

[DISCUSSION DRAFT]116TH CONGRESS
1ST SESSION**H. R.** _____

To amend the Federal Food, Drug, and Cosmetic Act to improve cosmetic safety, and for other purposes.

IN THE HOUSE OF REPRESENTATIVES

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

A BILL

To amend the Federal Food, Drug, and Cosmetic Act to improve cosmetic safety, and for other purposes.

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

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

4 (a) SHORT TITLE.—This Act may be cited as the
5 “Cosmetic Safety Enhancement Act of 2019”.

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

Sec. 1. Short title; table of contents.

TITLE I—COSMETIC SAFETY

- Sec. 101. Registration of cosmetics facilities and cosmetic ingredient statements.
- Sec. 102. Review of ingredients and nonfunctional constituents; safety of finished products.
- Sec. 103. Good manufacturing practices for cosmetics.
- Sec. 104. Adverse event reports.
- Sec. 105. Records inspection; mandatory recall authority.
- Sec. 106. Labeling.
- Sec. 107. Coal tar chemicals.
- Sec. 108. Animal testing alternatives.
- Sec. 109. Preemption.
- Sec. 110. Reporting.
- Sec. 111. Small businesses.
- Sec. 112. Applicability with respect to certain cosmetics.
- Sec. 113. Enforcement.
- Sec. 114. Consumer information.
- Sec. 115. Foreign supplier verification.

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

7 **“SEC. 604. DEFINITIONS.**

8 “In this chapter:

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

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

1 possible amounts for each ingredient and which may
2 include a variety of fragrances and colors, and in
3 some specific cosmetic applications, flavors.

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

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

15 “(B) cosmetic product retailers, including
16 individual sales representatives, retail distribu-
17 tion facilities, retail warehouses, and phar-
18 macies, that do not otherwise manufacture,
19 process, or package cosmetics at that location;

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

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

1 “(E) hotels and other entities that provide
2 complimentary cosmetics to guests;

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

6 “(G) domestic manufacturers with less
7 than \$100,000 in gross annual sales of cosmetic
8 products, except for any manufacturer that is
9 engaged in the manufacturing, processing, or
10 distributing of products intended to be injected
11 under the skin or into the eye, including tattoo
12 ink;

13 “(H) entities that manufacture or com-
14 pound cosmetic products solely for use in re-
15 search, teaching, or pilot plant production and
16 not for sale.

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

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

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

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

12 “(A) the brand owner, operator, or agent
13 in charge who is the domestic or foreign manu-
14 facturer, processor, or entity whose name ap-
15 pears on the label of a cosmetic product or a
16 cosmetic formulation distributed in the United
17 States, except for entities described in subpara-
18 graphs (A) through (H) of paragraph (3); or

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

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

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

1 “(1) REGISTRATION, IN GENERAL.—Each re-
2 sponsible person engaged in manufacturing, or proc-
3 essing, or whose name appears on the label of a cos-
4 metic product or a cosmetic formulation distributed
5 in the United States shall register all of the respon-
6 sible person’s facilities with the Food and Drug Ad-
7 ministration. A responsible person required to reg-
8 ister under this subsection shall, not later than 90
9 days after the Secretary announces the establish-
10 ment of an electronic registration system for pur-
11 poses of this section, submit a registration utilizing
12 such system which shall be effective for fiscal year
13 2019.

14 “(2) FEES.—If the average gross annual sales
15 in the United States of cosmetic products of all of
16 the responsible person’s facilities registered under
17 paragraph (1) for the previous 3-year period is
18 greater than **[\$500,000]**, a registration shall not be
19 complete under this subsection until the responsible
20 person has paid any registration fee required under
21 section 744L.

22 “(b) REGISTRATION FOR EXISTING PACKING OR
23 HOLDING FACILITIES.—Each facility engaged in packing
24 or holding a cosmetic product distributed in the United
25 States shall register with the Food and Drug Administra-

1 tion. Each facility required to register under this sub-
2 section shall, not later than 90 days after the Secretary
3 announces the establishment of an electronic registration
4 system for purposes of this section, submit a registration
5 utilizing such system which shall be effective for fiscal
6 year 2019.

7 “(c) REGISTRATION BY NEW FACILITIES.—A respon-
8 sible person first engaging after the date of enactment of
9 the Cosmetic Safety Enhancement Act of 2019 in an activ-
10 ity that would require it to register under subsection (a)
11 or (b) shall register with the Food and Drug Administra-
12 tion immediately upon engaging in such activity, and
13 thereafter in accordance with subsection (a) or (b).

14 “(d) CHANGES TO INFORMATION.—A responsible
15 person that submitted a registration under this section
16 shall notify the Food and Drug Administration of any
17 change to the information required under subsection (a)
18 or (b) not later than 30 days after the date of such
19 change, unless otherwise specified by the Food and Drug
20 Administration.

21 “(e) ANNUAL REGISTRATION RENEWAL.—A respon-
22 sible person that continues to engage in any activity that
23 would require registration under subsection (a) or (b) shall
24 submit to the Secretary an annual registration during the

1 first quarter of the fiscal year for which such renewed reg-
2 istration shall be effective.

3 “(f) **FORMAT; CONTENTS.**—

4 “(1) **ELECTRONIC FORMAT.**—Each registration
5 shall be submitted using an electronic format, as
6 specified in a registration form provided by the Food
7 and Drug Administration.

8 “(2) **CONTENTS.**—The registration shall con-
9 tain the following information:

10 “(A) Each facility’s name and full address,
11 identifying the precise physical location of the
12 facility.

13 “(B) The identity of the facility, including
14 the unique facility identifier, if any, previously
15 assigned by the Food and Drug Administration
16 to the facility under subsection (g).

17 “(C) All business trading names used by
18 the facility.

19 “(D) The product category or categories of
20 each cosmetic product or cosmetic formulation
21 manufactured, processed, packed, or held at the
22 facility or on whose label the facility’s name
23 and address appear.

1 “(E) The type or types of activities con-
2 ducted at the facility (such as manufacturing,
3 processing, packing, or holding).

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

7 “(G) In the case of a foreign facility, the
8 name, street address, telephone number, emer-
9 gency contact information for the facility, the
10 name of the United States agent for the facil-
11 ity, and the phone number and electronic con-
12 tact information of the United States agent.

13 “(H) The name, title, street address, tele-
14 phone number, and electronic contact informa-
15 tion of the individual submitting the registra-
16 tion.

17 “(I) An assurance that the Food and Drug
18 Administration will be permitted to inspect such
19 facility at the times and in the manner per-
20 mitted by this Act.

21 “(J) Additional information pertaining to
22 the facility or to the cosmetic products or cos-
23 metic formulations manufactured, processed,
24 packed, or held at the facility, or on whose label
25 the facility’s name and address appear, includ-

1 ing all brand names known to consumers, as
2 the Food and Drug Administration may require
3 by regulation.

4 “(3) ABBREVIATED REGISTRATION.—The Food
5 and Drug Administration shall provide for an abbrevi-
6 ated registration renewal process for any facility
7 that has not had any changes to such information
8 with respect to the facility or facilities involved since
9 the facility submitted the preceding registration.

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, if a re-
20 quired registration fee has not been paid within 30
21 days, or if the registration otherwise contains false,
22 incomplete, or inaccurate information.

23 “(2) TIMELY UPDATE OR CORRECTION.—If, not
24 later than 7 days after receipt of a notice of intent
25 to cancel, the facility corrects the registration in ac-

1 cordance with the basis for the cancellation, and the
2 required registration fee, if any, is paid, the Food
3 and Drug Administration shall not cancel such reg-
4 istration.

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

9 “(i) REGISTRY OF FACILITIES.—

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

17 “(2) PUBLIC AVAILABILITY EXCEPTIONS.—In-
18 formation derived from the registry or registration
19 documents that discloses the residential address of a
20 responsible person, facility, or that discloses specific
21 facilities where specific cosmetic products are manu-
22 factured or processed shall not be subject to disclo-
23 sure under section 552 of title 5, United States
24 Code.

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

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

9 “(b) SUBMISSION OF A COSMETIC INGREDIENT
10 STATEMENT.—

11 “(1) EXISTING COSMETIC PRODUCTS.—In the
12 case of a cosmetic product that is marketed on the
13 date of enactment of the Cosmetic Safety Enhance-
14 ment Act of 2019, the responsible person shall sub-
15 mit a cosmetic ingredient statement not later than
16 July 30, 2019. The responsible person shall submit
17 to the Food and Drug Administration an annual re-
18 newal of such statement during the first quarter of
19 the fiscal year for which such renewed statement is
20 applicable.

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

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

1 hancement Act of 2019 or a cosmetic product
2 that is reformulated after such date of enact-
3 ment, the responsible person shall submit a cos-
4 metic ingredient statement to the Food and
5 Drug Administration prior to first marketing
6 the new cosmetic product or the reformulated
7 cosmetic product, and annually thereafter dur-
8 ing the first quarter of the fiscal year for which
9 the cosmetic ingredient statement is applicable.

10 “(B) SMALL BUSINESSES.—The Food and
11 Drug Administration shall allow a responsible
12 person that is a business that meets the appli-
13 cable industry-based small business size stand-
14 ard established by the Administrator of the
15 Small Business Administration under section 3
16 of the Small Business Act to have an additional
17 time period, as determined by the Secretary, to
18 submit an initial new cosmetic ingredient state-
19 ment under subparagraph (A). Such responsible
20 person shall submit a cosmetic ingredient state-
21 ment annually thereafter during the first quar-
22 ter of the fiscal year.

23 “(C) DEFINITION.—A cosmetic product
24 shall not be considered first marketed or refor-
25 mulated after the date of enactment under sub-

1 paragraph (A) if the only change in such prod-
2 uct is in—

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

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

15 “(c) **FORMAT; CONTENTS.**—

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

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

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

1 “(i) the facility or facilities where the
2 cosmetic product is manufactured, proc-
3 essed, packed, or held or, if the same cos-
4 metic product is manufactured, processed,
5 packed, or held in more than one facility,
6 the unique facility identifier of each facility
7 where it is manufactured, processed,
8 packed, or held; and

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

13 “(B) The brand name and the full name
14 for the cosmetic product as it appears on the
15 label.

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

20 “(D) The applicable cosmetic category for
21 the cosmetic product.

22 “(E) A list of ingredients in the cosmetic
23 product, including a range of possible amounts
24 of each ingredient, and with each ingredient
25 identified by the name adopted in regulations

1 promulgated by the Food and Drug Adminis-
2 tration, if any, or by the common or usual
3 name of the ingredient. The cosmetic ingredient
4 statement shall contain—

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

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

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

23 “(III) if requested by the Food
24 and Drug Administration by means of
25 a written notification to the fragrance

1 or flavor supplier, the complete list of
2 ingredients in specific fragrances or
3 flavors (and the supplier shall have 30
4 days to provide such list to the Food
5 and Drug Administration); and

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

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

13 “(G) If applicable, information on labeling
14 required under section 614.

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

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

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

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

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

10 “(B) CONTENTS.—A responsible person
11 described in subparagraph (A) shall include in
12 each cosmetic ingredient statement under this
13 section, at a minimum, a list of ingredients in
14 the cosmetic product and the applicable cos-
15 metic category for the cosmetic product. If a
16 cosmetic product includes a fragrance or flavor
17 purchased from a fragrance or flavor supplier,
18 the responsible person must, at a minimum, in-
19 clude a list of all fragrances and flavors con-
20 tained in the cosmetic product and contact in-
21 formation for the fragrance or flavor supplier,
22 including the supplier’s name, street address,
23 telephone number, and electronic contact infor-
24 mation. In the case of a written notification
25 under paragraph (2)(E)(i)(III) provided by the

1 Food and Drug Administration to the respon-
2 sible person for the cosmetic manufacturer, the
3 Food and Drug Administration may request,
4 from the fragrance or flavor supplier, the com-
5 plete list of ingredients in specific fragrances or
6 flavors, and the supplier shall have 30 days to
7 provide such list to the Food and Drug Admin-
8 istration.

9 “(d) INCOMPLETE OR INACCURATE COSMETIC IN-
10 GREDIENT STATEMENT.—

11 “(1) IN GENERAL.—Not earlier than 10 days
12 after providing notice under paragraph (2), the Food
13 and Drug Administration may nullify a cosmetic in-
14 gredient statement filed under this section if the
15 Food and Drug Administration has reasonable
16 grounds to believe that the cosmetic ingredient state-
17 ment was not completed or updated in accordance
18 with this section or otherwise contains false, incom-
19 plete, or inaccurate information.

20 “(2) NOTICE OF NULLIFICATION.—A nullifica-
21 tion under paragraph (1) shall be preceded by notice
22 to the responsible person of the intent to cancel the
23 cosmetic ingredient statement and the basis for such
24 cancellation.

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

7 “(4) **EFFECT OF NULLIFICATION.**—If a cos-
8 metic ingredient statement is nullified under this
9 section, no person shall import, export, or otherwise
10 distribute the cosmetic product that was the subject
11 of the cosmetic ingredient statement.

12 “(e) **ADDITIONAL REQUIREMENTS.**—

13 “(1) **SAFETY REQUIREMENTS.**—In filing each
14 cosmetic ingredient statement for each cosmetic
15 product, the responsible person shall include an at-
16 testation that the safety of the product, including
17 the individual ingredients of such product and the
18 product as a whole, has been substantiated in ac-
19 cordance with section 609. In the case of a cosmetic
20 ingredient statement that includes a range of pos-
21 sible amounts (as described in subsection (c)(2)(E)),
22 the responsible person shall include an attestation
23 that the safety of the full range in the finished prod-
24 uct has been substantiated, in accordance with sec-
25 tion 609.

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

6 “(3) CHANGES TO INFORMATION.—

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

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

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

1 such an ingredient, the amount is within
2 the range previously reported.

3 “(B) SMALL BUSINESS.—The Food and
4 Drug Administration shall allow a responsible
5 person that is a business that meets the appli-
6 cable industry-based small business size stand-
7 ard established by the Administrator of the
8 Small Business Administration under section 3
9 of the Small Business Act to have an additional
10 time period, as determined by the Secretary, to
11 submit any change to the information required
12 to be in a cosmetic ingredient statement as de-
13 scribed in subparagraph (A).

14 “(f) COSMETIC PRODUCTS LIST.—At the time of the
15 initial submission of any cosmetic ingredient statement
16 under this section, the Food and Drug Administration
17 shall assign a unique cosmetic product listing number to
18 the cosmetic ingredient statement. Based on such cosmetic
19 ingredient statements, the Food and Drug Administration
20 shall compile and maintain a list of cosmetic products dis-
21 tributed in the United States, including the ingredients
22 of each such product, and shall make available such list
23 to any State, upon request. Information disclosed to a
24 State that is exempt from disclosure under section
25 552(b)(4) of title 5, United States Code, shall be treated

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

3 **“SEC. 607. SUSPENSION OF REGISTRATION OR COSMETIC**
4 **INGREDIENT STATEMENT.**

5 “(a) SUSPENSION OF REGISTRATION OF A FACIL-
6 ITY.—If the Food and Drug Administration determines
7 that a cosmetic formulation or cosmetic product manufac-
8 tured, processed, packed, or held by a registered facility
9 has a reasonable probability of causing serious adverse
10 health consequences or death to humans, the Food and
11 Drug Administration may suspend the registration of a
12 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 or responsible person,
25 as appropriate, of the intent to suspend the facility

1 registration or the cosmetic ingredient statement,
2 which shall specify the basis of the determination by
3 the Food and Drug Administration that the facility
4 registration or the cosmetic ingredient statement
5 should be suspended; and

6 “(2) an opportunity, within 2 business days of
7 the notice provided under paragraph (1), for the fa-
8 cility or responsible person, as appropriate, to ad-
9 dress the reasons for possible suspension of the facil-
10 ity registration or cosmetic ingredient statement.

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

17 “(e) EFFECT OF SUSPENSION.—

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

22 “(2) COSMETIC INGREDIENT STATEMENT.—If
23 the cosmetic ingredient statement for a cosmetic
24 product is suspended under this section, no person
25 shall import or export such cosmetic product or oth-

1 erwise distribute in the United States such cosmetic
2 product that is the subject of such statement.

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

7 **SEC. 102. REVIEW OF INGREDIENTS AND NONFUNCTIONAL**
8 **CONSTITUENTS; SAFETY OF FINISHED PROD-**
9 **UCTS.**

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

14 **“SEC. 608. REVIEW OF INGREDIENTS AND NONFUNCTIONAL**
15 **CONSTITUENTS.**

16 “(a) INGREDIENTS AND NONFUNCTIONAL CONSTITU-
17 ENTS SUBJECT TO REVIEW.—

18 “(1) IN GENERAL.—Beginning one year after
19 the date of enactment of Cosmetic Safety Enhance-
20 ment Act of 2019, the Food and Drug Administra-
21 tion shall review the safety of the cosmetic ingredi-
22 ents and nonfunctional constituents under para-
23 graph (3), as modified under subsection (c), if appli-
24 cable, and issue an order under subsection (d) with

1 respect to the use of each such ingredient and pres-
2 ence of each such nonfunctional constituent.

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

11 “(3) COSMETIC INGREDIENTS.—

12 “(A) INGREDIENTS TO BE CONSIDERED IN
13 FIRST YEAR.—Not later than one year after the
14 Secretary begins collecting user fees under this
15 section, the Food and Drug Administration
16 shall initiate the review for safety of the fol-
17 lowing cosmetic ingredients:

18 “(i) Diazolidinyl urea.

19 “(ii) Lead acetate.

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.—No later than two
2 years after the Secretary begins collecting
3 user fees under this section, and on an an-
4 nual basis thereafter, the Food and Drug
5 Administration shall select and complete a
6 review of at least 5 cosmetic ingredients or
7 nonfunctional constituents that were not
8 reviewed in the prior 3 years from a list
9 determined in consultation with industry
10 and consumer groups for review of safety.
11 The Food and Drug Administration may
12 combine selected cosmetics ingredients or
13 nonfunctional constituents into categories
14 for purposes of its review. The Food and
15 Drug Administration may modify such list
16 under subsection (c).

17 “(ii) CONSIDERATIONS.—The deter-
18 mination of which ingredients or functional
19 ingredients will be reviewed within a 3-year
20 period shall be publicized in annual reports
21 to Congress and the public, in accordance
22 with section 618, and subject to consulta-
23 tion as provided for in clause (iii). The re-
24 view of any cosmetic ingredient or non-
25 functional constituent shall commence with

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

4 “(iii) ADVISORY COMMITTEE.—Not
5 later than one year after the date of enact-
6 ment of the Cosmetic Safety Enhancement
7 Act of 2019, the Secretary shall—

8 “(I) rename the Food Advisory
9 Committee of the Food and Drug Ad-
10 ministration, as in existence on such
11 date of enactment, the Food and Cos-
12 metic Advisory Committee (in this
13 clause referred to as the ‘Advisory
14 Committee’);

15 “(II) expand the responsibilities
16 of the Advisory Committee to include
17 evaluating and making recommenda-
18 tions on broad scientific and technical
19 cosmetic-related issues, advising on
20 cosmetic ingredients and nonfunc-
21 tional constituents to be considered
22 for review, summarizing public com-
23 ments received by the Food and Drug
24 Administration related to cosmetic in-
25 gredient review, recommending cos-

1 metic ingredients or nonfunctional
2 constituents to be reviewed for safety
3 annually, and advising on other mat-
4 ters pertaining to the safety of new
5 cosmetics and cosmetic ingredients;
6 and

7 “(III) include in the membership
8 of the Advisory Committee equal num-
9 bers of individuals from the cosmetics
10 industry and cosmetics consumer
11 groups, together with such additional
12 members as the Secretary determines
13 appropriate, which additional mem-
14 bers may include medical practitioners
15 with an expertise in cosmetics issues.

16 “(4) COMMENT PERIOD.—The Food and Drug
17 Administration shall solicit public comment on which
18 cosmetic ingredients or nonfunctional constituents
19 on the list are of greatest interest to be reviewed
20 next for early review and which additional cosmetic
21 ingredients or nonfunctional constituents should be
22 added to the list. The public may submit comments
23 to the Food and Drug Administration at any time
24 during the year regarding which cosmetic ingredi-
25 ents or nonfunctional constituents of interest that

1 the Food and Drug Administration may consider
2 during that year or subsequent years.

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

13 “(c) INITIATIVE OF THE FDA.—The Food and Drug
14 Administration may at any time, after consultation with
15 the Food Advisory Committee, propose the issuance of an
16 order on the safety of a cosmetic ingredient or nonfunc-
17 tional constituent that was not previously listed in sub-
18 section (a) or under section 618(a)(3).

19 “(d) DETERMINATION ON SAFETY.—

20 “(1) INITIAL PROPOSED ADMINISTRATIVE
21 ORDER.—Following consideration of data and com-
22 ments to the public docket and any other informa-
23 tion before the Food and Drug Administration, the
24 Food and Drug Administration shall determine
25 whether there is adequate evidence to make an ini-

1 tial finding on the safety of the ingredient or non-
2 functional constituent. If the Food and Drug Ad-
3 ministration determines that there is adequate evi-
4 dence, the Food and Drug Administration shall issue
5 a proposed administrative order and shall post such
6 order on the Internet website of the Food and Drug
7 Administration, notwithstanding subchapter II of
8 chapter 5 of title 5, United States Code. If the Food
9 and Drug Administration issues a proposed adminis-
10 trative order under subparagraph (C) of subsection
11 (d)(4), the proposed administrative order shall in-
12 clude a compliance date by which use of the ingre-
13 dient or nonfunctional constituent in cosmetic prod-
14 ucts shall comply with the final administrative order,
15 when effective.

16 “(2) PUBLIC COMMENT.—Upon publication of
17 the proposed administrative order described in para-
18 graph (1), the Food and Drug Administration shall
19 open a docket for the submission of public comment,
20 including comment on whether any proposed compli-
21 ance date is feasible. The Food and Drug Adminis-
22 tration shall provide 30 days for public comment fol-
23 lowing publication of the proposed administrative
24 order.

1 “(3) FINAL ADMINISTRATIVE ORDER.—Fol-
2 lowing the public comment period described in para-
3 graph (2) and consideration of comments to the pub-
4 lic docket and any other information before the Food
5 and Drug Administration, the Food and Drug Ad-
6 ministration shall determine whether there is ade-
7 quate evidence to make a final finding on the safety
8 of the ingredient or nonfunctional constituent. If the
9 Food and Drug Administration determines that
10 there is adequate evidence, the Food and Drug Ad-
11 ministration shall issue a final administrative order
12 and shall post such order on the Internet website of
13 the Food and Drug Administration, notwithstanding
14 subchapter II of chapter 5 of title 5, United States
15 Code. If the Food and Drug Administration issues
16 a final administrative order under subparagraph (C)
17 of subsection (d)(4), the final administrative order
18 shall include a compliance date by which use of the
19 ingredient or nonfunctional constituent in cosmetic
20 products shall comply with the final administrative
21 order.

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

1 shall make a determination that the ingredient or
2 nonfunctional 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 nonfunctional constituent
13 as are necessary for the safety of cosmetic products
14 containing such ingredient or nonfunctional con-
15 stituent, including—

16 “(A) limits on the amount or concentration
17 of the ingredient or nonfunctional 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 614, 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 nonfunctional constituent; and

6 “(C) such other conditions as are nec-
7 essary for the safety of cosmetic products con-
8 taining such ingredient or nonfunctional con-
9 stituent.

10 “(6) PUBLIC NOTICE.—A final administrative
11 order under this subsection shall set forth the deter-
12 mination of the Food and Drug Administration on
13 safety, any conditions of use or tolerances under
14 subparagraph (A) or (B) of subsection (d)(4) and a
15 summary of the valid scientific evidence supporting
16 the finding. If the final administrative order does
17 not identify a compliance date, the order shall be ef-
18 fective upon its publication on the Internet website
19 of the Food and Drug Administration and shall be
20 considered final agency action.

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

1 “(f) INADEQUATE EVIDENCE.—

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

9 “(A) publish such finding on the Internet
10 website of the Food and Drug Administration
11 not later than 180 days after the close of the
12 relevant comment period for the ingredient or
13 nonfunctional constituent under subsection
14 (a)(2), in the case of a proposed order, or sub-
15 section (d)(2), in the case of a final order; and

16 “(B) include a notice providing interested
17 persons an additional 30 days from the notice
18 date to provide additional data and information.

19 “(2) DETERMINATION; ORDER.—

20 “(A) INADEQUATE DATA AND INFORMA-
21 TION.—If the Food and Drug Administration
22 determines, after considering any additional
23 data and information submitted under para-
24 graph (1)(B), that the available data and infor-
25 mation still are not adequate to make a deter-

1 mination regarding safety under subsection
2 (d)(4), the Food and Drug Administration
3 shall, within 180 days of the close of the addi-
4 tional time period provided under paragraph
5 (1)(B), issue a final administrative order—

6 “(i) making a determination that the
7 ingredient or nonfunctional constituent has
8 not been shown to be safe in cosmetic
9 products; and

10 “(ii) explaining why the available data
11 and information are not adequate to assess
12 the safety of the ingredient or nonfunc-
13 tional constituent.

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

1 section. If the Food and Drug Administration
2 determines, after considering any additional
3 data and information submitted under para-
4 graph (1)(B), that the available data and infor-
5 mation are adequate to make a determination
6 regarding safety under subsection (d)(4)(B),
7 the Food and Drug Administration shall, within
8 180 days of the close of the comment period,
9 issue a final order.

10 “(g) SAFETY ASSESSMENT.—

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

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

3 “(2) FACTORS.—In assessing the safety of an
4 ingredient or nonfunctional constituent, the Sec-
5 retary shall consider the following, among other rel-
6 evant factors, to the extent the Secretary determines
7 adequate data are available for such analyses:

8 “(A) The probable human exposure to the
9 ingredient or nonfunctional constituent from ex-
10 pected use in cosmetics.

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

24 “(C) Whether warnings or recommenda-
25 tions in a product label, as part of any condi-

1 tions of use or tolerances imposed by the Food
2 and Drug Administration, would be necessary
3 and appropriate to help ensure the safety of the
4 ingredient or nonfunctional constituent.

5 “(3) DATA AND INFORMATION.—

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

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

25 “(i) adverse event reports;

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

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

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

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

18 “(a) DETERMINATION.—

19 “(1) IN GENERAL.—Each responsible person
20 for a finished cosmetic product shall, before first dis-
21 tributing the product for sale, make a written deter-
22 mination that the product is safe under the condi-
23 tions of use recommended in the labeling of the
24 product. Such determination shall be based on ade-
25 quate evidence that each ingredient in the finished

1 product is safe for the use recommended or sug-
2 gested in the labeling of the product and that the
3 finished product is safe.

4 “(2) NEW INFORMATION.—If new information
5 relevant to the determination becomes available, the
6 responsible person shall promptly update the deter-
7 mination to address that information.

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

16 “(b) PRESUMPTION OF ADEQUATE EVIDENCE.—

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

21 “(A) with respect to each ingredient in the
22 finished product—

23 “(i) references to an official statement
24 by one or more expert medical or scientific
25 bodies that the ingredient is safe under the

1 conditions of use recommended or sug-
2 gested in the product's labeling; or

3 “(ii) appropriate safety testing of the
4 ingredient; and

5 “(B) appropriate safety substantiation of
6 the finished product beyond the safety substan-
7 tiation of individual ingredients and consider-
8 ation of the combination of ingredients.

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

13 “(A) the medical or scientific body is a
14 Federal, State, national, or international entity
15 with recognized expertise in chemical or cos-
16 metic safety, or other similarly recognized body
17 composed of scientific and medical experts;

18 “(B) the statement is based upon adequate
19 data to support the finding of safety, and such
20 data are available to the Food and Drug Ad-
21 ministration; and

22 “(C) the statement is published and en-
23 dorsed by the medical or scientific body and is
24 not a statement of an employee of such body
25 made in the individual capacity of the employee.

1 “(c) REBUTTAL OF PRESUMPTION.—Notwith-
2 standing subsection (b), a determination under subsection
3 (a) will not be presumed to be based on adequate evidence
4 if—

5 “(1) the Food and Drug Administration issues
6 an order under section 608 that an ingredient or
7 nonfunctional constituent in the finished product is
8 not safe under the product’s conditions of use or
9 customary or usual use; or

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

12 “(A) the manufacturer has not met the cri-
13 teria under subsection (b); or

14 “(B) the Food and Drug Administration
15 has information that raises significant questions
16 about the safety of the product or any of its in-
17 gredients.

18 “(d) TIMELY UPDATE.—Upon notice of inadequate
19 evidence under subsection (c), the responsible person shall
20 have 10 days to submit additional evidence to the Food
21 and Drug Administration regarding the safety of an ingre-
22 dient, nonfunctional constituent, or the entire cosmetic
23 product, and the Food and Drug Administration shall
24 have 30 days from the date of receipt of such additional

1 evidence to provide the responsible person with notice that
2 the criteria under subsection (b) have been met or not met.

3 “(e) RECORDS MAINTENANCE.—The responsible per-
4 son shall maintain records documenting the determination
5 required under this section and the information on which
6 it is based until 5 years after the finished product is no
7 longer marketed.

8 “(f) SUBMISSION OF RECORDS.—

9 “(1) IN GENERAL.—The records required under
10 subsection (e) shall, upon the written request of the
11 Food and Drug Administration to the responsible
12 person, be provided to the Food and Drug Adminis-
13 tration within a reasonable timeframe not to exceed
14 30 days, in electronic form.

15 “(2) CRITERIA.—The Food and Drug Adminis-
16 tration may require records under paragraph (1)
17 if—

18 “(A) the Food and Drug Administration
19 has a reasonable belief, described in written no-
20 tice, that—

21 “(i) the finished product may be
22 harmful based on adverse event reports or
23 other scientific information;

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

4 “(iii) the determination required
5 under subsection (a) is not supported by
6 adequate evidence; or

7 “(iv) one or more of the criteria to es-
8 tablish a presumption of adequate evidence
9 of safety in subsection (b) has not been
10 satisfied;

11 “(B) the Food and Drug Administration,
12 an expert regulatory body, or an expert body
13 composed of scientific and medical experts finds
14 an ingredient in the product to be unsafe under
15 the conditions of use of the product; or

16 “(C) the Food and Drug Administration
17 concludes that submission of the records will
18 serve the public health or otherwise enable the
19 Food and Drug Administration to fulfill the
20 cosmetic safety purposes of this section.

21 “(g) GUIDANCE AND REGULATIONS.—

22 “(1) IN GENERAL.—The Food and Drug Ad-
23 ministration shall issue guidance describing the evi-
24 dence necessary to support a determination under
25 subsection (a), and may, by regulation, establish ex-

1 exemptions to the requirements of this section, if the
2 Food and Drug Administration determines that such
3 exemptions are supported by adequate evidence and
4 would have no adverse effect on public health.

5 “(2) SMALL BUSINESSES.—The Food and Drug
6 Administration shall, after consultation with the
7 Small Business Administration and small businesses
8 that manufacture cosmetics, provide additional guid-
9 ance for small businesses on compliance with the re-
10 quirements of this section. Such guidance shall in-
11 clude specific examples of options for compliance
12 that do not place an undue burden on small busi-
13 nesses.”.

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

18 **SEC. 103. GOOD MANUFACTURING PRACTICES FOR COS-**
19 **METICS.**

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

1 **“SEC. 610. GOOD MANUFACTURING PRACTICES FOR COS-**
2 **METICS.**

3 “(a) IN GENERAL.—The Food and Drug Administra-
4 tion shall review national and international standards for
5 cosmetic good manufacturing practices that are in exist-
6 ence on the date of enactment of the Cosmetic Safety En-
7 hancement Act of 2019 and shall develop and implement,
8 through regulations, United States standards consistent,
9 to the extent the Food and Drug Administration deter-
10 mines practicable and appropriate, with such national and
11 international standards for cosmetic good manufacturing
12 practices to ensure that requirements of this chapter with
13 respect to the manufacture of cosmetic products are in
14 harmony.

15 “(b) TIMEFRAME.—The Food and Drug Administra-
16 tion shall publish a proposed rule described in subsection
17 (a) not later than 18 months after the date of enactment
18 of the Cosmetic Safety Enhancement Act of 2019 and
19 shall publish a final such rule not later than 3 years after
20 such date of enactment.”.

21 (b) EFFECTIVE DATE FOR COSMETIC MANUFACTUR-
22 ERS.—

23 (1) LARGE BUSINESSES.—For businesses of a
24 size greater than the Small Business Administra-
25 tion’s standard for a small business, section 610 of
26 the Federal Food, Drug, and Cosmetic Act (as

1 added by subsection (a)) shall take effect beginning
2 180 days after the date on which the Food and
3 Drug Administration publishes the final rule de-
4 scribed in subsection (a).

5 (2) **SMALL BUSINESSES.**—For businesses of a
6 size that meets the Small Business Administration’s
7 standard for a small business, section 610 of the
8 Federal Food, Drug, and Cosmetic Act (as added by
9 subsection (a)) shall take effect beginning 2 years
10 after the date the Food and Drug Administration
11 makes effective the final rule described in subsection
12 (a).

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

16 “(f) If the methods used in, or the facilities or con-
17 trols used for, its manufacture, processing, packing, or
18 holding do not conform to current good manufacturing
19 practice, as prescribed by the Food and Drug Administra-
20 tion.”.

21 **SEC. 104. ADVERSE EVENT REPORTS.**

22 Chapter VI of the Federal Food, Drug, and Cosmetic
23 Act (21 U.S.C. 361 et seq.), as amended by section
24 103(a), is further amended by adding at the end the fol-
25 lowing:

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

2 “(a) IN GENERAL.—With respect to any cosmetic
3 product distributed in the United States, the responsible
4 person shall submit, in electronic format, to the Food and
5 Drug Administration—

6 “(1) a report of any serious adverse event asso-
7 ciated with such cosmetic product, when used in the
8 United States, accompanied by a copy of the label
9 on or with the retail packaging of the cosmetic;

10 “(2) any new medical information, related to a
11 submitted serious adverse event report, that is re-
12 ceived by the responsible person; and

13 “(3) an annual report for all adverse events for
14 which information has received by the responsible
15 person.

16 “(b) DEFINITIONS.—In this section:

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

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

22 “(A) results in—

23 “(i) death;

24 “(ii) a life-threatening experience;

25 “(iii) inpatient hospitalization;

1 “(iv) a persistent or significant ad-
2 verse health condition, disability or inca-
3 pacity;

4 “(v) congenital anomaly or birth de-
5 fect; or

6 “(vi) significant disfigurement, includ-
7 ing serious and persistent rashes and infec-
8 tions, burns, or significant hair loss; or

9 “(B) requires, based on reasonable medical
10 judgment, a medical or surgical intervention to
11 prevent an outcome described in subparagraph
12 (A).

13 “(c) SUBMISSION OF REPORTS.—

14 “(1) SERIOUS ADVERSE EVENT REPORTS.—Ex-
15 cept as provided in paragraph (2), the responsible
16 person shall submit a serious adverse event report to
17 the Food and Drug Administration not later than 15
18 business days after information concerning the ad-
19 verse event is received. If a serious adverse event re-
20 port for a cosmetic with drug properties is filed
21 using Form FDA 3500A (or any successor form de-
22 veloped for such purpose) or its electronic equivalent
23 for over-the-counter drugs, the responsible person
24 shall not have to submit a duplicative serious ad-
25 verse event report under this section. Serious ad-

1 verse event reports under this section shall be made
2 available on the Internet website of the Food and
3 Drug Administration.

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

12 “(3) SEMIANNUAL REPORT.—

13 “(A) IN GENERAL.—Not later than Janu-
14 ary 1 and July 1 of each year, the responsible
15 person shall submit an electronic report for the
16 prior calendar year for each cosmetic product
17 marketed during that year.

18 “(B) CONTENTS.—Each report under this
19 paragraph shall contain a summary of all ad-
20 verse events received during the reporting pe-
21 riod, a complete list of individual reports, and
22 an estimate of the total number of product
23 units estimated to have been distributed to con-
24 sumers during such period. The report shall not
25 include consumer complaints that are solely re-

1 garding efficacy and do not contain any infor-
2 mation about an adverse event. The Food and
3 Drug Administration shall further specify the
4 contents of the annual electronic report by reg-
5 ulation or guidance.

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

13 “(d) REQUIREMENTS.—

14 “(1) IN GENERAL.—Each serious adverse event
15 report under this section shall be submitted to the
16 Food and Drug Administration using an electronic
17 system of the Food and Drug Administration. The
18 Food and Drug Administration shall make such elec-
19 tronic system available not later than 1 year after
20 the date of enactment of the Cosmetic Safety En-
21 hancement Act of 2019.

22 “(2) MODIFICATION.—The format of the re-
23 porting system may be modified by the Food and
24 Drug Administration and the reports may include
25 additional information. The Food and Drug Admin-

1 istration may, in guidance, further specify the for-
2 mat and contents of required reports.

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

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

11 “(B) a record about an individual who suf-
12 fered the serious adverse event under section
13 552a of title 5, United States Code;

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

20 “(D) contact information for the individual
21 reporting the serious adverse event.

22 “(4) RESPONSIBILITY TO GATHER INFORMA-
23 TION.—After an individual initiates the reporting of
24 a serious adverse event, the responsible person for
25 the cosmetic product shall actively gather all of the

1 information to complete and file the report with the
2 Food and Drug Administration.

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

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

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

24 “(g) MAINTENANCE OF RECORDS.—The responsible
25 person shall maintain records related to each report of an

1 adverse event received by the responsible person for a pe-
2 riod of 6 years.

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

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

16 **SEC. 105. RECORDS INSPECTION; MANDATORY RECALL AU-**
17 **THORITY.**

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

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

22 “(a) INSPECTION OF RECORDS.—Each manufac-
23 turer, processor, packer, holder, distributor, transporter,
24 or person whose name and address appear on the label
25 of a cosmetic shall, at the request of an officer or employee

1 duly designated by the Food and Drug Administration,
2 permit such officer or employee, upon presentation of ap-
3 propriate credentials and written notice to such person,
4 at reasonable times and within reasonable limits and in
5 a reasonable manner, to have access to and copy—

6 “(1) all records maintained under section 611
7 and in accordance with the rules promulgated by the
8 Food and Drug Administration under section 610,
9 as applicable;

10 “(2) all records maintained under section 609;
11 and

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

15 “(A) has a reasonable belief that the cos-
16 metic—

17 “(i) is adulterated;

18 “(ii) has caused a reportable serious
19 adverse event; or

20 “(iii) contains an ingredient that sub-
21 stantial new scientific information shows
22 may be unsafe when present in a cosmetic;
23 and

24 “(B) provides written notice of the basis
25 for the Food and Drug Administration’s rea-

1 sonable belief described in subparagraph (A), as
2 applicable.

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

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

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

23 “(e) LIMITATIONS.—This section shall not be con-
24 strued—

1 “(1) to limit the authority of the Food and
2 Drug Administration to inspect records or to require
3 establishment and maintenance of records under any
4 other provision of this Act; or

5 “(2) to have any legal effect on section 552 of
6 title 5, United States Code, or section 1905 of title
7 18, United States Code.

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

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

18 “(b) PREHEARING ORDER TO MANDATORILY CEASE
19 DISTRIBUTION AND GIVE NOTICE.—

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

1 “(A) immediately cease distribution of
2 such cosmetic; and

3 “(B) as applicable, immediately notify all
4 persons—

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

9 “(ii) to which such cosmetic has been
10 distributed, transported, or sold,

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

13 “(2) REQUIRED ADDITIONAL INFORMATION.—

14 “(A) IN GENERAL.—If a cosmetic covered
15 by a recall order issued under paragraph (1)(B)
16 has been distributed to a warehouse-based third
17 party logistics provider without providing such
18 provider sufficient information to know or rea-
19 sonably determine the precise identity of such
20 cosmetic covered by a recall order that is in its
21 possession, the notice provided by the respon-
22 sible person subject to the order issued under
23 paragraph (1)(B) shall include such information
24 as is necessary for the warehouse-based, third-
25 party logistics provider to identify 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
7 612; 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) POSTHEARING 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 an image of

1 the cosmetic that is the subject of the press release
2 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. 614. 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 608(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.—With re-
6 spect to cosmetics, the term ‘professional’ means an
7 individual who—

8 “(A) is licensed by an official State author-
9 ity to practice in the field of cosmetology, nail
10 care, barbering, and 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, as required for other cosmetic products
18 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
25 Administered Only by Licensed Professionals’.

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

4 “(1) in the primary language used on the label
5 or on packaging; and

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

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

17 “(e) CONTACT INFORMATION.—The label on each
18 cosmetic shall bear the domestic telephone number or elec-
19 tronic contact information, and it is encouraged that the
20 label include both the telephone number and electronic
21 contact information, that consumers may use to contact
22 the responsible person with respect to adverse events. The
23 contact number shall provide a means for consumers to
24 obtain additional information about ingredients in a cos-
25 metic, including the ability to ask if a specific ingredient

1 may be present that is not listed on the label, including
2 whether a specific ingredient may be contained in the fra-
3 grance or flavor used in the cosmetic. The responsible per-
4 son whose contact information appears on the cosmetic
5 product label is responsible for providing such information
6 to consumers and is charged with promptly obtaining the
7 information from suppliers if it is not readily available.
8 Suppliers are required to promptly release such informa-
9 tion upon request of the cosmetic manufacturer.”.

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

14 **SEC. 107. COAL TAR CHEMICALS.**

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

18 **“SEC. 615. COAL TAR CHEMICALS.**

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

25 “(b) COAL TAR HAIR DYES.—

1 “(1) IN GENERAL.—Specific ingredients in coal
2 tar hair dyes may be selected and reviewed under
3 section 608(a)(3).

4 “(2) LIMITATION.—The Food and Drug Ad-
5 ministration shall not make a determination that a
6 coal tar hair dye chemical is harmful solely because
7 the coal tar hair dye chemical can cause allergic re-
8 actions, if the Food and Drug Administration can
9 sustain the safe use of the coal tar hair dye chemical
10 through appropriate restrictions, which may in-
11 clude—

12 “(A) warnings;

13 “(B) limitations on the amount or con-
14 centration of the coal tar hair dye chemical; or

15 “(C) other such conditions that may help
16 to ensure the safety of cosmetics containing
17 coal tar hair dye chemicals.”.

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

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

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

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

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

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

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

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

14 【“(2) encourage—】

15 【“(A) the sharing of data across compa-
16 nies and organizations that are testing for safe-
17 ty in cosmetics, so as to avoid duplication of
18 animal tests; and】

19 【“(B) funding for research and validation
20 of alternative testing methods.】

21 【“(b) GUIDANCE.—Not later than 3 years after the
22 date of enactment of the Cosmetic Safety Enhancement
23 Act of 2019, the Food and Drug Administration shall
24 issue guidance on the acceptability of scientifically reliable
25 and relevant alternatives to animal testing for the safety

1 of cosmetic ingredients, nonfunctional constituents, and
2 finished cosmetic products, and encouraging the use of
3 such methods. The Food and Drug Administration shall
4 update such guidance on an annual basis.】

5 【“(c) RESOURCES REGARDING ANIMAL TESTING AL-
6 TERNATIVES.—Not later than 180 days after the date of
7 enactment of the Cosmetic Safety Enhancement Act of
8 2019, the Food and Drug Administration shall provide in-
9 formation on the Internet website of the Food and Drug
10 Administration regarding resources available for informa-
11 tion about non-animal methods, and methods that reduce
12 animal usage, in testing for the safety of cosmetic ingredi-
13 ents, nonfunctional constituents, and finished cosmetic
14 products.”.】

15 **【SEC. 109. PREEMPTION.**

16 【Chapter VI of the Federal Food, Drug, and Cos-
17 metic Act (21 U.S.C. 361 et seq.), as amended by section
18 108, is further amended by adding the following:】】

19 **【“SEC. 617. PREEMPTION.**

20 **【“(a) IN GENERAL.—【*To be supplied*】】**

21 **【“(b) SAVINGS.—Nothing in the amendments to this**
22 **Act made by the Cosmetic Safety Enhancement Act of**
23 **2019, nor any standard, rule, requirement, regulation, ad-**
24 **verse event report, safety assessment, safety determina-**
25 **tion, scientific assessment, or order issued or implemented**

1 pursuant to such amendments, shall be construed to mod-
2 ify or otherwise affect, preempt, or displace any cause of
3 action or State or Federal law creating a remedy for civil
4 relief or criminal cause of action, whether statutory or
5 based in common law.”.]

6 **SEC. 110. REPORTING.**

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

10 **“SEC. 618. REPORTING.**

11 “(a) PERFORMANCE REPORT.—Beginning with fiscal
12 year 2021, and not later than 60 days prior to the end
13 of each fiscal year for which fees are collected under sec-
14 tion 744L, the Food and Drug Administration shall pre-
15 pare and submit to Congress a report concerning the
16 progress of the Food and Drug Administration in achiev-
17 ing the objectives of the Cosmetic Safety Enhancement
18 Act of 2019 during such fiscal year and the future plans
19 of the Food and Drug Administration for meeting the ob-
20 jectives. The annual report for a fiscal year shall include—

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

24 “(2) identification of the cosmetic ingredients
25 and nonfunctional constituents that have been fully

1 reviewed for safety by the Food and Drug Adminis-
2 tration in the prior fiscal year and for which a final
3 administrative order has been released;

4 “(3) identification of the cosmetic ingredients
5 and nonfunctional constituents identified by the
6 Food and Drug Administration for review under sec-
7 tion 608(a)(3)(B) during the relevant time period
8 and identify which, if any, reviews are complete;

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

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

15 “(6) efforts of the Food and Drug Administra-
16 tion to reduce animal testing for safety of cosmetic
17 ingredients, nonfunctional constituents, and cosmetic
18 products.

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

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

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

5 **“SEC. 619. SMALL BUSINESSES.**

6 “(a) IN GENERAL.—The Commissioner, in coordina-
7 tion with the Administrator of the Small Business Admin-
8 istration, shall provide technical assistance, such as guid-
9 ance and expertise, to small businesses regarding compli-
10 ance with the Cosmetic Safety Enhancement Act of 2019,
11 including the amendments made by such Act.

12 “(b) COMPLIANCE GUIDE.—Not later than 180 days
13 after enactment of Cosmetic Safety Enhancement Act of
14 2019, the Secretary shall issue a small business guide set-
15 ting forth in plain language the requirements of sections
16 605 and 606 in order to assist small businesses in com-
17 plying.”.

18 **SEC. 112. APPLICABILITY WITH RESPECT TO CERTAIN COS-**
19 **METICS.**

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

23 **“SEC. 620. APPLICABILITY WITH RESPECT TO CERTAIN**
24 **COSMETICS.**

25 “In the case of a cosmetic product or a facility that
26 is subject to the requirements under this chapter and

1 chapter V, if any requirement under chapter V with re-
2 spect to such cosmetic or facility is substantially similar
3 to a requirement under this chapter, the cosmetic product
4 or facility shall be deemed to be in compliance with the
5 applicable requirement under this chapter if such product
6 or facility is in compliance with such substantially similar
7 requirement under chapter V, provided that the product
8 or facility has not obtained a waiver from the requirement
9 under chapter V.”.

10 **SEC. 113. ENFORCEMENT.**

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

14 (1) in paragraph (e)—

15 (A) by striking “504, 564,” and inserting
16 “504, 564, 611, 612”; and

17 (B) by striking “519, 564,” and inserting
18 “519, 564, 611,”;

19 (2) in paragraph (j) by inserting “607, 608,
20 610,” before “704”;

21 (3) in paragraph (ii)—

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

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

1 (4) in paragraph (xx) by inserting “or 613”
2 after “423”; and

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

4 “(fff) The failure to register in accordance with sec-
5 tion 605, the failure to submit a cosmetic ingredient state-
6 ment under section 606, the failure to provide any infor-
7 mation required by section 605 or 606, or the failure to
8 update the information required by section 605 or 606,
9 as required.”.

10 (b) ADULTERATION.—Section 601 of the Federal
11 Food, Drug, and Cosmetic Act (21 U.S.C. 361), as
12 amended by section 603, is further amended by adding
13 at the end the following:

14 “(g) If it contains, after the date prescribed under
15 section 608(e), an ingredient that the Food and Drug Ad-
16 ministration has determined under section 608(d)(4) to be
17 not safe, or not safe under the conditions of use rec-
18 ommended or suggested in the label or a nonfunctional
19 constituent that the Food and Drug Administration has
20 determined under section 608(d)(4) to be not safe or not
21 safe in the amount present in the cosmetic.

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

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

1 (1) in paragraph (b)—

2 (A) by striking “and (2)” and inserting
3 “(2)”; and

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

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

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

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

20 (d) GUIDANCE.—Not later than 1 year after the date
21 of enactment of this Act, the Food and Drug Administra-
22 tion shall issue guidance that defines the circumstances
23 that would constitute delaying, denying, or limiting inspec-
24 tion, or refusing to permit entry or inspection, for pur-

1 poses of section 602(g) of the Federal Food, Drug, and
2 Cosmetic Act, as added by subsection (c)(2).

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

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

7 (2) by striking “760 or 761)” and inserting
8 “604, 760, or 761”).

9 (f) FACTORY INSPECTION.—Section 704(a)(1) is
10 amended by inserting after the third sentence the fol-
11 lowing: “In the case of any person who manufactures,
12 processes, packs, holds, distributes, or imports a cosmetic
13 product, or distributes a cosmetic product and affixes its
14 name on the cosmetic label, the inspection shall extend
15 to all records and other information described in section
16 612 (regarding inspection of cosmetic records), when the
17 standard for records inspections under paragraph (1) or
18 (2) of subsection (a) of such section applies, subject to
19 the limitations under subsection (d) of such section.”.

20 **SEC. 114. CONSUMER INFORMATION.**

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

23 (1) final orders regarding the safety of a cos-
24 metic ingredient or nonfunctional constituent under
25 section 608(d)(3);

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

3 (3) identified counterfeit cosmetic products.

4 **SEC. 115. FOREIGN SUPPLIER VERIFICATION.**

5 (a) IN GENERAL.—Chapter VIII of the Federal
6 Food, Drug, and Cosmetic Act (21 U.S.C. 381 et seq.)
7 is amended by adding at the end the following:

8 **“SEC. 810. COSMETICS FOREIGN SUPPLIER VERIFICATION**
9 **PROGRAM.**

10 “(a) IN GENERAL.—

11 “(1) VERIFICATION REQUIREMENT.—Except as
12 provided under subsection (e), each importer shall
13 perform risk-based foreign supplier verification ac-
14 tivities for the purpose of verifying that the cosmetic
15 or cosmetic ingredient imported by the importer (or
16 agent thereof)—

17 “(A) has been manufactured according to
18 the cosmetic good manufacturing practices es-
19 tablished under section 610; and

20 “(B) is not adulterated under section 601
21 or misbranded under section 602.

22 “(2) IMPORTER DEFINED.—For purposes of
23 this section, the term ‘importer’ means, with respect
24 to a cosmetic finished product or cosmetic ingre-
25 dient—

1 “(A) the United States owner or consignee
2 of the cosmetic or cosmetic ingredient at the
3 time of entry of such cosmetic or cosmetic in-
4 gredient into the United States; or

5 “(B) in the case when there is no United
6 States owner or consignee as described in sub-
7 paragraph (A), the United States agent or rep-
8 resentative of a foreign owner or consignee of
9 the cosmetic or cosmetic ingredient at the time
10 of entry of such article into the United States.

11 “(b) GUIDANCE.—Not later than 1 year after the
12 date of enactment of the Cosmetic Safety Enhancement
13 Act of 2019, the Secretary shall issue guidance to assist
14 importers in developing foreign supplier verification pro-
15 grams.

16 “(c) REGULATIONS.—

17 “(1) IN GENERAL.—Not later than 1 year after
18 the date of enactment of Cosmetic Safety Enhance-
19 ment Act of 2019, the Secretary shall promulgate
20 regulations to provide for the content of the foreign
21 supplier verification program established under sub-
22 section (a).

23 “(2) REQUIREMENTS.—The regulations promul-
24 gated under paragraph (1)—

1 “(A) shall require that the foreign supplier
2 verification program of each importer be ade-
3 quate to provide assurances that each foreign
4 supplier to the importer produces the imported
5 cosmetic or cosmetic ingredient in compliance
6 with—

7 “(i) with cosmetic good manufac-
8 turing practices established under section
9 610; and

10 “(ii) sections 601 and 602; and

11 “(B) shall include such other requirements
12 as the Secretary deems necessary and appro-
13 priate to verify that cosmetics and cosmetic in-
14 gredients imported into the United States are
15 as safe as cosmetics and cosmetic ingredients
16 produced and sold within the United States.

17 “(3) CONSIDERATIONS.—In promulgating regu-
18 lations under this subsection, the Secretary shall, as
19 appropriate, take into account differences among im-
20 porters and types of imported cosmetics and cos-
21 metic ingredients, including based on the level of
22 risk posed by the imported cosmetic or cosmetic in-
23 gredient.

24 “(4) ACTIVITIES.—Verification activities under
25 a foreign supplier verification program under this

1 section may include monitoring records for ship-
2 ments, lot-by-lot certification of compliance, annual
3 on-site inspections, compliance with cosmetic good
4 manufacturing practices and other safety processes,
5 and periodically testing and sampling shipments.

6 “(d) RECORD MAINTENANCE AND ACCESS.—Records
7 of an importer related to a foreign supplier verification
8 program shall—

9 “(1) be maintained for a period of not less than
10 2 years; and

11 “(2) be made available promptly to a duly au-
12 thorized representative of the Secretary upon re-
13 quest.

14 “(e) EXEMPTIONS.—The Secretary, by notice pub-
15 lished in the Federal Register, shall establish an exemp-
16 tion from the requirements of this section for cosmetics
17 or cosmetic ingredients imported in small quantities for
18 research and evaluation purposes or for personal consump-
19 tion, provided that such cosmetics or cosmetic ingredients
20 are not intended for retail sale and are not sold or distrib-
21 uted to the public.

22 “(f) PUBLICATION OF LIST OF PARTICIPANTS.—The
23 Secretary shall publish and maintain on the Internet
24 website of the Food and Drug Administration a current
25 list that includes the name of, location of, and other infor-

1 mation deemed necessary by the Secretary about, import-
2 ers participating under this section.”.

3 (b) PROHIBITED ACT.—Section 301 of the Federal
4 Food, Drug, and Cosmetic Act (21 U.S.C. 331), as
5 amended by section 113, is further amended by adding
6 at the end the following:

7 “(ggg) The importation or offering for importation
8 of a cosmetic or cosmetic ingredient if the importer (as
9 defined in section 810) does not have in place a foreign
10 supplier verification program in compliance with such sec-
11 tion 810.”.

12 (c) EFFECTIVE DATE.—The amendments made by
13 this section shall take effect 2 years after the date of en-
14 actment of this Act.

15 **TITLE II—FEES RELATED TO** 16 **COSMETIC SAFETY**

17 **SEC. 201. FINDINGS.**

18 Congress finds that the fees authorized by the
19 amendments made by this title will be dedicated to cos-
20 metic safety activities, as set forth in the goals identified
21 for purposes of part 10 of subchapter C of chapter VII
22 of the Federal Food, Drug, and Cosmetic Act, in the let-
23 ters from the Secretary of Health and Human Services
24 to the Chairman of the Committee on Health, Education,
25 Labor, and Pensions of the Senate and the Chairman of

1 the Committee on Energy and Commerce of the House
2 of Representatives, as set forth in the Congressional
3 Record.

4 **SEC. 202. AUTHORITY TO ASSESS AND USE COSMETIC SAFE-**
5 **TY FEES.**

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

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

10 **“SEC. 744L. REGISTRATION FEE.**

11 “(a) ASSESSMENT AND COLLECTION.—

12 “(1) IN GENERAL.—Beginning in fiscal year
13 2019, the Secretary shall in accordance with this
14 section assess and collect an annual fee from every
15 responsible person required to register under section
16 605(a).

17 “(2) PAYABLE DATE.—Fees under this section
18 shall be due and payable—

19 “(A) for fiscal year 2019, with respect to
20 responsible parties required to register under
21 section 605 for such first program year, on the
22 date of registration; and

23 “(B) for fiscal year 2019 and each subse-
24 quent fiscal year, on the later of—

1 “(i) the date of registration or reg-
2 istration renewal, as applicable, under sec-
3 tion 605; or

4 “(ii) the date of enactment of an ap-
5 propriations Act providing for the collec-
6 tion and obligation of fees under this sec-
7 tion for the fiscal year involved.

8 “(b) DEFINITIONS.—In this section:

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

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

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

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

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

24 “(A) means activities related to compliance
25 by responsible parties required to register under

1 section 605 with the requirements of this Act
2 with respect to cosmetics, including—

3 “(i) administrative activities, such
4 as—

5 “(I) information technology ac-
6 quisition, management, maintenance,
7 and support;

8 “(II) the acquisition, administra-
9 tion, and maintenance of the cosmetic
10 registration system and the cosmetic
11 ingredient statement system under
12 section 606;

13 “(III) fee assessment and collec-
14 tion under this section; and

15 “(IV) the acquisition, leasing,
16 maintenance, renovation and repair of
17 facilities, fixtures, furniture, scientific
18 equipment, and other necessary mate-
19 rials and supplies for purposes of sub-
20 clauses (I) through (III); and

21 “(ii) implementation and enforcement
22 activities, such as the establishment of
23 good manufacturing practices, the review
24 of adverse event reports, inspection plan-

1 ning and inspections, and use of enforce-
2 ment tools;

3 “(B) includes activities related to imple-
4 mentation of section 608, regarding the review
5 of cosmetic ingredients and nonfunctional con-
6 stituents; and

7 “(C) activities of the Secretary related to
8 implementation of section 606.

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

15 “(c) FEE SETTING AND AMOUNTS.—

16 “(1) IN GENERAL.—Subject to subsection (d),
17 the Food and Drug Administration shall establish
18 the fees to be collected under this section for each
19 fiscal year after fiscal year 2019, based on the meth-
20 odology described in paragraph (3)(B), and shall
21 publish such fees in a Federal Register notice not
22 later than 60 days before the beginning of each such
23 fiscal year.

24 “(2) FEE EXEMPTION.—Any responsible party
25 required to register under section 605 whose average

1 gross annual sales of cosmetic products in the 3-year
2 period immediately preceding the fiscal year for
3 which the annual fee will be paid was not more than
4 **【\$500,000】**, shall be exempt from registration fees
5 under this section for that fiscal year.

6 “(3) ANNUAL FEE SETTING.—

7 “(A) FISCAL YEAR 2019.—For fiscal year
8 2019, to generate a total estimated revenue
9 amount of \$20,600,000, the amount of the reg-
10 istration fee under subsection (a) shall be as
11 follows:

12 “(i) TIER I-A.—For a responsible
13 party required to register under section
14 605 that has gross annual sales of
15 \$5,000,000,000 or more in 2015,
16 \$1,100,000.

17 “(ii) TIER I-B.—For a responsible
18 party required to register under section
19 605 that has gross annual sales of at least
20 \$4,000,000,000 per annum but less than
21 \$5,000,000,000 in 2015, \$840,000.

22 “(iii) TIER II-A.—For a responsible
23 party required to register under section
24 605 that has gross annual sales of at least

1 \$3,000,000,000 per annum but less than
2 \$4,000,000,000 in 2015, \$720,000.

3 “(iv) TIER II-B.—For a responsible
4 party required to register under section
5 605 that has gross annual sales of at least
6 \$2,000,000,000 per annum but less than
7 \$3,000,000,000 in 2015, \$600,000.

8 “(v) TIER III-A.—For a responsible
9 party required to register under section
10 605 that has gross annual sales of at least
11 \$1,000,000,000 per annum but less than
12 \$2,000,000,000 in 2015, \$500,000.

13 “(vi) TIER III-B.—For a responsible
14 party required to register under section
15 605 that has gross annual sales of at least
16 \$500,000,000 per annum but less than
17 \$1,000,000,000 in 2015, \$395,000.

18 “(vii) TIER IV-A.—For a responsible
19 party required to register under section
20 605 that has gross annual sales of at least
21 \$200,000,000 per annum but less than
22 \$500,000,000 in 2015, \$325,000.

23 “(viii) TIER IV-B.—For a responsible
24 party required to register under section
25 605 that has gross annual sales of at least

1 \$100,000,000 per annum but less than
2 \$200,000,000 in 2015, \$275,000.

3 “(ix) TIER V-A.—For a responsible
4 party required to register under section
5 605 that has gross annual sales of at least
6 \$80,000,000 per annum but less than
7 \$100,000,000 in 2015, \$185,000.

8 “(x) TIER V-B.—For a responsible
9 party required to register under section
10 605 that has gross annual sales of at least
11 \$60,000,000 per annum but less than
12 \$80,000,000 in 2015, \$95,000.

13 “(xi) TIER VI-A.—For a responsible
14 party required to register under section
15 605 that has gross annual sales of at least
16 \$40,000,000 per annum but less than
17 \$60,000,000 in 2015, \$15,000.

18 “(xii) TIER IV-B.—For a responsible
19 party required to register under section
20 605 that has gross annual sales of at least
21 \$20,000,000 per annum but less than
22 \$40,000,000 in 2015, \$12,000.

23 “(xiii) TIER VII-A.—For a responsible
24 party required to register under section
25 605 that has gross annual sales of at least

1 \$2,500,000 per annum but less than
2 \$20,000,000 in 2015, \$500.

3 “(xiv) TIER VII–B.—For a responsible
4 party required to register under section
5 605 that has gross annual sales of at least
6 **[\$500,000]** per annum but less than
7 \$2,500,000 in 2015, \$250.

8 “(B) FISCAL YEARS 2019–2023.—For fiscal
9 years 2019–2023, fees under subsection (a)
10 shall be established to generate a total esti-
11 mated revenue amount of \$20,600,000, as ad-
12 justed by subsection (d). Of that amount:

13 “(i) TIER I–A.—Responsible parties
14 required to register under section 605 that
15 have gross annual sales of \$5,000,000,000
16 or more in the fiscal year immediately pre-
17 ceding the fiscal year in which the annual
18 fee will be paid, shall be responsible, collec-
19 tively, for 10.7 percent.

20 “(ii) TIER I–B.—Responsible parties
21 required to register under section 605 that
22 have gross annual sales of at least
23 \$4,000,000,000 per annum but less than
24 \$5,000,000,000 in the fiscal year imme-
25 diately preceding the fiscal year in which

1 the annual fee will be paid, shall be re-
2 sponsible, collectively, for 4.1 percent.

3 “(iii) TIER II–A.—Responsible parties
4 required to register under section 605 that
5 have gross annual sales of at least
6 \$3,000,000,000 per annum but less than
7 \$4,000,000,000 in the fiscal year imme-
8 diately preceding the fiscal year in which
9 the annual fee will be paid, shall be re-
10 sponsible, collectively, for 3.5 percent.

11 “(iv) TIER II–B.—Responsible parties
12 required to register under section 605 that
13 have gross annual sales of at least
14 \$2,000,000,000 per annum but less than
15 \$3,000,000,000 in the fiscal year imme-
16 diately preceding the fiscal year in which
17 the annual fee will be paid, shall be re-
18 sponsible, collectively, for 2.9 percent.

19 “(v) TIER III–A.—Responsible parties
20 required to register under section 605 that
21 have gross annual sales of at least
22 \$1,000,000,000 per annum but less than
23 \$2,000,000,000 in the fiscal year imme-
24 diately preceding the fiscal year in which

1 the annual fee will be paid, shall be re-
2 sponsible, collectively, for 7.3 percent.

3 “(vi) TIER III–B.—Responsible parties
4 required to register under section 605 that
5 have gross annual sales of at least
6 \$500,000,000 per annum but less than
7 \$1,000,000,000 in the fiscal year imme-
8 diately preceding the fiscal year in which
9 the annual fee will be paid, shall be re-
10 sponsible, collectively, for 13.4 percent.

11 “(vii) TIER IV–A.—Responsible parties
12 required to register under section 605 that
13 have gross annual sales of at least
14 \$200,000,000 per annum but less than
15 \$500,000,000 in the fiscal year imme-
16 diately preceding the fiscal year in which
17 the annual fee will be paid, shall be re-
18 sponsible, collectively, for 15.8 percent.

19 “(viii) TIER IV–B.—Responsible par-
20 ties required to register under section 605
21 that have gross annual sales of at least
22 \$100,000,000 per annum but less than
23 \$200,000,000 in the fiscal year imme-
24 diately preceding the fiscal year in which

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

3 “(ix) TIER V-A.—Responsible parties
4 required to register under section 605 that
5 have gross annual sales of at least
6 \$80,000,000 per annum but less than
7 \$100,000,000 in the fiscal year imme-
8 diately preceding the fiscal year in which
9 the annual fee will be paid, shall be re-
10 sponsible, collectively, for 9 percent.

11 “(x) TIER V-B.—Responsible parties
12 required to register under section 605 that
13 have gross annual sales of at least
14 \$60,000,000 per annum but less than
15 \$80,000,000 in the fiscal year immediately
16 preceding the fiscal year in which the an-
17 nual fee will be paid, shall be responsible,
18 collectively, for 6.9 percent.

19 “(xi) TIER VI-A.—Responsible parties
20 required to register under section 605 that
21 have gross annual sales of at least
22 \$40,000,000 per annum but less than
23 \$60,000,000 in the fiscal year immediately
24 preceding the fiscal year in which the an-

1 nual fee will be paid, shall be responsible,
2 collectively, for 5.1 percent.

3 “(xii) TIER VI–B.—Responsible par-
4 ties required to register under section 605
5 that have gross annual sales of at least
6 \$20,000,000 per annum but less than
7 \$40,000,000 in the fiscal year immediately
8 preceding the fiscal year in which the an-
9 nual fee will be paid, shall be responsible,
10 collectively, for 4.4 percent.

11 “(xiii) TIER VII–A.—Responsible par-
12 ties required to register under section 605
13 that have gross annual sales of at least
14 \$2,500,000 per annum but less than
15 \$20,000,000 in the fiscal year immediately
16 preceding the fiscal year in which the an-
17 nual fee will be paid, shall be responsible,
18 collectively, for 1.2 percent.

19 “(xiv) TIER VII–B.—Responsible par-
20 ties required to register under section 605
21 that have gross annual sales of at least
22 \$500,000 per annum but less than
23 \$2,500,000 in the fiscal year immediately
24 preceding the fiscal year in which the an-
25 nual fee will be paid, shall be responsible,

1 collectively, for 2.4 percent, except that no
2 such responsible party shall be responsible
3 for more than \$250 per fiscal year.

4 “(d) ADJUSTMENTS.—

5 “(1) INFLATION ADJUSTMENT.—

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

13 “(i) one;

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

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

14 “(B) COMPOUNDED BASIS.—The adjust-
15 ment made each fiscal year under this sub-
16 section shall be added on a compounded basis
17 to the sum of all adjustments made each fiscal
18 year after fiscal year 2019 under this sub-
19 section.

20 “(C) ADJUSTMENT TO BASE FEE
21 AMOUNTS.—For each of fiscal years 2019
22 through 2023, the base fee amounts specified in
23 subsection (c)(3) shall be adjusted as needed,
24 on a uniform proportionate basis, to generate
25 the total revenue amounts under subsection

1 (c)(3), as adjusted for inflation under subpara-
2 graph (A).

3 “(2) FINAL YEAR ADJUSTMENT.—For fiscal
4 year 2023, the Food and Drug Administration may,
5 in addition to adjustments under paragraph (1), fur-
6 ther increase the fee revenues and fees established in
7 subsection (c) if such an adjustment is necessary to
8 provide for not more than 3 months of operating re-
9 serves of carryover fees for cosmetic safety activities
10 for the first 3 months of fiscal year 2024. If such
11 an adjustment is necessary, the rationale for the in-
12 crease, shall be contained in the annual Federal
13 Register notice establishing fees, in subsection
14 (c)(1), for fiscal year 2023. If the Food and Drug
15 Administration has carryover balances for such ac-
16 tivities in excess of 3 months of such operating re-
17 serves, the adjustment under this paragraph shall
18 not be made.

19 “(3) WORKLOAD ADJUSTMENT.—

20 “(A) IN GENERAL.—For fiscal year 2019
21 and each subsequent fiscal year, after fee reve-
22 nues established in subsection (c)(3)(B) are ad-
23 justed for a fiscal year for inflation in accord-
24 ance with paragraph (1), the fee revenues shall
25 be adjusted further for each fiscal year to re-

1 flect changes in the workload of the Food and
2 Drug Administration for actual changes in
3 workload volume due to the process of reviewing
4 cosmetic ingredients or nonfunctional constitu-
5 ents not listed under section 608(b).

6 “(B) DETERMINATION OF ADJUSTMENT.—
7 The adjustment shall be determined by the
8 Food and Drug Administration based on the
9 workload in the most recent 1-year period for
10 which workload data are available. The Food
11 and Drug Administration shall publish in the
12 Federal Register the fee revenues and fees re-
13 sulting from the adjustment and the supporting
14 methodologies.

15 “(C) MINIMUM REVENUES.—The adjust-
16 ment shall not result in fee revenues for a fiscal
17 year that are less than the sum of the amount
18 under subsection (c)(3)(B), as adjusted for in-
19 flation under paragraph (1).

20 “(e) LIMITATIONS.—

21 “(1) IN GENERAL.—With respect to the amount
22 that, under the salaries and expenses account of the
23 Food and Drug Administration, is appropriated for
24 a fiscal year for the cosmetics program in the Center
25 for Food Safety and Applied Nutrition and related

1 field activities, fees may not be assessed under sub-
2 section (a) for the fiscal year unless the amount so
3 appropriated for the fiscal year (excluding the
4 amount of fees appropriated for the fiscal year), is
5 equal to or greater than that assessed for fiscal year
6 2019, multiplied by the adjustment factor applicable
7 to the fiscal year involved. If the amount so appro-
8 priated prevents the Food and Drug Administration
9 from assessing fees under subsection (a), the Food
10 and Drug Administration is not required to carry
11 out any activities described in section 608 during
12 that fiscal year.

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

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

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

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

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

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

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

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

1 tember 30, 2019, for the salaries and expenses
2 account of the Food and Drug Administration,
3 fees authorized by this section for fiscal year
4 2019 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) STARTUP COSTS.—Until one year
11 after the Food and Drug Administration begins
12 collecting user fees under subsection(a), any
13 amounts available to the Center for Food Safe-
14 ty and Applied Nutrition (excluding user fees)
15 may be available and allocated as needed to pay
16 the costs of cosmetic regulation activities de-
17 scribed in this Act.

18 “(E) REIMBURSEMENT OF STARTUP
19 AMOUNTS.—

20 “(i) IN GENERAL.—Any amounts allo-
21 cated for the startup period pursuant to
22 subparagraph (B)(ii) shall be reimbursed
23 through any appropriated fees collected
24 under subsection (a), in such manner as
25 the Secretary determines appropriate to

1 ensure that such allocation results in no
2 net change in the total amount of funds
3 otherwise available, for a period not to ex-
4 ceed one year after the Food and Drug
5 Administration begins collecting user fees
6 under subsection (a), for Food and Drug
7 Administration programs and activities
8 (other than cosmetic regulation activities)
9 for such period.

10 “(ii) TREATMENT OF REIMBURSED
11 AMOUNTS.—Amounts reimbursed under
12 clause (i) shall be available for the pro-
13 grams and activities for which funds allo-
14 cated for the startup period were available,
15 prior to such allocation, until 1 year after
16 the Food and Drug Administration begins
17 collecting user fees under subsection (a),
18 notwithstanding any otherwise applicable
19 limits on amounts for such programs or
20 activities for a fiscal year.

21 “(3) AUTHORIZATION OF APPROPRIATIONS.—
22 For each of fiscal years 2019 through 2023, there
23 are authorized to be appropriated for fees under this
24 section \$20,600,000, as adjusted by subsection (d).

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

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

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

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

24 “(k) RECORDS.—Each responsible party required to
25 register under section 605 shall retain all records nec-

1 essary to demonstrate gross annual sales for at least 2
2 fiscal years after such information is reported in its reg-
3 istration. Such records shall be made available to the Food
4 and Drug Administration for review and duplication upon
5 request of the Food and Drug Administration.

6 “(l) SUNSET DATE.—Section 744 of the Federal
7 Food, Drug, and Cosmetic Act does not authorize the as-
8 sessment or collection of a fee for registration under sec-
9 tion 605 of such Act occurring after fiscal year 2023. The
10 amendments made by this title cease to be effective on
11 October 1, 2023.”.

12 **SEC. 203. DIRECT HIRING AUTHORITY TO SUPPORT ACTIVI-**
13 **TIES RELATED TO COSMETICS.**

14 Part 10 of subchapter C of chapter VII, as added
15 by section 202, is amended by inserting after section 744L
16 the following:

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

19 “(a) IN GENERAL.—The Food and Drug Administra-
20 tion shall have direct hiring authority with respect to the
21 appointment of employees into the competitive service or
22 the excepted service to administer the amendments made
23 by title I of the Cosmetic Safety Enhancement Act of
24 2019.

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