

114TH CONGRESS
1ST SESSION

S. 1014

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

IN THE SENATE OF THE UNITED STATES

APRIL 20, 2015

Mrs. FEINSTEIN (for herself and Ms. COLLINS) introduced the following bill; which was read twice and referred to the Committee on Health, Education, Labor, and Pensions

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 statements.

- 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;

4 “(G) domestic manufacturers with less
5 than \$100,000 in gross annual sales of cosmetic
6 products; or

7 “(H) entities that manufacture or com-
8 pound cosmetic products solely for use in re-
9 search, teaching, or pilot plant production and
10 not for sale.

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

22 “(5) NON-FUNCTIONAL CONSTITUENT.—The
23 term ‘non-functional constituent’ means any sub-
24 stance that is an incidental component of an ingre-
25 dient, a breakdown product of an ingredient or a by-

1 product of the manufacturing process that has not
2 been intentionally added as a separate substance and
3 serves no technical function in the cosmetic.

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

6 “(A) the brand owner who is the domestic
7 or foreign manufacturer, packer, or entity
8 whose name appears on a cosmetic product
9 label of a cosmetic product distributed in the
10 United States, except for entities described in
11 subparagraphs (A) through (H) of paragraph
12 (3); or

13 “(B) a contract manufacturer who provides
14 cosmetic products to the entities described in
15 subparagraphs (A) through (H) of paragraph
16 (3).”.

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

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

20 “(1) REGISTRATION, IN GENERAL.—Not later
21 than December 1, 2015, and at a similar time in
22 each subsequent year, as determined by the Food
23 and Drug Administration, each responsible person
24 engaged in manufacturing or processing a cosmetic
25 product or a cosmetic formulation distributed in the

1 United States shall register all of the responsible
2 person's facilities with the Food and Drug Adminis-
3 tration.

4 “(2) FEES.—If the average gross annual sales
5 in the United States of cosmetic products of all of
6 the responsible person's facilities registered under
7 paragraph (1) for the previous 3-year period is
8 greater than \$500,000, a registration shall not be
9 complete under this subsection until the responsible
10 person has paid any registration fee required under
11 section 744L.

12 “(b) REGISTRATION FOR EXISTING PACKING OR
13 HOLDING OF COSMETICS.—Not later than December 1,
14 2015, and at a similar time once every 3 years thereafter,
15 as determined by the Food and Drug Administration, each
16 person who owns or operates a cosmetic facility or facili-
17 ties engaged in packing or holding a cosmetic product dis-
18 tributed in the United States shall register each such facil-
19 ity with the Food and Drug Administration.

20 “(c) REGISTRATION BY NEW FACILITIES.—Any facil-
21 ity first engaging after the date of enactment of the Per-
22 sonal Care Products Safety Act in an activity that would
23 require it to register under subsection (a) or (b) shall reg-
24 ister with the Food and Drug Administration within 60

1 days of first engaging in such activity, and thereafter in
2 accordance with subsection (a) or (b).

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

9 “(e) FORMAT; CONTENTS.—

10 “(1) ELECTRONIC FORMAT.—Each registration
11 shall be submitted using an electronic format, as
12 specified in a registration form provided by the Food
13 and Drug Administration.

14 “(2) CONTENTS.—The registration shall con-
15 tain the following information:

16 “(A) Each facility’s name and full address,
17 identifying the precise physical location of the
18 facility.

19 “(B) The identity of the facility, including
20 the unique facility identifier, if any, previously
21 assigned by the Food and Drug Administration
22 to the facility under subsection (g).

23 “(C) All business trading names used by
24 the facility.

1 “(D) The product category or categories of
2 each cosmetic product or cosmetic formulation
3 manufactured, processed, packed, or held at the
4 facility or on whose label the facility’s name
5 and address appear.

6 “(E) The type of activity conducted at the
7 facility (such as manufacturing, processing,
8 packing, or holding).

9 “(F) The name, title, street address, tele-
10 phone number, and electronic contact informa-
11 tion of the emergency contact for the facility.

12 “(G) In the case of a foreign facility, the
13 name, street address, telephone number, emer-
14 gency contact information for the facility, the
15 name of the United States agent for the facil-
16 ity, and, if available, the electronic contact in-
17 formation of the United States agent.

18 “(H) The name, title, street address, tele-
19 phone number, and electronic contact informa-
20 tion of the individual submitting the registra-
21 tion.

22 “(I) An assurance that the Food and Drug
23 Administration will be permitted to inspect such
24 facility at the times and in the manner per-
25 mitted by this Act.

1 “(J) Additional information pertaining to
2 the facility or to the cosmetic products or cos-
3 metic formulations manufactured, processed,
4 packed, or held at the facility, or on whose label
5 the facility’s name and address appear, includ-
6 ing all brand names known to consumers, as
7 the Food and Drug Administration may require
8 by regulation.

9 “(3) ABBREVIATED REGISTRATION.—The Food
10 and Drug Administration shall provide for an abbrevi-
11 ated registration renewal process for any registrant
12 that has not had any changes to such information
13 with respect to the facility or facilities involved since
14 the registrant submitted the preceding registration.

15 “(f) INCOMPLETE OR INACCURATE REGISTRATION.—

16 “(1) IN GENERAL.—Not earlier than 10 days
17 after providing notice of the intent to cancel a reg-
18 istration and the basis for such cancellation, the
19 Food and Drug Administration may cancel a reg-
20 istration under this section if the Food and Drug
21 Administration has reasonable grounds to believe
22 that the registration was not properly completed or
23 updated in accordance with this section or otherwise
24 contains false, incomplete, or inaccurate information.

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

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

12 “(h) REGISTRY OF FACILITIES.—

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

20 “(2) PUBLIC AVAILABILITY EXCEPTIONS.—In-
21 formation derived from the registry or registration
22 documents that discloses the residential address of a
23 registrant or that discloses specific facilities where
24 specific cosmetic products are manufactured or proc-

1 essed shall not be subject to disclosure under section
2 552 of title 5, United States Code.

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

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

11 “(b) SUBMISSION OF A COSMETIC INGREDIENT
12 STATEMENT.—

13 “(1) EXISTING COSMETIC PRODUCTS.—In the
14 case of a cosmetic product that is marketed on the
15 date of enactment of the Personal Care Products
16 Safety Act, the responsible person shall submit a
17 cosmetic ingredient statement not later than Decem-
18 ber 1, 2015. The responsible person shall submit to
19 the Food and Drug Administration a renewal of
20 such statement on a yearly basis.

21 “(2) COSMETIC INGREDIENT STATEMENT FOR
22 NEW COSMETIC PRODUCTS.—

23 “(A) IN GENERAL.—Except as provided
24 under subparagraph (B), in the case of a cos-
25 metic product that is first marketed after the

1 date of enactment of the Personal Care Prod-
2 ucts Safety Act or a cosmetic product that is
3 reformulated after such date of enactment, the
4 responsible person shall submit a cosmetic in-
5 gredient statement to the Food and Drug Ad-
6 ministration within 60 days of first marketing
7 the new cosmetic product or the reformulated
8 cosmetic product, and annually thereafter.

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

21 “(C) DEFINITION.—A cosmetic product
22 shall not be considered first marketed or refor-
23 mulated after the date of enactment under sub-
24 paragraph (A) if the only change in such prod-
25 uct is in—

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

4 “(ii) the addition or subtraction of a
5 fragrance, flavor, or color, or such other
6 interchangeable ingredients specified by
7 the Food and Drug Administration in reg-
8 ulations or guidance, previously reported
9 as a potential ingredient under subsection
10 (c)(2)(E), if, in the case of such an addi-
11 tion, the amount is within the range pre-
12 viously reported.

13 “(c) **FORMAT; CONTENTS.**—

14 “(1) **FORM.**—For each cosmetic product, the
15 cosmetic ingredient statement shall be submitted
16 using an electronic format, as specified in a cosmetic
17 and ingredient form provided by the Food and Drug
18 Administration.

19 “(2) **CONTENTS.**—The cosmetic ingredient
20 statement shall include the following information:

21 “(A) The unique identifier, assigned under
22 section 605(g), as applicable, of—

23 “(i) the facility or facilities where the
24 cosmetic product is manufactured, proc-
25 essed, packed, or held or, if the same cos-

1 metic product is manufactured, processed,
2 packed, or held in more than one facility,
3 the unique facility identifier of each facility
4 where it is manufactured, processed,
5 packed, or held; and

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

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

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

17 “(D) The applicable cosmetic category for
18 the cosmetic product.

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

1 name of the ingredient. The cosmetic ingredient
2 statement shall contain—

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

7 “(I) in the case of fragrances
8 that are purchased from a fragrance
9 supplier, the fragrances shall be iden-
10 tified by the name or code provided by
11 the supplier, and include the name
12 and contact information for the fra-
13 grance supplier;

14 “(II) in the case of flavors that
15 are purchased from a flavor supplier,
16 the flavors shall be identified by the
17 name or code provided by the sup-
18 plier, and include the name and con-
19 tact information for the flavor sup-
20 plier; and

21 “(III) in the case of a notifica-
22 tion provided by the Food and Drug
23 Administration to the responsible per-
24 son for the cosmetic manufacturer,
25 the Food and Drug Administration

1 may request, from the fragrance or
2 flavor supplier, the complete list of in-
3 gredients in specific fragrances or fla-
4 vors and the supplier shall have 30
5 days to provide such list to the Food
6 and Drug Administration; and

7 “(ii) other appropriate interchange-
8 able ingredients as the Food and Drug Ad-
9 ministration may specify in regulations or
10 guidance that may be included in the prod-
11 uct, with ranges of possible amounts.

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

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

16 “(H) Such additional information per-
17 taining to the cosmetic product as the Food and
18 Drug Administration may require.

19 “(3) COSMETIC INGREDIENT STATEMENT FOR
20 CERTAIN SMALL BUSINESSES.—

21 “(A) IN GENERAL.—Notwithstanding any
22 other provision of this subsection, the Food and
23 Drug Administration may permit a simplified
24 cosmetic ingredient statement under this sec-
25 tion for a responsible person that—

1 “(i) is a business that meets the appli-
2 cable industry-based small business size
3 standard established by the Administrator
4 of the Small Business Administration
5 under section 3 of the Small Business Act;
6 and

7 “(ii) has had an average of less than
8 \$500,000 in annual domestic cosmetic
9 sales over the previous 3 years.

10 “(B) CONTENTS.—A responsible person
11 described in subparagraph (A) shall include in
12 each cosmetic ingredient statement under this
13 section, at a minimum, a list of ingredients in
14 the cosmetic product and the applicable cos-
15 metic category for the cosmetic product.

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

18 “(1) IN GENERAL.—Not earlier than 10 days
19 after providing notice under paragraph (2), the Food
20 and Drug Administration may nullify a cosmetic in-
21 gredient statement filed under this section if the
22 Food and Drug Administration has reasonable
23 grounds to believe that the cosmetic ingredient state-
24 ment was not completed or updated in accordance

1 with this section or otherwise contains false, incom-
2 plete, or inaccurate information.

3 “(2) NOTICE OF NULLIFICATION.—A nullifica-
4 tion under paragraph (1) shall be preceded by notice
5 to the responsible person of the intent to cancel the
6 cosmetic ingredient statement and the basis for such
7 cancellation.

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

14 “(e) ADDITIONAL REQUIREMENTS.—

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

1 safety of the full range in the finished product has
2 been substantiated, in accordance with section 609.

3 “(2) ABBREVIATED FILING.—The Food and
4 Drug Administration shall provide for an abbrevi-
5 ated renewal process for any such filing with re-
6 spect to which there has been no change since the
7 responsible person submitted the previous filing.

8 “(3) CHANGES TO INFORMATION.—

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

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

21 “(ii) the addition or subtraction of a
22 fragrance, flavor, or color, or such other
23 interchangeable ingredients specified by
24 the Food and Drug Administration in reg-
25 ulations or guidance, previously reported

1 as a potential ingredient under subsection
2 (c)(2)(E), if, in the case of an addition of
3 such an ingredient, the amount is within
4 the range previously reported.

5 “(B) SMALL BUSINESS.—The Food and
6 Drug Administration shall allow a responsible
7 person that is a business that meets the appli-
8 cable industry-based small business size stand-
9 ard established by the Administrator of the
10 Small Business Administration under section 3
11 of the Small Business Act to have a period
12 longer than 60 days, but not longer than the
13 next annual registration deadline under section
14 605(a)(1), to submit any change to the infor-
15 mation required to be in a cosmetic ingredient
16 statement as described in subparagraph (A).

17 “(f) COSMETIC PRODUCTS LIST.—At the time of the
18 initial submission of any cosmetic ingredient statement
19 under this section, the Food and Drug Administration
20 shall assign a unique cosmetic product listing number to
21 the cosmetic ingredient statement. Based on such cosmetic
22 ingredient statements, the Food and Drug Administration
23 shall compile and maintain a list of cosmetic products dis-
24 tributed in the United States, including the ingredients
25 of each such product, and shall make available such list

1 to any State, upon request. Information disclosed to a
2 State that is exempt from disclosure under section
3 552(b)(4) of title 5, United States Code, shall be treated
4 as a trade secret and confidential information by the
5 State.

6 **“SEC. 607. SUSPENSION OF REGISTRATION OR COSMETIC**
7 **INGREDIENT STATEMENT.**

8 “(a) SUSPENSION OF REGISTRATION OF A FACIL-
9 ITY.—If the Food and Drug Administration determines
10 that a cosmetic formulation or cosmetic product manufac-
11 tured, processed, packed, or held by a registered facility
12 has a reasonable probability of causing serious adverse
13 health consequences or death to humans, and there is rea-
14 son to believe that other formulations or products manu-
15 factured, processed, packed, or held by the facility may
16 be similarly affected because of a failure affecting multiple
17 products in that facility, the Food and Drug Administra-
18 tion may suspend the registration of a facility.

19 “(b) SUSPENSION OF COSMETIC INGREDIENT STATE-
20 MENT.—If the Food and Drug Administration determines
21 that a cosmetic product manufactured in a registered fa-
22 cility has a reasonable probability of causing serious ad-
23 verse health consequences or death to humans, the Food
24 and Drug Administration may suspend the cosmetic ingre-
25 dient statement of that product.

1 “(c) NOTICE OF SUSPENSION.—Before suspending a
2 facility registration or a cosmetic ingredient statement
3 under this section, the Food and Drug Administration
4 shall provide—

5 “(1) notice to the facility registrant of the cos-
6 metic product or formulation or other responsible
7 person, as appropriate, of the intent to suspend the
8 facility registration or the cosmetic ingredient state-
9 ment, which shall specify the basis of the determina-
10 tion by the Food and Drug Administration that the
11 facility or the cosmetic ingredient should be sus-
12 pended and recommendations for specific actions to
13 avoid suspension; and

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

19 “(d) REINSTATEMENT.—Upon a determination by
20 the Food and Drug Administration that adequate grounds
21 do not exist to continue the suspension actions, the Food
22 and Drug Administration shall promptly vacate the sus-
23 pension and reinstate the registration of the facility or the
24 cosmetic ingredient statement.

25 “(e) EFFECT OF SUSPENSION.—

1 “(1) REGISTRATION.—If the registration of a
2 facility is suspended under this section, no person
3 shall import or export cosmetics or otherwise dis-
4 tribute cosmetics from such facility.

5 “(2) COSMETIC INGREDIENT STATEMENT.—If
6 the cosmetic ingredient statement for a cosmetic
7 product is suspended under this section, no person
8 shall import or export such cosmetic product or oth-
9 erwise distribute in the United States such cosmetic
10 product that is the subject of such statement.

11 “(f) NO DELEGATION.—The authority conferred by
12 this section to issue an order to suspend a registration
13 or vacate an order of suspension shall not be delegated
14 to any officer or employee other than the Commissioner.”.

15 **SEC. 102. REVIEW OF INGREDIENTS AND NON-FUNCTIONAL**
16 **CONSTITUENTS; SAFETY OF FINISHED PROD-**
17 **UCTS.**

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

22 **“SEC. 608. REVIEW OF INGREDIENTS AND NON-FUNC-**
23 **TIONAL CONSTITUENTS.**

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

1 “(1) IN GENERAL.—Beginning in fiscal year
2 2016, the Food and Drug Administration shall re-
3 view the safety of the cosmetic ingredients and non-
4 functional constituents under paragraph (3), as
5 modified under subsection (c), if applicable, and
6 issue an order under subsection (d) with respect to
7 the use of each such ingredient and presence of each
8 such non-functional constituent.

9 “(2) PUBLIC NOTICE AND COMMENT.—At the
10 initiation of the review of each cosmetic ingredient
11 or non-functional constituent, the Food and Drug
12 Administration shall open a docket for the submis-
13 sion of public comment and additional data relevant
14 to the safety of the ingredient or non-functional con-
15 stituent. The Food and Drug Administration shall
16 provide 60 days for public comment.

17 “(3) COSMETIC INGREDIENTS.—

18 “(A) INGREDIENTS TO BE CONSIDERED IN
19 FIRST YEAR.—During fiscal year 2016, the
20 Food and Drug Administration shall initiate the
21 review for safety of the following cosmetic in-
22 gredients:

23 “(i) Diazolidinyl urea.

24 “(ii) Lead acetate.

1 “(iii) Methylene glycol/methanediol/
2 formaldehyde.

3 “(iv) Propyl paraben.

4 “(v) Quaternium-15.

5 “(B) INGREDIENTS TO BE CONSIDERED IN
6 SUBSEQUENT YEARS.—

7 “(i) IN GENERAL.—Beginning in fis-
8 cal year 2017, the Food and Drug Admin-
9 istration shall annually select and complete
10 a review of at least 5 cosmetic ingredients
11 or non-functional constituents that were
12 not reviewed in the prior 3 years from a
13 list determined in consultation with indus-
14 try and consumer groups for review of
15 safety. The Food and Drug Administration
16 may modify such list under subsection (c).

17 “(ii) CONSIDERATIONS.—The deter-
18 mination of which ingredients or functional
19 ingredients will be reviewed in a given year
20 shall be publicized in annual reports to
21 Congress and the public, in accordance
22 with section 618, and subject to consulta-
23 tion as provided for in clause (iii). The re-
24 view of any cosmetic ingredient or non-
25 functional constituent shall commence with

1 a public announcement by the Food and
2 Drug Administration and the opening of a
3 docket as required under paragraph (2).

4 “(iii) CONSULTATION.—The Food and
5 Drug Administration shall establish a Cos-
6 metics Safety Advisory Committee, which
7 shall include equal numbers of individuals
8 from the cosmetics industry and consumer
9 groups, and other individuals, as the Food
10 and Drug Administration determines ap-
11 propriate, including medical practitioners.
12 Such advisory committee shall advise the
13 Food and Drug Administration on cos-
14 metic ingredients and non-functional con-
15 stituents to be considered for review, sum-
16 marize public comments received pursuant
17 to paragraph (4), and recommend 5 cos-
18 metic ingredients or non-functional con-
19 stituents to be reviewed for safety each
20 year, as described in clause (i). The Food
21 and Drug Administration may consult with
22 the Cosmetics Safety Advisory Committee
23 on other matters pertaining to cosmetic
24 safety.

1 “(4) COMMENT PERIOD.—As part of the annual
2 reporting to Congress and the public under section
3 618, the Food and Drug Administration shall solicit
4 public comment on which cosmetic ingredients or
5 non-functional constituents on the list are of great-
6 est interest to be reviewed next for early review and
7 which additional cosmetic ingredients or non-func-
8 tional constituents should be added to the list. The
9 public may submit comments to the Food and Drug
10 Administration at any time during the year regard-
11 ing which cosmetic ingredients or non-functional
12 constituents of interest that the Food and Drug Ad-
13 ministration may consider during that year or subse-
14 quent years.

15 “(b) LIST.—The Food and Drug Administration
16 shall maintain a list, posted on the Internet website of the
17 Food and Drug Administration, of the cosmetic ingredi-
18 ents and non-functional constituents for which final orders
19 have been issued under subsection (d)(3), the finding
20 made for each such ingredient or non-functional con-
21 stituent under subsection (d)(4), as modified by any order
22 under subsection (f), and, if applicable, compliance dates
23 that are the subject of a final order under subsection (e).

24 “(c) INITIATIVE OF THE FDA.—The Food and Drug
25 Administration may at any time, after consultation with

1 the Cosmetics Safety Advisory Committee, propose the
2 issuance of an order on the safety of a cosmetic ingredient
3 or non-functional constituent that was not previously list-
4 ed in subsection (a) or under section 618(a)(3).

5 “(d) DETERMINATION ON SAFETY.—

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

20 “(2) PUBLIC COMMENT.—Upon publication of
21 the proposed administrative order described in para-
22 graph (1), the Food and Drug Administration shall
23 open a docket for the submission of public comment.
24 The Food and Drug Administration shall provide 30

1 days for public comment following publication of the
2 proposed administrative order.

3 “(3) FINAL ADMINISTRATIVE ORDER.—Fol-
4 lowing the public comment period described in para-
5 graph (2) and consideration of comments to the pub-
6 lic docket and any other information before the Food
7 and Drug Administration, the Food and Drug Ad-
8 ministration shall determine whether there is ade-
9 quate evidence to make a final finding on the safety
10 of the ingredient or non-functional constituent. If
11 the Food and Drug Administration determines that
12 there is adequate evidence, the Food and Drug Ad-
13 ministration shall issue a final administrative order
14 and shall post such order on the Internet website of
15 the Food and Drug Administration, notwithstanding
16 subchapter II of chapter 5 of title 5, United States
17 Code.

18 “(4) DETERMINATIONS.—In the proposed ad-
19 ministrative order or the final administrative order,
20 as applicable, the Food and Drug Administration
21 shall make a determination that the ingredient or
22 non-functional constituent is—

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

1 “(B) safe in cosmetic products without the
2 need for specified conditions of use or toler-
3 ances; or

4 “(C) not safe in cosmetic products.

5 “(5) CONDITIONS OF USE AND TOLERANCES.—

6 An order under paragraph (4)(A) shall include such
7 conditions on the use of an ingredient or such toler-
8 ances on the presence of a non-functional con-
9 stituent as are necessary for the safety of cosmetic
10 products containing such ingredient or non-func-
11 tional constituent, including—

12 “(A) limits on the amount or concentration
13 of the ingredient or non-functional constituent
14 that may be present in a cosmetic product, in-
15 cluding limits in products intended for children
16 and other vulnerable populations, and limits on
17 use near the eye or mucosal membranes;

18 “(B) warnings that are necessary or appro-
19 priate under section 614, including warnings re-
20 lated to use by children, pregnant women, popu-
21 lations with high exposure to the ingredient
22 (such as workers who are exposed through pro-
23 duction practices or handling of final products),
24 or other vulnerable populations, to help ensure

1 safe use of cosmetic products containing the in-
2 gredient or non-functional constituent; and

3 “(C) such other conditions as are nec-
4 essary for the safety of cosmetic products con-
5 taining such ingredient or non-functional con-
6 stituent.

7 “(6) PUBLIC NOTICE.—A final order under this
8 subsection shall set forth the determination of the
9 Food and Drug Administration on safety, any condi-
10 tions of use or tolerances under subparagraph (A) or
11 (B) of paragraph (4) and a summary of the valid
12 scientific evidence supporting the finding. The order
13 shall be effective upon its publication on the Internet
14 website of the Food and Drug Administration and
15 shall be considered final agency action.

16 “(e) ORDER.—If the Food and Drug Administration
17 issues a final administrative order under subparagraph
18 (A) or (C) of subsection (d)(4), the Food and Drug Ad-
19 ministration shall, at the same time as publication of the
20 notice under subsection (d)(6), publish a proposed order
21 identifying dates by which use of the ingredient or non-
22 functional constituent in cosmetic products shall comply
23 with the final administrative order, and provide 60 days
24 for public comment, including comment on whether com-
25 pliance is feasible within the proposed dates. After consid-

1 ering comments on the proposed order, the Food and
2 Drug Administration shall publish in the Federal Register
3 a final order.

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

9 “(g) INADEQUATE EVIDENCE.—

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

17 “(A) publish such finding on the Internet
18 website of the Food and Drug Administration
19 not later than 90 days after the close of the rel-
20 evant comment period for the ingredient or
21 non-functional constituent under subsection
22 (a)(2), in the case of a proposed order, or sub-
23 section (d)(2), in the case of a final order; and

24 “(B)(i) include a notice providing inter-
25 ested persons an additional 30 days from the

1 notice date to provide additional data and infor-
2 mation; and

3 “(ii) if, after the 30-day period under
4 clause (i), the Food and Drug Administration
5 determines that additional safety substantiation
6 with respect to such ingredient or non-func-
7 tional constituent is necessary to make a safety
8 determination, include a notice specifying an
9 additional time period, not to exceed 18 months
10 from the notice date, and plan to obtain such
11 data and information.

12 “(2) DETERMINATION; ORDER.—

13 “(A) INADEQUATE DATA AND INFORMA-
14 TION.—If the Food and Drug Administration
15 determines, after considering any additional
16 data and information submitted under para-
17 graph (1)(B), that the available data and infor-
18 mation still are not adequate to make a deter-
19 mination regarding safety under subsection
20 (d)(4), the Food and Drug Administration
21 shall, within 90 days of the close of the addi-
22 tional time period provided under paragraph
23 (1)(B), issue a proposed order or a final admin-
24 istrative order—

1 “(i) making a determination that the
2 ingredient or non-functional constituent
3 has not been shown to be safe in cosmetic
4 products; and

5 “(ii) explaining why the available data
6 and information are not adequate to assess
7 the safety of the ingredient or non-func-
8 tional constituent.

9 “(B) ADEQUATE DATA AND INFORMA-
10 TION.—If the Food and Drug Administration
11 determines, after considering any additional
12 data and information submitted under para-
13 graph (1)(B), that the available data and infor-
14 mation are adequate to make a determination
15 regarding safety under subsection (d)(4), the
16 Food and Drug Administration shall, within
17 180 days of the close of the comment period,
18 issue a proposed order, followed by a final
19 order, on such cosmetic ingredient or non-func-
20 tional constituent, in accordance with such sub-
21 section.

22 “(h) SAFETY ASSESSMENT.—

23 “(1) IN GENERAL.—In assessing the safety of
24 an ingredient or non-functional constituent, the
25 Food and Drug Administration shall consider wheth-

1 er there is adequate evidence to support a reasonable
2 certainty among competent scientists that the ingre-
3 dient is not harmful under the recommended or sug-
4 gested conditions of use or customary or usual use,
5 or that a non-functional constituent is not harmful
6 under the recommended or suggested tolerance levels
7 or the level at which it is customarily or usually
8 present. The Food and Drug Administration may
9 not consider an ingredient or non-functional con-
10 stituent harmful solely because it can cause minor
11 adverse health reactions, such as minor transient al-
12 lergic reactions or minor transient skin irritations,
13 in some users.

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

18 “(A) The probable human exposure to the
19 ingredient or non-functional constituent from
20 expected use in cosmetics.

21 “(B) The probable cumulative and aggre-
22 gate effect in humans of relevant exposure to
23 the ingredient or non-functional constituent or
24 to any chemically or pharmacologically related
25 substances from use in cosmetics or other prod-

1 ucts with similar routes of exposure under rec-
2 ommended or suggested conditions of use or
3 their customary use, to the extent adequate
4 data is available for analysis. In appropriate
5 cases, the Food and Drug Administration may
6 consider available information on the total expo-
7 sure to an ingredient or non-functional con-
8 stituent from all sources.

9 “(C) Whether warnings or recommenda-
10 tions in a product label, as part of any condi-
11 tions of use or tolerances imposed by the Food
12 and Drug Administration, would be necessary
13 and appropriate to help ensure the safety of the
14 ingredient or non-functional constituent.

15 “(3) DATA AND INFORMATION.—

16 “(A) REQUIRED INFORMATION.—A deter-
17 mination that an ingredient or non-functional
18 constituent is safe in cosmetics shall be based
19 upon adequate evidence submitted or otherwise
20 known to the Food and Drug Administration,
21 which shall include full reports of all available
22 studies, published or unpublished, that are ade-
23 quately designed to show whether the ingredient
24 or non-functional constituent is safe. Such stud-
25 ies may include in vitro and in silico studies

1 and epidemiological studies, biomonitoring stud-
2 ies, and studies focused on various points dur-
3 ing the lifespan of the subject, that use scientif-
4 ically valid methodology.

5 “(B) ADDITIONAL RELEVANT INFORMA-
6 TION.—The Food and Drug Administration
7 shall consider any other relevant information
8 related to the safety of the ingredient or non-
9 functional constituent, including—

10 “(i) adverse event reports;

11 “(ii) findings and information from
12 State, Federal, national, and international
13 entities and other bodies composed of sci-
14 entific and medical experts;

15 “(iii) if the ingredient or non-func-
16 tional constituent is lawfully used or
17 present in other products regulated by the
18 Food and Drug Administration, the sci-
19 entific basis for such use; and

20 “(iv) experience with the ingredient or
21 non-functional constituent in products that
22 are distributed in the United States or in
23 other countries, if such experience is well-
24 documented and has resulted in substantial

1 human exposure to the ingredient or non-
2 functional constituent over time.”.

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

4 “(a) DETERMINATION.—

5 “(1) IN GENERAL.—Each responsible person
6 for a finished cosmetic product shall, before first dis-
7 tributing the product for sale, make a written deter-
8 mination that the product is safe under the condi-
9 tions of use recommended in the labeling of the
10 product. Such determination shall be based on ade-
11 quate evidence that each ingredient in the finished
12 product is safe for the use recommended or sug-
13 gested in the labeling of the product and that the
14 finished product is safe.

15 “(2) NEW INFORMATION.—If new information
16 relevant to the determination becomes available, the
17 responsible person shall promptly update the deter-
18 mination to address that information.

19 “(3) SAFETY WITH RESPECT TO RANGES OF
20 POSSIBLE AMOUNTS.—In the case of a cosmetic
21 product for which there is a range of possible
22 amounts of cosmetic ingredients included in the cos-
23 metic ingredient statement, as described in section
24 606(c)(2)(E), the safety determination under para-

1 graph (1) shall include substantiation of the safety
2 of the full range in the finished product.

3 “(b) PRESUMPTION OF ADEQUATE EVIDENCE.—

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

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

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

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

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

21 “(2) STATEMENT OF AN EXPERT MEDICAL OR
22 SCIENTIFIC BODY.—For purposes of this section, a
23 statement of an expert medical or scientific body is
24 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 under subsection (b); or

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

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

16 “(e) **RECORDS MAINTENANCE.**—The responsible per-
17 son shall maintain records documenting the determination
18 required under this section and the information on which
19 it is based until 5 years after the finished product is no
20 longer marketed.

21 “(f) **SUBMISSION OF RECORDS.**—

22 “(1) **IN GENERAL.**—The records required under
23 subsection (e) shall, upon the written request of the
24 Food and Drug Administration to the responsible
25 person, be provided to the Food and Drug Adminis-

1 tration within a reasonable timeframe not to exceed
2 60 days, in either electronic or paper form.

3 “(2) CRITERIA.—The Food and Drug Adminis-
4 tration may require records under paragraph (1)
5 if—

6 “(A) the Food and Drug Administration
7 has a reasonable belief, described in written no-
8 tice, that—

9 “(i) the finished product may be
10 harmful based on adverse event reports or
11 other scientific information;

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

15 “(iii) the responsible person has not
16 made the determination required under
17 subsection (a), or such determination is
18 not supported by adequate evidence; or

19 “(iv) one or more of the criteria to es-
20 tablish a presumption of adequate evidence
21 of safety in subsection (b) has not been
22 satisfied;

23 “(B) the Food and Drug Administration,
24 an expert regulatory body, or an expert body
25 composed of scientific and medical experts finds

1 an ingredient in the product to be unsafe under
2 the conditions of use of the product; or

3 “(C) the Food and Drug Administration
4 concludes that submission of the records will
5 serve the public health or otherwise enable the
6 Food and Drug Administration to fulfill the
7 cosmetic safety purposes of this section.

8 “(g) GUIDANCE AND REGULATIONS.—

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

17 “(2) SMALL BUSINESSES.—The Food and Drug
18 Administration shall, after consultation with the
19 Small Business Administration and small businesses
20 that manufacture cosmetics, provide additional guid-
21 ance for small businesses on compliance with the re-
22 quirements of this section. Such guidance shall in-
23 clude specific examples of options for compliance
24 that do not place an undue burden on small busi-
25 nesses.”.

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

5 **SEC. 103. GOOD MANUFACTURING PRACTICES FOR COS-**
6 **METICS.**

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

11 **“SEC. 610. GOOD MANUFACTURING PRACTICES FOR COS-**
12 **METICS.**

13 “(a) IN GENERAL.—The Food and Drug Administra-
14 tion shall review national and international standards for
15 cosmetic good manufacturing practices that are in exist-
16 ence on the date of enactment of the Personal Care Prod-
17 ucts Safety Act and shall develop and implement, through
18 regulations, United States standards consistent, to the ex-
19 tent the Food and Drug Administration determines prac-
20 ticable and appropriate, with such national and inter-
21 national standards for cosmetic good manufacturing prac-
22 tices to ensure that requirements of this chapter with re-
23 spect to the manufacture of cosmetic products are in har-
24 mony.

1 “(b) TIMEFRAME.—The Food and Drug Administra-
2 tion shall publish a proposed rule described in subsection
3 (a) not later than 18 months after the date of enactment
4 of the Personal Care Products Safety Act and shall pub-
5 lish a final such rule not later than 3 years after such
6 date of enactment.”.

7 (b) EFFECTIVE DATE FOR COSMETIC MANUFACTUR-
8 ERS.—

9 (1) LARGE BUSINESSES.—For businesses of a
10 size greater than the Small Business Administra-
11 tion’s standard for a small business, section 610 of
12 the Federal Food, Drug, and Cosmetic Act (as
13 added by subsection (a)) shall take effect beginning
14 180 days after the date on which the Food and
15 Drug Administration makes effective cosmetic good
16 manufacturing practices.

17 (2) SMALL BUSINESSES.—For businesses of a
18 size that meets the Small Business Administration’s
19 standard for a small business, section 610 of the
20 Federal Food, Drug, and Cosmetic Act (as added by
21 subsection (a)) shall take effect beginning 2 years
22 after the date the Food and Drug Administration
23 makes effective cosmetic good manufacturing prac-
24 tices.

1 (c) ENFORCEMENT.—Section 601 of Chapter VI of
2 the Federal Food, Drug, and Cosmetic Act (21 U.S.C.
3 361) is amended by adding at the end the following:

4 “(f) If the methods used in, or the facilities or con-
5 trols used for, its manufacture, processing, packing, or
6 holding do not conform to current good manufacturing
7 practice, as prescribed by the Food and Drug Administra-
8 tion.”.

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 and infec-
16 tions; 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), the responsible
24 person shall submit a serious adverse event report to
25 the Food and Drug Administration not later than 15

1 business days after information concerning the ad-
2 verse event is received. If a serious adverse event re-
3 port for a cosmetic with drug properties is filed
4 using Form FDA 3500A (or any successor form de-
5 veloped for such purpose) or its electronic equivalent
6 for over-the-counter drugs, the responsible person
7 shall not have to submit a duplicative serious ad-
8 verse event report under this section.

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

17 “(3) ANNUAL REPORT.—

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

23 “(B) CONTENTS.—Each report under this
24 paragraph shall contain a summary of all ad-
25 verse events received during the reporting pe-

1 riod, a complete list of individual reports, and
2 an estimate of the total number of product
3 units estimated to have been distributed to con-
4 sumers during such period. The report shall not
5 include consumer complaints that are solely re-
6 garding efficacy and do not contain any infor-
7 mation about an adverse event. The Food and
8 Drug Administration shall further specify the
9 contents of the annual electronic report by reg-
10 ulation or guidance.

11 “(4) EXEMPTION.—The Food and Drug Ad-
12 ministration may establish by regulation an exemp-
13 tion to any of the requirements under this sub-
14 section if the Food and Drug Administration deter-
15 mines that such exemption is supported by adequate
16 evidence and would have no adverse effect on public
17 health.

18 “(d) REQUIREMENTS.—

19 “(1) IN GENERAL.—Each serious adverse event
20 report under this section shall be submitted to the
21 Food and Drug Administration using an electronic
22 system of the Food and Drug Administration. The
23 Food and Drug Administration shall make such elec-
24 tronic system available not later than 1 year after

1 the date of enactment of the Personal Care Products
2 Safety Act.

3 “(2) MODIFICATION.—The format of the re-
4 porting system may be modified by the Food and
5 Drug Administration and the reports may include
6 additional information. The Food and Drug Admin-
7 istration may, in guidance, further specify the for-
8 mat and contents of required reports.

9 “(3) SCOPE OF SERIOUS ADVERSE EVENT RE-
10 PORT.—A serious adverse event report (including all
11 information submitted in the initial report or added
12 later) submitted to the Food and Drug Administra-
13 tion under subsection (a) includes—

14 “(A) a report under section 756 with re-
15 spect to safety and related to a specific cos-
16 metic product;

17 “(B) a record about an individual who suf-
18 fered the serious adverse event under section
19 552a of title 5, United States Code;

20 “(C) a medical or similar file documenting
21 the serious adverse event, the disclosure of
22 which would constitute a violation of section
23 552(b)(6) of such title 5, and shall not be pub-
24 licly disclosed unless all personally identifiable
25 information is redacted; and

1 “(D) contact information for the individual
2 reporting the serious adverse event.

3 “(4) RESPONSIBILITY TO GATHER INFORMA-
4 TION.—After an individual initiates the reporting of
5 a serious adverse event, the responsible person for
6 the cosmetic product shall actively gather all of the
7 information to complete and file the report with the
8 Food and Drug Administration.

9 “(5) NO ADVERSE EVENTS TO REPORT.—The
10 Food and Drug Administration shall provide an op-
11 tion as part of the electronic registration process for
12 the responsible person to indicate if such responsible
13 person had no adverse events to report over the pre-
14 vious year. With respect to a responsible person who
15 received no adverse event reports for a year, the an-
16 nual adverse event report requirement may be met
17 by indicating no such events on the annual registra-
18 tion form.

19 “(e) LIMITATION WITH RESPECT TO ADVERSE
20 EVENT REPORTS.—The submission of an adverse event
21 report in compliance with subsection (a) shall not con-
22 stitute an admission that the cosmetic involved caused or
23 contributed to the adverse event.

24 “(f) CONTACT INFORMATION.—The label of a cos-
25 metic shall bear the domestic telephone number or elec-

1 tronic contact information, and it is encouraged that the
2 label include both the telephone number and electronic
3 contact information, through which the responsible person
4 may receive a report of an adverse event.

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

9 “(h) AVAILABILITY TO STATES.—The Food and
10 Drug Administration shall make available records sub-
11 mitted under this section to any State, upon request. In-
12 formation disclosed to a State that is exempt from dislo-
13 sure under section 552(b)(4) of title 5, United States
14 Code, shall be treated as a trade secret and confidential
15 information by the State.

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

1 **SEC. 105. RECORDS INSPECTION; MANDATORY RECALL AU-**
2 **THORITY.**

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

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

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

15 “(1) all records maintained under section 611
16 and in accordance with the rules promulgated by the
17 Food and Drug Administration under section 610,
18 as applicable; and

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

22 “(A) has a reasonable belief that the cos-
23 metic—

24 “(i) is adulterated;

25 “(ii) has caused a reportable serious
26 adverse event; or

1 “(iii) contains an ingredient that sub-
2 stantial new scientific information shows
3 may be unsafe when present in a cosmetic;
4 and

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

8 “(b) EXCLUSIONS.—No inspection authorized by this
9 section shall extend to financial data, pricing data, per-
10 sonnel data (other than data as to qualification of tech-
11 nical and professional personnel performing functions sub-
12 ject to this Act), research data (other than safety data)
13 or sales data other than shipment data.

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

18 “(d) PROTECTION OF SENSITIVE INFORMATION.—
19 The Food and Drug Administration shall take appropriate
20 measures to ensure that there are effective procedures to
21 prevent the unauthorized disclosure of any trade secret or
22 confidential information that is obtained by the Food and
23 Drug Administration pursuant to this section. Information
24 disclosed to a State that is exempt from disclosure under
25 section 552(b)(4) of title 5, United States Code, shall be

1 treated as a trade secret and confidential information by
2 the State.

3 “(e) LIMITATIONS.—This section shall not be con-
4 strued—

5 “(1) to limit the authority of the Food and
6 Drug Administration to inspect records or to require
7 establishment and maintenance of records under any
8 other provision of this Act; or

9 “(2) to have any legal effect on section 552 of
10 title 5, United States Code, or section 1905 of title
11 18, United States Code.”.

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

13 “(a) VOLUNTARY PROCEDURES.—If the Food and
14 Drug Administration determines that there is a reasonable
15 probability that a cosmetic is adulterated under section
16 601 or misbranded under section 602 and the use of or
17 exposure to such cosmetic is likely to cause serious adverse
18 health consequences or death, the Food and Drug Admin-
19 istration shall provide the responsible person with an op-
20 portunity to voluntarily cease distribution and recall such
21 article.

22 “(b) PREHEARING ORDER TO MANDATORILY CEASE
23 DISTRIBUTION AND GIVE NOTICE.—

24 “(1) IN GENERAL.—If the responsible person
25 refuses to or does not voluntarily cease distribution

1 or recall such cosmetic within the time and in the
2 manner prescribed by the Food and Drug Adminis-
3 tration, the Food and Drug Administration may
4 order such person to—

5 “(A) immediately cease distribution of
6 such cosmetic; and

7 “(B) as applicable, immediately notify all
8 persons—

9 “(i) manufacturing, processing, pack-
10 ing, transporting, holding, receiving, dis-
11 tributing, or importing and selling such
12 cosmetic; and

13 “(ii) to which such cosmetic has been
14 distributed, transported, or sold,
15 to immediately cease distribution of such cos-
16 metic.

17 “(2) REQUIRED ADDITIONAL INFORMATION.—

18 “(A) IN GENERAL.—If a cosmetic covered
19 by a recall order issued under paragraph (1)(B)
20 has been distributed to a warehouse-based third
21 party logistics provider without providing such
22 provider sufficient information to know or rea-
23 sonably determine the precise identity of such
24 cosmetic covered by a recall order that is in its
25 possession, the notice provided by the respon-

1 sible person subject to the order issued under
2 paragraph (1)(B) shall include such information
3 as is necessary for the warehouse-based third
4 party logistics provider to identify the cosmetic.

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

7 “(i) to exempt a warehouse-based
8 third party logistics provider from the re-
9 quirements of this chapter, including the
10 requirements of this section and section
11 612; or

12 “(ii) to exempt a warehouse-based
13 third party logistics provider from being
14 the subject of a mandatory recall order.

15 “(3) DETERMINATION TO LIMIT AREAS AF-
16 FFECTED.—If the Food and Drug Administration re-
17 quires a responsible person to cease distribution
18 under paragraph (1)(A) of a cosmetic, the Food and
19 Drug Administration may limit the size of the geo-
20 graphic area and the markets affected by such ces-
21 sation if such limitation would not compromise the
22 public health.

23 “(c) HEARING ON ORDER.—The Food and Drug Ad-
24 ministration shall provide the responsible party subject to
25 an order under subsection (b) with an opportunity for an

1 informal hearing, to be held as soon as possible, but not
2 later than 2 days after the issuance of the order, on the
3 actions required by the order and on why the cosmetic that
4 is the subject of the order should not be recalled.

5 “(d) POST-HEARING RECALL ORDER AND MODIFICA-
6 TION OF ORDER.—

7 “(1) AMENDMENT OF ORDER.—If, after pro-
8 viding opportunity for an informal hearing under
9 subsection (c), the Food and Drug Administration
10 determines that removal of the cosmetic from com-
11 merce is necessary, the Food and Drug Administra-
12 tion shall, as appropriate—

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

15 “(B) specify a timetable in which the recall
16 shall occur;

17 “(C) require periodic reports to the Food
18 and Drug Administration describing the
19 progress of the recall; and

20 “(D) provide notice to consumers to whom
21 such cosmetic was, or may have been, distrib-
22 uted.

23 “(2) VACATING OF ORDER.—If, after such hear-
24 ing, the Food and Drug Administration determines
25 that adequate grounds do not exist to continue the

1 actions required by the order, or that such actions
2 should be modified, the Food and Drug Administra-
3 tion shall vacate the order or modify the order.

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

8 “(f) PUBLIC NOTIFICATION.—In conducting a recall
9 under this section, the Food and Drug Administration
10 shall—

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

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

18 “(B) that includes, at a minimum—

19 “(i) the name of the cosmetic subject
20 to the recall;

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

23 “(iii) to the extent practicable, infor-
24 mation for consumers about similar cos-

1 metics that are not affected by the recall;
2 and

3 “(2) ensure publication on the Internet website
4 of the Food and Drug Administration an image of
5 the cosmetic that is the subject of the press release
6 described in paragraph (1), if available.

7 “(g) NO DELEGATION.—The authority conferred by
8 this section to order a recall or vacate a recall order shall
9 not be delegated to any officer or employee other than the
10 Commissioner.

11 “(h) EFFECT.—Nothing in this section shall affect
12 the authority of the Food and Drug Administration to re-
13 quest or participate in a voluntary recall, or to issue an
14 order to cease distribution or to recall under any other
15 provision of this chapter or under the Public Health Serv-
16 ice Act.”.

17 **SEC. 106. LABELING.**

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

22 **“SEC. 614. LABELING.**

23 “(a) SAFETY REVIEW AND LABELING.—Following a
24 review of cosmetic ingredients that determines that warn-
25 ings are required to help ensure safe use of cosmetic prod-

1 ucts under section 608(d)(5), the Food and Drug Admin-
 2 istration shall require labeling of cosmetics that are not
 3 appropriate for use in the entire population, including
 4 warnings that vulnerable populations, such as children or
 5 pregnant women, should limit or avoid using the product.

6 “(b) COSMETIC PRODUCTS FOR PROFESSIONAL
 7 USE.—

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

11 “(A) is licensed by an official State author-
 12 ity to practice in the field of cosmetology, nail
 13 care, barbering, and or esthetics;

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

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

18 “(2) LISTING OF INGREDIENTS.—Cosmetic
 19 products used and sold by professionals shall list all
 20 ingredients, as required for other cosmetic products
 21 under this chapter.

22 “(3) PROFESSIONAL USE LABELING.—In the
 23 case of a cosmetic product intended to be used only
 24 by a professional on account of a specific ingredient
 25 or increased concentration of an ingredient that re-

1 quires safe handling by trained professionals, the
2 product shall bear a statement as follows: ‘To be Ad-
3 ministered Only by Licensed Professionals’.

4 “(c) DISPLAY.—The warning required under sub-
5 section (a) and the statement required under subsection
6 (b)(3) shall be prominently displayed—

7 “(1) in the primary language used on the label;
8 and

9 “(2) in conspicuous and legible type in contrast
10 by typography, layout, or color with other material
11 printed or displayed on the label.

12 “(d) INTERNET SALES.—In the case of Internet sales
13 of cosmetics, each Internet website offering cosmetic prod-
14 ucts for sale to consumers shall provide the same informa-
15 tion that is included on the packaging of the cosmetic
16 products as regularly available, and the warnings and
17 statements described in subsection (c) shall be promi-
18 nently and conspicuously displayed on the website.

19 “(e) CONTACT INFORMATION.—The label on each
20 cosmetic shall bear the domestic telephone number or elec-
21 tronic contact information, and it is encouraged that the
22 label include both the telephone number and electronic
23 contact information, that consumers may use to contact
24 the responsible person with respect to adverse events. The
25 contact number shall provide a means for consumers to

1 obtain additional information about ingredients in a cos-
2 metic, including the ability to ask if a specific ingredient
3 may be present that is not listed on the label, including
4 whether a specific ingredient may be contained in the fra-
5 grance or flavor used in the cosmetic. The manufacturer
6 of the cosmetic is responsible for providing such informa-
7 tion, including obtaining the information from suppliers
8 if it is not readily available. Suppliers are required to re-
9 lease such information upon request of the cosmetic manu-
10 facturer.”.

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

15 **SEC. 107. COAL TAR CHEMICALS.**

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

19 **“SEC. 615. COAL TAR CHEMICALS.**

20 “(a) IN GENERAL.—Under section 608, the Food and
21 Drug Administration may review any cosmetic ingredient
22 in order to determine if it is safe in cosmetic products
23 without the need for specified conditions of use or toler-
24 ances, safe in cosmetic products under specified conditions
25 of use or tolerances, or not safe in cosmetic products.

1 “(b) COAL TAR HAIR DYES.—Specific chemicals in
2 coal tar hair dyes may be selected and reviewed under sec-
3 tion 608(a)(3).”.

4 **SEC. 108. ANIMAL TESTING ALTERNATIVES.**

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

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

9 “(a) IN GENERAL.—To minimize the use of animal
10 testing for safety of cosmetic ingredients, non-functional
11 constituents, and finished cosmetic products, the Food
12 and Drug Administration shall—

13 “(1) encourage the use of alternative testing
14 methods that provide information that is equivalent
15 or superior in scientific quality to the animal testing
16 method to—

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

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

23 “(2) encourage—

24 “(A) the sharing of data across companies
25 and organizations that are testing for safety in

1 cosmetics, so as to avoid duplication of animal
2 tests; and

3 “(B) funding for research and validation of
4 alternative testing methods.

5 “(b) GUIDANCE.—Not later than 3 years after the
6 date of enactment of the Personal Care Products Safety
7 Act, the Food and Drug Administration shall issue guid-
8 ance on the acceptability of scientifically reliable and rel-
9 evant alternatives to animal testing for the safety of cos-
10 metic ingredients, non-functional constituents, and fin-
11 ished cosmetic products, and encouraging the use of such
12 methods. The Food and Drug Administration shall update
13 such guidance on an annual basis.

14 “(c) RESOURCES REGARDING ANIMAL TESTING AL-
15 TERNATIVES.—Not later than 180 days after the date of
16 enactment of the Personal Care Products Safety Act, the
17 Food and Drug Administration shall provide information
18 on the Internet website of the Food and Drug Administra-
19 tion regarding resources available for information about
20 non-animal methods, and methods that reduce animal
21 usage, in testing for the safety of cosmetic ingredients,
22 non-functional constituents, and finished cosmetic prod-
23 ucts.”.

1 **SEC. 109. PREEMPTION.**

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

5 **“SEC. 617. PREEMPTION.**

6 “(a) REGISTRATION, GOOD MANUFACTURING PRAC-
7 TICES, RECALLS, ADVERSE EVENT REPORTING.—Except
8 for a State requirement that is in full effect and imple-
9 mented on the date of enactment of the Personal Care
10 Products Safety Act, no State or political subdivision of
11 a State may establish or continue in effect any require-
12 ment for cosmetics with respect to registration, good man-
13 ufacturing practices, mandatory recalls, or adverse event
14 reporting.

15 “(b) SAFETY OF COSMETIC INGREDIENTS AND NON-
16 FUNCTIONAL CONSTITUENTS.—

17 “(1) IN GENERAL.—Except for a State require-
18 ment that is more restrictive than a final order
19 issued under section 608(d)(3) and that is in full ef-
20 fect and implemented on the date of enactment of
21 the Personal Care Products Safety Act, no State or
22 political subdivision of a State may establish or con-
23 tinue in effect any requirement with respect to the
24 safety of a cosmetic ingredient or non-functional
25 constituent that is the subject of a final order under

1 section 608(d)(3) that is different from, or in addi-
2 tion to, a final order issued under section 608(d)(3).

3 “(2) DELAYED EFFECT OF NEW STATE RE-
4 QUIREMENTS.—From the date that the Food and
5 Drug Administration has made public the final selec-
6 tion of a cosmetic ingredient or non-functional con-
7 stituent to be reviewed in the coming year under sec-
8 tion 608(a)(3)(B), and opened the public comment
9 period under section 608(a)(2), until the date that
10 is one year after the Food and Drug Administration
11 has made public such selection, no State or political
12 subdivision of a State may establish any new re-
13 quirement related to such cosmetic ingredient or
14 non-functional constituent.

15 “(3) SCOPE.—This subsection shall not be con-
16 strued to modify or affect the authority of a State
17 or political subdivision of a State with respect to
18 such safety requirements unrelated to the scope of
19 the safety assessment under section 608.

20 “(4) SENSE OF CONGRESS.—It is the sense of
21 Congress that a State or political subdivision that
22 regulates the safety of cosmetics with respect to the
23 health of humans beyond the scope of section 608
24 should utilize the safety assessment criteria de-
25 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) RULE OF CONSTRUCTION REGARDING PRODUCT
15 LIABILITY.—Notwithstanding any other provision of this
16 Act, no provision of this chapter relating to a cosmetic
17 shall be construed to modify or otherwise affect any action
18 or the liability of any person under State or Federal com-
19 mon law.

20 “(e) LIMITATION.—The Personal Care Products
21 Safety Act, including the amendments made by such Act,
22 shall not be construed to preempt any State statute, public
23 initiative, referendum, or common law, except as expressly
24 provided in this section.”.

1 **SEC. 110. REPORTING.**

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

5 **“SEC. 618. REPORTING.**

6 “(a) PERFORMANCE REPORT.—Beginning with fiscal
7 year 2016, and not later than 60 days prior to the end
8 of each fiscal year for which fees are collected under sec-
9 tion 744L, the Food and Drug Administration shall pre-
10 pare and submit to Congress a report concerning the
11 progress of the Food and Drug Administration in achiev-
12 ing the objectives of the Personal Care Products Safety
13 Act during such fiscal year and the future plans of the
14 Food and Drug Administration for meeting the objectives.
15 The annual report for a fiscal year shall include—

16 “(1) the number of registered facilities and cos-
17 metic ingredient statements on file with the Food
18 and Drug Administration;

19 “(2) identification of the cosmetic ingredients
20 and non-functional constituents that have been fully
21 reviewed for safety by the Food and Drug Adminis-
22 tration in the prior fiscal year and for which a final
23 administrative order has been released;

24 “(3) identification of at least 5 specific cosmetic
25 ingredients and non-functional constituents that will

1 be reviewed by the Food and Drug Administration
2 in the next fiscal year;

3 “(4) the number of facilities inspected and
4 mandatory recalls that transpired during that fiscal
5 year;

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

9 “(6) any trends identified by the Food and
10 Drug Administration about adverse event reports re-
11 lated to specific cosmetic ingredients or non-func-
12 tional constituents; and

13 “(7) efforts of the Food and Drug Administra-
14 tion to reduce animal testing for safety of cosmetic
15 ingredients, non-functional constituents, and cos-
16 metic products.

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

22 “(c) PUBLIC INPUT ON SAFETY REVIEW.—Upon re-
23 lease of the report described in subsection (a), the Food
24 and Drug Administration shall provide the public with an
25 opportunity to provide feedback on subsection (a)(3) by—

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

3 “(A) recommend additional cosmetic ingre-
4 dients and non-functional constituents to be
5 considered for review for safety in future years;
6 and

7 “(B) comment on the priorities for the spe-
8 cific cosmetic ingredients and non-functional
9 constituents that the Food and Drug Adminis-
10 tration anticipates will be reviewed in the next
11 fiscal year;

12 “(2) announcing on the Internet website of the
13 Food and Drug Administration, within the first 30
14 days of the new fiscal year, any amendments to sub-
15 section (a)(3) based on public input, pursuant to
16 paragraph (1); and

17 “(3) together with the final announcement of 5
18 specific cosmetic ingredients and non-functional con-
19 stituents that will be reviewed in the coming year
20 under subsection (a)(3), providing a comment period
21 for further public input, pursuant to section
22 608(a)(2).”.

1 **SEC. 111. SMALL BUSINESSES.**

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

5 **“SEC. 619. SMALL BUSINESSES.**

6 “The Commissioner, in coordination with the Admin-
7 istrator of the Small Business Administration, shall pro-
8 vide technical assistance, such as guidance and expertise,
9 to small businesses regarding compliance with the Per-
10 sonal Care Products Safety Act, including the amend-
11 ments made by such Act.”.

12 **SEC. 112. APPLICABILITY WITH RESPECT TO CERTAIN COS-**
13 **METICS.**

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

17 **“SEC. 620. APPLICABILITY WITH RESPECT TO CERTAIN**
18 **COSMETICS.**

19 “In the case of a cosmetic product or a facility that
20 is subject to the requirements under this chapter and
21 chapter V, if any requirement under chapter V with re-
22 spect to such cosmetic or facility is substantially similar
23 to a requirement under this chapter, the cosmetic product
24 or facility shall be deemed to be in compliance with the
25 applicable requirement under this chapter if such product
26 or facility is in compliance with such substantially similar

1 requirement under chapter V, provided that the product
2 or facility has not obtained a waiver from the requirement
3 under chapter V.”.

4 **SEC. 113. ENFORCEMENT.**

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

8 (1) in subsection (e)—

9 (A) by striking “504, 564” and inserting
10 “504, 564, 611, or 612”; and

11 (B) by striking “519, 564” and inserting
12 “519, 564, 611,”;

13 (2) in subsection (j) by inserting “607, 608,
14 610,” before “704”;

15 (3) in subsection (ii)—

16 (A) by striking “760 or 761)” and insert-
17 ing “604, 760, or 761)”;

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

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

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

23 “(ddd) The failure to register in accordance with sec-
24 tion 605, the failure to submit a cosmetic ingredient state-
25 ment under section 606, the failure to provide any infor-

1 mation required by section 605 or 606, or the failure to
2 update the information required by section 605 or 606,
3 as required.”.

4 (b) ADULTERATION.—Section 601 of the Federal
5 Food, Drug, and Cosmetic Act (21 U.S.C. 361), as
6 amended by section 103, is further amended by adding
7 at the end the following:

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

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

19 (c) MISBRANDING.—Section 602 is amended—

20 (1) in subsection (b)—

21 (A) by striking “and (2)” and inserting
22 “(2)”; and

23 (B) by inserting “; and (3) a domestic ad-
24 dress or a domestic telephone number, and it is
25 encouraged that the label include both a domes-

1 tic address and a domestic telephone number,
2 through which the responsible person may re-
3 ceive a report of an adverse event associated
4 with the use of such cosmetic product” after
5 “numerical count”; and

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

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

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

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

21 (e) IMPORTS.—Section 801(a) is amended—

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

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

3 (f) **FACTORY INSPECTION.**—Section 704(a)(1) is
4 amended by inserting after the third sentence the fol-
5 lowing: “In the case of any person who manufactures,
6 processes, packs, holds, distributes, or imports a cosmetic
7 product, or distributes a cosmetic product and affixes its
8 name on the cosmetic label, the inspection shall extend
9 to all records and other information described in section
10 612 (regarding inspection of cosmetic records), when the
11 standard for records inspections under paragraph (1) or
12 (2) of subsection (a) of such section applies, subject to
13 the limitations under subsection (d) 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);

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

22 (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 2016, 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 cosmetic facility engaged
3 in manufacturing or processing, or whose name and
4 address appear on the label of a cosmetic product
5 distributed in the United States, except that this
6 subsection shall not apply to entities described in
7 subparagraphs (A) through (H) of section 604(3).

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

12 “(b) DEFINITIONS.—In this section:

13 “(1) ADJUSTMENT FACTOR.—The term ‘adjust-
14 ment factor’ applicable to a fiscal year means the
15 Consumer Price Index for all urban consumers (all
16 items; United States city average) for October of the
17 preceding fiscal year divided by such index for Octo-
18 ber 2015.

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

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

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

1 “(3) COSMETIC SAFETY ACTIVITIES.—The term
2 ‘cosmetic safety activities’—

3 “(A) means activities related to compliance
4 by registrants under section 605 with the re-
5 quirements of this Act with respect to cos-
6 metics, including—

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

15 “(ii) implementation and enforcement
16 activities, such as the establishment of
17 good manufacturing practices, the review
18 of adverse event reports, inspection plan-
19 ning and inspections, and use of enforce-
20 ment tools; and

21 “(B) includes activities related to imple-
22 mentation of section 608, regarding the review
23 of cosmetic ingredients and non-functional con-
24 stituents.

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

7 “(c) FEE SETTING AND AMOUNTS.—

8 “(1) IN GENERAL.—Subject to subsection (d),
9 the Food and Drug Administration shall establish
10 the fees to be collected under this section for each
11 fiscal year after fiscal year 2016, based on the meth-
12 odology described in paragraph (3)(B), and shall
13 publish such fees in a Federal Register notice not
14 later than 60 days before the beginning of each such
15 fiscal year.

16 “(2) FEE EXEMPTION.—Any registrant whose
17 average gross annual sales of cosmetic products in
18 the 3-year period immediately preceding the fiscal
19 year for which the annual fee will be paid was not
20 more than \$500,000, shall be exempt from registra-
21 tion fees under this section for that fiscal year.

22 “(3) ANNUAL FEE SETTING.—

23 “(A) FISCAL YEAR 2016.—For fiscal year
24 2016, to generate a total estimated revenue
25 amount of \$20,600,000, the amount of the reg-

1 istration fee under subsection (a) shall be as
2 follows:

3 “(i) TIER I–A.—For a registrant that
4 has gross annual sales of \$5,000,000,000
5 or more in 2015, \$1,100,000.

6 “(ii) TIER I–B.—For a registrant that
7 has gross annual sales of at least
8 \$4,000,000,000 per annum but less than
9 \$5,000,000,000 in 2015, \$840,000.

10 “(iii) TIER II–A.—For a registrant
11 that has gross annual sales of at least
12 \$3,000,000,000 per annum but less than
13 \$4,000,000,000 in 2015, \$720,000.

14 “(iv) TIER II–B.—For a registrant
15 that has gross annual sales of at least
16 \$2,000,000,000 per annum but less than
17 \$3,000,000,000 in 2015, \$600,000.

18 “(v) TIER III–A.—For a registrant
19 that has gross annual sales of at least
20 \$1,000,000,000 per annum but less than
21 \$2,000,000,000 in 2015, \$500,000.

22 “(vi) TIER III–B.—For a registrant
23 that has gross annual sales of at least
24 \$500,000,000 per annum but less than
25 \$1,000,000,000 in 2015, \$395,000.

1 “(vii) TIER IV-A.—For a registrant
2 that has gross annual sales of at least
3 \$200,000,000 per annum but less than
4 \$500,000,000 in 2015, \$325,000.

5 “(viii) TIER IV-B.—For a registrant
6 that has gross annual sales of at least
7 \$100,000,000 per annum but less than
8 \$200,000,000 in 2015, \$275,000.

9 “(ix) TIER V-A.—For a registrant
10 that has gross annual sales of at least
11 \$80,000,000 per annum but less than
12 \$100,000,000 in 2015, \$185,000.

13 “(x) TIER V-B.—For a registrant that
14 has gross annual sales of at least
15 \$60,000,000 per annum but less than
16 \$80,000,000 in 2015, \$95,000.

17 “(xi) TIER VI-A.—For a registrant
18 that has gross annual sales of at least
19 \$40,000,000 per annum but less than
20 \$60,000,000 in 2015, \$15,000.

21 “(xii) TIER IV-B.—For a registrant
22 that has gross annual sales of at least
23 \$20,000,000 per annum but less than
24 \$40,000,000 in 2015, \$12,000.

1 “(xiii) TIER VII–A.—For a registrant
2 that has gross annual sales of at least
3 \$2,500,000 per annum but less than
4 \$20,000,000 in 2015, \$500.

5 “(xiv) TIER VII–B.—For a registrant
6 that has gross annual sales of at least
7 \$500,000 per annum but less than
8 \$2,500,000 in 2015, \$250.

9 “(B) FISCAL YEARS 2017–2022.—For fiscal
10 years 2017–2022, fees under subsection (a)
11 shall be established to generate a total esti-
12 mated revenue amount of \$20,600,000, as ad-
13 justed by subsection (d). Of that amount:

14 “(i) TIER I–A.—Registrants that have
15 gross annual sales of \$5,000,000,000 or
16 more in the fiscal year immediately pre-
17 ceding the fiscal year in which the annual
18 fee will be paid, shall be responsible, collec-
19 tively, for 10.7 percent.

20 “(ii) TIER I–B.—Registrants that
21 have gross annual sales of at least
22 \$4,000,000,000 per annum but less than
23 \$5,000,000,000 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 4.1 percent.

3 “(iii) TIER II-A.—Registrants that
4 have gross annual sales of at least
5 \$3,000,000,000 per annum but less than
6 \$4,000,000,000 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 3.5 percent.

10 “(iv) TIER II-B.—Registrants that
11 have gross annual sales of at least
12 \$2,000,000,000 per annum but less than
13 \$3,000,000,000 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 2.9 percent.

17 “(v) TIER III-A.—Registrants that
18 have gross annual sales of at least
19 \$1,000,000,000 per annum but less than
20 \$2,000,000,000 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 7.3 percent.

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

1 \$500,000,000 per annum but less than
2 \$1,000,000,000 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 13.4 percent.

6 “(vii) TIER IV–A.—Registrants that
7 have gross annual sales of at least
8 \$200,000,000 per annum but less than
9 \$500,000,000 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 15.8 percent.

13 “(viii) TIER IV–B.—Registrants that
14 have gross annual sales of at least
15 \$100,000,000 per annum but less than
16 \$200,000,000 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 13.3 percent.

20 “(ix) TIER V–A.—Registrants that
21 have gross annual sales of at least
22 \$80,000,000 per annum but less than
23 \$100,000,000 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 9 percent.

3 “(x) TIER V-B.—Registrants that
4 have gross annual sales of at least
5 \$60,000,000 per annum but less than
6 \$80,000,000 in the fiscal year immediately
7 preceding the fiscal year in which the an-
8 nual fee will be paid, shall be responsible,
9 collectively, for 6.9 percent.

10 “(xi) TIER VI-A.—Registrants that
11 have gross annual sales of at least
12 \$40,000,000 per annum but less than
13 \$60,000,000 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 5.1 percent.

17 “(xii) TIER VI-B.—Registrants that
18 have gross annual sales of at least
19 \$20,000,000 per annum but less than
20 \$40,000,000 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 4.4 percent.

24 “(xiii) TIER VII-A.—Registrants that
25 have gross annual sales of at least

1 \$2,500,000 per annum but less than
2 \$20,000,000 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 1.2 percent.

6 “(xiv) TIER VII–B.—Registrants that
7 have gross annual sales of at least
8 \$500,000 per annum but less than
9 \$2,500,000 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 2.4 percent, except that no
13 such registrant shall be responsible for
14 more than \$250 per fiscal year.

15 “(d) ADJUSTMENTS.—

16 “(1) INFLATION ADJUSTMENT.—

17 “(A) IN GENERAL.—For fiscal year 2017
18 and each subsequent fiscal year, the revenues
19 and fee amounts under subsection (c)(3)(B)
20 shall be adjusted by the Food and Drug Admin-
21 istration in the annual Federal Register notice
22 establishing fees in subsection (c)(1), by an
23 amount equal to the sum of—

24 “(i) one;

1 “(ii) the average annual percent
2 change in the cost, per full-time equivalent
3 position of the Food and Drug Administra-
4 tion, of all personnel compensation and
5 benefits paid with respect to such positions
6 for the first 3 of the preceding 4 fiscal
7 years for which data are available, multi-
8 plied by the average proportion of per-
9 sonnel compensation and benefits costs to
10 total Food and Drug Administration costs
11 for the first 3 years of the preceding 4 fis-
12 cal years for which data are available; and

13 “(iii) the average annual percent
14 change that occurred in the Consumer
15 Price Index for urban consumers (Wash-
16 ington-Baltimore, DC6 MD-VA-WV; not
17 seasonally adjusted; all items less food and
18 energy; annual index) for the first 3 years
19 of the preceding 4 years for which data are
20 available multiplied by the average propor-
21 tion of all costs other than personnel com-
22 pensation and benefits costs to total Food
23 and Drug Administration costs for the
24 first 3 years of the preceding 4 fiscal years
25 for which data are available.

1 “(B) COMPOUNDED BASIS.—The adjust-
2 ment made each fiscal year under this sub-
3 section shall be added on a compounded basis
4 to the sum of all adjustments made each fiscal
5 year after fiscal year 2016 under this sub-
6 section.

7 “(2) FINAL YEAR ADJUSTMENT.—For fiscal
8 year 2022, the Food and Drug Administration may,
9 in addition to adjustments under paragraph (1), fur-
10 ther increase the fee revenues and fees established in
11 subsection (c) if such an adjustment is necessary to
12 provide for not more than 3 months of operating re-
13 serves of carryover fees for cosmetic safety activities
14 for the first 3 months of fiscal year 2023. If such
15 an adjustment is necessary, the rationale for the in-
16 crease, shall be contained in the annual Federal
17 Register notice establishing fees, in subsection
18 (c)(1), for fiscal year 2022. If the Food and Drug
19 Administration has carryover balances for such ac-
20 tivities in excess of 3 months of such operating re-
21 serves, the adjustment under this subparagraph
22 shall not be made.

23 “(3) WORKLOAD ADJUSTMENT.—

24 “(A) IN GENERAL.—For fiscal year 2017
25 and each subsequent fiscal year, after fee reve-

1 nues established in subsection (c)(3)(B) are ad-
2 justed for a fiscal year for inflation in accord-
3 ance with paragraph (1), the fee revenues shall
4 be adjusted further for each fiscal year to re-
5 flect changes in the workload of the Food and
6 Drug Administration for actual changes in
7 workload volume due to the process of reviewing
8 cosmetic ingredients or non-functional constitu-
9 ents not listed under section 608(b).

10 “(B) DETERMINATION OF ADJUSTMENT.—

11 The adjustment shall be determined by the
12 Food and Drug Administration based on the
13 workload in the most recent 1-year period for
14 which workload data is available. The Food and
15 Drug Administration shall publish in the Fed-
16 eral Register the fee revenues and fees resulting
17 from the adjustment and the supporting meth-
18 odologies.

19 “(C) MINIMUM REVENUES.—The adjust-

20 ment shall not result in fee revenues for a fiscal
21 year that are less than the sum of the amount
22 under subsection (c)(3)(B), as adjusted for in-
23 flation under subparagraph (1).

24 “(e) LIMITATIONS.—

1 “(1) IN GENERAL.—With respect to the amount
2 that, under the salaries and expenses account of the
3 Food and Drug Administration, is appropriated for
4 a fiscal year for the cosmetics program in the Center
5 for Food Safety and Applied Nutrition and related
6 field activities, fees may not be assessed under sub-
7 section (a) for the fiscal year unless the amount so
8 appropriated for the fiscal year (excluding the
9 amount of fees appropriated for the fiscal year), is
10 equal to or greater than that assessed for fiscal year
11 2015, multiplied by the adjustment factor applicable
12 to the fiscal year involved.

13 “(2) AUTHORITY.—If the Food and Drug Ad-
14 ministration does not assess fees under subsection
15 (a) during any portion of a fiscal year because of
16 paragraph (1) and if at a later date in such fiscal
17 year the Food and Drug Administration may assess
18 such fees, the Food and Drug Administration may
19 assess and collect such fees, without any modifica-
20 tion in the rate, for registration under section 605
21 at any time in such fiscal year.

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

23 “(1) IN GENERAL.—Fees authorized under sub-
24 section (a) shall be collected and available for obliga-
25 tion only to the extent and in the amount provided

1 in advance in appropriations Acts. Such fees are au-
2 thorized to remain available until expended. Such
3 sums as may be necessary may be transferred from
4 the Food and Drug Administration salaries and ex-
5 penses appropriation account without fiscal year lim-
6 itation to such appropriation account for salaries
7 and expenses with such fiscal year limitation. The
8 sums transferred shall be available solely for cos-
9 metic safety activities.

10 “(2) COLLECTIONS AND APPROPRIATIONS
11 ACTS.—The fees authorized by this section—

12 “(A) IN GENERAL.—Subject to subpara-
13 graphs (C) and (D), the fees authorized by this
14 section shall be collected and available in each
15 fiscal year in an amount not to exceed the
16 amount specified in appropriation Acts, or oth-
17 erwise made available for obligation for such
18 fiscal year.

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

23 “(C) FEE COLLECTIONS DURING FIRST
24 PROGRAM YEAR.—Until the date of enactment
25 of an Act making appropriations through Sep-

1 tember 30, 2015, for the salaries and expenses
2 account of the Food and Drug Administration,
3 fees authorized by this section for fiscal year
4 2016 may be collected and shall be credited to
5 such account to remain available until ex-
6 pended. Fees collected under this subparagraph
7 shall be considered discretionary for purposes of
8 the Balanced Budget and Emergency Deficit
9 Control Act of 1985.

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

1 “(3) AUTHORIZATION OF APPROPRIATIONS.—
2 For each of fiscal years 2016–2022, there are au-
3 thorized to be appropriated for fees under this sec-
4 tion \$20,600,000, as adjusted by subsection (d).

5 “(4) OFFSET OF OVERCOLLECTIONS; RECOVERY
6 OF COLLECTION SHORTFALLS.—

7 “(A) OFFSET OF OVERCOLLECTIONS.—If
8 the sum of the cumulative amount of fees col-
9 lected under this section for the fiscal years
10 2016 through 2020 exceeds the cumulative
11 amount appropriated pursuant to paragraph (3)
12 for fiscal years 2016–2021, the excess amount
13 shall be credited to the appropriation account of
14 the Food and Drug Administration as provided
15 in paragraph (1), and shall be subtracted from
16 the amount of fees that would otherwise be au-
17 thorized to be collected under this section pur-
18 suant to appropriation Acts for fiscal year
19 2022.

20 “(B) RECOVERY OF COLLECTION SHORT-
21 FALLS.—

22 “(i) 2018.—For fiscal year 2018, the
23 amount of fees otherwise authorized to be
24 collected under this section shall be in-
25 creased by the amount, if any, by which

1 the amount collected under this section
2 and appropriated for fiscal year 2016 falls
3 below the amount of fees authorized for
4 fiscal year 2016 under paragraph (3).

5 “(ii) 2019.—For fiscal year 2019, the
6 amount of fees otherwise authorized to be
7 collected under this section shall be in-
8 creased by the amount, if any, by which
9 the amount collected under this section
10 and appropriated for fiscal year 2017 falls
11 below the amount of fees authorized for
12 fiscal year 2017 under paragraph (3).

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

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

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

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

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

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

22 “(i) COLLECTION OF UNPAID FEES.—In any case
23 where the Food and Drug Administration does not receive
24 payment of a fee assessed under subsection (a), such fee
25 shall be treated as a claim of the United States Govern-

1 ment subject to subchapter II of chapter 37 of title 31,
2 United States Code.

3 “(j) CONSTRUCTION.—This section may not be con-
4 strued to require that the number of full-time equivalent
5 positions in the Department of Health and Human Serv-
6 ices, for officers, employees, and advisory committees not
7 engaged in cosmetic activities, be reduced to offset the
8 number of officers, employees, and advisory committees so
9 engaged.

10 “(k) RECORDS.—Each facility shall retain all records
11 necessary to demonstrate the facility’s gross annual sales
12 for at least 2 fiscal years after such information is re-
13 ported in the facility’s registration. Such records shall be
14 made available to the Food and Drug Administration for
15 review and duplication upon request of the Food and Drug
16 Administration.”.

17 **SEC. 203. DIRECT HIRING AUTHORITY TO SUPPORT ACTIVI-**
18 **TIES RELATED TO COSMETICS.**

19 Part 10 of subchapter C of chapter VII, as added
20 by section 202, is amended by inserting after section 744L
21 the following:

22 **“SEC. 744M. DIRECT HIRING AUTHORITY TO SUPPORT AC-**
23 **TIVITIES RELATED TO COSMETICS.**

24 “(a) IN GENERAL.—The Food and Drug Administra-
25 tion shall have direct hiring authority with respect to the

1 appointment of employees into the competitive service or
2 the excepted service to administer the amendments made
3 by title I of the Personal Care Products Safety Act.

4 “(b) SUNSET.—The authority under subsection (a)
5 shall terminate on the date that is 3 years after the date
6 of enactment of such title.”.

○