to
4 the cosmetic ingredients to be reviewed in the
5 first year, in accordance with section
6 608(a)(3)(A), for the 1-year period beginning
7 on the date that is 6 months after the date of
8 enactment of the Personal Care Products Safe-
9 ty Act, no State or political subdivision of a
10 State may establish any new requirement re-
11 lated to such cosmetic ingredient or non-func-
12 tional constituent.

13 “(2) SCOPE.—Subsection (a)(2) shall not be
14 construed to affect the authority of a State or polit-
15 ical subdivision of a State with respect to any re-
16 quirement for the safety of a cosmetic ingredient or
17 non-functional constituent that is unrelated to the
18 scope of the safety assessment under section 608.

19 “(3) SENSE OF CONGRESS.—It is the sense of
20 Congress that a State or political subdivision that
21 regulates the safety of cosmetics with respect to the
22 health of humans beyond the scope of section 608
23 should utilize the safety assessment criteria de-
24 scribed in section 608(h).

1 “(c) STATE REQUIREMENT THAT IS IN FULL EF-
2 FECT AND IMPLEMENTED.—For purposes of this section:

3 “(1) STATE REQUIREMENT.—A State require-
4 ment includes a State requirement that is adopted
5 by a State public initiative or referendum.

6 “(2) FULL EFFECT AND IMPLEMENTED.—The
7 term ‘full effect and implemented’ includes require-
8 ments of States that are implemented after the date
9 of enactment of the Personal Care Products Safety
10 Act, if such requirements are under a law that was
11 in effect, or a lawful program that was established
12 and functioning, prior to the date of enactment of
13 the Personal Care Products Safety Act.

14 “(d) LIMITATION.—Nothing in the amendments to
15 this Act made by the Personal Care Products Safety Act
16 shall be construed to preempt any State statute, public
17 initiative, referendum, or other State action, except as ex-
18 pressly provided in this section.

19 “(e) SAVINGS.—Nothing in the amendments to this
20 Act made by the Personal Care Products Safety Act, nor
21 any standard, rule, requirement, regulation, adverse event
22 report, safety assessment, safety determination, scientific
23 assessment, or order issued or implemented pursuant to
24 such amendments, shall be construed to modify or other-
25 wise affect, preempt, or displace any cause of action or

1 State or Federal law creating a remedy for civil relief or
2 criminal cause of action, whether statutory or based in
3 common law.”.

4 **SEC. 110. REPORTING.**

5 Chapter VI of the Federal Food, Drug, and Cosmetic
6 Act (21 U.S.C. 361 et seq.), as amended by section 109,
7 is further amended by adding at the end the following:

8 **“SEC. 618. REPORTING.**

9 “(a) PERFORMANCE REPORT.—Beginning with fiscal
10 year 2018, and not later than 60 days prior to the end
11 of each fiscal year for which fees are collected under sec-
12 tion 744L, the Food and Drug Administration shall pre-
13 pare and submit to Congress a report concerning the
14 progress of the Food and Drug Administration in achiev-
15 ing the objectives of the Personal Care Products Safety
16 Act during such fiscal year and the future plans of the
17 Food and Drug Administration for meeting the objectives.
18 The annual report for a fiscal year shall include—

19 “(1) the number of registered facilities and cos-
20 metic ingredient statements on file with the Food
21 and Drug Administration;

22 “(2) identification of the cosmetic ingredients
23 and non-functional constituents that have been fully
24 reviewed for safety by the Food and Drug Adminis-

1 tration in the prior fiscal year and for which a final
2 administrative order has been released;

3 “(3) identification of at least 5 specific cosmetic
4 ingredients and non-functional constituents that will
5 be reviewed by the Food and Drug Administration
6 in the next fiscal year;

7 “(4) the number of facilities inspected and
8 mandatory recalls that transpired during that fiscal
9 year;

10 “(5) the number of serious adverse event re-
11 ports received by the Food and Drug Administration
12 during that fiscal year;

13 “(6) any trends identified by the Food and
14 Drug Administration about adverse event reports re-
15 lated to specific cosmetic ingredients or non-func-
16 tional constituents; and

17 “(7) efforts of the Food and Drug Administra-
18 tion to reduce animal testing for safety of cosmetic
19 ingredients, non-functional constituents, and cos-
20 metic products.

21 “(b) PUBLIC AVAILABILITY.—The Food and Drug
22 Administration shall make the reports required under sub-
23 sections (a) available to the public on the Internet website
24 of the Food and Drug Administration on the date of sub-
25 mission of such reports to Congress.

1 “(c) PUBLIC INPUT ON SAFETY REVIEW.—Upon re-
2 lease of the report described in subsection (a), the Food
3 and Drug Administration shall provide the public with an
4 opportunity to provide feedback, at any time during the
5 year, on subsection (a)(3) by—

6 “(1) providing an electronic portal, upon release
7 of the report, enabling the public to—

8 “(A) comment on the cosmetic ingredients
9 or non-functional constituents under review for
10 the current year;

11 “(B) recommend additional cosmetic ingre-
12 dients and non-functional constituents to be
13 considered for review for safety in future years;
14 and

15 “(C) comment on the priorities for the spe-
16 cific cosmetic ingredients and non-functional
17 constituents that the Food and Drug Adminis-
18 tration anticipates will be reviewed in the next
19 fiscal year;

20 “(2) announcing on the Internet website of the
21 Food and Drug Administration, within the first 30
22 days of the new fiscal year, any amendments to the
23 list of cosmetic ingredients and non-functional con-
24 stituents submitted pursuant to subsection (a)(3)

1 based on public input, pursuant to paragraph (1);
2 and

3 “(3) together with the final announcement of at
4 least 5 specific cosmetic ingredients and non-func-
5 tional constituents that will be reviewed in the com-
6 ing year under section 608, providing a comment pe-
7 riod for further public input, pursuant to section
8 608(a)(2).”.

9 **SEC. 111. SMALL BUSINESSES.**

10 Chapter VI of the Federal Food, Drug, and Cosmetic
11 Act (21 U.S.C. 361 et seq.), as amended by section 110,
12 is further amended by adding at the end the following:

13 **“SEC. 619. SMALL BUSINESSES.**

14 “The Commissioner, in coordination with the Admin-
15 istrator of the Small Business Administration, shall pro-
16 vide technical assistance, such as guidance and expertise,
17 to small businesses regarding compliance with the Per-
18 sonal Care Products Safety Act, including the amend-
19 ments made by such Act.”.

20 **SEC. 112. APPLICABILITY WITH RESPECT TO CERTAIN COS-**
21 **METICS.**

22 Chapter VI of the Federal Food, Drug, and Cosmetic
23 Act (21 U.S.C. 361 et seq.), as amended by section 111,
24 is further amended by adding at the end the following:

1 **“SEC. 620. APPLICABILITY WITH RESPECT TO CERTAIN**
2 **COSMETICS.**

3 “In the case of a cosmetic product or a facility that
4 is subject to the requirements under this chapter and
5 chapter V, if any requirement under chapter V with re-
6 spect to such cosmetic or facility is substantially similar
7 to a requirement under this chapter, the cosmetic product
8 or facility shall be deemed to be in compliance with the
9 applicable requirement under this chapter if such product
10 or facility is in compliance with such substantially similar
11 requirement under chapter V, provided that the product
12 or facility has not obtained a waiver from the requirement
13 under chapter V. In the case of a cosmetic product or fa-
14 cility that is subject to, and in compliance with, a fee
15 under subchapter C of chapter VII, other than a fee under
16 part 10 of such subchapter, any fee under such part 10
17 shall be waived with respect to such cosmetic product or
18 facility (with respect to cosmetic products).”.

19 **SEC. 113. 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 subsection (e)—

24 (A) by striking “504, 564,” and inserting
25 “504, 564, 611, 612,”; and

1 (B) by striking “519, 564,” and inserting
2 “519, 564, 611,”;

3 (2) in subsection (j), by inserting “607, 608,
4 610,” before “704”;

5 (3) in subsection (ii)—

6 (A) by striking “760 or 761) or” and in-
7 serting “604, 760, or 761) or”;

8 (B) by striking “760 or 761) submitted”
9 and inserting “611, 760, or 761) submitted”;

10 (4) in subsection (xx) by inserting “or 613”
11 after “423”; and

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

13 “(eee) The failure to register in accordance with sec-
14 tion 605, **the failure to submit a cosmetic ingredient**
15 **statement under section 606**, the failure to provide any
16 information required by section 605 or 606, or the failure
17 to update the information required by section 605 or 606,
18 as required.”.

19 (b) ADULTERATION.—Section 601 of the Federal
20 Food, Drug, and Cosmetic Act (21 U.S.C. 361) is amend-
21 ed by adding at the end the following:

22 “(f) If the methods used in, or the facilities or con-
23 trols used for, its manufacture, processing, packing, or
24 holding do not conform to current good manufacturing

1 practice, as prescribed by the Food and Drug Administra-
2 tion in accordance with section 610.

3 “(g) If it contains, after the date prescribed under
4 section 608(e), an ingredient that the Food and Drug Ad-
5 ministration has determined under section 608(d)(4) to be
6 not safe, or not safe under the conditions of use rec-
7 ommended or suggested in the label or a non-functional
8 constituent that the Food and Drug Administration has
9 determined under section 608(d)(4) to be not safe or not
10 safe in the amount present in the cosmetic.

11 “(h) If it is a cosmetic product for which any require-
12 ment of section 609 (relating to safety substantiation) is
13 not met.”.

14 (c) MISBRANDING.—Section 602 of the Federal
15 Food, Drug, and Cosmetic Act (21 U.S.C. 362) is amend-
16 ed—

17 (1) in subsection (b)—

18 (A) by striking “and (2)” and inserting
19 “(2)”; and

20 (B) by inserting “; and (3) a domestic ad-
21 dress or a domestic telephone number, and [it
22 is encouraged] that the label include both a do-
23 mestic address and a domestic telephone num-
24 ber, through which the responsible person may
25 receive a report of an adverse event associated

1 with the use of such cosmetic product” after
2 “numerical count”; and

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

4 “(g) If it has been manufactured, processed, packed,
5 or held in any factory, warehouse, or establishment and
6 the responsible person, operator, or agent of such factory,
7 warehouse, or establishment delays, denies, or limits an
8 inspection, or refuses to permit entry or inspection.

9 “(h) If its labeling does not conform with a require-
10 ment under section 614.”.

11 (d) GUIDANCE.—Not later than 1 year after the date
12 of enactment of this Act, the Food and Drug Administra-
13 tion shall issue guidance that defines the circumstances
14 that would constitute delaying, denying, or limiting inspec-
15 tion, or refusing to permit entry or inspection, for pur-
16 poses of section 602(g) of the Federal Food, Drug, and
17 Cosmetic Act, as added by subsection (c)(2).

18 (e) IMPORTS.—Section 801(a) of the Federal Food,
19 Drug, and Cosmetic Act (21 U.S.C. 381(a)) is amended—

20 (1) by striking “section 760 or 761” the first,
21 third, and fourth place such term appears and in-
22 serting “section 611, 760, or 761”; and

23 (2) by striking “760 or 761)” and inserting
24 “604, 760, or 761)”.

1 (f) **FACTORY INSPECTION.**—Section 704(a)(1) of the
2 Federal Food, Drug, and Cosmetic Act (21 U.S.C.
3 374(a)(1)) is amended by inserting after the third sen-
4 tence the following: “In the case of any person who manu-
5 factures, processes, packs, holds, distributes, or imports
6 a cosmetic product, or distributes a cosmetic product and
7 affixes its name on the cosmetic label, the inspection shall
8 extend to all records and other information described in
9 section 612 (regarding inspection of cosmetic records),
10 when the standard for records inspections under para-
11 graph (1) or (2) of subsection (a) of such section applies,
12 subject to the limitations under subsections (d) and (e)
13 of such section.”.

14 **SEC. 114. CONSUMER INFORMATION.**

15 The Food and Drug Administration shall post on its
16 Internet website information for consumers regarding—

17 (1) final orders regarding the safety of a cos-
18 metic ingredient or non-functional constituent under
19 section 608(d)(3) of the Federal Food, Drug, and
20 Cosmetic Act;

21 (2) cosmetic product recalls (including vol-
22 untary and mandatory recalls); and

23 (3) identified counterfeit cosmetic products.

1 **TITLE II—FEES RELATED TO**
2 **COSMETIC SAFETY**

3 **SEC. 201. FINDINGS.**

4 Congress finds that the fees authorized by the
5 amendments made by this title will be dedicated to cos-
6 metic safety activities, as set forth in the goals identified
7 for purposes of part 10 of subchapter C of chapter VII
8 of the Federal Food, Drug, and Cosmetic Act, in the let-
9 ters from the Secretary of Health and Human Services
10 to the Chairman of the Committee on Health, Education,
11 Labor, and Pensions of the Senate and the Chairman of
12 the Committee on Energy and Commerce of the House
13 of Representatives, as set forth in the Congressional
14 Record.

15 **SEC. 202. AUTHORITY TO ASSESS AND USE COSMETIC SAFE-**
16 **TY FEES.**

17 Subchapter C of chapter VII of the Federal Food,
18 Drug, and Cosmetic Act (21 U.S.C. 379f et seq.) is
19 amended by adding at the end the following:

20 **“PART 10—FEES RELATING TO COSMETICS**

21 **“SEC. 744L. REGISTRATION FEE.**

22 “(a) ASSESSMENT AND COLLECTION.—

23 “(1) IN GENERAL.—Beginning in fiscal year
24 2018, the Food and Drug Administration shall as-
25 sess and collect an annual fee from every responsible

1 person (referred to in this section as a ‘registrant’)
2 who owns or operates any facility (as defined in sec-
3 tion 604(3)) engaged in manufacturing or proc-
4 essing, or whose name and address appear on the
5 label of a cosmetic product distributed in the United
6 States, except that this subsection shall not apply to
7 contract manufacturers if a responsible person has
8 already paid the appropriate fee with respect to the
9 cosmetic product, to ensure no double fees are paid.

10 “(2) PAYABLE DATE.—A fee under this section
11 shall be payable during the period of initial registra-
12 tion and on the date of registration each year there-
13 after as prescribed in section 605(a)(1).

14 “(b) DEFINITIONS.—In this section:

15 “(1) ADJUSTMENT FACTOR.—The term ‘adjust-
16 ment factor’ applicable to a fiscal year means the
17 Consumer Price Index for all urban consumers (all
18 items; United States city average) for October of the
19 preceding fiscal year divided by such index for Octo-
20 ber 2017.

21 “(2) AFFILIATE.—The term ‘affiliate’ means
22 any business entity that has a relationship with a
23 second business entity if, directly or indirectly—

24 “(A) one business entity controls, or has
25 power to control, the other business entity; or

1 “(B) a third-party controls, or has the
2 power to control, both of the business entities.

3 “(3) COSMETIC PRODUCT.—The term ‘cosmetic
4 product’ has the meaning given such term in section
5 604(2).

6 “(4) COSMETIC SAFETY ACTIVITIES.—The term
7 ‘cosmetic safety activities’—

8 “(A) means activities related to compliance
9 by registrants under section 605 with the re-
10 quirements of this Act with respect to cos-
11 metics, including—

12 “(i) administrative activities, such as
13 information technology support, human re-
14 sources, financial management, the admin-
15 istration and maintenance of the cosmetic
16 registration system and the cosmetic ingre-
17 dient statement system under sections 605
18 and 606, and fee assessment and collection
19 under this section; and

20 “(ii) implementation and enforcement
21 activities, such as the establishment of
22 good manufacturing practices, the review
23 of adverse event reports, inspection plan-
24 ning and inspections, and use of enforce-
25 ment tools; and

1 “(B) includes activities related to imple-
2 mentation of section 608, regarding the review
3 of cosmetic ingredients and non-functional con-
4 stituents.

5 “(5) GROSS ANNUAL SALES.—The term ‘gross
6 annual sales’ means the average United States gross
7 annual sales for the previous 3-year period of cos-
8 metics for a registrant, including the sales of all of
9 its affiliates, as reported in the registration under
10 section 605.

11 “(c) FEE SETTING AND AMOUNTS.—

12 “(1) IN GENERAL.—Subject to subsection (d),
13 the Food and Drug Administration shall establish
14 the fees to be collected under this section for each
15 fiscal year after fiscal year 2018, based on the meth-
16 odology described in paragraph (3)(B), and shall
17 publish such fees in a Federal Register notice not
18 later than 60 days before the beginning of each such
19 fiscal year.

20 “(2) FEE EXEMPTION.—Any registrant whose
21 gross annual sales of cosmetic products in the 3-year
22 period immediately preceding the fiscal year for
23 which the annual fee will be paid was not more than
24 \$2,000,000, shall be exempt from registration fees
25 under this section for that fiscal year.

1 “(3) ANNUAL FEE SETTING.—

2 “(A) FISCAL YEAR 2018.—For fiscal year
3 2018, to generate a total estimated revenue
4 amount of \$20,600,000, the amount of the reg-
5 istration fee under subsection (a) shall be as
6 follows:

7 “(i) TIER I-A.—For a registrant that
8 has gross annual sales of \$5,000,000,000
9 or more in 2017, \$1,350,000.

10 “(ii) TIER I-B.—For a registrant that
11 has gross annual sales of at least
12 \$4,000,000,000 per annum but less than
13 \$5,000,000,000 in 2017, \$850,000.

14 “(iii) TIER II-A.—For a registrant
15 that has gross annual sales of at least
16 \$3,000,000,000 per annum but less than
17 \$4,000,000,000 in 2017, \$730,000.

18 “(iv) TIER II-B.—For a registrant
19 that has gross annual sales of at least
20 \$2,000,000,000 per annum but less than
21 \$3,000,000,000 in 2017, \$610,000.

22 “(v) TIER III-A.—For a registrant
23 that has gross annual sales of at least
24 \$1,000,000,000 per annum but less than
25 \$2,000,000,000 in 2017, \$500,000.

1 “(vi) TIER III-B.—For a registrant
2 that has gross annual sales of at least
3 \$500,000,000 per annum but less than
4 \$1,000,000,000 in 2017, \$395,000.

5 “(vii) TIER IV-A.—For a registrant
6 that has gross annual sales of at least
7 \$200,000,000 per annum but less than
8 \$500,000,000 in 2017, \$325,000.

9 “(viii) TIER IV-B.—For a registrant
10 that has gross annual sales of at least
11 \$100,000,000 per annum but less than
12 \$200,000,000 in 2017, \$275,000.

13 “(ix) TIER V-A.—For a registrant
14 that has gross annual sales of at least
15 \$80,000,000 per annum but less than
16 \$100,000,000 in 2017, \$185,000.

17 “(x) TIER V-B.—For a registrant that
18 has gross annual sales of at least
19 \$60,000,000 per annum but less than
20 \$80,000,000 in 2017, \$95,000.

21 “(xi) TIER VI-A.—For a registrant
22 that has gross annual sales of at least
23 \$40,000,000 per annum but less than
24 \$60,000,000 in 2017, \$15,000.

1 “(xii) TIER IV–B.—For a registrant
2 that has gross annual sales of at least
3 \$20,000,000 per annum but less than
4 \$40,000,000 in 2017, \$12,000.

5 “(xiii) TIER VII–A.—For a registrant
6 that has gross annual sales of at least
7 \$10,000,000 per annum but less than
8 \$20,000,000 in 2017, \$500.

9 “(xiv) TIER VII–B.—For a registrant
10 that has gross annual sales of at least
11 \$5,000,000 per annum but less than
12 \$10,000,000 in 2017, \$350.

13 “(xv) TIER VIII–A.—For a registrant
14 that has gross annual sales of at least
15 \$2,000,000 per annum but less than
16 \$5,000,000 in 2017, \$250.

17 “(B) FISCAL YEARS 2019–2024.—For fiscal
18 years 2019 through 2024, fees under subsection
19 (a) shall be established to generate a total esti-
20 mated revenue amount of \$20,600,000, as ad-
21 justed by subsection (d). Of that amount:

22 “(i) TIER I–A.—Registrants that have
23 gross annual sales of \$5,000,000,000 or
24 more in the fiscal year immediately pre-
25 ceding the fiscal year in which the annual

1 fee will be paid, shall be responsible, collec-
2 tively, for 10.7 percent.

3 “(ii) TIER I–B.—Registrants that
4 have gross annual sales of at least
5 \$4,000,000,000 per annum but less than
6 \$5,000,000,000 in the fiscal year imme-
7 diately preceding the fiscal year in which
8 the annual fee will be paid, shall be re-
9 sponsible, collectively, for 4.1 percent.

10 “(iii) TIER II–A.—Registrants that
11 have gross annual sales of at least
12 \$3,000,000,000 per annum but less than
13 \$4,000,000,000 in the fiscal year imme-
14 diately preceding the fiscal year in which
15 the annual fee will be paid, shall be re-
16 sponsible, collectively, for 3.5 percent.

17 “(iv) TIER II–B.—Registrants that
18 have gross annual sales of at least
19 \$2,000,000,000 per annum but less than
20 \$3,000,000,000 in the fiscal year imme-
21 diately preceding the fiscal year in which
22 the annual fee will be paid, shall be re-
23 sponsible, collectively, for 2.9 percent.

24 “(v) TIER III–A.—Registrants that
25 have gross annual sales of at least

1 \$1,000,000,000 per annum but less than
2 \$2,000,000,000 in the fiscal year imme-
3 diately preceding the fiscal year in which
4 the annual fee will be paid, shall be re-
5 sponsible, collectively, for 7.3 percent.

6 “(vi) TIER III-B.—Registrants that
7 have gross annual sales of at least
8 \$500,000,000 per annum but less than
9 \$1,000,000,000 in the fiscal year imme-
10 diately preceding the fiscal year in which
11 the annual fee will be paid, shall be re-
12 sponsible, collectively, for 13.4 percent.

13 “(vii) TIER IV-A.—Registrants that
14 have gross annual sales of at least
15 \$200,000,000 per annum but less than
16 \$500,000,000 in the fiscal year imme-
17 diately preceding the fiscal year in which
18 the annual fee will be paid, shall be re-
19 sponsible, collectively, for 15.8 percent.

20 “(viii) TIER IV-B.—Registrants that
21 have gross annual sales of at least
22 \$100,000,000 per annum but less than
23 \$200,000,000 in the fiscal year imme-
24 diately preceding the fiscal year in which

1 the annual fee will be paid, shall be re-
2 sponsible, collectively, for 13.3 percent.

3 “(ix) TIER V-A.—Registrants that
4 have gross annual sales of at least
5 \$80,000,000 per annum but less than
6 \$100,000,000 in the fiscal year imme-
7 diately preceding the fiscal year in which
8 the annual fee will be paid, shall be re-
9 sponsible, collectively, for 9 percent.

10 “(x) TIER V-B.—Registrants that
11 have gross annual sales of at least
12 \$60,000,000 per annum but less than
13 \$80,000,000 in the fiscal year immediately
14 preceding the fiscal year in which the an-
15 nual fee will be paid, shall be responsible,
16 collectively, for 6.9 percent.

17 “(xi) TIER VI-A.—Registrants that
18 have gross annual sales of at least
19 \$40,000,000 per annum but less than
20 \$60,000,000 in the fiscal year immediately
21 preceding the fiscal year in which the an-
22 nual fee will be paid, shall be responsible,
23 collectively, for 5.1 percent.

24 “(xii) TIER VI-B.—Registrants that
25 have gross annual sales of at least

1 \$20,000,000 per annum but less than
2 \$40,000,000 in the fiscal year immediately
3 preceding the fiscal year in which the an-
4 nual fee will be paid, shall be responsible,
5 collectively, for 4.4 percent.

6 “(xiii) TIER VII–A.—Registrants that
7 have gross annual sales of at least
8 \$10,000,000 per annum but less than
9 \$20,000,000 in the fiscal year immediately
10 preceding the fiscal year in which the an-
11 nual fee will be paid, shall be responsible,
12 collectively, for 1.2 percent.

13 “(xiv) TIER VII–B.—Registrants that
14 have gross annual sales of at least
15 \$5,000,000 per annum but less than
16 \$10,000,000 in the fiscal year immediately
17 preceding the fiscal year in which the an-
18 nual fee will be paid, shall be responsible,
19 collectively, for 1.2 percent, except that no
20 such registrant shall be responsible for
21 more than \$350 per fiscal year.

22 “(xv) TIER VIII–A.—Registrants that
23 have gross annual sales of at least
24 \$2,000,000 per annum but less than
25 \$5,000,000 in the fiscal year immediately

1 preceding the fiscal year in which the an-
2 nual fee will be paid, shall be responsible,
3 collectively, for 1.2 percent, except that no
4 such registrant shall be responsible for
5 more than \$250 per fiscal year.

6 “(d) ADJUSTMENTS.—

7 “(1) INFLATION ADJUSTMENT.—

8 “(A) IN GENERAL.—For fiscal year 2019
9 and each subsequent fiscal year, the revenues
10 and fee amounts under subsection (c)(3)(B)
11 shall be adjusted by the Food and Drug Admin-
12 istration in the annual Federal Register notice
13 establishing fees in subsection (c)(1), by an
14 amount equal to the sum of—

15 “(i) one;

16 “(ii) the average annual percent
17 change in the cost, per full-time equivalent
18 position of the Food and Drug Administra-
19 tion, of all personnel compensation and
20 benefits paid with respect to such positions
21 for the first 3 of the preceding 4 fiscal
22 years for which data are available, multi-
23 plied by the average proportion of per-
24 sonnel compensation and benefits costs to
25 total Food and Drug Administration costs

1 for the first 3 years of the preceding 4 fis-
2 cal years for which data are available; and
3 “(iii) the average annual percent
4 change that occurred in the Consumer
5 Price Index for urban consumers (Wash-
6 ington-Baltimore, DC6 MD-VA-WV; not
7 seasonally adjusted; all items less food and
8 energy; annual index) for the first 3 years
9 of the preceding 4 years for which data are
10 available multiplied by the average propor-
11 tion of all costs other than personnel com-
12 pensation and benefits costs to total Food
13 and Drug Administration costs for the
14 first 3 years of the preceding 4 fiscal years
15 for which data are available.

16 “(B) COMPOUNDED BASIS.—The adjust-
17 ment made each fiscal year under this sub-
18 section shall be added on a compounded basis
19 to the sum of all adjustments made each fiscal
20 year after fiscal year 2018 under this sub-
21 section.

22 “(2) FINAL YEAR ADJUSTMENT.—For fiscal
23 year 2024, the Food and Drug Administration may,
24 in addition to adjustments under paragraph (1), fur-
25 ther increase the fee revenues and fees established in

1 subsection (c) if such an adjustment is necessary to
2 provide for not more than 3 months of operating re-
3 serves of carryover fees for cosmetic safety activities
4 for the first 3 months of fiscal year **[2025]**. If such
5 an adjustment is necessary, the rationale for the in-
6 crease, shall be contained in the annual Federal
7 Register notice establishing fees, in subsection
8 (c)(1), for fiscal year 2024. If the Food and Drug
9 Administration has carryover balances for such ac-
10 tivities in excess of 3 months of such operating re-
11 serves, the adjustment under this subparagraph
12 shall not be made.

13 “(3) WORKLOAD ADJUSTMENT.—

14 “(A) IN GENERAL.—For fiscal year 2019
15 and each subsequent fiscal year, after fee reve-
16 nues established in subsection (c)(3)(B) are ad-
17 justed for a fiscal year for inflation in accord-
18 ance with paragraph (1), the fee revenues shall
19 be adjusted further for each fiscal year to re-
20 flect changes in the workload of the Food and
21 Drug Administration for actual changes in
22 workload volume due to the process of reviewing
23 cosmetic ingredients or non-functional constitu-
24 ents not listed under section 608(b).

1 “(B) DETERMINATION OF ADJUSTMENT.—

2 The adjustment shall be determined by the
3 Food and Drug Administration based on the
4 workload in the most recent 1-year period for
5 which workload data is available. The Food and
6 Drug Administration shall publish in the Fed-
7 eral Register the fee revenues and fees resulting
8 from the adjustment and the supporting meth-
9 odologies.

10 “(C) MINIMUM REVENUES.—The adjust-
11 ment shall not result in fee revenues for a fiscal
12 year that are less than the sum of the amount
13 under subsection (c)(3)(B), as adjusted for in-
14 flation under subparagraph (1).

15 “(e) LIMITATIONS.—

16 “(1) IN GENERAL.—With respect to the amount
17 that, under the salaries and expenses account of the
18 Food and Drug Administration, is appropriated for
19 a fiscal year for the cosmetics program in the Center
20 for Food Safety and Applied Nutrition and related
21 field activities, fees may not be assessed under sub-
22 section (a) for the fiscal year unless the amount so
23 appropriated for the fiscal year (excluding the
24 amount of fees appropriated for the fiscal year), is
25 equal to or greater than that assessed for fiscal year

1 2017, multiplied by the adjustment factor applicable
2 to the fiscal year involved.

3 “(2) AUTHORITY.—If the Food and Drug Ad-
4 ministration does not assess fees under subsection
5 (a) during any portion of a fiscal year because of
6 paragraph (1) and if at a later date in such fiscal
7 year the Food and Drug Administration may assess
8 such fees, the Food and Drug Administration may
9 assess and collect such fees, without any modifica-
10 tion in the rate, for registration under section 605
11 at any time in such fiscal year.

12 “(f) CREDITING AND AVAILABILITY OF FEES.—

13 “(1) IN GENERAL.—Fees authorized under sub-
14 section (a) shall be collected and available for obliga-
15 tion only to the extent and in the amount provided
16 in advance in appropriations Acts. Such fees are au-
17 thorized to remain available until expended. Such
18 sums as may be necessary may be transferred from
19 the Food and Drug Administration salaries and ex-
20 penses appropriation account without fiscal year lim-
21 itation to such appropriation account for salaries
22 and expenses with such fiscal year limitation. The
23 sums transferred shall be available solely for cos-
24 metic safety activities.

1 “(2) COLLECTIONS AND APPROPRIATIONS
2 ACTS.—

3 “(A) IN GENERAL.—Subject to subpara-
4 graphs (C) and (D), the fees authorized by this
5 section shall be collected and available in each
6 fiscal year in an amount not to exceed the
7 amount specified in appropriation Acts, or oth-
8 erwise made available for obligation for such
9 fiscal year.

10 “(B) USE OF FEES AND LIMITATION.—
11 The fees authorized by this section shall be col-
12 lected and available only to defray the costs of
13 cosmetic safety activities.

14 “(C) FEE COLLECTIONS DURING FIRST
15 PROGRAM YEAR.—Until the date of enactment
16 of an Act making appropriations through Sep-
17 tember 30, 2017, for the salaries and expenses
18 account of the Food and Drug Administration,
19 fees authorized by this section for fiscal year
20 2018 may be collected and shall be credited to
21 such account to remain available until ex-
22 pended. Fees collected under this subparagraph
23 shall be considered discretionary for purposes of
24 the Balanced Budget and Emergency Deficit
25 Control Act of 1985.

1 “(D) REIMBURSEMENT OF START-UP
2 AMOUNTS.—Any amounts allocated to establish
3 programs under sections 605 and 606, prior to
4 collection of fees, may be reimbursed through
5 any appropriated fees collected under this sec-
6 tion, in such manner as the Food and Drug Ad-
7 ministration determines appropriate. Any
8 amounts reimbursed under this subparagraph
9 shall be available for the programs and activi-
10 ties for which funds allocated to establish the
11 programs were available, prior to such alloca-
12 tion, until the end of the fiscal year in which
13 the reimbursement occurs, notwithstanding any
14 otherwise applicable limits on amounts for such
15 program or activities for a fiscal year.

16 “(3) AUTHORIZATION OF APPROPRIATIONS.—
17 For each of fiscal years 2018 through 2024, there
18 are authorized to be appropriated for fees under this
19 section \$20,600,000, as adjusted by subsection (d).

20 “(4) OFFSET OF OVERCOLLECTIONS; RECOVERY
21 OF COLLECTION SHORTFALLS.—

22 “(A) OFFSET OF OVERCOLLECTIONS.—If
23 the sum of the cumulative amount of fees col-
24 lected under this section for the fiscal years
25 2018 through 2022 exceeds the cumulative

1 amount appropriated pursuant to paragraph (3)
2 for fiscal years 2018 through 2023, the excess
3 amount shall be credited to the appropriation
4 account of the Food and Drug Administration
5 as provided in paragraph (1), and shall be sub-
6 tracted from the amount of fees that would oth-
7 erwise be authorized to be collected under this
8 section pursuant to appropriation Acts for fiscal
9 year 2024.

10 “(B) RECOVERY OF COLLECTION SHORT-
11 FALLS.—

12 “(i) 2020.—For fiscal year 2020, the
13 amount of fees otherwise authorized to be
14 collected under this section shall be in-
15 creased by the amount, if any, by which
16 the amount collected under this section
17 and appropriated for fiscal year 2018 falls
18 below the amount of fees authorized for
19 fiscal year 2018 under paragraph (3).

20 “(ii) 2021.—For fiscal year 2021, the
21 amount of fees otherwise authorized to be
22 collected under this section shall be in-
23 creased by the amount, if any, by which
24 the amount collected under this section
25 and appropriated for fiscal year 2019 falls

1 below the amount of fees authorized for
2 fiscal year 2019 under paragraph (3).

3 “(iii) 2022.—For fiscal year 2022,
4 the amount of fees otherwise authorized to
5 be collected under this section shall be in-
6 creased by the amount, if any, by which
7 the amount collected under this section
8 and appropriated for fiscal year 2020 falls
9 below the amount of fees authorized for
10 fiscal year 2020 under paragraph (3).

11 “(iv) 2023.—For fiscal year 2023, the
12 amount of fees otherwise authorized to be
13 collected under this section shall be in-
14 creased by the amount, if any, by which
15 the amount collected under this section
16 and appropriated for fiscal year 2021 falls
17 below the amount of fees authorized for
18 fiscal year 2021 under paragraph (3).

19 “(v) 2024.—For fiscal year 2024, the
20 amount of fees otherwise authorized to be
21 collected under this section shall be in-
22 creased by the amount, if any, by which
23 the amount collected under this section
24 and appropriated for fiscal year 2022 falls

1 below the amount of fees authorized for
2 fiscal year 2022 under paragraph (3).

3 “(g) EFFECT OF FAILURE TO PAY FEES.—The Food
4 and Drug Administration shall not consider a registration
5 submitted to be complete until such fee under subsection
6 (a) is paid. Until the fee is paid, the registration is incom-
7 plete and the registrant is deemed to have failed to reg-
8 ister in accordance with section 605.

9 “(h) FALSE STATEMENTS.—Any statement or rep-
10 resentation made to the Food and Drug Administration
11 shall be subject to section 1001 of title 18, United States
12 Code.

13 “(i) COLLECTION OF UNPAID FEES.—In any case
14 where the Food and Drug Administration does not receive
15 payment of a fee assessed under subsection (a), such fee
16 shall be treated as a claim of the United States Govern-
17 ment subject to subchapter II of chapter 37 of title 31,
18 United States Code.

19 “(j) CONSTRUCTION.—This section may not be con-
20 strued to require that the number of full-time equivalent
21 positions in the Department of Health and Human Serv-
22 ices, for officers, employees, and advisory committees not
23 engaged in cosmetic activities, be reduced to offset the
24 number of officers, employees, and advisory committees so
25 engaged.

