

**AMENDMENT TO H.R. 5333**  
**OFFERED BY M**\_\_. \_\_\_\_\_

At the end of the bill, add the following:

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

7   **“SEC. 604. DEFINITIONS.**

8           “In this chapter:

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

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

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.”.

