

116TH CONGRESS
1ST SESSION

S. _____

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

IN THE SENATE OF THE UNITED STATES

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

A BILL

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

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

3 **SECTION 1. SHORT TITLE; TABLE OF CONTENTS.**

4 (a) **SHORT TITLE.**—This Act may be cited as the
5 “Personal Care Products Safety Act”.

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

Sec. 1. Short title; table of contents.

TITLE I—COSMETIC SAFETY

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

Sec. 102. Review of ingredients and non-functional constituents.

- 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. Sense of the Senate on animal testing.
- 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 preparation of cosmetic raw ingre-
 15 dients, which may come in a range of possible
 16 amounts for each ingredient, for purposes of intro-

1 duction into interstate commerce as a finished prod-
2 uct.

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 or processes cosmetic
7 products or cosmetic formulations, or any other enti-
8 ty whose name and address appear on the label of
9 a cosmetic product. Such term does not include—

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

13 “(B) cosmetic product retailers, including
14 individual sales representatives, direct sellers,
15 retail distribution facilities, and pharmacies,
16 that do not otherwise manufacture, process, or
17 package cosmetics at that location;

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

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

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

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

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

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

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

17 “(H) an establishment that solely performs
18 1 or more of the following with respect to cos-
19 metic products: labeling, relabeling, packaging,
20 repackaging, holding, or distributing.

21 “(4) FOREIGN FACILITY.—The term ‘foreign fa-
22 cility’ means a facility that manufactures or proc-
23 esses a cosmetic formulation or cosmetic product
24 that is exported to the United States without further
25 processing or packaging inside the United States. A

1 cosmetic is not considered to have undergone further
2 processing or packaging for purposes of this defini-
3 tion solely on the basis that labeling was added or
4 that any similar activity of a de minimis nature was
5 carried out with respect to the cosmetic.

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

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

15 “(A) the brand owner who is the domestic
16 or foreign manufacturer or entity whose name
17 appears on a cosmetic product label of a cos-
18 metic product distributed in the United States,
19 except for entities described in subparagraphs
20 (A) through (H) of paragraph (3); or

21 “(B) a contract manufacturer who provides
22 cosmetic products to the entities described in
23 subparagraphs (A) through (H) of paragraph
24 (3).”.

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

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

4 “(1) REGISTRATION, IN GENERAL.—Not later
5 than December 1, 2019, and at a similar time in
6 each subsequent year, as determined by the Food
7 and Drug Administration, each responsible person
8 engaged in manufacturing or processing a cosmetic
9 product or a cosmetic formulation distributed in the
10 United States shall register all of the responsible
11 person’s facilities with the Food and Drug Adminis-
12 tration.

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

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

1 of first engaging in such activity, and thereafter in accord-
2 ance with subsection (a).

3 “(c) CONTRACT MANUFACTURERS.—If a facility
4 manufactures or processes cosmetic products on behalf of
5 a responsible person, the Food and Drug Administration
6 shall require only a single registration for such facility
7 even if such facility is manufacturing or processing its own
8 cosmetic products or cosmetic products on behalf of more
9 than 1 responsible person. Such single registration may
10 be submitted to the Food and Drug Administration by
11 such facility or any responsible person whose products are
12 manufactured or processed at such facility.

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

19 “(e) FORMAT; CONTENTS.—

20 “(1) ELECTRONIC FORMAT.—Each registration
21 shall be submitted using an electronic format, as
22 specified in a registration form provided by the Food
23 and Drug Administration.

24 “(2) CONTENTS.—

1 “(A) IN GENERAL.—Except as provided in
2 subparagraph (B), the registration shall contain
3 the following information:

4 “(i) Each facility’s name and full ad-
5 dress, identifying the precise physical loca-
6 tion of the facility.

7 “(ii) The identity of the facility, in-
8 cluding the unique facility identifier, if
9 any, previously assigned by the Food and
10 Drug Administration to the facility under
11 subsection (h).

12 “(iii) All business trading names used
13 by the facility.

14 “(iv) The product category or cat-
15 egories of each cosmetic product or cos-
16 metic formulation manufactured or proc-
17 essed at the facility or on whose label the
18 facility’s name and address appear.

19 “(v) The type of activity conducted at
20 the facility (such as manufacturing or
21 processing).

22 “(vi) The name, title, street address,
23 telephone number, and electronic contact
24 information of the emergency contact for
25 the facility.

1 “(vii) In the case of a foreign facility,
2 the name, street address, telephone num-
3 ber, emergency contact information, and
4 name of the United States agent for the
5 facility, and, if available, the electronic
6 contact information of the United States
7 agent.

8 “(viii) The name, title, street address,
9 telephone number, and electronic contact
10 information of the individual submitting
11 the registration.

12 “(ix) An assurance that the Food and
13 Drug Administration will be permitted to
14 inspect such facility at the times and in
15 the manner permitted by this Act.

16 “(x) Additional information pertaining
17 to the facility or to the cosmetic products
18 or cosmetic formulations manufactured or
19 processed at the facility, or on whose label
20 the facility’s name and address appear, in-
21 cluding all brand names known to con-
22 sumers, as the Food and Drug Administra-
23 tion may require by regulation.

24 “(xi) An ingredient listing for all cos-
25 metic products manufactured or processed

1 in such facility, in accordance with sub-
2 section (f), which, for each relevant cos-
3 metic product, may be submitted to the
4 Food and Drug Administration as part of
5 such registration or separately.

6 “(xii) A written assurance that each
7 cosmetic product manufactured or proc-
8 essed in such facility has been substan-
9 tiated for safety or carries the warning re-
10 quired under section 740.10 of title 21,
11 Code of Federal Regulations (or any suc-
12 cessor regulations). The responsible person
13 shall maintain records documenting any
14 such substantiation of safety and the infor-
15 mation on which such determination is
16 based until 5 years after the finished prod-
17 uct is no longer marketed, except that a
18 responsible person for a domestic company
19 whose sales are under \$2,000,000 per year
20 shall maintain such records for at least 2
21 years after the finished product is no
22 longer marketed.

23 “(B) SMALL BUSINESSES.—

24 “(i) REQUIREMENTS.—In the case of
25 a registrant described in clause (ii), the

1 registration shall contain the following in-
2 formation:

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

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

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

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

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

1 cosmetic products produced in a pri-
2 vate residence); and

3 “(II) who does not produce—

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

6 “(bb) lip products with
7 color;

8 “(cc) products that are in-
9 jected;

10 “(dd) products that are in-
11 tended for internal use; or

12 “(ee) products that are
13 meant to alter appearance for
14 more than 24 hours.

15 “(iii) GUIDANCE.—The Food and
16 Drug Administration shall, after consulta-
17 tion with the Small Business Administra-
18 tion and small businesses that manufac-
19 ture cosmetics, provide additional guidance
20 for small businesses on compliance with
21 the requirements of this section that would
22 apply to small business registrants. Such
23 guidance shall include specific examples of
24 options for compliance that do not place an
25 undue burden on small businesses.

1 “(3) ABBREVIATED REGISTRATION.—The Food
2 and Drug Administration shall provide for an abbrevi-
3 ated registration renewal process for any registrant
4 that has not had any changes to the required infor-
5 mation with respect to the facility or facilities in-
6 volved since the registrant submitted the preceding
7 registration.

8 “(f) COSMETIC PRODUCT INGREDIENT LISTING.—

9 “(1) IN GENERAL.—The ingredient listing re-
10 quired pursuant to subsection (e)(2)(A)(xi) shall in-
11 clude—

12 “(A) the unique identifier assigned under
13 section (h), as applicable, of—

14 “(i) each facility where the cosmetic
15 product is manufactured or processed; and

16 “(ii) the facility whose name and ad-
17 dress appear on the label, unless the state-
18 ment is filed by a contract manufacturer
19 described in section 604(6)(B);

20 “(B) the brand name and the full name for
21 the cosmetic product as it appears on the label;

22 “(C) the cosmetic product listing number,
23 if any, previously assigned to the cosmetic prod-
24 uct by the Food and Drug Administration
25 under paragraph (4);

1 “(D) the applicable cosmetic category for
2 the cosmetic product;

3 “(E) a list of ingredients in the cosmetic
4 product, including a range of possible amounts
5 of each ingredient, identified by the name
6 adopted in regulations promulgated by the Food
7 and Drug Administration, if any, or by the
8 common or usual name of the ingredient, which
9 shall include—

10 “(i) a list of fragrances, flavors, and
11 colors that may be included in the product,
12 interchangeably, with ranges of possible
13 amounts, which shall include—

14 “(I) in the case of fragrances
15 that are purchased from a fragrance
16 supplier, identification of the fra-
17 grances by the name or code provided
18 by the supplier, including the name
19 and contact information for the fra-
20 grance supplier; and

21 “(II) in the case of flavors that
22 are purchased from a flavor supplier,
23 identification of the flavors by the
24 name or code provided by the sup-
25 plier, including the name and contact

1 information for the flavor supplier;

2 and

3 “(ii) other appropriate interchange-

4 able ingredients as the Food and Drug Ad-

5 ministration may specify in regulations or

6 guidance that may be included in the prod-

7 uct, with ranges of possible amounts;

8 “(F) the title and full contact information

9 of each individual submitting the statement;

10 “(G) if applicable, information on the la-

11 beling required under section 612; and

12 “(H) if applicable, information showing

13 that the cosmetic ingredient or ingredients in

14 the product meet any specified conditions of use

15 or tolerances required following a final deter-

16 mination of safety under section 607(d).

17 “(2) ADDITIONAL INFORMATION.—In the case

18 of a cosmetic ingredient statement that includes a

19 list of fragrances or flavors that are purchased from

20 a fragrance or flavor supplier as described in para-

21 graph (1)(E)(i), upon request by the Food and Drug

22 Administration, the fragrance or flavor supplier shall

23 submit to the Food and Drug Administration the

24 complete list of ingredients in specific fragrances or

1 flavors, not later than 30 days after receiving such
2 request.

3 “(3) COSMETIC PRODUCT INGREDIENT STATE-
4 MENT FOR NEW OR REFORMULATED COSMETIC
5 PRODUCTS.—

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

17 “(B) SMALL BUSINESSES.—The Food and
18 Drug Administration shall allow a responsible
19 person that is a business that meets the appli-
20 cable industry-based small business size stand-
21 ard established by the Administrator of the
22 Small Business Administration under section 3
23 of the Small Business Act to have a period
24 longer than 60 days to submit an initial new

1 cosmetic ingredient statement under subpara-
2 graph (A).

3 “(C) DEFINITION.—A cosmetic product
4 shall not be considered first marketed or refor-
5 mulated after the date of enactment under sub-
6 paragraph (A) if the only change in such prod-
7 uct is in—

8 “(i) the amount of an existing ingre-
9 dient if it is within the range previously re-
10 ported under paragraph (1)(E); or

11 “(ii) the addition or subtraction of a
12 fragrance, flavor, or color, or such other
13 interchangeable ingredients specified by
14 the Food and Drug Administration in reg-
15 ulations or guidance, previously reported
16 as a potential ingredient under paragraph
17 (1)(E), if, in the case of such an addition,
18 the amount is within the range previously
19 reported.

20 “(4) COSMETIC PRODUCTS LIST.—At the time
21 of the initial submission of any cosmetic ingredient
22 statement under this section, the Food and Drug
23 Administration shall assign a unique cosmetic prod-
24 uct listing number to the cosmetic ingredient state-
25 ment. Based on such cosmetic ingredient statements,

1 the Food and Drug Administration shall compile
2 and maintain a list of cosmetic products distributed
3 in the United States, including the ingredients of
4 each such product, and shall make available such list
5 to any State, upon request. Information disclosed to
6 a State that is exempt from disclosure under section
7 552(b)(4) of title 5, United States Code, shall be
8 treated as a trade secret and confidential informa-
9 tion by the State.

10 “(g) INCOMPLETE OR INACCURATE REGISTRA-
11 TION.—

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

21 “(2) TIMELY UPDATE OR CORRECTION.—If, not
22 later than 7 days after receipt of a notice of intent
23 to cancel, the responsible person corrects the reg-
24 istration in accordance with the basis for the can-
25 cellation, and the required registration fee, if any, is

1 paid, the Food and Drug Administration shall not
2 cancel such registration.

3 “(h) UNIQUE IDENTIFIER.—At the time of the initial
4 registration of any cosmetic facility under this section, the
5 Food and Drug Administration shall assign a unique iden-
6 tifier to the facility.

7 “(i) REGISTRY OF FACILITIES.—

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

15 “(2) PUBLIC AVAILABILITY EXCEPTIONS.—In-
16 formation derived from the registry or registration
17 documents that discloses the residential address of a
18 registrant or that discloses specific facilities where
19 specific cosmetic products are manufactured or proc-
20 essed shall not be subject to disclosure under section
21 552 of title 5, United States Code.

22 **“SEC. 606. SUSPENSION OF REGISTRATION OR COSMETIC**
23 **INGREDIENT STATEMENT.**

24 “(a) SUSPENSION OF REGISTRATION OF A FACIL-
25 ITY.—If the Food and Drug Administration determines

1 that a cosmetic formulation or cosmetic product manufac-
2 tured or processed by a registered facility and distributed
3 in the United States has a reasonable probability of caus-
4 ing serious adverse health consequences or death to hu-
5 mans, and the Food and Drug Administration has a rea-
6 sonable belief that other products manufactured or proc-
7 essed by the facility may be similarly affected because of
8 a failure that cannot be isolated to a single product or
9 products or is sufficiently pervasive to raise concerns
10 about other products manufactured in the facility, the
11 Food and Drug Administration may suspend the registra-
12 tion of a facility.

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

20 “(c) NOTICE OF SUSPENSION.—Before suspending a
21 facility registration or a cosmetic ingredient statement
22 under this section, the Food and Drug Administration
23 shall provide—

24 “(1) notice to the facility registrant of the cos-
25 metic product or formulation or other responsible

1 person, as appropriate, of the intent to suspend the
2 facility registration or the cosmetic ingredient state-
3 ment, which shall specify the basis of the determina-
4 tion by the Food and Drug Administration that the
5 facility or the cosmetic ingredient should be sus-
6 pended and recommendations for specific actions to
7 avoid suspension; and

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

13 “(d) REINSTATEMENT.—Upon a determination by
14 the Food and Drug Administration that adequate grounds
15 do not exist to continue the suspension actions, the Food
16 and Drug Administration shall promptly vacate the sus-
17 pension and reinstate the registration of the facility or the
18 cosmetic ingredient statement.

19 “(e) EFFECT OF SUSPENSION.—

20 “(1) REGISTRATION.—If the registration of a
21 facility is suspended under this section, no person
22 shall introduce or deliver for introduction into inter-
23 state commerce cosmetics or cosmetic products from
24 such facility.

1 “(2) COSMETIC INGREDIENT STATEMENT.—If
2 the cosmetic ingredient statement for a cosmetic
3 product is suspended under this section, no person
4 shall introduce or deliver for introduction into inter-
5 state commerce any cosmetic product that is the
6 subject of such statement.

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

11 **SEC. 102. REVIEW OF INGREDIENTS AND NON-FUNCTIONAL**
12 **CONSTITUENTS.**

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

17 **“SEC. 607. REVIEW OF INGREDIENTS AND NON-FUNC-**
18 **TIONAL CONSTITUENTS.**

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

21 “(1) IN GENERAL.—Beginning in fiscal year
22 2020, the Food and Drug Administration shall re-
23 view the safety of the cosmetic ingredients and non-
24 functional constituents listed under paragraph (3),
25 as modified under subsection (c), if applicable, and

1 issue an order under subsection (d) with respect to
2 the use of each such ingredient and presence of each
3 such non-functional constituent.

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

12 “(3) COSMETIC INGREDIENTS.—

13 “(A) INGREDIENTS TO BE CONSIDERED IN
14 FIRST YEAR.—During fiscal year 2020, the
15 Food and Drug Administration shall initiate the
16 review for safety of the following cosmetic in-
17 gredients:

18 “(i) Diazolidinyl urea.

19 “(ii) Diethyl phthalate.

20 “(iii) Methylene glycol/methanediol/
21 formaldehyde.

22 “(iv) Propyl paraben.

23 “(v) Quaternium-15.

24 “(B) INGREDIENTS TO BE CONSIDERED IN
25 SUBSEQUENT YEARS.—

1 “(i) IN GENERAL.—Beginning in fis-
2 cal year 2021, the Food and Drug Admin-
3 istration shall annually select and complete
4 a safety review of at least 5 cosmetic ingre-
5 dients or non-functional constituents that
6 were not reviewed in the prior 3 years,
7 from a list determined in consultation with
8 the cosmetic industry and consumer and
9 health groups. The Food and Drug Admin-
10 istration may combine selected cosmetics
11 ingredients or non-functional constituents
12 into categories for purposes of such review.
13 The Food and Drug Administration may
14 modify such list under subsection (c).

15 “(ii) CONSIDERATIONS.—The deter-
16 mination of which ingredients or functional
17 ingredients will be reviewed in a given year
18 shall be publicized in annual reports to
19 Congress and the public, in accordance
20 with section 616. The review of any cos-
21 metic ingredient or non-functional con-
22 stituent shall commence with a public an-
23 nouncement by the Food and Drug Admin-
24 istration and the opening of a docket as re-
25 quired under paragraph (2).

1 “(4) COMMENT PERIOD.—As part of the annual
2 reporting to Congress and the public under section
3 616, 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 the Food and Drug Adminis-
13 tration may consider during that year or subsequent
14 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), if applicable, and, if applicable, com-
23 pliance dates that are the subject of a final order under
24 subsection (e).

1 “(c) INITIATIVE OF THE FDA.—The Food and Drug
2 Administration may at any time propose the issuance of
3 an order on the safety of a cosmetic ingredient or non-
4 functional constituent that was not previously listed in
5 subsection (a) or under section 616(a)(3). The Food and
6 Drug Administration shall follow the same procedures and
7 policies for review of any cosmetic ingredient or non-func-
8 tional constituent so proposed as for the ingredients and
9 constituents reviewed pursuant to subsection (a).

10 “(d) DETERMINATION ON SAFETY.—

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

1 “(2) PUBLIC COMMENT.—Upon publication of
2 the proposed administrative order described in para-
3 graph (1), the Food and Drug Administration shall
4 open a docket for the submission of public comment.
5 The Food and Drug Administration shall provide 30
6 days for public comment following publication of the
7 proposed administrative order.

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

23 “(4) DETERMINATIONS.—In the proposed ad-
24 ministrative order or the final administrative order,
25 as applicable, the Food and Drug Administration

1 shall make a determination that the ingredient or
2 non-functional constituent is—

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

5 “(B) safe in cosmetic products without the
6 need for specified conditions of use or toler-
7 ances; or

8 “(C) not safe in cosmetic products.

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

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

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

22 “(B) warnings that are necessary or appro-
23 priate under section 612, including warnings re-
24 lated to use by children, pregnant women, popu-
25 lations with high exposure to the ingredient

1 (such as workers who are exposed through pro-
2 duction practices or handling of final products),
3 or other vulnerable populations, to help ensure
4 safe use of cosmetic products containing the in-
5 gredient or non-functional constituent; and

6 “(C) such other screening, safety protocol,
7 or other similar conditions as are necessary for
8 the safety of cosmetic products containing such
9 ingredient or non-functional constituent.

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

19 “(e) ORDER.—

20 “(1) IN GENERAL.—If the Food and Drug Ad-
21 ministration issues a final administrative order
22 under subparagraph (A) or (C) of subsection (d)(4),
23 the Food and Drug Administration shall, at the
24 same time as publication of the notice under sub-
25 section (d)(6), publish a proposed order identifying

1 dates by which use of the ingredient or non-func-
2 tional constituent in cosmetic products shall comply
3 with the final administrative order, and provide 60
4 days for public comment, including comment on
5 whether compliance is feasible within the proposed
6 dates. After considering comments on the proposed
7 order, the Food and Drug Administration shall pub-
8 lish in the Federal Register a final order.

9 “(2) CONTENT.—The public notice information
10 regarding the final order under paragraph (1) shall
11 include a summary that is written in plain and un-
12 derstandable language that is comprehensible and
13 meaningful for consumers. The summary shall in-
14 clude information on any conditions of use or warn-
15 ings required under section 612, including the appli-
16 cation to vulnerable populations, the types of safety
17 studies evaluated, and any additional relevant infor-
18 mation that was part of the review process.

19 “(f) MODIFICATION OF AN ORDER.—An order issued
20 under subsection (d) or (e) may be modified or revoked
21 by the Food and Drug Administration on the initiative of
22 the Food and Drug Administration or in response to a
23 petition.

24 “(g) INADEQUATE EVIDENCE.—

1 “(1) NOTICE; EXTENSION.—If the Food and
2 Drug Administration determines that the available
3 data and information are not adequate to make a
4 proposed or final determination regarding safety
5 under subsection (d)(4), with respect to a cosmetic
6 ingredient or non-functional constituent, the Food
7 and Drug Administration shall—

8 “(A) publish such finding on the Internet
9 website of the Food and Drug Administration
10 not later than 90 days after the close of the rel-
11 evant comment period for the ingredient or
12 non-functional constituent under subsection
13 (a)(2), in the case of a proposed order, or sub-
14 section (d)(2), in the case of a final order; and

15 “(B)(i) include a notice providing inter-
16 ested persons an additional 30 days from the
17 notice date to provide additional data and infor-
18 mation; and

19 “(ii) if, after the 30-day period under
20 clause (i), the Food and Drug Administration
21 determines that additional safety substantiation
22 with respect to such ingredient or non-func-
23 tional constituent is necessary to make a safety
24 determination—

1 “(I) include a notice specifying an ad-
2 ditional time period, not to exceed 18
3 months from the notice date, during which
4 time the assurance made by a responsible
5 person under section 605(e)(2)(A)(xii) with
6 respect to the safety of such cosmetic in-
7 gredient or non-functional constituent shall
8 be deemed to be in compliance with the re-
9 quirements of this Act, but shall not affect
10 final determinations of safety under sub-
11 section (d); and

12 “(II) plan to obtain such data and in-
13 formation.

14 “(2) DETERMINATION; ORDER.—

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

1 (1)(B), issue a proposed order or a final admin-
2 istrative order—

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

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

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

24 “(h) SAFETY ASSESSMENT.—

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

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

21 “(A) The probable human exposure to the
22 ingredient or non-functional constituent from
23 expected use in cosmetics.

24 “(B) The probable cumulative and aggre-
25 gate effect in humans of relevant exposure to

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

12 “(C) Whether warnings or recommenda-
13 tions in a product label required under section
14 612, as part of any conditions of use or toler-
15 ances imposed by the Food and Drug Adminis-
16 tration, would be necessary and appropriate to
17 help ensure the safety of the ingredient or non-
18 functional constituent.

19 “(3) DATA AND INFORMATION.—

20 “(A) REQUIRED INFORMATION.—A deter-
21 mination that an ingredient or non-functional
22 constituent is safe in cosmetics shall be based
23 upon adequate evidence submitted or otherwise
24 known to the Food and Drug Administration,
25 which shall include full reports of all available

1 studies, published or unpublished, that are ade-
2 quately designed to show whether the ingredient
3 or non-functional constituent is safe. Such stud-
4 ies may include in vitro and in silico studies
5 and epidemiological studies, biomonitoring stud-
6 ies, and studies focused on various points dur-
7 ing the lifespan of the subject, that use scientif-
8 ically valid methodology.

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

14 “(i) adverse event reports;

15 “(ii) findings and information from
16 State, Federal, national, and international
17 entities and other bodies composed of sci-
18 entific and medical experts;

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

24 “(iv) experience with the ingredient or
25 non-functional constituent in products that

1 are distributed in the United States or in
2 other countries, if such experience is well-
3 documented and has resulted in substantial
4 human exposure to the ingredient or non-
5 functional constituent over time.

6 “(i) COAL-TAR HAIR DYE.—Coal-tar hair dye shall
7 be subject to the conditions of section 601(a) unless the
8 Food and Drug Administration has issued a final deter-
9 mination for a coal-tar hair dye ingredient under sub-
10 section (d)(4)(C).”.

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

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

17 **“SEC. 608. GOOD MANUFACTURING PRACTICES FOR COS-**
18 **METICS.**

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

1 appropriate, with such national and international standards
2 for cosmetic good manufacturing practices to ensure that
3 requirements of this chapter with respect to the manufac-
4 ture of cosmetic products are in harmony.

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

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

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

18 (1) LARGE BUSINESSES.—For businesses of a
19 size greater than the Small Business Administra-
20 tion’s standard for a small business, section 608 of
21 the Federal Food, Drug, and Cosmetic Act (as
22 added by subsection (a)) shall take effect beginning
23 180 days after the date on which the Food and
24 Drug Administration makes effective cosmetic good
25 manufacturing practices.

1 (2) **SMALL BUSINESSES.**—For businesses of a
2 size that meets the Small Business Administration’s
3 standard for a small business, section 608 of the
4 Federal Food, Drug, and Cosmetic Act (as added by
5 subsection (a)) shall take effect beginning 2 years
6 after the date the Food and Drug Administration
7 makes effective cosmetic good manufacturing prac-
8 tices.

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

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

14 **“SEC. 609. ADVERSE EVENT REPORTING FOR COSMETICS.**

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

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

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

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

6 “(A) results in—

7 “(i) death;

8 “(ii) a life-threatening experience;

9 “(iii) inpatient hospitalization;

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

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

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

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

21 “(c) SUBMISSION OF REPORTS.—

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

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

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

18 “(3) CONSOLIDATION OF REPORTS.—The Food
19 and Drug Administration shall provide for systems
20 to enable the responsible person to submit a single
21 report that includes duplicate reports of, or new
22 medical information related to, a serious adverse
23 event.

24 “(4) ANNUAL REPORT.—

1 “(A) IN GENERAL.—Not later than March
2 1 of each year, except as provided under sub-
3 paragraph (C), the responsible person shall sub-
4 mit an electronic report for the prior calendar
5 year for each cosmetic product marketed during
6 that year.

7 “(B) CONTENTS.—Each report under this
8 paragraph shall contain a summary of all ad-
9 verse events received during the reporting pe-
10 riod, a complete list of individual reports, and
11 an estimate of the total number of product
12 units estimated to have been distributed to con-
13 sumers in the United States during such period.
14 The report shall not include consumer com-
15 plaints that are solely regarding efficacy and do
16 not contain any information about an adverse
17 event. The Food and Drug Administration shall
18 further specify the contents of the annual elec-
19 tronic report by regulation or guidance.

20 “(C) SMALL BUSINESS EXCEPTION.—In
21 the case of a domestic facility for which the av-
22 erage gross annual sales in cosmetic products in
23 the United States over the previous 3-year pe-
24 riod is not more than \$2,000,000, the respon-

1 sible person is not required to submit an annual
2 report under this paragraph.

3 “(5) EXEMPTION.—The Food and Drug Ad-
4 ministration may establish by regulation an exemp-
5 tion to any of the requirements under this sub-
6 section if the Food and Drug Administration deter-
7 mines that such exemption is supported by adequate
8 evidence and would have no adverse effect on public
9 health.

10 “(d) REQUIREMENTS.—

11 “(1) IN GENERAL.—Each serious adverse event
12 report under this section shall be submitted to the
13 Food and Drug Administration using an electronic
14 system of the Food and Drug Administration. The
15 Food and Drug Administration shall make such elec-
16 tronic system available not later than 1 year after
17 the date of enactment of the Personal Care Products
18 Safety Act.

19 “(2) MODIFICATION.—The format of the re-
20 porting system may be modified by the Food and
21 Drug Administration and the reports may include
22 additional information. The Food and Drug Admin-
23 istration may, in guidance, further specify the for-
24 mat and contents of required reports.

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

6 “(A) a report under section 756 with re-
7 spect to safety and related to a specific cos-
8 metic product;

9 “(B) a record about an individual who suf-
10 fered the serious adverse event under section
11 552a of title 5, United States Code;

12 “(C) a medical or similar file documenting
13 the serious adverse event, the disclosure of
14 which would constitute a violation of section
15 552(b)(6) of such title 5, and shall not be pub-
16 licly disclosed unless all personally identifiable
17 information is redacted; and

18 “(D) contact information for the individual
19 reporting the serious adverse event.

20 “(4) RESPONSIBILITY TO GATHER INFORMA-
21 TION.—After an individual initiates the reporting of
22 a serious adverse event, the responsible person for
23 the cosmetic product shall actively gather all of the
24 information to complete and file the report with the
25 Food and Drug Administration.

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

11 “(e) LIMITATION WITH RESPECT TO ADVERSE
12 EVENT REPORTS.—The submission of an adverse event
13 report in compliance with subsection (a) shall not con-
14 stitute an admission that the cosmetic involved caused or
15 contributed to the adverse event.

16 “(f) CONTACT INFORMATION.—The label of a cos-
17 metic shall bear the domestic telephone number or elec-
18 tronic contact information, and it is encouraged that the
19 label include both the telephone number and electronic
20 contact information, through which the responsible person
21 may receive a report of an adverse event.

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

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

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

14 **SEC. 105. RECORDS INSPECTION; MANDATORY RECALL AU-**
15 **THORITY.**

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

19 **“SEC. 610. INSPECTION OF COSMETIC RECORDS.**

20 “(a) INSPECTION OF RECORDS.—Each manufacturer
21 or processor of a cosmetic shall, at the request of an offi-
22 cer or employee duly designated by the Food and Drug
23 Administration, permit such officer or employee, upon
24 presentation of appropriate credentials and written notice
25 to such person, at reasonable times and within reasonable

1 limits and in a reasonable manner, to have access to and
2 copy—

3 “(1) all records maintained under section
4 605(e)(2)(A)(xii) or 609 and in accordance with the
5 rules promulgated by the Food and Drug Adminis-
6 tration under section 608, as applicable; and

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

10 “(A) has a reasonable belief that the cos-
11 metic—

12 “(i) is adulterated;

13 “(ii) has caused a reportable serious
14 adverse event; or

15 “(iii) contains an ingredient that sub-
16 stantial new scientific information shows
17 may be unsafe when present in a cosmetic;
18 and

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

22 “(b) EXCLUSIONS.—No inspection authorized by this
23 section shall extend to financial data, pricing data, per-
24 sonnel data (other than data as to qualification of tech-
25 nical and professional personnel performing functions sub-

1 ject to this Act), research data (other than safety data),
2 or sales data other than shipment data.

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

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

17 “(e) LIMITATIONS.—This section shall not be con-
18 strued—

19 “(1) to limit the authority of the Food and
20 Drug Administration to inspect records or to require
21 establishment and maintenance of records under any
22 other provision of this Act; or

23 “(2) to have any legal effect on section 552 of
24 title 5, United States Code, or section 1905 of title
25 18, United States Code.

1 “(f) SUBMISSION OF RECORDS.—

2 “(1) IN GENERAL.—Any records required to be
3 maintained by a responsible person under section
4 605(e)(2)(A)(xii) shall, upon the written request of
5 the Food and Drug Administration to the respon-
6 sible person, be provided to the Food and Drug Ad-
7 ministration within a reasonable timeframe not to
8 exceed 60 days, in either electronic or paper form.

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

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

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

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

21 “(B) the Food and Drug Administration,
22 an expert regulatory body, or an expert body
23 composed of scientific and medical experts finds
24 an ingredient in the product to be unsafe under
25 the conditions of use of the product; or

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

6 **“SEC. 611. MANDATORY RECALL AUTHORITY.**

7 “(a) VOLUNTARY PROCEDURES.—If the Food and
8 Drug Administration determines that there is a reasonable
9 probability that a cosmetic is adulterated under section
10 601 or misbranded under section 602 and the use of or
11 exposure to such cosmetic is likely to cause serious adverse
12 health consequences or death, the Food and Drug Admin-
13 istration shall provide the responsible person with an op-
14 portunity to voluntarily cease distribution and recall such
15 article.

16 “(b) PREHEARING ORDER TO MANDATORILY CEASE
17 DISTRIBUTION AND GIVE NOTICE.—

18 “(1) IN GENERAL.—If the responsible person
19 refuses to or does not voluntarily cease distribution
20 or recall such cosmetic within the time and in the
21 manner prescribed by the Food and Drug Adminis-
22 tration, the Food and Drug Administration may
23 order such person to—

24 “(A) immediately cease distribution of
25 such cosmetic; and

1 “(B) as applicable, immediately notify all
2 persons—

3 “(i) manufacturing, processing, pack-
4 ing, transporting, holding, receiving, dis-
5 tributing, or importing and selling such
6 cosmetic; and

7 “(ii) to which such cosmetic has been
8 distributed, transported, or sold (except
9 consumers),

10 to immediately cease distribution of such cos-
11 metic.

12 “(2) REQUIRED ADDITIONAL INFORMATION.—

13 “(A) IN GENERAL.—If a cosmetic covered
14 by a recall order issued under paragraph (1)(B)
15 has been distributed to a warehouse-based
16 third-party logistics provider without providing
17 such provider sufficient information to know or
18 reasonably determine the precise identity of
19 such cosmetic covered by a recall order that is
20 in its possession, the notice provided by the re-
21 sponsible person subject to the order issued
22 under paragraph (1)(B) shall include such in-
23 formation as is necessary for the warehouse-
24 based third-party logistics provider to identify
25 the cosmetic.

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

3 “(i) to exempt a warehouse-based
4 third-party logistics provider from the re-
5 quirements of this chapter, including the
6 requirements of this section and section
7 610; or

8 “(ii) to exempt a warehouse-based
9 third-party logistics provider from being
10 the subject of a mandatory recall order.

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

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

1 “(d) POST-HEARING RECALL ORDER AND MODIFICA-
2 TION OF ORDER.—

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

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

11 “(B) specify a timetable in which the recall
12 shall occur;

13 “(C) require periodic reports to the Food
14 and Drug Administration describing the
15 progress of the recall; and

16 “(D) provide notice to consumers to whom
17 such cosmetic was, or may have been, distrib-
18 uted.

19 “(2) VACATING OF ORDER.—If, after such hear-
20 ing, the Food and Drug Administration determines
21 that adequate grounds do not exist to continue the
22 actions required by the order, or that such actions
23 should be modified, the Food and Drug Administra-
24 tion shall vacate the order or modify the order.

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

5 “(f) PUBLIC NOTIFICATION.—In conducting a recall
6 under this section, the Food and Drug Administration
7 shall—

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

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

15 “(B) that includes, at a minimum—

16 “(i) the name of the cosmetic subject
17 to the recall;

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

20 “(iii) to the extent practicable, infor-
21 mation for consumers about similar cos-
22 metics that are not affected by the recall;
23 and

24 “(2) ensure publication on the Internet website
25 of the Food and Drug Administration of an image

1 of the cosmetic that is the subject of the press re-
2 lease described in paragraph (1), if available.

3 “(g) NO DELEGATION.—The authority conferred by
4 this section to order a recall or vacate a recall order shall
5 not be delegated to any officer or employee other than the
6 Commissioner.

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

13 **SEC. 106. LABELING.**

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

18 **“SEC. 612. LABELING.**

19 “(a) SAFETY REVIEW AND LABELING.—Following a
20 review of cosmetic ingredients that determines that warn-
21 ings are required to help ensure safe use of cosmetic prod-
22 ucts under section 607(d)(5), the Food and Drug Admin-
23 istration shall require labeling of cosmetics that are not
24 appropriate for use in the entire population, including

1 warnings that vulnerable populations, such as children or
2 pregnant women, should limit or avoid using the product.

3 “(b) COSMETIC PRODUCTS FOR PROFESSIONAL
4 USE.—

5 “(1) DEFINITION OF PROFESSIONAL.—For pur-
6 poses of this section, with respect to cosmetics, the
7 term ‘professional’ means an individual who—

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

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

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

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

19 “(3) PROFESSIONAL USE LABELING.—In the
20 case of a cosmetic product intended to be used only
21 by a professional on account of a specific ingredient
22 or increased concentration of an ingredient that re-
23 quires safe handling by trained professionals, the
24 product shall bear a statement as follows: ‘To be Ad-
25 ministered Only by Licensed Professionals’.

1 “(c) REQUIREMENTS.—

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

5 “(A) in the primary language used on the
6 label; and

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

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

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

24 “(e) CONTACT INFORMATION.—The label on each
25 cosmetic 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, that consumers may use to contact
4 the responsible person with respect to adverse events. The
5 contact number shall provide a means for consumers to
6 obtain additional information about ingredients in a cos-
7 metic, including the ability to ask if a specific ingredient
8 may be present that is not listed on the label, including
9 whether a specific ingredient may be contained in the fra-
10 grance or flavor used in the cosmetic. The manufacturer
11 of the cosmetic is responsible for providing such informa-
12 tion, including obtaining the information from suppliers
13 if it is not readily available. Suppliers are required to re-
14 lease such information upon request of the cosmetic manu-
15 facturer.”.

16 (b) EFFECTIVE DATE.—Section 612 of the Federal
17 Food, Drug, and Cosmetic Act, as added by subsection
18 (a), shall take effect on the date that is 1 year after the
19 date of enactment of this Act.

20 **SEC. 107. COAL TAR CHEMICALS.**

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

1 **“SEC. 613. COAL TAR CHEMICALS.**

2 “Specific ingredients in coal tar hair dyes may be se-
3 lected and reviewed under section 607. If the Food and
4 Drug Administration reviews a coal-tar ingredient found
5 in hair dye and makes a safety determination under sec-
6 tion 607(d) for such ingredient, such determination shall
7 include consideration for the safe use of such ingredient
8 through appropriate conditions of use, which may include
9 a specific label requirement, specified limits of concentra-
10 tions, or other such conditions of use as the Food and
11 Drug Administration determines appropriate, including a
12 finding of not safe under any conditions if appropriate.”.

13 **SEC. 108. SENSE OF THE SENATE ON ANIMAL TESTING.**

14 (a) ANIMAL TESTING.—Chapter VI of the Federal
15 Food, Drug, and Cosmetic Act (21 U.S.C. 361 et seq.),
16 as amended by section 107, is further amended by adding
17 the following:

18 **“SEC. 614. ANIMAL TESTING.**

19 “It is the sense of the Senate that animal testing
20 should not be used for the purposes of safety testing on
21 cosmetic products and should be phased out with the ex-
22 ception of appropriate allowances.”.

23 **SEC. 109. PREEMPTION.**

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

1 **“SEC. 615. PREEMPTION.**

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

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

10 “(2) with respect to the safety of a cosmetic in-
11 gredient or non-functional constituent that is the
12 subject of a final order on a determination of safety
13 under this chapter, unless the requirement of the
14 State or political subdivision is more restrictive than
15 the final order under section 607(d)(3).

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

18 “(1) DELAYED EFFECT OF NEW STATE RE-
19 QUIREMENTS.—

20 “(A) IN GENERAL.—From the date that
21 the Food and Drug Administration has made
22 public the final selection of a cosmetic ingre-
23 dient or non-functional constituent to be re-
24 viewed in the coming year under section
25 607(a)(3)(B) and opened the public comment
26 period under section 607(a)(2), until the date

1 that is one year after the Food and Drug Ad-
2 ministration has made public such selection, no
3 State or political subdivision of a State may es-
4 tablish any new requirement related to such
5 cosmetic ingredient or non-functional con-
6 stituent.

7 “(B) INITIAL REVIEW.—With respect to
8 the cosmetic ingredients to be reviewed in the
9 first year, in accordance with section
10 607(a)(3)(A), for the 1-year period beginning
11 on the date that is 6 months after the date of
12 enactment of the Personal Care Products Safe-
13 ty Act, no State or political subdivision of a
14 State may establish any new requirement re-
15 lated to such cosmetic ingredient or non-func-
16 tional constituent.

17 “(2) SCOPE.—Subsection (a)(2) shall not be
18 construed to affect the authority of a State or polit-
19 ical subdivision of a State with respect to any re-
20 quirement for the safety of a cosmetic ingredient or
21 non-functional constituent that is unrelated to the
22 scope of the safety assessment under section 607.

23 “(3) SENSE OF CONGRESS.—It is the sense of
24 Congress that a State or political subdivision that
25 regulates the safety of cosmetics with respect to the

1 health of humans beyond the scope of section 607
2 should utilize the safety assessment criteria de-
3 scribed in section 607(h).

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

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

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

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

22 “(e) SAVINGS.—Nothing in the amendments to this
23 Act made by the Personal Care Products Safety Act, nor
24 any standard, rule, requirement, regulation, adverse event
25 report, safety assessment, safety determination, scientific

1 assessment, or order issued or implemented pursuant to
2 such amendments, shall be construed to modify or other-
3 wise affect, preempt, or displace any cause of action or
4 State or Federal law creating a remedy for civil relief or
5 criminal cause of action, whether statutory or based in
6 common law.

7 “(f) SENSE OF THE SENATE.—It is the sense of the
8 Senate that subsection (e) does not negate the other provi-
9 sions of this section.”.

10 **SEC. 110. REPORTING.**

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

14 **“SEC. 616. REPORTING.**

15 “(a) PERFORMANCE REPORT.—Beginning with fiscal
16 year 2020, and not later than 60 days prior to the end
17 of each fiscal year for which fees are collected under sec-
18 tion 744L, the Food and Drug Administration shall pre-
19 pare and submit to Congress a report concerning the
20 progress of the Food and Drug Administration in achiev-
21 ing the objectives of the Personal Care Products Safety
22 Act during such fiscal year and the future plans of the
23 Food and Drug Administration for meeting the objectives.
24 The annual report for a fiscal year shall include—

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

4 “(2) identification of the cosmetic ingredients
5 and non-functional constituents that have been fully
6 reviewed for safety by the Food and Drug Adminis-
7 tration in the prior fiscal year and for which a final
8 administrative order has been released;

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

13 “(4) the number of facilities inspected and
14 mandatory recalls that transpired during that fiscal
15 year;

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

19 “(6) any trends identified by the Food and
20 Drug Administration about adverse event reports re-
21 lated to specific cosmetic ingredients or non-func-
22 tional constituents.

23 “(b) PUBLIC AVAILABILITY.—The Food and Drug
24 Administration shall make the reports required under sub-
25 section (a) available to the public on the Internet website

1 of the Food and Drug Administration on the date of sub-
2 mission of such reports to Congress.

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

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

11 “(A) comment on the cosmetic ingredients
12 or non-functional constituents under review for
13 the current year;

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

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

23 “(2) announcing on the Internet website of the
24 Food and Drug Administration, within the first 30
25 days of the new fiscal year, any amendments to the

1 list of cosmetic ingredients and non-functional con-
2 stituents submitted pursuant to subsection (a)(3)
3 based on public input, pursuant to paragraph (1);
4 and

5 “(3) together with the final announcement of at
6 least 5 specific cosmetic ingredients and non-func-
7 tional constituents that will be reviewed in the com-
8 ing year under section 607, providing a comment pe-
9 riod for further public input, pursuant to section
10 607(a)(2).”.

11 **SEC. 111. SMALL BUSINESSES.**

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

15 **“SEC. 617. SMALL BUSINESSES.**

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

1 **SEC. 112. APPLICABILITY WITH RESPECT TO CERTAIN COS-**
2 **METICS.**

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

6 **“SEC. 618. APPLICABILITY WITH RESPECT TO CERTAIN**
7 **COSMETICS.**

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

1 **SEC. 113. ENFORCEMENT.**

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

5 (1) in paragraph (e)—

6 (A) by striking “504, 564,” and inserting
7 “504, 564, 609, 610,”; and

8 (B) by striking “519, 564,” and inserting
9 “519, 564, 609,”;

10 (2) in paragraph (j), by inserting “606, 607,
11 608,” before “704”;

12 (3) in paragraph (ii)—

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

15 (B) by striking “761) submitted” and in-
16 serting “761 or as described in section 609)
17 submitted”;

18 (4) in paragraph (xx) by inserting “or 611”
19 after “423”; and

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

21 “(fff) The failure to register in accordance with sec-
22 tion 605, the failure to provide any information required
23 by section 605, or the failure to update the information
24 required by section 605, as required.”.

1 (b) ADULTERATION.—Section 601 of the Federal
2 Food, Drug, and Cosmetic Act (21 U.S.C. 361) is amend-
3 ed 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 in accordance with section 608.

9 “(g) If it contains, after the date prescribed under
10 section 607(e), an ingredient that the Food and Drug Ad-
11 ministration has determined under section 607(d)(4) to be
12 not safe, or not safe under the conditions of use rec-
13 ommended or suggested in the label or a non-functional
14 constituent that the Food and Drug Administration has
15 determined under section 607(d)(4) to be not safe or not
16 safe in the amount present in the cosmetic.

17 “(h) If it is a cosmetic product for which assurances
18 regarding safety substantiation have not been supplied
19 under section 605(e)(2)(A)(xii).”.

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

23 (1) in paragraph (b)—

24 (A) by striking “and (2)” and inserting

25 “(2)”; and

1 (B) by inserting “; and (3) a domestic ad-
2 dress or a domestic telephone number, and it is
3 encouraged that the label include both a domes-
4 tic address and a domestic telephone number,
5 through which the responsible person may re-
6 ceive a report of an adverse event associated
7 with the use of such cosmetic product” after
8 “numerical count”; and

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

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

15 “(h) If its labeling does not conform with a require-
16 ment under section 612.”.

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

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

1 (1) by striking “section 760 or 761” the first,
2 third, and fourth place such term appears and in-
3 serting “section 609, 760, or 761”; and

4 (2) by striking “760 or 761)” and inserting
5 “604, 760, or 761)”.

6 (f) **FACTORY INSPECTION.**—Section 704(a)(1) of the
7 Federal Food, Drug, and Cosmetic Act (21 U.S.C.
8 374(a)(1)) is amended by inserting after the third sen-
9 tence the following: “In the case of any person who manu-
10 factures, processes, distributes, or imports a cosmetic
11 product, or distributes a cosmetic product and affixes its
12 name on the cosmetic label, the inspection shall extend
13 to all records and other information described in section
14 610 (regarding inspection of cosmetic records), when the
15 standard for records inspections under paragraph (1) or
16 (2) of subsection (a) of such section applies, subject to
17 the limitations under subsections (d) and (e) of such sec-
18 tion.”.

19 **SEC. 114. CONSUMER INFORMATION.**

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

22 (1) final orders regarding the safety of a cos-
23 metic ingredient or non-functional constituent under
24 section 607(d)(3) of the Federal Food, Drug, and
25 Cosmetic Act;

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

3 (3) identified counterfeit cosmetic products.

4 **TITLE II—FEES RELATED TO**
5 **COSMETIC SAFETY**

6 **SEC. 201. FINDINGS.**

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

18 **SEC. 202. AUTHORITY TO ASSESS AND USE COSMETIC SAFE-**
19 **TY FEES.**

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

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

24 **“SEC. 744L. REGISTRATION FEE.**

25 “(a) ASSESSMENT AND COLLECTION.—

1 “(1) IN GENERAL.—Beginning in fiscal year
2 2020, the Food and Drug Administration shall as-
3 sess and collect an annual fee from every responsible
4 person (referred to in this section as a ‘registrant’)
5 who owns or operates any facility (as defined in sec-
6 tion 604(3)) engaged in manufacturing or proc-
7 essing, or whose name and address appear on the
8 label of a cosmetic product distributed in the United
9 States, except that this subsection shall not apply to
10 contract manufacturers if a responsible person has
11 already paid the appropriate fee with respect to the
12 cosmetic product, to ensure no double fees are paid.

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

17 “(b) DEFINITIONS.—In this section:

18 “(1) ADJUSTMENT FACTOR.—The term ‘adjust-
19 ment factor’ applicable to a fiscal year means the
20 Consumer Price Index for all urban consumers (all
21 items; United States city average) for October of the
22 preceding fiscal year divided by such index for Octo-
23 ber 2019.

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

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

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

8 “(3) COSMETIC PRODUCT.—The term ‘cosmetic
9 product’ has the meaning given such term in section
10 604(2).

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

13 “(A) means activities related to compliance
14 by registrants under section 605 with the re-
15 quirements of this Act with respect to cos-
16 metics, including—

17 “(i) administrative activities, such as
18 information technology support, human re-
19 sources, financial management, the admin-
20 istration and maintenance of the cosmetic
21 registration system and the cosmetic ingre-
22 dient statement system under section 605,
23 and fee assessment and collection under
24 this section; and

1 “(ii) implementation and enforcement
2 activities, such as the establishment of
3 good manufacturing practices, the review
4 of adverse event reports, inspection plan-
5 ning and inspections, and use of enforce-
6 ment tools; and

7 “(B) includes activities related to imple-
8 mentation of section 607, regarding the review
9 of cosmetic ingredients and non-functional con-
10 stituents.

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

17 “(c) FEE SETTING AND AMOUNTS.—

18 “(1) IN GENERAL.—Subject to subsection (d),
19 the Food and Drug Administration shall establish
20 the fees to be collected under this section for each
21 fiscal year after fiscal year 2020, based on the meth-
22 odology described in paragraph (3), and shall pub-
23 lish such fees in a Federal Register notice not later
24 than 60 days before the beginning of each such fis-
25 cal year.

1 “(2) FEE EXEMPTION.—Any registrant whose
2 gross annual sales of cosmetic products in the 3-year
3 period immediately preceding the fiscal year for
4 which the annual fee will be paid was not more than
5 \$10,000,000, shall be exempt from registration fees
6 under this section for that fiscal year.

7 “(3) ANNUAL FEE SETTING.—For fiscal years
8 2020 through 2025, to generate a total estimated
9 annual revenue amount of \$20,600,000, the amount
10 of the registration fee under subsection (a) shall be
11 as follows:

12 “(A) TIER I–A.—For a registrant that has
13 gross annual sales of \$5,000,000,000 or more
14 in 2018, \$1,350,000.

15 “(B) TIER I–B.—For a registrant that has
16 gross annual sales of at least \$4,000,000,000
17 per annum but less than \$5,000,000,000 in
18 2018, \$850,000.

19 “(C) TIER II–A.—For a registrant that has
20 gross annual sales of at least \$3,000,000,000
21 per annum but less than \$4,000,000,000 in
22 2018, \$730,000.

23 “(D) TIER II–B.—For a registrant that
24 has gross annual sales of at least

1 \$2,000,000,000 per annum but less than
2 \$3,000,000,000 in 2018, \$610,000.

3 “(E) TIER III-A.—For a registrant that
4 has gross annual sales of at least
5 \$1,000,000,000 per annum but less than
6 \$2,000,000,000 in 2018, \$500,000.

7 “(F) TIER III-B.—For a registrant that
8 has gross annual sales of at least \$500,000,000
9 per annum but less than \$1,000,000,000 in
10 2018, \$395,000.

11 “(G) TIER IV-A.—For a registrant that
12 has gross annual sales of at least \$200,000,000
13 per annum but less than \$500,000,000 in 2018,
14 \$325,000.

15 “(H) TIER IV-B.—For a registrant that
16 has gross annual sales of at least \$100,000,000
17 per annum but less than \$200,000,000 in 2018,
18 \$275,000.

19 “(I) TIER V-A.—For a registrant that has
20 gross annual sales of at least \$80,000,000 per
21 annum but less than \$100,000,000 in 2018,
22 \$185,000.

23 “(J) TIER V-B.—For a registrant that has
24 gross annual sales of at least \$60,000,000 per

1 annum but less than \$80,000,000 in 2018,
2 \$95,000.

3 “(K) TIER VI–A.—For a registrant that
4 has gross annual sales of at least \$40,000,000
5 per annum but less than \$60,000,000 in 2018,
6 \$15,000.

7 “(L) TIER IV–B.—For a registrant that
8 has gross annual sales of at least \$20,000,000
9 per annum but less than \$40,000,000 in 2018,
10 \$12,000.

11 “(M) TIER VII–A.—For a registrant that
12 has gross annual sales of at least \$10,000,000
13 per annum but less than \$20,000,000 in 2018,
14 \$500.

15 “(d) ADJUSTMENTS.—

16 “(1) INFLATION ADJUSTMENT.—

17 “(A) IN GENERAL.—For fiscal year 2021
18 and each subsequent fiscal year, the revenues
19 and fee amounts under subsection (c)(3) shall
20 be adjusted by the Food and Drug Administra-
21 tion in the annual Federal Register notice es-
22 tablishing 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 2020 under this sub-
6 section.

7 “(2) FINAL YEAR ADJUSTMENT.—For fiscal
8 year 2025, 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 2026. 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 2025. 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 2021
25 and each subsequent fiscal year, after fee reve-

1 nues established in subsection (c)(3) 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 607(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), as adjusted for infla-
23 tion 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 2019, 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.—

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, 2020, for the salaries and expenses
2 account of the Food and Drug Administration,
3 fees authorized by this section for fiscal year
4 2020 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 section 605, prior to collection
13 of fees, may be reimbursed through any appro-
14 priated fees collected under this section, in such
15 manner as the Food and Drug Administration
16 determines appropriate. Any amounts reim-
17 bursed under this subparagraph shall be avail-
18 able for the programs and activities for which
19 funds allocated to establish the programs were
20 available, prior to such allocation, until the end
21 of the fiscal year in which the reimbursement
22 occurs, notwithstanding any otherwise applica-
23 ble limits on amounts for such program or ac-
24 tivities for a fiscal year.

1 “(3) AUTHORIZATION OF APPROPRIATIONS.—
2 For each of fiscal years 2020 through 2026, there
3 are authorized to be appropriated for fees under this
4 section \$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 2020 through 2024 exceeds the cumulative
11 amount appropriated pursuant to paragraph (3)
12 for fiscal years 2020 through 2025, the excess
13 amount shall be credited to the appropriation
14 account of the Food and Drug Administration
15 as provided in paragraph (1), and shall be sub-
16 tracted from the amount of fees that would oth-
17 erwise be authorized to be collected under this
18 section pursuant to appropriation Acts for fiscal
19 year 2026.

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

22 “(i) 2022.—For fiscal year 2022, 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 2020 falls
3 below the amount of fees authorized for
4 fiscal year 2020 under paragraph (3).

5 “(ii) 2023.—For fiscal year 2023, 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 221 falls
11 below the amount of fees authorized for
12 fiscal year 2021 under paragraph (3).

13 “(iii) 2024.—For fiscal year 2024,
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 2022 falls
19 below the amount of fees authorized for
20 fiscal year 2022 under paragraph (3).

21 “(iv) 2025.—For fiscal year 2025, 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 2023 falls
2 below the amount of fees authorized for
3 fiscal year 2023 under paragraph (3).

4 “(v) 2026.—For fiscal year 2026, 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 2024 falls
10 below the amount of fees authorized for
11 fiscal year 2024 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 of the Fed-
20 eral Food, Drug, and Cosmetic Act, as added by section
21 202, is amended by inserting after section 744L the fol-
22 lowing:

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

3 “(a) IN GENERAL.—The Food and Drug Administra-
4 tion shall have direct hiring authority with respect to the
5 appointment of employees into the competitive service or
6 the excepted service to administer the amendments made
7 by title I of the Personal Care Products Safety Act.

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