

AMENDMENT TO H.R. _____
OFFERED BY M____. _____

[Amending OTCMONOGRAPH __05, dated January 12, 2018]

At the end of the bill, insert the following new title:

1 **TITLE III—COSMETIC SAFETY**

2 **SEC. 300. SHORT TITLE; TABLE OF CONTENTS.**

3 (a) **SHORT TITLE.**—This title may be cited as the
4 “Cosmetic Safety Enhancement Act of 2018”.

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

TITLE III—COSMETIC SAFETY

Sec. 300. Short title; table of contents.

Subtitle A—Cosmetic Safety

Sec. 301. Registration of cosmetics facilities and cosmetic ingredient statements.

Sec. 302. Review of ingredients and nonfunctional constituents; safety of finished products.

Sec. 303. Good manufacturing practices for cosmetics.

Sec. 304. Adverse event reports.

Sec. 305. Records inspection; mandatory recall authority.

Sec. 306. Labeling.

Sec. 307. Coal tar chemicals.

Sec. 308. Animal testing alternatives.

Sec. 309. Preemption.

Sec. 310. Reporting.

Sec. 311. Small businesses.

Sec. 312. Applicability with respect to certain cosmetics.

Sec. 313. Enforcement.

Sec. 314. Consumer information.

Sec. 315. Foreign supplier verification.

Subtitle B—Fees Related to Cosmetic Safety

Sec. 321. Findings.

Sec. 322. Authority to assess and use cosmetic safety fees.

Sec. 323. Direct hiring authority to support activities related to cosmetics.

1 **Subtitle A—Cosmetic Safety**

2 **SEC. 301. REGISTRATION OF COSMETICS FACILITIES AND**
3 **COSMETIC INGREDIENT STATEMENTS.**

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

7 **“SEC. 604. DEFINITIONS.**

8 “In this chapter:

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

13 “(2) COSMETIC PRODUCT.—The term ‘cosmetic
14 product’ means a cosmetic comprised of a specified
15 set of ingredients, which may come in a range of
16 possible amounts for each ingredient and which may
17 include a variety of fragrances and colors, and in
18 some specific cosmetic applications, flavors.

19 “(3) FACILITY.—The term ‘facility’ includes
20 any factory, warehouse, or establishment (including
21 a factory, warehouse, or establishment of an im-
22 porter) that manufactures, processes, packs, or holds
23 cosmetic products or cosmetic formulations, or any
24 other entity whose name and address appear on the

1 label of a cosmetic product. Such term does not in-
2 clude—

3 “(A) beauty shops and salons that do not
4 otherwise manufacture, process, or package cos-
5 metics at that location;

6 “(B) cosmetic product retailers, including
7 individual sales representatives, retail distribu-
8 tion facilities, retail warehouses, and phar-
9 macies, that do not otherwise manufacture,
10 process, or package cosmetics at that location;

11 “(C) hospitals, physicians’ offices, and
12 health care clinics;

13 “(D) public health agencies and other non-
14 profit entities that provide cosmetics directly to
15 the consumer;

16 “(E) hotels and other entities that provide
17 complimentary cosmetics to guests;

18 “(F) trade shows and other venues where
19 cosmetic product samples are provided free of
20 charge;

21 “(G) domestic manufacturers with less
22 than \$100,000 in gross annual sales of cosmetic
23 products, except for any manufacturer that is
24 engaged in the manufacturing, processing, or
25 distributing of products intended to be injected

1 under the skin or into the eye, including tattoo
2 ink;

3 “(H) entities that manufacture or com-
4 pound cosmetic products solely for use in re-
5 search, teaching, or pilot plant production and
6 not for sale.

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

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

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

3 “(A) the brand owner, operator, or agent
4 in charge who is the domestic or foreign manu-
5 facturer, processor, or entity whose name ap-
6 pears on the label of a cosmetic product or a
7 cosmetic formulation distributed in the United
8 States, except for entities described in subpara-
9 graphs (A) through (H) of paragraph (3); or

10 “(B) a contract manufacturer who provides
11 cosmetic products to the entities described in
12 subparagraphs (A) through (H) of paragraph
13 (3).

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

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

17 “(1) REGISTRATION, IN GENERAL.—Each re-
18 sponsible person engaged in manufacturing, or proc-
19 essing, or whose name appears on the label of a cos-
20 metic product or a cosmetic formulation distributed
21 in the United States shall register all of the respon-
22 sible person’s facilities with the Food and Drug Ad-
23 ministration. A responsible person required to reg-
24 ister under this subsection shall, not later than 90
25 days after the Secretary announces the establish-

1 ment of an electronic registration system for pur-
2 poses of this section, submit a registration utilizing
3 such system which shall be effective for fiscal year
4 2018.

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

13 “(b) REGISTRATION FOR EXISTING PACKING OR
14 HOLDING FACILITIES.—Each facility engaged in packing
15 or holding a cosmetic product distributed in the United
16 States shall register with the Food and Drug Administra-
17 tion. Each facility required to register under this sub-
18 section shall, not later than 90 days after the Secretary
19 announces the establishment of an electronic registration
20 system for purposes of this section, submit a registration
21 utilizing such system which shall be effective for fiscal
22 year 2018.

23 “(c) REGISTRATION BY NEW FACILITIES.—A respon-
24 sible person first engaging after the date of enactment of
25 the Cosmetic Safety Enhancement Act of 2018 in an activ-

1 ity that would require it to register under subsection (a)
2 or (b) shall register with the Food and Drug Administra-
3 tion immediately upon engaging in such activity, and
4 thereafter in accordance with subsection (a) or (b).

5 “(d) CHANGES TO INFORMATION.—A responsible
6 person that submitted a registration under this section
7 shall notify the Food and Drug Administration of any
8 change to the information required under subsection (a)
9 or (b) not later than 30 days after the date of such
10 change, unless otherwise specified by the Food and Drug
11 Administration.

12 “(e) ANNUAL REGISTRATION RENEWAL.—A respon-
13 sible person that continues to engage in any activity that
14 would require registration under subsection (a) or (b) shall
15 submit to the Secretary an annual registration during the
16 first quarter of the fiscal year for which such renewed reg-
17 istration shall be effective.

18 “(f) FORMAT; CONTENTS.—

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

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

1 “(A) Each facility’s name and full address,
2 identifying the precise physical location of the
3 facility.

4 “(B) The identity of the facility, including
5 the unique facility identifier, if any, previously
6 assigned by the Food and Drug Administration
7 to the facility under subsection (g).

8 “(C) All business trading names used by
9 the facility.

10 “(D) The product category or categories of
11 each cosmetic product or cosmetic formulation
12 manufactured, processed, packed, or held at the
13 facility or on whose label the facility’s name
14 and address appear.

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

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

21 “(G) In the case of a foreign facility, the
22 name, street address, telephone number, emer-
23 gency contact information for the facility, the
24 name of the United States agent for the facil-

1 ity, and the phone number and electronic con-
2 tact information of the United States agent.

3 “(H) The name, title, street address, tele-
4 phone number, and electronic contact informa-
5 tion of the individual submitting the registra-
6 tion.

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

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

19 “(3) ABBREVIATED REGISTRATION.—The Food
20 and Drug Administration shall provide for an abbrevi-
21 ated registration renewal process for any facility
22 that has not had any changes to such information
23 with respect to the facility or facilities involved since
24 the facility submitted the preceding registration.

1 “(g) INCOMPLETE OR INACCURATE REGISTRA-
2 TION.—

3 “(1) IN GENERAL.—Not earlier than 10 days
4 after providing notice of the intent to cancel a reg-
5 istration and the basis for such cancellation, the
6 Food and Drug Administration may cancel a reg-
7 istration under this section if the Food and Drug
8 Administration has reasonable grounds to believe
9 that the registration was not properly completed or
10 updated in accordance with this section, if a re-
11 quired registration fee has not been paid within 30
12 days, or if the registration otherwise contains false,
13 incomplete, or inaccurate information.

14 “(2) TIMELY UPDATE OR CORRECTION.—If, not
15 later than 7 days after receipt of a notice of intent
16 to cancel, the facility corrects the registration in ac-
17 cordance with the basis for the cancellation, and the
18 required registration fee, if any, is paid, the Food
19 and Drug Administration shall not cancel such reg-
20 istration.

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

25 “(i) REGISTRY OF FACILITIES.—

1 “(1) IN GENERAL.—The Food and Drug Ad-
2 ministration shall compile, maintain, and update a
3 registry of facilities that are registered under this
4 section, and shall remove from such registry the
5 name of any facility whose registration under this
6 section is cancelled. The registry shall be publicly
7 available.

8 “(2) PUBLIC AVAILABILITY EXCEPTIONS.—In-
9 formation derived from the registry or registration
10 documents that discloses the residential address of a
11 responsible person, facility, or that discloses specific
12 facilities where specific cosmetic products are manu-
13 factured or processed shall not be subject to disclo-
14 sure under section 552 of title 5, United States
15 Code.

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

17 “(a) IN GENERAL.—For each cosmetic product, the
18 responsible person shall submit to the Food and Drug Ad-
19 ministration a cosmetic ingredient statement, at such time
20 and in such manner as the Food and Drug Administration
21 may prescribe. The cosmetic ingredient statement shall
22 not become effective until the responsible person pays any
23 applicable fee required under section 744L.

24 “(b) SUBMISSION OF A COSMETIC INGREDIENT
25 STATEMENT.—

1 “(1) EXISTING COSMETIC PRODUCTS.—In the
2 case of a cosmetic product that is marketed on the
3 date of enactment of the Cosmetic Safety Enhance-
4 ment Act of 2018, the responsible person shall sub-
5 mit a cosmetic ingredient statement not later than
6 July 30, 2018. The responsible person shall submit
7 to the Food and Drug Administration an annual re-
8 newal of such statement during the first quarter of
9 the fiscal year for which such renewed statement is
10 applicable.

11 “(2) COSMETIC INGREDIENT STATEMENT FOR
12 NEW COSMETIC PRODUCTS.—

13 “(A) IN GENERAL.—Except as provided
14 under subparagraph (B), in the case of a cos-
15 metic product that is first marketed after the
16 date of enactment of the Cosmetic Safety En-
17 hancement Act of 2018 or a cosmetic product
18 that is reformulated after such date of enact-
19 ment, the responsible person shall submit a cos-
20 metic ingredient statement to the Food and
21 Drug Administration prior to first marketing
22 the new cosmetic product or the reformulated
23 cosmetic product, and annually thereafter dur-
24 ing the first quarter of the fiscal year for which
25 the cosmetic ingredient statement is applicable.

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

14 “(C) DEFINITION.—A cosmetic product
15 shall not be considered first marketed or refor-
16 mulated after the date of enactment under sub-
17 paragraph (A) if the only change in such prod-
18 uct is in—

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

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

1 ulations or guidance, previously reported
2 as a potential ingredient under subsection
3 (c)(2)(E), if, in the case of such an addi-
4 tion, the amount is within the range pre-
5 viously reported.

6 “(c) FORMAT; CONTENTS.—

7 “(1) FORM.—For each cosmetic product, the
8 cosmetic ingredient statement shall be submitted
9 using an electronic format, as specified in a cosmetic
10 and ingredient form provided by the Food and Drug
11 Administration.

12 “(2) CONTENTS.—The cosmetic ingredient
13 statement shall include the following information:

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

16 “(i) the facility or facilities where the
17 cosmetic product is manufactured, proc-
18 essed, packed, or held or, if the same cos-
19 metic product is manufactured, processed,
20 packed, or held in more than one facility,
21 the unique facility identifier of each facility
22 where it is manufactured, processed,
23 packed, or held; and

24 “(ii) the facility whose name and ad-
25 dress appear on the label, unless the state-

1 ment is filed by a contract manufacturer,
2 described in section 604(6)(B).

3 “(B) The brand name and the full name
4 for the cosmetic product as it appears on the
5 label.

6 “(C) The cosmetic product listing number,
7 if any, previously assigned by the Food and
8 Drug Administration under subsection (f) to
9 the cosmetic product.

10 “(D) The applicable cosmetic category for
11 the cosmetic product.

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

20 “(i) a list of fragrances, flavors, and
21 colors that may be included in the product,
22 interchangeably, with ranges of possible
23 amounts, which shall include—

24 “(I) in the case of fragrances
25 that are purchased from a fragrance

1 supplier, the fragrances shall be iden-
2 tified by the name or code provided by
3 the supplier, and include the name
4 and contact information for the fra-
5 grance supplier;

6 “(II) in the case of flavors that
7 are purchased from a flavor supplier,
8 the flavors shall be identified by the
9 name or code provided by the sup-
10 plier, and include the name and con-
11 tact information for the flavor sup-
12 plier; and

13 “(III) if requested by the Food
14 and Drug Administration by means of
15 a written notification to the fragrance
16 or flavor supplier, the complete list of
17 ingredients in specific fragrances or
18 flavors (and the supplier shall have 30
19 days to provide such list to the Food
20 and Drug Administration); and

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

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

3 “(G) If applicable, information on labeling
4 required under section 614.

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

8 “(3) COSMETIC INGREDIENT STATEMENT FOR
9 CERTAIN SMALL BUSINESSES.—

10 “(A) IN GENERAL.—Notwithstanding any
11 other provision of this subsection, the Food and
12 Drug Administration may permit a simplified
13 cosmetic ingredient statement under this sec-
14 tion for a responsible person that—

15 “(i) is a business that meets the appli-
16 cable industry-based small business size
17 standard established by the Administrator
18 of the Small Business Administration
19 under section 3 of the Small Business Act;
20 and

21 “(ii) has had an average of less than
22 \$500,000 in annual domestic cosmetic
23 sales over the previous 3 years.

24 “(B) CONTENTS.—A responsible person
25 described in subparagraph (A) shall include in

1 each cosmetic ingredient statement under this
2 section, at a minimum, a list of ingredients in
3 the cosmetic product and the applicable cos-
4 metic category for the cosmetic product. If a
5 cosmetic product includes a fragrance or flavor
6 purchased from a fragrance or flavor supplier,
7 the responsible person must, at a minimum, in-
8 clude a list of all fragrances and flavors con-
9 tained in the cosmetic product and contact in-
10 formation for the fragrance or flavor supplier,
11 including the supplier's name, street address,
12 telephone number, and electronic contact infor-
13 mation. In the case of a written notification
14 under paragraph (2)(E)(i)(III) provided by the
15 Food and Drug Administration to the respon-
16 sible person for the cosmetic manufacturer, the
17 Food and Drug Administration may request,
18 from the fragrance or flavor supplier, the com-
19 plete list of ingredients in specific fragrances or
20 flavors, and the supplier shall have 30 days to
21 provide such list to the Food and Drug Admin-
22 istration.

23 “(d) INCOMPLETE OR INACCURATE COSMETIC IN-
24 GREDIENT STATEMENT.—

1 “(1) IN GENERAL.—Not earlier than 10 days
2 after providing notice under paragraph (2), the Food
3 and Drug Administration may nullify a cosmetic in-
4 gredient statement filed under this section if the
5 Food and Drug Administration has reasonable
6 grounds to believe that the cosmetic ingredient state-
7 ment was not completed or updated in accordance
8 with this section or otherwise contains false, incom-
9 plete, or inaccurate information.

10 “(2) NOTICE OF NULLIFICATION.—A nullifica-
11 tion under paragraph (1) shall be preceded by notice
12 to the responsible person of the intent to cancel the
13 cosmetic ingredient statement and the basis for such
14 cancellation.

15 “(3) TIMELY UPDATE OR CORRECTION.—If the
16 cosmetic ingredient statement is appropriately up-
17 dated or corrected not later than 7 days after notice
18 is provided under paragraph (1), the Food and Drug
19 Administration shall not nullify such cosmetic ingre-
20 dient statement.

21 “(4) EFFECT OF NULLIFICATION.—If a cos-
22 metic ingredient statement is nullified under this
23 section, no person shall import, export, or otherwise
24 distribute the cosmetic product that was the subject
25 of the cosmetic ingredient statement.

1 “(e) ADDITIONAL REQUIREMENTS.—

2 “(1) SAFETY REQUIREMENTS.—In filing each
3 cosmetic ingredient statement for each cosmetic
4 product, the responsible person shall include an at-
5 testation that the safety of the product, including
6 the individual ingredients of such product and the
7 product as a whole, has been substantiated in ac-
8 cordance with section 609. In the case of a cosmetic
9 ingredient statement that includes a range of pos-
10 sible amounts (as described in subsection (c)(2)(E)),
11 the responsible person shall include an attestation
12 that the safety of the full range in the finished prod-
13 uct has been substantiated, in accordance with sec-
14 tion 609.

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

20 “(3) CHANGES TO INFORMATION.—

21 “(A) IN GENERAL.—Except as provided in
22 subparagraph (B), the responsible person shall
23 notify the Food and Drug Administration with-
24 in 60 days of any change to the information re-
25 quired to be in a cosmetic ingredient statement,

1 including discontinuation of the manufacture of
2 a cosmetic product, except that notification
3 under this paragraph is not required for a
4 change in—

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

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

17 “(B) SMALL BUSINESS.—The Food and
18 Drug Administration shall allow a responsible
19 person that is a business that meets the appli-
20 cable industry-based small business size stand-
21 ard established by the Administrator of the
22 Small Business Administration under section 3
23 of the Small Business Act to have an additional
24 time period, as determined by the Secretary, to
25 submit any change to the information required

1 to be in a cosmetic ingredient statement as de-
2 scribed in subparagraph (A).

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

17 **“SEC. 607. SUSPENSION OF REGISTRATION OR COSMETIC**
18 **INGREDIENT STATEMENT.**

19 “(a) SUSPENSION OF REGISTRATION OF A FACIL-
20 ITY.—If the Food and Drug Administration determines
21 that a cosmetic formulation or cosmetic product manufac-
22 tured, processed, packed, or held by a registered facility
23 has a reasonable probability of causing serious adverse
24 health consequences or death to humans, the Food and

1 Drug Administration may suspend the registration of a
2 facility.

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

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

14 “(1) notice to the facility or responsible person,
15 as appropriate, of the intent to suspend the facility
16 registration or the cosmetic ingredient statement,
17 which shall specify the basis of the determination by
18 the Food and Drug Administration that the facility
19 registration or the cosmetic ingredient statement
20 should be suspended; and

21 “(2) an opportunity, within 2 business days of
22 the notice provided under paragraph (1), for the fa-
23 cility or responsible person, as appropriate, to ad-
24 dress the reasons for possible suspension of the facil-
25 ity registration or cosmetic ingredient statement.

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

7 “(e) EFFECT OF SUSPENSION.—

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

12 “(2) COSMETIC INGREDIENT STATEMENT.—If
13 the cosmetic ingredient statement for a cosmetic
14 product is suspended under this section, no person
15 shall import or export such cosmetic product or oth-
16 erwise distribute in the United States such cosmetic
17 product that is the subject of such statement.

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

1 **SEC. 302. REVIEW OF INGREDIENTS AND NONFUNCTIONAL**
2 **CONSTITUENTS; SAFETY OF FINISHED PROD-**
3 **UCTS.**

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

8 **“SEC. 608. REVIEW OF INGREDIENTS AND NONFUNCTIONAL**
9 **CONSTITUENTS.**

10 “(a) INGREDIENTS AND NONFUNCTIONAL CONSTITU-
11 ENTS SUBJECT TO REVIEW.—

12 “(1) IN GENERAL.—Beginning one year after
13 the date of enactment of Cosmetic Safety Enhance-
14 ment Act of 2018, the Food and Drug Administra-
15 tion shall review the safety of the cosmetic ingredi-
16 ents and nonfunctional constituents under para-
17 graph (3), as modified under subsection (c), if appli-
18 cable, and issue an order under subsection (d) with
19 respect to the use of each such ingredient and pres-
20 ence of each such nonfunctional constituent.

21 “(2) PUBLIC NOTICE AND COMMENT.—At the
22 initiation of the review of each cosmetic ingredient
23 or nonfunctional constituent, the Food and Drug
24 Administration shall open a docket for the submis-
25 sion of public comment and additional data relevant
26 to the safety of the ingredient or nonfunctional con-

1 stituent. The Food and Drug Administration shall
2 provide 60 days for public comment.

3 “(3) COSMETIC INGREDIENTS.—

4 “(A) INGREDIENTS TO BE CONSIDERED IN
5 FIRST YEAR.—Not later than one year after the
6 Secretary begins collecting user fees under this
7 section, the Food and Drug Administration
8 shall initiate the review for safety of the fol-
9 lowing cosmetic ingredients:

10 “(i) Diazolidinyl urea.

11 “(ii) Lead acetate.

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

14 “(iv) Propyl paraben.

15 “(v) Quaternium-15.

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

18 “(i) IN GENERAL.—No later than two
19 years after the Secretary begins collecting
20 user fees under this section, and on an an-
21 nual basis thereafter, the Food and Drug
22 Administration shall select and complete a
23 review of at least 5 cosmetic ingredients or
24 nonfunctional constituents that were not
25 reviewed in the prior 3 years from a list

1 determined in consultation with industry
2 and consumer groups for review of safety.
3 The Food and Drug Administration may
4 combine selected cosmetics ingredients or
5 nonfunctional constituents into categories
6 for purposes of its review. The Food and
7 Drug Administration may modify such list
8 under subsection (c).

9 “(ii) CONSIDERATIONS.—The deter-
10 mination of which ingredients or functional
11 ingredients will be reviewed within a 3-year
12 period shall be publicized in annual reports
13 to Congress and the public, in accordance
14 with section 618, and subject to consulta-
15 tion as provided for in clause (iii). The re-
16 view of any cosmetic ingredient or non-
17 functional constituent shall commence with
18 a public announcement by the Food and
19 Drug Administration and the opening of a
20 docket as required under paragraph (2).

21 “(iii) ADVISORY COMMITTEE.—Not
22 later than one year after the date of enact-
23 ment of the Cosmetic Safety Enhancement
24 Act of 2018, the Secretary shall—

1 “(I) rename the Food Advisory
2 Committee of the Food and Drug Ad-
3 ministration, as in existence on such
4 date of enactment, the Food and Cos-
5 metic Advisory Committee (in this
6 clause referred to as the ‘Advisory
7 Committee’);

8 “(II) expand the responsibilities
9 of the Advisory Committee to include
10 evaluating and making recommenda-
11 tions on broad scientific and technical
12 cosmetic-related issues, advising on
13 cosmetic ingredients and nonfunc-
14 tional constituents to be considered
15 for review, summarizing public com-
16 ments received by the Food and Drug
17 Administration related to cosmetic in-
18 gredient review, recommending cos-
19 metic ingredients or nonfunctional
20 constituents to be reviewed for safety
21 annually, and advising on other mat-
22 ters pertaining to the safety of new
23 cosmetics and cosmetic ingredients;
24 and

1 “(III) include in the membership
2 of the Advisory Committee equal num-
3 bers of individuals from the cosmetics
4 industry and cosmetics consumer
5 groups, together with such additional
6 members as the Secretary determines
7 appropriate, which additional mem-
8 bers may include medical practitioners
9 with an expertise in cosmetics issues.

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

22 “(b) LIST.—The Food and Drug Administration
23 shall maintain a list, posted on the Internet website of the
24 Food and Drug Administration, of the cosmetic ingredi-
25 ents and nonfunctional constituents for which final orders

1 have been issued under subsection (d)(3), the finding
2 made for each such ingredient or nonfunctional con-
3 stituent under subsection (d)(4), as modified by any order
4 under subsection (e), and, if applicable, compliance dates
5 that are the subject of a final order under subsection
6 (d)(3).

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

13 “(d) DETERMINATION ON SAFETY.—

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

1 Administration, notwithstanding subchapter II of
2 chapter 5 of title 5, United States Code. If the Food
3 and Drug Administration issues a proposed adminis-
4 trative order under subparagraph (C) of subsection
5 (d)(4), the proposed administrative order shall in-
6 clude a compliance date by which use of the ingre-
7 dient or nonfunctional constituent in cosmetic prod-
8 ucts shall comply with the final administrative order,
9 when effective.

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

19 “(3) FINAL ADMINISTRATIVE ORDER.—Fol-
20 lowing the public comment period described in para-
21 graph (2) and consideration of comments to the pub-
22 lic docket and any other information before the Food
23 and Drug Administration, the Food and Drug Ad-
24 ministration shall determine whether there is ade-
25 quate evidence to make a final finding on the safety

1 of the ingredient or nonfunctional constituent. If the
2 Food and Drug Administration determines that
3 there is adequate evidence, the Food and Drug Ad-
4 ministration shall issue a final administrative order
5 and shall post such order on the Internet website of
6 the Food and Drug Administration, notwithstanding
7 subchapter II of chapter 5 of title 5, United States
8 Code. If the Food and Drug Administration issues
9 a final administrative order under subparagraph (C)
10 of subsection (d)(4), the final administrative order
11 shall include a compliance date by which use of the
12 ingredient or nonfunctional constituent in cosmetic
13 products shall comply with the final administrative
14 order.

15 “(4) DETERMINATIONS.—In the proposed ad-
16 ministrative order or the final administrative order,
17 as applicable, the Food and Drug Administration
18 shall make a determination that the ingredient or
19 nonfunctional constituent is—

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

22 “(B) safe in cosmetic products without the
23 need for specified conditions of use or toler-
24 ances; or

25 “(C) not safe in cosmetic products.

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

2 An order under paragraph (4)(A) shall include such
3 conditions on the use of an ingredient or such toler-
4 ances on the presence of a nonfunctional constituent
5 as are necessary for the safety of cosmetic products
6 containing such ingredient or nonfunctional con-
7 stituent, including—

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

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

23 “(C) such other conditions as are nec-
24 essary for the safety of cosmetic products con-

1 taining such ingredient or nonfunctional con-
2 stituent.

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

14 “(e) MODIFICATION OF AN ORDER.—An order issued
15 under subsection (d) may be modified or revoked by the
16 Food and Drug Administration on the initiative of the
17 Food and Drug Administration or in response to a peti-
18 tion.

19 “(f) INADEQUATE EVIDENCE.—

20 “(1) NOTICE; EXTENSION.—If the Food and
21 Drug Administration determines that the available
22 data and information are not adequate to make a
23 proposed or final determination regarding safety
24 under subsection (d)(4), with respect to a cosmetic

1 ingredient or nonfunctional constituent, the Food
2 and Drug Administration shall—

3 “(A) publish such finding on the Internet
4 website of the Food and Drug Administration
5 not later than 180 days after the close of the
6 relevant comment period for the ingredient or
7 nonfunctional constituent under subsection
8 (a)(2), in the case of a proposed order, or sub-
9 section (d)(2), in the case of a final order; and

10 “(B) include a notice providing interested
11 persons an additional 30 days from the notice
12 date to provide additional data and information.

13 “(2) DETERMINATION; ORDER.—

14 “(A) INADEQUATE 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 still are not adequate to make a deter-
20 mination regarding safety under subsection
21 (d)(4), the Food and Drug Administration
22 shall, within 180 days of the close of the addi-
23 tional time period provided under paragraph
24 (1)(B), issue a final administrative order—

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

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

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

1 regarding safety under subsection (d)(4)(B),
2 the Food and Drug Administration shall, within
3 180 days of the close of the comment period,
4 issue a final order.

5 “(g) SAFETY ASSESSMENT.—

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

22 “(2) FACTORS.—In assessing the safety of an
23 ingredient or nonfunctional constituent, the Sec-
24 retary shall consider the following, among other rel-

1 evant factors, to the extent the Secretary determines
2 adequate data are available for such analyses:

3 “(A) The probable human exposure to the
4 ingredient or nonfunctional constituent from ex-
5 pected use in cosmetics.

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

19 “(C) Whether warnings or recommenda-
20 tions in a product label, as part of any condi-
21 tions of use or tolerances imposed by the Food
22 and Drug Administration, would be necessary
23 and appropriate to help ensure the safety of the
24 ingredient or nonfunctional constituent.

25 “(3) DATA AND INFORMATION.—

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

15 “(B) ADDITIONAL RELEVANT INFORMA-
16 TION.—The Food and Drug Administration
17 shall consider any other relevant information
18 related to the safety of the ingredient or non-
19 functional constituent, including—

20 “(i) adverse event reports;

21 “(ii) findings and information from
22 State, Federal, national, and international
23 entities and other bodies composed of sci-
24 entific and medical experts;

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

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

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

14 “(a) DETERMINATION.—

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

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

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

13 “(b) PRESUMPTION OF ADEQUATE EVIDENCE.—

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

18 “(A) with respect to each ingredient in the
19 finished product—

20 “(i) references to an official statement
21 by one or more expert medical or scientific
22 bodies that the ingredient is safe under the
23 conditions of use recommended or sug-
24 gested in the product’s labeling; or

1 “(ii) appropriate safety testing of the
2 ingredient; and

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

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

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

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

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

24 “(c) REBUTTAL OF PRESUMPTION.—Notwith-
25 standing subsection (b), a determination under subsection

1 (a) will not be presumed to be based on adequate evidence
2 if—

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

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

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

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

16 “(d) TIMELY UPDATE.—Upon notice of inadequate
17 evidence under subsection (c), the responsible person shall
18 have 10 days to submit additional evidence to the Food
19 and Drug Administration regarding the safety of an ingre-
20 dient, nonfunctional constituent, or the entire cosmetic
21 product, and the Food and Drug Administration shall
22 have 30 days from the date of receipt of such additional
23 evidence to provide the responsible person with notice that
24 the criteria under subsection (b) have been met or not met.

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

6 “(f) SUBMISSION OF RECORDS.—

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

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

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

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

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

1 “(iii) the determination required
2 under subsection (a) is not supported by
3 adequate evidence; or

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

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

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

18 “(g) GUIDANCE AND REGULATIONS.—

19 “(1) IN GENERAL.—The Food and Drug Ad-
20 ministration shall issue guidance describing the evi-
21 dence necessary to support a determination under
22 subsection (a), and may, by regulation, establish ex-
23 emptions to the requirements of this section, if the
24 Food and Drug Administration determines that such

1 exemptions are supported by adequate evidence and
2 would have no adverse effect on public health.

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

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

16 **SEC. 303. GOOD MANUFACTURING PRACTICES FOR COS-**
17 **METICS.**

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

22 **“SEC. 610. GOOD MANUFACTURING PRACTICES FOR COS-**
23 **METICS.**

24 “(a) IN GENERAL.—The Food and Drug Administra-
25 tion shall review national and international standards for

1 cosmetic good manufacturing practices that are in exist-
2 ence on the date of enactment of the Cosmetic Safety En-
3 hancement Act of 2018 and shall develop and implement,
4 through regulations, United States standards consistent,
5 to the extent the Food and Drug Administration deter-
6 mines practicable and appropriate, with such national and
7 international standards for cosmetic good manufacturing
8 practices to ensure that requirements of this chapter with
9 respect to the manufacture of cosmetic products are in
10 harmony.

11 “(b) TIMEFRAME.—The Food and Drug Administra-
12 tion shall publish a proposed rule described in subsection
13 (a) not later than 18 months after the date of enactment
14 of the Cosmetic Safety Enhancement Act of 2018 and
15 shall publish a final such rule not later than 3 years after
16 such date of enactment.”.

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

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

1 Drug Administration publishes the final rule de-
2 scribed in subsection (a).

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

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

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

19 **SEC. 304. ADVERSE EVENT REPORTS.**

20 Chapter VI of the Federal Food, Drug, and Cosmetic
21 Act (21 U.S.C. 361 et seq.), as amended by section
22 103(a), is further amended by adding at the end the fol-
23 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 2018.

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. 305. 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. 306. 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. 307. 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. 308. 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; and

13 “(2) encourage—

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

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

20 “(b) GUIDANCE.—Not later than 3 years after the
21 date of enactment of the Cosmetic Safety Enhancement
22 Act of 2018, the Food and Drug Administration shall
23 issue guidance on the acceptability of scientifically reliable
24 and relevant alternatives to animal testing for the safety
25 of cosmetic ingredients, nonfunctional constituents, and

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

4 “(c) RESOURCES REGARDING ANIMAL TESTING AL-
5 TERNATIVES.—Not later than 180 days after the date of
6 enactment of the Cosmetic Safety Enhancement Act of
7 2018, the Food and Drug Administration shall provide in-
8 formation on the Internet website of the Food and Drug
9 Administration regarding resources available for informa-
10 tion about non-animal methods, and methods that reduce
11 animal usage, in testing for the safety of cosmetic ingredi-
12 ents, nonfunctional constituents, and finished cosmetic
13 products.”.

14 **SEC. 309. PREEMPTION.**

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

18 **“SEC. 617. PREEMPTION.**

19 “(a) IN GENERAL.—No State or political subdivision
20 of a State may establish or continue in effect any require-
21 ment for cosmetics, other than a requirement that is in
22 full effect and implemented on the date of enactment of
23 the Cosmetic Safety Enhancement Act of 2018—

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

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

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

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

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

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

3 “(B) INITIAL REVIEW.—With respect to
4 the cosmetic ingredients to be reviewed pursu-
5 ant to section 608(a)(3)(A), no State or polit-
6 ical subdivision may, during the 1-year period
7 beginning on the date that is 6 months after
8 the date of enactment of the Cosmetic Safety
9 Enhancement Act of 2018, establish any new
10 requirement related to such cosmetic ingredient.

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

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

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

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

4 “(2) FULL EFFECT AND IMPLEMENTED.—The
5 term ‘full effect and implemented’ includes require-
6 ments of States that are implemented after the date
7 of enactment of the Cosmetic Safety Enhancement
8 Act of 2018, if such requirements are under a law
9 that was in effect, or a lawful program that was es-
10 tablished and functioning, prior to such date of en-
11 actment.

12 “(d) LIMITATION.—Nothing in the amendments to
13 this Act made by the Cosmetic Safety Enhancement Act
14 of 2018 shall be construed to preempt any State statute,
15 public initiative, referendum, or other State action, except
16 as expressly provided in this section.

17 “(e) SAVINGS.—Nothing in the amendments to this
18 Act made by the Cosmetic Safety Enhancement Act of
19 2018, nor any standard, rule, requirement, regulation, ad-
20 verse event report, safety assessment, safety determina-
21 tion, scientific assessment, or order issued or implemented
22 pursuant to such amendments, shall be construed to mod-
23 ify or otherwise affect, preempt, or displace any cause of
24 action or State or Federal law creating a remedy for civil

1 relief or criminal cause of action, whether statutory or
2 based in common law.”.

3 **SEC. 310. REPORTING.**

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

7 **“SEC. 618. REPORTING.**

8 “(a) PERFORMANCE REPORT.—Beginning with fiscal
9 year 2019, and not later than 60 days prior to the end
10 of each fiscal year for which fees are collected under sec-
11 tion 744L, the Food and Drug Administration shall pre-
12 pare and submit to Congress a report concerning the
13 progress of the Food and Drug Administration in achiev-
14 ing the objectives of the Cosmetic Safety Enhancement
15 Act of 2018 during such fiscal year and the future plans
16 of the Food and Drug Administration for meeting the ob-
17 jectives. The annual report for a fiscal year shall include—

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

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

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

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

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

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

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

21 **SEC. 311. SMALL BUSINESSES.**

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

1 **“SEC. 619. SMALL BUSINESSES.**

2 “(a) IN GENERAL.—The Commissioner, in coordina-
3 tion with the Administrator of the Small Business Admin-
4 istration, shall provide technical assistance, such as guid-
5 ance and expertise, to small businesses regarding compli-
6 ance with the Cosmetic Safety Enhancement Act of 2018,
7 including the amendments made by such Act.

8 “(b) COMPLIANCE GUIDE.—Not later than 180 days
9 after enactment of Cosmetic Safety Enhancement Act of
10 2018, the Secretary shall issue a small business guide set-
11 ting forth in plain language the requirements of sections
12 605 and 606 in order to assist small businesses in com-
13 plying.”.

14 **SEC. 312. APPLICABILITY WITH RESPECT TO CERTAIN COS-**
15 **METICS.**

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

19 **“SEC. 620. APPLICABILITY WITH RESPECT TO CERTAIN**
20 **COSMETICS.**

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

1 applicable requirement under this chapter if such product
2 or facility is in compliance with such substantially similar
3 requirement under chapter V, provided that the product
4 or facility has not obtained a waiver from the requirement
5 under chapter V.”.

6 **SEC. 313. ENFORCEMENT.**

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

10 (1) in subsection (e)—

11 (A) by striking “504, 564” and inserting
12 “504, 564, 611, or 612”; and

13 (B) by striking “519, 564” and inserting
14 “519, 564, 611,”;

15 (2) in subsection (j) by inserting “607, 608,
16 610,” before “704”;

17 (3) in subsection (ii)—

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

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

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

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

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

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

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

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

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

23 (1) in subsection (b)—

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

25 “(2)”; and

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

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

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

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

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

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

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

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

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

17 **SEC. 314. CONSUMER INFORMATION.**

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

20 (1) final orders regarding the safety of a cos-
21 metic ingredient or nonfunctional constituent under
22 section 608(d)(3);

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

25 (3) identified counterfeit cosmetic products.

1 **SEC. 315. FOREIGN SUPPLIER VERIFICATION.**

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

5 **“SEC. 810. COSMETICS FOREIGN SUPPLIER VERIFICATION**
6 **PROGRAM.**

7 “(a) IN GENERAL.—

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

14 “(A) has been manufactured according to
15 the cosmetic good manufacturing practices es-
16 tablished under section 610; and

17 “(B) is not adulterated under section 601
18 or misbranded under section 602.

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

23 “(A) the United States owner or consignee
24 of the cosmetic or cosmetic ingredient at the
25 time of entry of such cosmetic or cosmetic in-
26 gredient into the United States; or

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

7 “(b) GUIDANCE.—Not later than 1 year after the
8 date of enactment of the Cosmetic Safety Enhancement
9 Act of 2018, the Secretary shall issue guidance to assist
10 importers in developing foreign supplier verification pro-
11 grams.

12 “(c) REGULATIONS.—

13 “(1) IN GENERAL.—Not later than 1 year after
14 the date of enactment of Cosmetic Safety Enhance-
15 ment Act of 2018, the Secretary shall promulgate
16 regulations to provide for the content of the foreign
17 supplier verification program established under sub-
18 section (a).

19 “(2) REQUIREMENTS.—The regulations promul-
20 gated under paragraph (1)—

21 “(A) shall require that the foreign supplier
22 verification program of each importer be ade-
23 quate to provide assurances that each foreign
24 supplier to the importer produces the imported

1 cosmetic or cosmetic ingredient in compliance
2 with—

3 “(i) with cosmetic good manufac-
4 turing practices established under section
5 610; and

6 “(ii) sections 601 and 602; and

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

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

20 “(4) ACTIVITIES.—Verification activities under
21 a foreign supplier verification program under this
22 section may include monitoring records for ship-
23 ments, lot-by-lot certification of compliance, annual
24 on-site inspections, compliance with cosmetic good

1 manufacturing practices and other safety processes,
2 and periodically testing and sampling shipments.

3 “(d) RECORD MAINTENANCE AND ACCESS.—Records
4 of an importer related to a foreign supplier verification
5 program shall—

6 “(1) be maintained for a period of not less than
7 2 years; and

8 “(2) be made available promptly to a duly au-
9 thorized representative of the Secretary upon re-
10 quest.

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

19 “(f) PUBLICATION OF LIST OF PARTICIPANTS.—The
20 Secretary shall publish and maintain on the Internet
21 website of the Food and Drug Administration a current
22 list that includes the name of, location of, and other infor-
23 mation deemed necessary by the Secretary about, import-
24 ers participating under this section.”.

1 (b) PROHIBITED ACT.—Section 301 of the Federal
2 Food, Drug, and Cosmetics Act (21 U.S.C. 331), as
3 amended by section 313, is further amended by adding
4 at the end the following:

5 “(fff) The importation or offering for importation of
6 a cosmetic or cosmetic ingredient if the importer (as de-
7 fined in section 810) does not have in place a foreign sup-
8 plier verification program in compliance with such section
9 810.”.

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

13 **Subtitle B—Fees Related to** 14 **Cosmetic Safety**

15 **SEC. 321. FINDINGS.**

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

1 of Representatives, as set forth in the Congressional
2 Record.

3 **SEC. 322. AUTHORITY TO ASSESS AND USE COSMETIC SAFE-**
4 **TY FEES.**

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

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

9 **“SEC. 744L. REGISTRATION FEE.**

10 “(a) ASSESSMENT AND COLLECTION.—

11 “(1) IN GENERAL.—Beginning in fiscal year
12 2018, the Secretary shall in accordance with this
13 section assess and collect an annual fee from every
14 responsible person required to register under section
15 605(a).

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

18 “(A) for fiscal year 2018, with respect to
19 responsible parties required to register under
20 section 605 for such first program year, on the
21 date of registration; and

22 “(B) for fiscal year 2018 and each subse-
23 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 2018, 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 2018.—For fiscal year
8 2018, 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 2018–2022.—For fiscal
9 years 2018–2022, 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 2018
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 2018 under this sub-
19 section.

20 “(C) ADJUSTMENT TO BASE FEE
21 AMOUNTS.—For each of fiscal years 2018
22 through 2022, 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 2022, 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 2023. 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 2022. 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 2018
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 2018, 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, 2018, for the salaries and expenses
2 account of the Food and Drug Administration,
3 fees authorized by this section for fiscal year
4 2018 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 2018 through 2022, 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 2022. The
10 amendments made by this title cease to be effective on
11 October 1, 2022.”.

12 **SEC. 323. 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 302, 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 2018.

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.”.

