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(Original Signature of Member)

116TH CONGRESS
1ST SESSION

H. R. 5279

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

IN THE HOUSE OF REPRESENTATIVES

December 3, 2019

MR . Pallone introduced the following bill; which was referred to the
Committee on Energy and Commerce

A BILL

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

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

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

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

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

Sec. 1. Short title; table of contents.

TITLE I—COSMETIC SAFETY

1 “(2) CONTRACT MANUFACTURER.—The term
2 ‘contract manufacturer’ means a manufacturer (in-
3 cluding the owner, operator, or agent in charge (or
4 any affiliate thereof)) of a cosmetic ingredient, cos-
5 metic formulation, or cosmetic product that does not
6 sell any such cosmetic ingredient, cosmetic formula-
7 tion, or cosmetic product unless there is a specific
8 contractual agreement in place with respect to that
9 sale.

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

14 “(4) COSMETIC INGREDIENT.—The term ‘cos-
15 metic ingredient’ means any single chemical entity
16 or mixture used as a component in the manufacture
17 of a finished cosmetic product or cosmetic formula-
18 tion.

19 “(5) COSMETIC PRODUCT.—(A) The term ‘cos-
20 metic product’ means a finished cosmetic comprised
21 of a specified set of cosmetic ingredients, which may
22 come in a range of possible amounts for each cos-
23 metic ingredient and which may include a variety of
24 fragrances and colors, and in some specific cosmetic
25 applications, flavors.

1 “(B) Such term shall include tattoo ink whether
2 or not labeled as a finished cosmetic.

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

11 “(A) beauty shops and salons that do not
12 otherwise manufacture, process, or package cos-
13 metic products or cosmetic formulations at that
14 location, including beauty stores or counters
15 that offer customized or personalized cosmetic
16 products or cosmetic formulations tailored to
17 individual consumers for sale solely in-person;

18 “(B) cosmetic product retailers, including
19 individual sales representatives, direct sellers
20 (as defined in section 3508 of the Internal Rev-
21 enue Code of 1986), retail distribution facilities,
22 retail franchises, retail warehouses, and phar-
23 macies, that do not otherwise manufacture,
24 process, or package cosmetic products or cos-
25 metic formulations at that location;

1 “(C) entities that manufacture or com-
2 pound cosmetic products solely for use in re-
3 search, teaching, or pilot plant production and
4 not for sale;

5 “(D) hospitals, physicians’ offices, and
6 health care clinics;

7 “(E) hotels, airlines, and other entities
8 that provide complimentary cosmetic products
9 to guests;

10 “(F) public health agencies and other non-
11 profit entities that provide cosmetic products or
12 cosmetic formulations directly to the consumer;
13 or

14 “(G) trade shows and other venues where
15 cosmetic product samples are provided free of
16 charge.

17 “(7) FOREIGN FACILITY.—The term ‘foreign fa-
18 cility’ means a facility that manufactures, processes,
19 packs, or holds, cosmetic products or cosmetic for-
20 mulations that are exported to the United States
21 without further processing or packaging inside the
22 United States. A cosmetic product or cosmetic for-
23 mulation is not considered to have undergone fur-
24 ther processing or packaging for purposes of this
25 definition solely on the basis that labeling was added

1 or that any similar activity of a de minimis nature
2 was carried out with respect to the cosmetic product
3 or cosmetic formulation.

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

11 “(9) PROFESSIONAL.—With respect to a cos-
12 metic product, the term ‘professional’ means—

13 “(A) a dermatologist or other health care
14 professional that administers or provides cos-
15 metic products to patients; or

16 “(B) a cosmetologist, nail technician, bar-
17 ber, or esthetician who administers or provides
18 cosmetics within the scope of their business
19 practices.

20 “(10) PROFESSIONAL USE.—With respect to a
21 cosmetic product, the term ‘professional use’ means
22 a preparation of a cosmetic formulation intended
23 only for use by professionals in settings such as cos-
24 metology, nail care, barbering, esthetics, health care,

1 and other professions as determined by the Sec-
2 retary through regulation.

3 “(11) RESPONSIBLE PERSON.—The term ‘re-
4 sponsible person’ means the brand owner, operator,
5 or agent in charge who is the domestic or foreign
6 manufacturer, processor, or entity whose name ap-
7 pears on the label of a cosmetic product or a cos-
8 metic formulation distributed in the United States.

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

10 “(a) REGISTRATION FOR MANUFACTURING AND
11 PROCESSING FACILITIES.—

12 “(1) IN GENERAL.—The owner, operator, or
13 agent in charge of (or an affiliate thereof) a facility
14 engaged in manufacturing, or processing, of a cos-
15 metic product or a cosmetic formulation distributed
16 in the United States shall register with the Sec-
17 retary.

18 “(2) ELECTRONIC REGISTRATION SYSTEM.—

19 The Secretary shall—

20 “(A) maintain an electronic registration
21 system for purposes of this section; and

22 “(B) not later than one year after the date
23 of enactment of the Cosmetic Safety Enhance-
24 ment Act of 2019, announce that such system
25 is operational.

1 “(3) INITIAL REGISTRATION OF EXISTING FA-
2 CILITIES.—Not later than the date that is 6 months
3 after the date of the announcement required by
4 paragraph (2)(B), each facility engaged in an activ-
5 ity described in paragraph (1) shall be registered
6 under such paragraph.

7 “(4) INITIAL REGISTRATION OF NEW FACILI-
8 TIES.—In the case of a facility that first engages in
9 an activity described in paragraph (1) on or after
10 the date that is 18 months after the date of enact-
11 ment of the Cosmetic Safety Enhancement Act of
12 2019, such a facility shall register with the Sec-
13 retary immediately upon engaging in such activity.

14 “(5) SINGLE REGISTRATION.—The Secretary
15 shall require only a single registration per registra-
16 tion period for a facility required to be registered
17 under paragraph (1), regardless of whether such fa-
18 cility is manufacturing or processing—

19 “(A) its own cosmetic products or cosmetic
20 formulations; or

21 “(B) cosmetic products or cosmetic formu-
22 lations on behalf of more than one owner, oper-
23 ator, or agent in charge (or affiliate thereof).

24 “(b) REGISTRATION FOR PACKING OR HOLDING FA-
25 CILITIES.—Each facility engaged in packing or holding a

1 cosmetic product or cosmetic formulation distributed in
2 the United States shall register with the Food and Drug
3 Administration. Each such facility shall, not later than 6
4 months after the Secretary announces the establishment
5 of an electronic registration system for purposes of this
6 section, submit a registration utilizing such system.

7 “(c) ANNUAL REGISTRATION RENEWAL.—A facility
8 that continues to engage in any activity that would require
9 registration under subsection (a) or (b) shall submit to
10 the Secretary an annual registration during the first quar-
11 ter of the fiscal year for which such renewed registration
12 shall be effective.

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

20 “(e) CHANGES TO INFORMATION.—A facility that
21 submitted a registration under this section shall notify the
22 Secretary of any change to the information required under
23 subsection (a) or (b) not later than 30 days after the date
24 of such change, unless otherwise specified by the Sec-
25 retary.

1 “(f) FORMAT; CONTENTS.—

2 “(1) ELECTRONIC FORMAT.—Each registration
3 shall be submitted using an electronic format, as
4 specified in a registration form provided by Sec-
5 retary.

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

8 “(A) Each facility’s name (including any
9 parent company of the facility) and full ad-
10 dress, identifying the precise physical location
11 of the facility.

12 “(B) The identity of the facility, including
13 the unique facility identifier, if any, previously
14 assigned by Secretary to the facility under sub-
15 section (i).

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

18 “(D) The product category(as identified
19 under section 720.4(c) of title 21, Code of Fed-
20 eral Regulations (or any successor regulation),
21 or other cosmetic categories as determined ap-
22 propriate by the Secretary (including by guid-
23 ance) of each cosmetic product or cosmetic for-
24 mulation manufactured, processed, packed, or

1 held at the facility or on whose label the facili-
2 ty's name and address appear.

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

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

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

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

19 “(I) An assurance that the Secretary will
20 be permitted to inspect such facility at the
21 times and in the manner permitted by this Act.

22 “(J) Additional information pertaining to
23 the facility or to the cosmetic products or cos-
24 metic formulations manufactured, processed,
25 packed, or held at the facility, or on whose label

1 the facility's name and address appear, includ-
2 ing all brand names known to consumers, as
3 the Secretary may require by regulation.

4 “(3) ABBREVIATED REGISTRATION.—The Sec-
5 retary shall provide for an abbreviated registration
6 renewal process for any facility that has not had any
7 changes to the information submitted by the facility
8 for the preceding registration.

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

11 “(1) IN GENERAL.—Subject to paragraph (2),
12 the Secretary may cancel a registration of a facility
13 under this section if—

14 “(A) the Secretary has reasonable grounds
15 to believe that the registration was not properly
16 completed or updated in accordance with this
17 section;

18 “(B) a required registration fee has not
19 been paid within 30 days; or

20 “(C) the registration otherwise contains
21 false, incomplete, or inaccurate information.

22 “(2) NOTIFICATION.—The Secretary shall, at
23 least 10 days before canceling a registration pursu-
24 ant to paragraph (1), provide notice to the facility
25 of the intent of the Secretary to cancel such reg-

1 istration that contains the Secretary’s basis for the
2 determination to so cancel the registration.

3 “(3) **TIMELY UPDATE OR CORRECTION.**—If, not
4 later than 7 days after receipt of a notice of intent
5 to cancel under paragraph (2), the facility corrects
6 the registration in accordance with the basis for the
7 cancellation, and the required registration fee, if
8 any, is paid, the Secretary shall not cancel such reg-
9 istration.

10 “(h) **UNIQUE IDENTIFIER.**—At the time of the initial
11 registration of any cosmetic facility under this section, the
12 Secretary shall assign a unique identifier to the facility
13 and provide such identifier to such facility in writing.

14 “(i) **REGISTRY OF FACILITIES.**—

15 “(1) **IN GENERAL.**—The Secretary shall com-
16 pile, maintain, and update a registry of facilities
17 that are registered under this section, and shall re-
18 move from such registry the name of any facility
19 whose registration under this section is cancelled.
20 The registry shall be publicly available.

21 “(2) **PUBLIC AVAILABILITY EXCEPTIONS.**—In-
22 formation derived from the registry or registration
23 documents that discloses the residential address of
24 an owner, operator, or agent in charge of (or an af-
25 filiate thereof) a facility engaged in manufacturing,

1 processing, packing, or holding a cosmetic product
2 or formulation, or a facility owned by such person,
3 or that discloses specific facilities where specific
4 brands of cosmetic products are manufactured or
5 processed shall not be subject to disclosure under
6 section 552 of title 5, United States Code.

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

8 “(a) IN GENERAL.—For each cosmetic product, the
9 responsible person shall submit to the Secretary a cos-
10 metic ingredient statement, at such time and in such man-
11 ner as the Secretary may prescribe. The cosmetic ingre-
12 dient statement shall not become effective until the re-
13 sponsible person pays any applicable fee required under
14 section 744M.

15 “(b) SUBMISSION OF A COSMETIC INGREDIENT
16 STATEMENT.—

17 “(1) EXISTING COSMETIC PRODUCTS.—In the
18 case of a cosmetic product or cosmetic formulation
19 that is marketed on the date of enactment of the
20 Cosmetic Safety Enhancement Act of 2019, the re-
21 sponsible person shall—

22 “(A) not later than the date that is 6
23 months after the date of the announcement of
24 an electronic registration system required by
25 section 605, submit to the Secretary a cosmetic

1 ingredient statement in accordance with this
2 section; and

3 “(B) beginning one year after the ingre-
4 dient statement is submitted under subpara-
5 graph (A) and each year thereafter, submit to
6 the Secretary a renewal of such statement, con-
7 sistent with the requirements in subsection (e),
8 during the first quarter of the fiscal year for
9 which such renewed statement is applicable.

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

12 “(A) IN GENERAL.—Except as provided
13 under subparagraph (B), in the case of a cos-
14 metic product or cosmetic formulation that is
15 first marketed after the date of enactment of
16 the Cosmetic Safety Enhancement Act of 2019
17 or a cosmetic product or cosmetic formulation
18 that is reformulated after such date of enact-
19 ment, the responsible person shall —

20 “(i) submit to the Secretary a cos-
21 metic ingredient statement prior to first
22 marketing the new cosmetic product, new
23 cosmetic formulation, or the reformulated
24 cosmetic product or reformulated cosmetic
25 formulation; and

1 “(ii) beginning one year after the in-
2 ingredient statement is submitted under
3 clause (i), submit to the Secretary annually
4 thereafter a renewal of such statement
5 during the first quarter of the fiscal year
6 for which the cosmetic ingredient state-
7 ment is applicable, consistent with the re-
8 quirements in subsection (e).

9 “(B) SMALL BUSINESSES.—In the case of
10 a responsible person that is a small business,
11 the Secretary shall allow such responsible per-
12 son to have an additional time period, of a du-
13 ration to be determined by the Secretary, in
14 which to submit the first cosmetic ingredient
15 statement under subparagraph (A). Such re-
16 sponsible person shall, consistent with the re-
17 quirements in subsection (e), submit a cosmetic
18 ingredient statement annually thereafter during
19 the first quarter of the applicable fiscal year.

20 “(C) APPLICABILITY.—In applying sub-
21 paragraph (A), a cosmetic product or cosmetic
22 formulation shall not be considered to be first
23 marketed or reformulated after the date of en-
24 actment of the Cosmetic Safety Enhancement

1 Act of 2019 if the only change in such product
2 or formulation is—

3 “(i) a change in the amount of an ex-
4 isting ingredient that is previously reported
5 under subsection (c)(2)(E); or

6 “(ii) the addition or subtraction of a
7 fragrance, flavor, or color, or such other
8 interchangeable ingredients specified by
9 the Secretary in regulations or guidance,
10 previously reported as a potential ingre-
11 dient under subsection (c)(2).

12 “(3) ABBREVIATED RENEWAL.—The Secretary
13 shall provide for an abbreviated process for the re-
14 newal of any cosmetic ingredient statement under
15 this subsection with respect to which there has been
16 no change since the responsible person submitted the
17 previous statement.

18 “(c) FORMAT; CONTENTS.—

19 “(1) FORM.—For each cosmetic ingredient
20 statement submitted with respect to a cosmetic prod-
21 uct or cosmetic formulation under this section, such
22 statement shall be submitted using an electronic for-
23 mat, as specified in a form specified by the Sec-
24 retary.

1 “(2) CONTENTS.—Each such cosmetic ingre-
2 dient statement shall include the following informa-
3 tion:

4 “(A) The unique identifier, assigned under
5 section 605(h), as applicable, of—

6 “(i) the facility or facilities where the
7 cosmetic product or cosmetic formulation
8 is manufactured, processed, packed, or
9 held or, if the same cosmetic product or
10 cosmetic formulation is manufactured,
11 processed, packed, or held in more than
12 one facility, the unique facility identifier of
13 each facility where it is manufactured,
14 processed, packed, or held; and

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

19 “(B) The brand name and the full name
20 for the cosmetic product or cosmetic formula-
21 tion as it appears on the label.

22 “(C) The listing number, if any, previously
23 assigned by the Secretary under subsection (f)
24 to the cosmetic product or cosmetic formula-
25 tion.

1 “(D) The applicable cosmetic category for
2 the cosmetic product or cosmetic formulation.

3 “(E) A list of ingredients in the cosmetic
4 product or cosmetic formulation that—

5 “(i) with respect to each such ingre-
6 dient, the name adopted in regulations pro-
7 mulgated by the Secretary, if any, or by
8 the common or usual name of the ingre-
9 dient; and

10 “(ii) is consistent with the regulations
11 promulgated by the Food and Drug Ad-
12 ministration related to cosmetic labeling
13 requirements; and

14 “(iii) contains a list of fragrances, fla-
15 vors, and colors that may be included in
16 the product, interchangeably, which shall
17 include—

18 “(I) in the case of fragrances,
19 each fragrance allergen contained in
20 the cosmetic product as described in
21 section 615, and for fragrances that
22 are purchased from a fragrance sup-
23 plier, the fragrances shall be identified
24 by the name or code provided by the
25 supplier, and include the name and

1 contact information for the fragrance
2 supplier;

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

10 “(iv) other appropriate interchange-
11 able ingredients as the Secretary may
12 specify in regulations or guidance that may
13 be included in the product;

14 “(v) in the case of an ingredient
15 (other than a fragrance, flavor, or color)
16 that has been designated for review under
17 section 608, includes potential ranges and
18 amounts of such ingredient.

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

21 “(G) If applicable, information on labeling
22 required under section 614.

23 “(H) Such additional information per-
24 taining to the cosmetic product as the Secretary
25 may require by regulation.

1 “(3) CONFIDENTIALITY.—Fragrance ingredi-
2 ents included in a cosmetic ingredient statement
3 under paragraph (2)(E), other than fragrance aller-
4 gens, shall be treated as confidential commercial or
5 trade secret information.

6 “(4) CONTRACT MANUFACTURING ORGANIZA-
7 TION FACILITIES.—If a facility manufactures or
8 process cosmetic products or cosmetic formulations
9 on behalf of an owner, operator, or agent in charge
10 whose name appears on the label of such products
11 or formulations, the Secretary shall require only a
12 single cosmetic ingredient statement for such cos-
13 metic product. Such single cosmetic ingredient state-
14 ment shall be submitted to the Secretary by the re-
15 sponsible person.

16 “(5) COSMETIC INGREDIENT STATEMENT FOR
17 CERTAIN SMALL BUSINESSES.—

18 “(A) IN GENERAL.—Notwithstanding any
19 other provision of this subsection, in the case of
20 a responsible person that has had an average of
21 less than \$1,000,000 in annual domestic cos-
22 metic sales over the previous 3 years, the Sec-
23 retary may allow such responsible person—

1 “(i) to submit a simplified cosmetic
2 ingredient statement under this section;
3 and

4 “(ii) an additional time period, of a
5 duration to be determined by the Sec-
6 retary, in which to submit such simplified
7 cosmetic ingredient statement.

8 “(B) CONTENTS.—A responsible person
9 described in subparagraph (A) shall include in
10 each cosmetic ingredient statement submitted
11 under this section, at a minimum—

12 “(i) a list of ingredients in the cos-
13 metic product or cosmetic formulation, in-
14 cluding any fragrance allergens as de-
15 scribed in section 614(e);

16 “(ii) the applicable cosmetic category
17 for the cosmetic product or cosmetic for-
18 mulation; and

19 “(iii) in the case of a cosmetic product
20 or cosmetic formulation that includes a
21 fragrance or flavor purchased from a fra-
22 grance or flavor supplier, the contact infor-
23 mation for the fragrance or flavor supplier,
24 including the supplier’s name, street ad-

1 dress, telephone number, and electronic
2 contact information.

3 “(d) INCOMPLETE OR INACCURATE COSMETIC IN-
4 GREDIENT STATEMENT.—

5 “(1) IN GENERAL.—Not earlier than 30 days
6 after providing notice under paragraph (2) and sub-
7 ject to paragraph (3), the Secretary may nullify a
8 cosmetic ingredient statement submitted under this
9 section if the Secretary has reasonable grounds to
10 believe that, except for minor or immaterial errors,
11 the cosmetic ingredient statement was not completed
12 or updated in accordance with this section or other-
13 wise contains false, incomplete, or inaccurate infor-
14 mation.

15 “(2) NOTICE OF NULLIFICATION.—If the Sec-
16 retary nullifies a cosmetic ingredient statement
17 under paragraph (1), the Secretary shall provide to
18 the responsible person submitting such cosmetic in-
19 gredient statement under this section notice of any
20 such nullification, including the basis for such nul-
21 lification.

22 “(3) TIMELY UPDATE OR CORRECTION.—In the
23 case of a cosmetic ingredient statement with respect
24 to which the Secretary has provided notice under
25 paragraph (2), the Secretary shall not nullify such

1 cosmetic ingredient statement if the cosmetic ingre-
2 dient statement is appropriately updated or cor-
3 rected not later than 10 days after the date on
4 which such notice is provided.

5 “(4) EFFECT OF NULLIFICATION.—No person
6 shall import, export, or otherwise distribute any cos-
7 metic product or cosmetic formulation that is the
8 subject of a cosmetic ingredient statement that is
9 nullified under this subsection.

10 “(e) ADDITIONAL REQUIREMENTS.—

11 “(1) SAFETY REQUIREMENTS.—In submitting a
12 cosmetic ingredient statement for each cosmetic
13 product or cosmetic formulation under this section,
14 a responsible person shall include an attestation that
15 the safety of the product or formulation, including
16 the individual ingredients of such product or formu-
17 lation, has been substantiated in accordance with
18 section 609.

19 “(2) CHANGES TO INFORMATION.—Not later
20 than 90 days after any change to the information re-
21 quired to be in a cosmetic ingredient statement
22 under this section, the responsible person shall no-
23 tify the Secretary of such change, including the dis-
24 continuation of the manufacture of a cosmetic prod-

1 uct. Such notification is not required for a change
2 described in subsection (b)(2)(C).

3 “(f) COSMETIC PRODUCTS LIST.—

4 “(1) LISTING NUMBER.—At the time of the ini-
5 tial submission of any cosmetic ingredient statement
6 under this section, the Secretary shall—

7 “(A) assign a unique cosmetic product list-
8 ing number to the cosmetic ingredient state-
9 ment; and

10 “(B) provide such number to the respon-
11 sible person who submitted such statement in
12 writing.

13 “(2) COSMETIC PRODUCTS LIST.—Using cos-
14 metic ingredient statements submitted under this
15 section, the Secretary shall—

16 “(A) compile and maintain a list of cos-
17 metic products or cosmetic formulations distrib-
18 uted in the United States, including the ingre-
19 dients of each such product or formulation; and

20 “(B) upon request of any State, shall make
21 such list available to such State .

22 “(3) CONFIDENTIALITY.—Information disclosed
23 to a State that is exempt from disclosure under sec-
24 tion 552(b)(4) of title 5, United States Code, shall
25 be treated as a trade secret and confidential infor-

1 “(b) SUSPENSION OF COSMETIC INGREDIENT STATE-
2 MENT.—If the Secretary determines that a cosmetic prod-
3 uct or cosmetic formulation manufactured in a registered
4 facility has a reasonable probability of causing serious ad-
5 verse health consequences or death to humans, the Sec-
6 retary may suspend the cosmetic ingredient statement of
7 that product or formulation.

8 “(c) NOTICE OF SUSPENSION.—Before suspending
9 the registration of a facility or a cosmetic ingredient state-
10 ment under this section, the Secretary shall provide—

11 “(1) notice to the facility or responsible person,
12 as appropriate, of the intent to suspend such reg-
13 istration or the cosmetic ingredient statement, which
14 shall specify the basis of the determination by the
15 Secretary for that suspension; and

16 “(2) an opportunity, within 2 business days of
17 the notice provided under paragraph (1), for the fa-
18 cility or responsible person that is the subject of
19 such notice, as appropriate, to address the reasons
20 for possible suspension of the registration of the fa-
21 cility or cosmetic ingredient statement.

22 “(d) REINSTATEMENT.—Upon a determination by
23 the Secretary that adequate grounds do not exist to con-
24 tinue the suspension actions under subsection (a) or (b),
25 the Secretary shall promptly vacate the suspension and re-

1 instate the registration of the facility or the cosmetic in-
2 gredient statement.

3 “(e) EFFECT OF SUSPENSION.—If the registration of
4 a facility is suspended under this section, no person shall
5 import or export cosmetics or otherwise distribute cos-
6 metic products or cosmetic formulations from such facil-
7 ity.

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

12 **SEC. 102. REVIEW OF INGREDIENTS AND NONFUNCTIONAL**
13 **CONSTITUENTS; SAFETY OF FINISHED PROD-**
14 **UCTS.**

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

19 **“SEC. 608. REVIEW OF INGREDIENTS AND NONFUNCTIONAL**
20 **CONSTITUENTS.**

21 “(a) INGREDIENTS AND NONFUNCTIONAL CONSTITU-
22 ENTS SUBJECT TO REVIEW.—

23 “(1) IN GENERAL.—Not later than 3 years
24 after the date of the enactment of the Cosmetic
25 Safety Enhancement Act of 2019, the Secretary

1 shall review the safety of cosmetic ingredients or
2 nonfunctional constituents (or categories thereof).
3 Upon the completion of such review, the Secretary
4 shall issue an order under subsection (d) with re-
5 spect to the use of each such ingredient (or a cat-
6 egory thereof) and presence of each such nonfunc-
7 tional constituent in cosmetic products or cosmetic
8 formulations (or a category thereof).

9 “(2) INGREDIENTS AND NONFUNCTIONAL
10 CONSTITUTENTS TO BE REVIEWED.—The Secretary
11 shall select and complete a review, on an ongoing
12 basis, of cosmetic ingredients or nonfunctional con-
13 stituents that were not reviewed in the prior 3 years.
14 Such ingredients or nonfunctional constituents, in-
15 cluding any classes of ingredients or nonfunctional
16 constituents, should be selected after consultation
17 with stakeholders, including industry and consumer
18 groups.

19 “(3) PROCESS FOR REVIEW.—The Secretary
20 shall—

21 “(A) publish in the Federal Register a list
22 of the ingredients, nonfunctional constituents
23 (or categories thereof) identified for review
24 under paragraph (2); and

1 “(B) open a public docket to solicit public
2 input and data relevant to the safety of the in-
3 gredients, nonfunctional constituents (or classes
4 or categories thereof) so listed for a period of
5 not less than 60 days.

6 “(4) PUBLIC COMMENT.—Comments may be
7 submitted to the Secretary at any time with respect
8 to the safety of cosmetic ingredients or nonfunc-
9 tional constituents (or categories thereof), regardless
10 of whether such ingredients or constituents (or cat-
11 egories thereof) have been selected for review under
12 this subsection.

13 “(b) REVIEWED INGREDIENTS AND NONFUNCTIONAL
14 CONSTITUENTS.—The Secretary shall maintain a list,
15 posted on the Internet website of the Food and Drug Ad-
16 ministration, of each cosmetic ingredient, nonfunctional
17 constituent, and category of ingredients or nonfunctional
18 constituents for which final orders have been issued under
19 subsection (d)(3), and with respect to each such ingredient
20 or nonfunctional constituent—

21 “(1) the finding made for each such ingredient,
22 nonfunctional constituent, or category under sub-
23 section (d)(4), as modified by any order under sub-
24 section (e); and

1 “(2) if applicable, compliance dates that are the
2 subject of a final order under subsection (d)(3).

3 “(c) INITIATIVE OF THE FDA.—The Secretary may,
4 at any time, propose the issuance of an order on the safety
5 of a cosmetic ingredient or nonfunctional constituent (or
6 category thereof) that was not previously listed pursuant
7 to subsection (a).

8 “(d) DETERMINATION ON SAFETY.—

9 “(1) PROPOSED ADMINISTRATIVE ORDER.—Fol-
10 lowing consideration of data and comments to the
11 public docket opened under subsection (a)(3) and
12 any other information before the Secretary with re-
13 spect to the safety of a cosmetic ingredient or non-
14 functional constituent (or category thereof), the Sec-
15 retary shall—

16 “(A) determine whether there is adequate
17 evidence to make an initial finding for purposes
18 of making a determination described in para-
19 graph (4);

20 “(B) if the Secretary determines that there
21 is adequate evidence to make such a finding,
22 issue a proposed administrative order con-
23 taining the Secretary’s initial determination on
24 the safety of such ingredient or nonfunctional
25 constituent (or category thereof) as described in

1 paragraph (4) and shall post such order on the
2 Internet website of the Food and Drug Admin-
3 istration, notwithstanding subchapter II of
4 chapter 5 of title 5, United States Code; and

5 “(C) in the case of a proposed administra-
6 tive order in which the Secretary makes the de-
7 termination described in subparagraph (C) of
8 paragraph (4), include in such order a compli-
9 ance date by which the sale of the ingredient,
10 nonfunctional constituent (or category thereof)
11 in cosmetic products or cosmetic formulations
12 shall comply with the requirements specified in
13 the final administrative order.

14 “(2) PUBLIC COMMENT.—The Secretary shall
15 open a public docket for the submission of public
16 comments (including comments on whether any pro-
17 posed compliance date included in such order is fea-
18 sible)—

19 “(A) in the case of a proposed administra-
20 tive order under paragraph (1), for a period of
21 not less than 60 days, beginning on the date of
22 the issuance of the order; or

23 “(B) in the case of a final administrative
24 order under paragraph (3), for a period of not
25 less than 60 days, beginning on the date that

1 is at least 60 days before the effective date of
2 the order.

3 “(3) FINAL ADMINISTRATIVE ORDER.—Fol-
4 lowing the public comment period under paragraph
5 (2) and consideration of comments to the public
6 docket under such paragraph and any other infor-
7 mation before the Secretary, the Secretary shall—

8 “(A) determine whether there is adequate
9 evidence to make an initial finding for purposes
10 of making a determination described in para-
11 graph (4);

12 “(B) if the Secretary determines that there
13 is adequate evidence to make such a final find-
14 ing, the Secretary shall issue a final administra-
15 tive order and shall post such order on the
16 Internet website of the Food and Drug Admin-
17 istration, notwithstanding subchapter II of
18 chapter 5 of title 5, United States Code; and

19 “(C) in the case of a final administrative
20 order in which the Secretary makes the deter-
21 mination described in subparagraph (C) of
22 paragraph (4), include in such order a compli-
23 ance date by which the sale of the ingredient,
24 nonfunctional constituent (or category thereof)

1 in cosmetic products or cosmetic formulations
2 shall comply with the final administrative order.

3 “(4) DETERMINATIONS.—In a proposed admin-
4 istrative order issued under paragraph (1) or a final
5 administrative order issued under paragraph (3), as
6 applicable, the Secretary shall make a determination
7 that the ingredient or nonfunctional constituent is—

8 “(A) safe in cosmetic products without the
9 need for specified conditions of use or toler-
10 ances;

11 “(B) safe in cosmetic products under spec-
12 ified conditions of use or tolerances; or

13 “(C) not safe in cosmetic products.

14 “(5) CONDITIONS OF USE AND TOLERANCES.—
15 An order under paragraph (4)(B) shall include such
16 conditions on the use of an ingredient or such toler-
17 ances on the presence of a nonfunctional constituent
18 (or category thereof) as are necessary for the safety
19 of cosmetic products containing such ingredient or
20 nonfunctional constituent (or category thereof), in-
21 cluding—

22 “(A) limits on the amount or concentration
23 of the ingredient or nonfunctional constituent
24 (or category thereof) that may be present in a
25 cosmetic product, including limits in products

1 intended for children, pregnant women, and
2 other vulnerable populations, and limits on use
3 near the eye or mucosal membranes;

4 “(B) warnings that are necessary or appro-
5 priate under section 614, including warnings re-
6 lated to use by children, pregnant women, popu-
7 lations with high exposure to the ingredient
8 (such as workers who are exposed through pro-
9 duction practices or handling of final products),
10 or other vulnerable populations, to help ensure
11 safe use of cosmetic products containing the in-
12 gredient or nonfunctional constituent (or a cat-
13 egory thereof); and

14 “(C) such other conditions as are nec-
15 essary for the safety of cosmetic products con-
16 taining such ingredient or nonfunctional con-
17 stituent (or category thereof).

18 “(6) CONTENTS OF ORDER.—A final adminis-
19 trative order under this subsection shall—

20 “(A) set forth the determination of the
21 Secretary on safety;

22 “(B) include a summary of the valid sci-
23 entific evidence supporting the determination;

24 “(C) include any conditions of use or toler-
25 ances under paragraph (4)(B); and

1 “(D) be effective upon its publication on
2 the Internet website of the Food and Drug Ad-
3 ministration and shall be considered final agen-
4 cy action unless a later compliance date is oth-
5 erwise specified.

6 “(e) MODIFICATION OF AN ORDER.—An order issued
7 under subsection (d) may be modified or revoked by the
8 Secretary on the initiative of the Secretary or in response
9 to a petition.

10 “(f) INADEQUATE EVIDENCE.—

11 “(1) NOTICE; EXTENSION.—If the Secretary de-
12 termines that available data and information are not
13 adequate to make a proposed or final determination
14 under subsection (d), with respect to the safety of a
15 cosmetic ingredient or nonfunctional constituent (or
16 a category thereof), the Secretary shall—

17 “(A) publish such determination on the
18 Internet website of the Food and Drug Admin-
19 istration not later than 180 days after the close
20 of the relevant comment period for the ingre-
21 dient or nonfunctional constituent (or category
22 thereof) under paragraph (2) or (3) of sub-
23 section (d), as applicable; and

24 “(B) include in such publication a notice
25 providing interested persons an additional 30

1 days from the date on which the notice is pub-
2 lished to provide additional data and informa-
3 tion and an opportunity for a meeting pursuant
4 to paragraph (2).

5 “(2) MEETINGS.—The Secretary may offer a
6 responsible person of such cosmetic ingredient or
7 nonfunctional constituent (or category thereof) a
8 confidential meeting with respect to a finding under
9 paragraph (1), to discuss matters relating to the
10 data and information requirements to support a de-
11 termination of safety of such ingredient or nonfunc-
12 tional constituent (or category thereof), which may
13 involve confidential information. Such meeting
14 should be convened in a reasonable time period
15 agreed upon between the responsible person and the
16 Secretary.

17 “(3) DETERMINATION; ORDER.—

18 “(A) INADEQUATE DATA AND INFORMA-
19 TION.—If the Secretary determines that the
20 available data and information are not adequate
21 to make a proposed or final determination
22 under subsection (d) with respect to the safety
23 of a cosmetic ingredient or nonfunctional con-
24 stituent (or category thereof), the Secretary
25 shall—

1 “(i) publish such finding on the Inter-
2 net website of the Food and Drug Admin-
3 istration not later than 180 days after the
4 close of the relevant comment period for
5 the ingredient or nonfunctional constituent
6 (or category thereof) under paragraph (2)
7 or (3) of subsection (d), as applicable; and

8 “(ii) include in such publication a no-
9 tice providing interested persons an addi-
10 tional 30 days from the date on which the
11 notice is published to provide additional
12 data and information and an opportunity
13 for a meeting pursuant to paragraph (2).

14 “(B) ADEQUATE DATA AND INFORMA-
15 TION.—If the Secretary determines, after con-
16 sidering any additional data and information
17 submitted pursuant to paragraph (1)(B), that
18 the available data and information are adequate
19 to make a determination with respect to the
20 safety of a cosmetic ingredient or nonfunctional
21 constituent (or category thereof), the Secretary
22 shall—

23 “(i) in the case of a determination de-
24 scribed in subparagraph (A) of subsection
25 (d)(4), within 180 days of the close of the

1 applicable comment period under sub-
2 section (d)(2), issue a final administrative
3 order, with respect to such cosmetic ingre-
4 dient or nonfunctional constituent (or cat-
5 egory thereof), in accordance with sub-
6 section (d)(3);

7 “(ii) in the case of a determination
8 described in subparagraph (B) of sub-
9 section (d)(4), within 180 days of the close
10 of the applicable comment period under
11 subsection (d)(2), issue a proposed admin-
12 istrative order, followed by a final adminis-
13 trative order, with respect to such cosmetic
14 ingredient or nonfunctional constituent (or
15 category thereof), in accordance with sub-
16 section (d)(3); and

17 “(iii) in the case of a determination
18 described in subparagraph (C) of sub-
19 section (d)(4), within 180 days of the close
20 of the applicable comment period under
21 subsection (d)(2), issue a final administra-
22 tive order, with respect to such cosmetic
23 ingredient or nonfunctional constituent (or
24 category thereof), in accordance with
25 (d)(3) specifying the date by which sale of

1 such ingredient or nonfunctional con-
2 stituent must cease.

3 “(g) SAFETY ASSESSMENT STANDARDS.—

4 “(1) IN GENERAL.—In assessing the safety of
5 an ingredient or nonfunctional constituent (or cat-
6 egory thereof) under this section, the Secretary shall
7 consider—

8 “(A) whether there is adequate evidence to
9 support a reasonable certainty among com-
10 petent scientists that—

11 “(i) in the case of a cosmetic ingre-
12 dient, the ingredient is not harmful under
13 the recommended or suggested conditions
14 of use or customary or usual use; or

15 “(ii) in the case of a nonfunctional
16 constituent, that the nonfunctional con-
17 stituent is not harmful under the rec-
18 ommended or suggested tolerance levels or
19 the level at which it is customarily or usu-
20 ally present;

21 “(B) the probable human exposure to the
22 ingredient or nonfunctional constituent (or cat-
23 egory thereof) from expected use in cosmetic
24 products and cosmetic formulations;

1 “(C) the probable cumulative and aggre-
2 gate effect in humans of relevant exposure to
3 the ingredient or nonfunctional constituent (or
4 category thereof) or to any chemically or phar-
5 macologically related substances from use in
6 cosmetics or other products with similar routes
7 of exposure under recommended or suggested
8 conditions of use or their customary use, to the
9 extent adequate data is available for analysis,
10 and if appropriate, available information on the
11 total exposure to a cosmetic ingredient or non-
12 functional constituent from all sources; and

13 “(D) whether warnings or recommenda-
14 tions in a cosmetic product label, as part of any
15 conditions of use or tolerances imposed by the
16 Secretary in a determination described in sub-
17 paragraph (B) of subsection (d)(4), would be
18 necessary and appropriate to help ensure the
19 safety of the ingredient or nonfunctional con-
20 stituent (or category thereof).

21 “(2) MINOR ADVERSE REACTIONS.—The Sec-
22 retary may not consider a cosmetic ingredient or
23 nonfunctional constituent (or category thereof)
24 harmful under paragraph (1) solely because it can
25 cause minor adverse health reactions, such as minor

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

3 “(3) DATA AND INFORMATION.—

4 “(A) REQUIRED INFORMATION.—A deter-
5 mination that a cosmetic ingredient or nonfunc-
6 tional constituent (or category thereof) is safe
7 in cosmetics under this section shall be based
8 upon adequate evidence submitted or otherwise
9 known to the Secretary, which shall include full
10 reports of all available studies, published or un-
11 published, that are adequately designed to show
12 whether the ingredient or nonfunctional con-
13 stituent is safe. Such studies may include in
14 vitro and in silico studies and epidemiological
15 studies, biomonitoring studies, and studies fo-
16 cused on various points during the lifespan of
17 the subject, that use scientifically valid method-
18 ology.

19 “(B) ADDITIONAL RELEVANT INFORMA-
20 TION.—The Secretary shall consider any other
21 relevant information related to the safety of a
22 cosmetic ingredient or nonfunctional constituent
23 (or category thereof), including—

24 “(i) adverse event reports;

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

5 “(iii) if the ingredient or nonfunc-
6 tional constituent (or category thereof) is
7 lawfully used or present in other products
8 regulated by the Secretary, the scientific
9 basis for such use; and

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

18 “(h) COAL TAR HAIR DYE.—In assessing for pur-
19 poses of this section the safety of coal tar hair dye or any
20 ingredient or nonfunctional constituent therein, the Sec-
21 retary shall not make a determination that the dye, ingre-
22 dient, or nonfunctional constituent is not safe for use in
23 cosmetic products solely because the dye, ingredient, or
24 nonfunctional constituent can cause allergic reactions.

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

2 “(a) DETERMINATION.—

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

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

17 “(b) PRESUMPTION OF ADEQUATE EVIDENCE.—

18 “(1) IN GENERAL.—Except as provided in sub-
19 section (c), a determination made under subsection
20 (a) with respect to a finished cosmetic product shall
21 be presumed to be based on adequate evidence if it
22 is supported by—

23 “(A) with respect to each ingredient in the
24 finished cosmetic product—

25 “(i) references to an official statement
26 by one or more expert medical or scientific

1 bodies that the ingredient is safe under the
2 conditions of use recommended or sug-
3 gested in the product’s labeling or under
4 such conditions of use as are customary or
5 usual; or

6 “(ii) appropriate safety testing of the
7 ingredient; and

8 “(B) appropriate safety substantiation of
9 the finished cosmetic product beyond the safety
10 substantiation of individual ingredients and
11 consideration of the combination of ingredients.

12 “(2) STATEMENT OF AN EXPERT MEDICAL OR
13 SCIENTIFIC BODY.—For purposes of applying para-
14 graph (1)(A)(i), a statement of an expert medical or
15 scientific body is an official statement of that body,
16 if—

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

22 “(B) the statement is based upon adequate
23 data to support the finding of safety, and such
24 data are available to the Secretary; and

1 “(C) the statement is published and en-
2 dorsed by the medical or scientific body and is
3 not a statement of an employee of such body
4 made in the individual capacity of the employee.

5 “(c) REBUTTAL OF PRESUMPTION.—Notwith-
6 standing subsection (b), a determination under subsection
7 (a) will not be presumed to be based on adequate evidence
8 if—

9 “(1) the Secretary issues an order under section
10 608 that an ingredient or nonfunctional constituent
11 in the finished product is not safe under the prod-
12 uct’s conditions of use or customary or usual use; or

13 “(2) the Secretary has provided the manufac-
14 turer with notice that—

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

17 “(B) the Secretary has information that
18 raises significant questions about the safety of
19 the product or any of its ingredients.

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

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

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

9 “(f) SUBMISSION OF RECORDS.—

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

15 “(2) CRITERIA.—The Secretary may require
16 records under paragraph (1) if—

17 “(A) the Secretary has a reasonable belief,
18 described in written notice, 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 Secretary, an expert regulatory
9 body, or an expert body composed of scientific
10 and medical experts finds an ingredient in the
11 product to be unsafe under the conditions of
12 use of the product; or

13 “(C) the Secretary concludes that submis-
14 sion of the records will serve the public health
15 or otherwise enable the Secretary to fulfill the
16 cosmetic safety purposes of this section.

17 “(g) GUIDANCE AND REGULATIONS.—

18 “(1) IN GENERAL.—The Secretary shall issue
19 guidance describing the evidence necessary to sup-
20 port a determination under subsection (a), and may,
21 by regulation, establish exemptions to the require-
22 ments of this section, if the Secretary determines
23 that such exemptions are supported by adequate evi-
24 dence and would have no adverse effect on public
25 health.

1 “(2) SMALL BUSINESSES.—The Secretary shall,
2 after consultation with the Small Business Adminis-
3 tration and small businesses that manufacture cos-
4 metics, provide additional guidance for small busi-
5 nesses on compliance with the requirements of this
6 section. Such guidance shall include specific exam-
7 ples of options for compliance that do not place an
8 undue burden on small businesses.”.

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

13 (c) PUBLIC MEETING AND GUIDANCE.—

14 (1) PUBLIC MEETING.—Not later than 12
15 months after the date of the enactment of this Act,
16 the Secretary of Health and Human Services (in this
17 subsection referred to as the “Secretary”) shall con-
18 vene a public meeting to describe and solicit public
19 input regarding the ingredient review process under
20 section 608 of the Federal Food, Drug, and Cos-
21 metic Act (as added by subsection (a)). Such meet-
22 ing shall include representatives from the cosmetics
23 industry, medical practitioners and scientific experts
24 with cosmetic expertise, and consumer and public
25 health advocacy organizations.

1 (2) GUIDANCE.—Not less than one year after
2 the public meeting conducted under paragraph (1),
3 the Secretary shall issue one or more guidance docu-
4 ments to implement section 608 of the Federal
5 Food, Drug, and Cosmetic Act (as added by sub-
6 section (a)). Such guidance documents shall include
7 information regarding—

8 (A) the types of scientific evidence, clinical
9 studies, data, or other information needed to
10 support the review of cosmetic ingredients or
11 nonfunctional constituents (or categories there-
12 of) selected for review under such section;

13 (B) the recommended format in which to
14 submit to the Secretary such data and informa-
15 tion, including any applicable foreign data and
16 information, related to a cosmetic ingredient or
17 nonfunctional constituent (or category thereof)
18 that has been selected for such review;

19 (C) the manner and the number of days by
20 which the Secretary intends to review and re-
21 spond to such data and information, including
22 with respect to providing a scientific rationale
23 for any additional data and information;

24 (D) the process for communication be-
25 tween the Secretary and industry related to an

1 ingredient or nonfunctional constituent (or a
2 category thereof) that has been selected for re-
3 view; and

4 (E) includes such other information as the
5 Secretary determines appropriate.

6 (3) TIMING.—Not later than 24 months after
7 the date of the enactment of this Act, the Secretary
8 shall issue draft guidance under paragraph (1) on
9 the implementation of section 608 of the Federal
10 Food, Drug, and Cosmetic Act (as added by sub-
11 section (a)). The Secretary shall issue final guidance
12 on the implementation of such section not later than
13 6 months after the date on which the comment pe-
14 riod for the draft guidance closes.

15 (d) GAO STUDY.—Not later than 6 years after the
16 date of the enactment of this Act, the Comptroller General
17 of the United States shall submit to the Committee on
18 Energy and Commerce of the House of Representatives
19 and the Committee on Health, Education, Labor, and
20 Pensions of the Senate a report addressing the effective-
21 ness and overall impact of the ingredient review program
22 established under section 608 of the Federal Food, Drug,
23 and Cosmetic Act (as added by subsection (a)), including
24 with respect to its impact on the safety of cosmetic ingre-
25 dients—

1 (1) for each ingredient or nonfunctional con-
2 stituent (or category thereof) selected for review—

3 (A) whether the ingredient or nonfunc-
4 tional constituent (or category thereof) was de-
5 termined—

6 (i) to be safe in cosmetic products
7 without the need for specified conditions of
8 use or tolerances;

9 (ii) to be safe in cosmetic products
10 under specified conditions of use of toler-
11 ances; or

12 (iii) to be not safe in cosmetic prod-
13 ucts;

14 (B) the timeline for such review;

15 (C) the types of scientific evidence, clinical
16 studies, data, or other information used to
17 make such a determination;

18 (D) whether, and to what extent, the re-
19 view of the ingredient or nonfunctional con-
20 stituent (or category thereof) resulted in cos-
21 metic products being reformulated or removed
22 from the market; and

23 (E) the impact the review and determina-
24 tion had on consumer use and access to such
25 product; and

1 (2) an analysis of the ingredient, nonfunctional
2 constituent (or category thereof) review conducted
3 under such section 608, including—

4 (A) the resources used by the Secretary in
5 reviewing ingredients and nonfunctional con-
6 stituents (or categories thereof), including the
7 effects of the program on other cosmetic safety
8 activities of the Secretary;

9 (B) the impact of such section on innova-
10 tion and consumer access to cosmetic products;
11 and

12 (C) whether any improvements to the pro-
13 gram under such section 608 are necessary for
14 increasing the efficiency and effectiveness of the
15 review of cosmetic ingredients, nonfunctional
16 constituents, or categories thereof.

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

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

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

25 “(a) IN GENERAL.—The Secretary shall—

1 “(1) review national and international stand-
2 ards for cosmetic good manufacturing practices that
3 are in effect on the date of enactment of the Cos-
4 metic Safety Enhancement Act of 2019; and

5 “(2) issue a rule establishing current good man-
6 ufacturing standards consistent, to the extent the
7 Secretary determines practicable and appropriate,
8 with such national and international standards.

9 “(b) CONTENT OF REGULATIONS.—The regulations
10 issued pursuant to subsection (a)(2)—

11 “(1) may specify requirements for the use of
12 certain analytical or recordkeeping methods by a
13 manufacturer as may be necessary to ensure that a
14 cosmetic product or cosmetic formulation is not inju-
15 rious to health under the recommended or suggested
16 conditions of use, or customary or usual use of the
17 product or formulation; and

18 “(2) shall not—

19 “(A) impose standards for which there is
20 no current and generally available analytic
21 method; or

22 “(B) apply to facilities meeting the criteria
23 to be considered a facility under section 604(6),
24 including retail stores or counters offering cus-
25 tomized or personalized cosmetics to consumers,

1 or to entities that are in compliance with the
2 good manufacturing practice regulations speci-
3 fied in parts 210 and 211 of title 21, Code of
4 Federal Regulations (or any successor regula-
5 tions).

6 “(c) TIMEFRAME.—The Secretary shall publish a
7 proposed rule described in subsection (a) not later than
8 24 months after the date of enactment of the Cosmetic
9 Safety Enhancement Act of 2019 and shall publish a final
10 such rule not later than 36 months after such date of en-
11 actment.”.

12 (b) EFFECTIVE DATE FOR COSMETIC MANUFACTUR-
13 ERS.—Regulations issued pursuant to section 610 of the
14 Federal Food, Drug, and Cosmetic Act (as added by sub-
15 section (a)) shall apply with respect to—

16 (1) large manufacturers (as defined in section
17 744L of such Act (as added by section 202 of this
18 Act), beginning 180 days after the date on which the
19 final rule described in subsection (a) is effective;

20 (2) mid-size manufacturers (as defined in sec-
21 tion 744L of such Act (as added by section 202 of
22 this Act), beginning 210 days after such date; and

23 (3) small manufacturers (as defined in section
24 744L of such Act (as added by section 202 of this
25 Act), beginning 2 years after such date.

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

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

8 **SEC. 104. ADVERSE EVENT REPORTS.**

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

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

14 “(a) SUBMISSION OF SERIOUS ADVERSE EVENT RE-
15 PORTS.—

16 “(1) IN GENERAL.—With respect to any cos-
17 metic product distributed in the United States, the
18 responsible person shall submit, not later than 15
19 days after the receipt by the responsible person,
20 using an electronic system developed under sub-
21 section (b), to the Secretary any report of a serious
22 adverse event associated with the use of the cosmetic
23 product, accompanied by a copy of the label on or
24 with the retail packaging of the cosmetic product.

1 “(2) NEW MEDICAL INFORMATION.—During the
2 12-month period following the submission of a seri-
3 ous adverse event report under paragraph (1), with
4 respect to any cosmetic product distributed in the
5 United States, the responsible person shall submit,
6 not later than 15 days after the receipt by the re-
7 sponsible person, using an electronic system devel-
8 oped under subsection (b), to the Secretary any new
9 medical information related to such serious adverse
10 event report that is received by the responsible per-
11 son.

12 “(3) PUBLICATION.—The Secretary shall make
13 publicly available on the Internet website of the
14 Food and Drug Administration reports submitted
15 under paragraph (1).

16 “(4) NO DUPLICATION.—In the case of cos-
17 metic product that is also a drug for which a serious
18 adverse event report is filed using Form FDA
19 3500A (or any successor form developed for such
20 purpose) or its electronic equivalent for over-the-
21 counter drugs, the responsible person shall not be
22 required to submit a serious adverse event report
23 under paragraph (1) with respect to that cosmetic
24 product.

1 “(b) REQUIREMENTS FOR SERIOUS ADVERSE EVENT
2 REPORTS.—

3 “(1) ELECTRONIC SYSTEM.—

4 “(A) IN GENERAL.—The Secretary shall,
5 not later than 1 year after the date of enact-
6 ment of the Cosmetic Safety Enhancement Act
7 of 2019, develop and implement an electronic
8 system for use for the submission of serious ad-
9 verse event reports under this section.

10 “(B) MODIFICATION.—The format of the
11 electronic system developed and implemented
12 under paragraph (1) may be modified by the
13 Secretary and the reports may include addi-
14 tional information. The Secretary may, in guid-
15 ance, further specify the format and contents of
16 required reports.

17 “(2) CONTENT OF REPORTS.—A serious ad-
18 verse event report submitted under paragraph (1) of
19 subsection (a) shall include all information sub-
20 mitted with the initial report and any information
21 subsequently added to such report pursuant to para-
22 graph (2) of such subsection and—

23 “(A) any report by the responsible person
24 under section 756 with respect to the safety of

1 the cosmetic product that is the subject of the
2 report;

3 “(B) information on the individual or indi-
4 viduals with respect to whom the adverse event
5 report is submitted, in accordance with the dis-
6 closure requirements of section 552a of title 5,
7 United States Code;

8 “(C) notwithstanding section 552(b)(6) of
9 title 5, United States Code, medical (or similar)
10 documentation of the serious adverse event that
11 is the subject of the report, with all personally
12 identifiable information redacted; and

13 “(D) contact information for the individual
14 or individuals reporting the serious adverse
15 event.

16 “(3) RESPONSIBILITY TO GATHER INFORMA-
17 TION.—After an individual initiates the reporting of
18 a serious adverse event, the responsible person for
19 the cosmetic product shall actively gather all of the
20 information reasonably available to such person to
21 complete and file the report with the Secretary
22 under subsection (a)(1).

23 “(4) NO ADVERSE EVENTS TO REPORT.—The
24 Secretary shall provide an option as part of the elec-
25 tronic registration process for the responsible person

1 to indicate if such responsible person had no adverse
2 events to report over the previous year. With respect
3 to a responsible person who received no adverse
4 event reports for a year, the annual adverse event
5 report requirement may be met by indicating no
6 such events on the annual registration form.

7 “(5) EXEMPTION.—The Secretary may estab-
8 lish by regulation an exemption to any of the re-
9 quirements under this section if the Secretary deter-
10 mines that such exemption is supported by adequate
11 evidence and would have no adverse effect on public
12 health.

13 “(c) REQUIREMENTS FOR OTHER ADVERSE EVENT
14 REPORTS.—

15 “(1) IN GENERAL.—Each responsible person
16 shall maintain records related to each report of an
17 adverse event (including serious adverse events) as-
18 sociated with each cosmetic product marketed by
19 such responsible person and received by such respon-
20 sible person for a period of 6 years. Such records
21 shall be made available to an officer or an employee
22 duly designated by the Secretary upon request, at
23 reasonable times and within reasonable limits and in
24 a reasonable manner, including allowing electronic
25 access and to copy such records.

1 “(2) CONTENT.—Records required to be main-
2 tained under this paragraph shall contain all infor-
3 mation reasonably available, including—

4 “(A) a summary of all adverse events re-
5 ceived during the calendar year for each cos-
6 metic product marketed;

7 “(B) a complete list of individual reports
8 of adverse events for each cosmetic product
9 marketed and with respect to each such event,
10 the same information required to be included in
11 a report with respect to a serious adverse event
12 under subsection (b)(2), subject to the same
13 conditions with respect to the disclosure of such
14 information;

15 “(C) an estimate of the total number of
16 product units estimated to have been distrib-
17 uted to consumers during the period specified
18 in paragraph (1); and

19 “(D) such other information as may be
20 specified in regulation or guidance issued by the
21 Secretary.

22 “(3) RULE OF CONSTRUCTION.—This section
23 shall not be construed to require the inclusion in any
24 report under this section any consumer complaint

1 that concerns solely efficacy and does not contain
2 any information about an adverse event.

3 “(d) LIMITATION WITH RESPECT TO ADVERSE
4 EVENT REPORTS.— Section 756 shall apply with respect
5 to the submission of an adverse event report in compliance
6 with subsection (a).

7 “(e) CONTACT INFORMATION.—The label of a cos-
8 metic product shall bear the domestic address, and either
9 the domestic telephone number or electronic contact infor-
10 mation, through which the responsible person may receive
11 a report of an adverse event.

12 “(f) AVAILABILITY TO STATES.—The Secretary shall
13 make records submitted under this section available to any
14 State, upon request, to the extent permissible under the
15 laws governing disclosure of information by the Secretary.
16 Information disclosed to a State that is exempt from dis-
17 closure under section 552(b)(4) of title 5, United States
18 Code, shall be treated as a trade secret and confidential
19 information by the State. Such State and its employees
20 in possession of such information shall be subject to the
21 same laws governing information disclosure as employees
22 of the Food and Drug Administration.

23 “(g) PROTECTION OF INFORMATION.—A serious ad-
24 verse event report submitted to the Secretary under sub-
25 section (a), including any new medical information sub-

1 mitted under paragraph (2) of such subsection, or an ad-
2 verse event report voluntarily submitted to the Secretary,
3 shall be considered to be a safety report under section 756
4 and may be accompanied by a statement, which shall be
5 a part of any report that is released for public disclosure,
6 that denies that the report or the records constitute an
7 admission that the product involved caused or contributed
8 to the adverse event.

9 “(h) EFFECTIVE DATES.—

10 “(1) SERIOUS ADVERSE EVENTS.—The require-
11 ment under this section to report serious adverse
12 events shall become effective on the date that the
13 Secretary publicizes the availability of the electronic
14 system described in subsection (b)(1).

15 “(2) OTHER ADVERSE EVENTS.—The require-
16 ment under this section to maintain records relating
17 to adverse events which are not serious adverse
18 events shall become effective 18 months after the
19 date of the enactment of the Cosmetic Safety En-
20 hancement Act of 2019.

21 “(i) DEFINITIONS.—In this section:

22 “(1) ADVERSE EVENT.—The term ‘adverse
23 event’ means, with respect to a cosmetic product, a
24 health-related or medical event associated with the
25 use of such product, including a risk of illness or in-

1 jury. Such term does not include any instance of a
2 consumer complaint that such product did not work
3 as advertised or marketed.

4 “(2) SERIOUS ADVERSE EVENT.—The term ‘se-
5 rious adverse event’ means, with respect to a cos-
6 metic product, an adverse event that—

7 “(A) results in—

8 “(i) death;

9 “(ii) a life-threatening experience;

10 “(iii) inpatient hospitalization;

11 “(iv) a persistent or significant ad-
12 verse health condition, disability or inca-
13 pacity;

14 “(v) congenital anomaly or birth de-
15 fect; or

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

19 “(B) requires, based on reasonable medical
20 judgment, a medical or surgical intervention to
21 prevent an outcome described in subparagraph
22 (A).”.

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

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

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

7 “(a) INSPECTION OF RECORDS.—Each facility, in-
8 cluding a facility owned or operated by a responsible per-
9 son for a cosmetic product shall, at the request of an offi-
10 cer or employee duly designated by the Secretary, permit
11 such officer or employee, upon presentation of appropriate
12 credentials and written notice to such person, at reason-
13 able times and within reasonable limits and in a reason-
14 able manner, to have access to and copy, or receive elec-
15 tronically records maintained by or on behalf of such per-
16 son in any format (including paper and electronic formats)
17 and at any location, including—

18 “(1) all records maintained under section 611
19 and in accordance with the rules promulgated by the
20 Secretary under section 610, as applicable;

21 “(2) all records maintained under section 609;

22 “(3) any records relating to the list of ingredi-
23 ents in specific fragrances or flavors of a cosmetic
24 product or cosmetic formulation, if requested by the
25 Secretary by means of a written notification; and

1 “(4) except as provided in subsection (b), all
2 other records relating to the cosmetic product or
3 cosmetic formulation and to any other cosmetic
4 product or cosmetic formulation the Secretary rea-
5 sonably believes is likely to be affected in a similar
6 manner, if the Secretary—

7 “(A) has a reasonable belief that the cos-
8 metic product or cosmetic formulation—

9 “(i) is adulterated;

10 “(ii) has caused a reportable serious
11 adverse event; or

12 “(iii) contains an ingredient for which
13 new scientific information shows may be
14 unsafe when present in a cosmetic product
15 or cosmetic formulation; and

16 “(B) provides written notice to the respon-
17 sible person of the basis for the Secretary’s rea-
18 sonable belief described in subparagraph (A), as
19 applicable.

20 “(b) EXCLUSIONS.—

21 “(1) IN GENERAL.—No inspection authorized
22 by this section shall extend to—

23 “(A) recipes, financial data, pricing data,
24 personnel data (other than data as to qualifica-
25 tion of technical and professional personnel per-

1 forming functions subject to this Act), research
2 data (other than safety data) or sales data
3 other than shipment and distribution data; or

4 “(B) except as provided in paragraph (2),
5 information related to ingredient in fragrances
6 or flavors of a cosmetic product or cosmetic for-
7 mulation.

8 “(2) EXCEPTION.—The Secretary may obtain
9 information related to the ingredients in fragrances
10 or flavors in an identified product only by a request
11 in a written notification provided to the manufac-
12 turer pursuant to a for-cause inspection. In response
13 to such written notification, the manufacturer of
14 such fragrance or flavor shall provide information
15 about the ingredients in the specified fragrance or
16 flavor that the Secretary determines is necessary to
17 assist its investigation, in the manufacturer’s pre-
18 ferred electronic or written format, to the Secretary
19 upon receipt of such notification. Any information
20 provided in response to such written notification
21 shall be considered a trade secret under section
22 301(j) and, notwithstanding such section, shall only
23 be disclosed if the Secretary determines such disclo-
24 sure is necessary to protect the public health. The
25 authority to determine such disclosure is necessary

1 to protect the public health shall not be delegated to
2 any officer or employee other than the director of
3 the applicable office.

4 “(c) PROTECTION OF SENSITIVE INFORMATION.—
5 The Secretary shall take appropriate measures to ensure
6 that there are effective procedures to prevent the unau-
7 thorized disclosure of any trade secret or confidential in-
8 formation that is obtained by the Secretary pursuant to
9 this section. Information disclosed to a State shall be pur-
10 suant to the laws governing disclosure of information.
11 Confidential information disclosed to the State that is ex-
12 empt from disclosure under section 552(b)(4) of title 5,
13 United States Code, shall be treated as confidential infor-
14 mation by the State. Such State and its employees in pos-
15 session of such information under this section shall be sub-
16 ject to the same laws governing information disclosure as
17 employees of the Food and Drug Administration.

18 “(d) LIMITATIONS.—This section shall not be con-
19 strued—

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

24 “(2) to require the Secretary to publicly disclose
25 any information that is exempt from disclosure

1 under section 522 of title 5, United States Code, or
2 section 1905 of title 18, United States Code.

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

4 “(a) VOLUNTARY PROCEDURES.—If the Secretary
5 determines that there is a reasonable probability that a
6 cosmetic product is adulterated under section 601 or mis-
7 branded under section 602 and the use of, and exposure
8 to, such cosmetic product is likely to cause serious adverse
9 health consequences or death, the Secretary shall provide
10 the responsible person with an opportunity to voluntarily
11 cease distribution and recall such article.

12 “(b) PREHEARING ORDER TO MANDATORILY CEASE
13 DISTRIBUTION AND GIVE NOTICE.—

14 “(1) IN GENERAL.—If the domestic responsible
15 person refuses to or does not voluntarily cease dis-
16 tribution or recall such cosmetic product within the
17 time and in the manner prescribed by the Secretary,
18 the Secretary may order such person to—

19 “(A) immediately cease distribution of
20 such cosmetic product; and

21 “(B) as applicable, immediately order all
22 facilities—

23 “(i) manufacturing, processing, pack-
24 ing, transporting, holding, receiving, dis-

1 tributing, or importing and selling such
2 cosmetic product; and

3 “(ii) to which such cosmetic product
4 has been distributed, transported, or sold,
5 to immediately cease distribution of such cos-
6 metic product.

7 “(2) REQUIRED ADDITIONAL INFORMATION.—

8 “(A) IN GENERAL.—In the case of a cos-
9 metic product that is subject to a recall order
10 issued under paragraph (1)(B) with respect to
11 which the responsible person, before the
12 issuance of such order, distributed to a ware-
13 house-based third party logistics provider with-
14 out providing such logistics provider with suffi-
15 cient information to know or reasonably deter-
16 mine the precise identity of such cosmetic prod-
17 uct, the notice provided by the domestic respon-
18 sible person pursuant to such order shall in-
19 clude such information as is necessary for the
20 logistics provider to identify the cosmetic prod-
21 uct.

22 “(B) RULES OF CONSTRUCTION.—Nothing
23 in this paragraph shall be construed to exempt
24 a warehouse-based, third-party logistics pro-
25 vider from—

1 “(i) the requirements of this chapter,
2 including the requirements of this section
3 and section 612; or

4 “(ii) being the subject of a mandatory
5 recall order under this section.

6 “(3) DETERMINATION TO LIMIT AREAS AF-
7 FECTED.—If the Secretary requires a domestic re-
8 sponsible person to cease distribution under para-
9 graph (1)(A) of a cosmetic product, the Secretary
10 may limit the size of the geographic area and the
11 markets affected by such cessation if such limitation
12 would not compromise the public health.

13 “(c) HEARING ON ORDER.—The Secretary shall pro-
14 vide the responsible party subject to an order under sub-
15 section (b) with an opportunity for an informal hearing,
16 to be held as soon as possible, but not later than 2 days
17 after the issuance of the order, on the actions required
18 by the order and on why the cosmetic product that is the
19 subject of the order should not be recalled.

20 “(d) POSTHEARING RECALL ORDER AND MODIFICA-
21 TION OF ORDER.—

22 “(1) AMENDMENT OF ORDER.—If, after pro-
23 viding opportunity for an informal hearing under
24 subsection (c), the Secretary determines that re-

1 removal of the cosmetic product from commerce is
2 necessary, the Secretary shall, as appropriate—

3 “(A) amend the order to require recall of
4 such cosmetic product or other appropriate ac-
5 tion;

6 “(B) specify a timetable in which the recall
7 shall occur;

8 “(C) require periodic reports to the Sec-
9 retary describing the progress of the recall; and

10 “(D) provide notice to consumers to whom
11 such cosmetic product was, or may have been,
12 distributed.

13 “(2) VACATING OF ORDER.—If, after such hear-
14 ing, the Secretary determines that adequate grounds
15 do not exist to continue the actions required by the
16 order, or that such actions should be modified, the
17 Secretary shall vacate the order or modify the order.

18 “(e) COOPERATION AND CONSULTATION.—The Sec-
19 retary shall work with State and local public health offi-
20 cials in carrying out this section, as appropriate.

21 “(f) PUBLIC NOTIFICATION.—In conducting a recall
22 under this section, the Secretary shall—

23 “(1) ensure that a press release is published re-
24 garding the recall, and that alerts and public notices

1 are issued, as appropriate, in order to provide notifi-
2 cation—

3 “(A) of the recall to consumers and retail-
4 ers to whom such cosmetic product was, or may
5 have been, distributed; and

6 “(B) that includes, at a minimum—

7 “(i) the name of the cosmetic product
8 subject to the recall;

9 “(ii) a description of the risk associ-
10 ated with the use of such cosmetic product;
11 and

12 “(iii) to the extent practicable, infor-
13 mation for consumers about similar cos-
14 metic products that are not affected by the
15 recall; and

16 “(2) ensure publication on the Internet website
17 of the Food and Drug Administration of an image
18 of the cosmetic product that is the subject of the
19 press release described in paragraph (1), if available.

20 “(g) NO DELEGATION.—The authority conferred by
21 this section to order a recall or vacate a recall order shall
22 not be delegated to any officer or employee other than the
23 Commissioner of Food and Drugs.

24 “(h) RULE OF CONSTRUCTION.—Nothing in this sec-
25 tion shall affect the authority of the Secretary to request

1 or participate in a voluntary recall, or to issue an order
2 to cease distribution or to recall any article under any
3 other provision of this Act or under the Public Health
4 Service Act.

5 “(i) DEFINITION.—In this section, the term ‘domestic
6 responsible person’ means a person who is the domestic
7 contact for a responsible person.”.

8 **SEC. 106. LABELING AND INTERNET SALES.**

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

13 **“SEC. 614. LABELING AND INTERNET SALES.**

14 “(a) SAFETY REVIEW AND LABELING.—If a warning
15 or condition of use is required pursuant to section
16 608(d)(4) to ensure the safe use of a cosmetic ingredient,
17 the Secretary shall require appropriate labeling of any cos-
18 metic product that contains such ingredient, including if
19 such ingredient—

20 “(1) is not appropriate for use in the entire
21 population; or

22 “(2) requires warnings that children, pregnant
23 women, and other vulnerable populations should
24 limit or avoid using the product.

1 “(b) COSMETIC PRODUCTS FOR PROFESSIONAL
2 USE.—

3 “(1) LISTING OF INGREDIENTS.—The labeling
4 of cosmetic products used and sold by professionals
5 shall list all ingredients, as required for other cos-
6 metic products pursuant to section 602(g).

7 “(2) PROFESSIONAL USE LABELING.—In the
8 case of a cosmetic product that is intended to be
9 used only by a professional on account of a specific
10 ingredient or increased concentration of an ingre-
11 dient and requires safe handling by trained profes-
12 sionals, the product shall bear a statement as fol-
13 lows: ‘For Professional Use Only’.

14 “(c) DISPLAY.—A warning required under subsection
15 (a) and any statement required under subsection (b)(2)
16 shall be prominently displayed—

17 “(1) in the primary language used on the label
18 or on packaging; and

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

22 “(d) INTERNET SALES.—

23 “(1) IN GENERAL.—In the case of Internet
24 sales of cosmetic products, each primary seller offer-
25 ing a cosmetic product for sale to consumers on an

1 Internet website shall prominently and conspicuously
2 display on such Internet website—

3 “(A) the same information that is included
4 on the packaging of the cosmetic product as
5 regularly available, such as any warnings, ingre-
6 dient list, and contact information; and

7 “(B) the warnings and statements de-
8 scribed in subsection (c).

9 “(2) DEFINITION.—For purposes of this sub-
10 section, the term ‘primary seller’ refers to the entity
11 who offers a cosmetic product for sale on an Inter-
12 net website, including the responsible person.

13 **“SEC. 615. FRAGRANCE INGREDIENTS.**

14 “(a) FRAGRANCE INGREDIENTS.—Not later than two
15 years after the date of enactment of the Cosmetic Safety
16 Enhancement Act of 2019, the responsible person shall
17 include on the label of any cosmetic products containing
18 one or more fragrance allergens, a list of each such fra-
19 grance allergen included in such cosmetic product that is
20 consistent with national and international regulations for
21 fragrance allergens labeling.

22 “(b) CONTACT INFORMATION.—

23 “(1) IN GENERAL.—The contact information on
24 the label on a cosmetic product for consumers to re-
25 port adverse events shall also provide a means for

1 consumers to obtain additional information about
2 the inclusion of any recognized fragrance allergen
3 required to be included on such label under sub-
4 section (e).

5 “(2) RESPONSE.—

6 “(A) IN GENERAL.—The responsible per-
7 son shall—

8 “(i) upon receipt of a request for in-
9 formation under paragraph (1), promptly
10 obtain and provide such information to the
11 requesting consumer; and

12 “(ii) in the case of information in the
13 possession of a supplier, promptly obtain
14 such information from such supplier, if
15 reasonably available.

16 “(B) SUPPLIER.—A supplier shall prompt-
17 ly provide information requested pursuant to
18 subparagraph (A)(ii).”.

19 (b) INGREDIENT STATEMENT.—Section 602 of the
20 Federal Food, Drug, and Cosmetic Act (21 U.S.C. 362)
21 is amended by adding at the end the following:

22 “(g) If its labeling or packaging does not contain a
23 listing of ingredients that meets the requirements of part
24 701 of title 21, Code of Federal Regulations (as in effect

1 on date of enactment of the Cosmetic Safety Enhancement
2 Act of 2019) (or any successor regulations).”.

3 (c) EFFECTIVE DATE.—The amendments made by
4 this section shall apply with respect to products introduced
5 or delivered for introduction into interstate commerce on
6 or after the date that is 2 years after the date of enact-
7 ment of this Act.

8 **SEC. 107. CONSUMER INFORMATION.**

9 The Secretary of Health and Human Services, acting
10 through the Commissioner of Food and Drugs, shall post
11 on its Internet website information for consumers regard-
12 ing—

13 (1) final orders regarding the safety of a cos-
14 metic ingredient or nonfunctional constituent under
15 section 608(d)(3);

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

18 (3) identified counterfeit cosmetic products.

19 **SEC. 108. SMALL BUSINESSES.**

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

23 **“SEC. 616. SMALL BUSINESSES.**

24 “(a) IN GENERAL.—The Commissioner, in coordina-
25 tion with the Administrator of the Small Business Admin-

1 istration, shall provide technical assistance, such as guid-
2 ance and expertise, to small businesses regarding compli-
3 ance with the Cosmetic Safety Enhancement Act of 2019,
4 including the amendments made by such Act.

5 “(b) COMPLIANCE GUIDE.—Not later than 180 days
6 after the date of the enactment of Cosmetic Safety En-
7 hancement Act of 2019, the Secretary shall issue a small
8 business guide setting forth in plain language the require-
9 ments of sections 605 and 606 in order to assist small
10 businesses in complying with such requirements.”.

11 **SEC. 109. ANIMAL TESTING RESTRICTIONS.**

12 (a) IN GENERAL.—Section 601 of the Federal Food,
13 Drug, and Cosmetic Act (21 U.S.C. 361) is amended by
14 adding at the end the following:

15 “(f) If the cosmetic product, cosmetic formulation, or
16 cosmetic ingredient was developed or manufactured using
17 an animal test that was conducted or contracted by the
18 manufacturer, or any affiliate or supplier of the manufac-
19 turer, unless one of the following applies:

20 “(1) With respect to a cosmetic ingredient of
21 the cosmetic product or cosmetic formulation, an
22 animal test is required by the Secretary to evaluate
23 the safety of such ingredient or formulation.

24 “(2) With respect to a cosmetic ingredient of
25 the cosmetic product or cosmetic formulation, the

1 cosmetic ingredient or cosmetic formulation is in
2 wide use and cannot be replaced by another ingre-
3 dient that is capable of performing a similar func-
4 tion without posing a potentially greater risk to
5 human health and there is not an alternative method
6 for testing the cosmetic ingredient that is accepted
7 by the Secretary and the Interagency Coordinating
8 Committee on Validation of Alternative Methods.

9 “(3) The animal test was conducted to comply
10 with a requirement of another Federal agency or a
11 State or foreign regulatory authority.

12 “(4) In the case of a cosmetic product, cosmetic
13 formulation, or cosmetic ingredient that is also a
14 drug, the animal test was conducted with respect to
15 the approval under chapter V of the application sub-
16 mitted with respect to such product, formulation, or
17 ingredient.

18 “(5) The animal test was conducted for pur-
19 poses not related to developing or manufacturing the
20 cosmetic product, cosmetic formulation, or cosmetic
21 ingredient, and in response to a requirement of a
22 Federal, State, or foreign regulatory authority.’”.

23 (b) APPLICABILITY.—The amendment made by sub-
24 section (a) shall apply with respect to cosmetic products
25 or cosmetic formulations introduced or delivered for intro-

1 duction into interstate commerce on or after the date that
2 is two years after the date of enactment of this Act.

3 (c) GUIDANCE.—Not later than 1 year after the date
4 of enactment of this Act, the Secretary shall issue guid-
5 ance on the acceptability of scientifically reliable and rel-
6 evant alternatives to animal testing for the safety of cos-
7 metic products, cosmetic formulations, and cosmetic ingre-
8 dients, and encouraging the use of such methods.

9 (d) RESOURCES REGARDING ANIMAL TESTING AL-
10 TERNATIVES.—Not later than 180 days after the date of
11 enactment of this Act, the Secretary shall publish informa-
12 tion on the Internet website of the Food and Drug Admin-
13 istration regarding resources available for information
14 about non-animal methods, and methods that reduce ani-
15 mal usage, in testing for the safety of cosmetic products,
16 cosmetic formulations, and cosmetic ingredients.

17 (e) RULES OF CONSTRUCTION.—

18 (1) USE OF EVIDENCE.—Nothing in this sec-
19 tion, or the amendment made by this section, shall
20 be construed to prohibit any entity from reviewing,
21 assessing, or retaining evidence generated from ani-
22 mal testing.

23 (2) ACCEPTANCE OF DATA BY SECRETARY.—
24 Nothing in this section, or the amendment made by
25 this section, shall be construed to prohibit the Sec-

1 retary from accepting data from animal testing con-
2 ducted—

3 (A) prior to the date specified in sub-
4 section (b); or

5 (B) on or after such date—

6 (i) in the case of a cosmetic product,
7 cosmetic formulation, or cosmetic ingre-
8 dient that is also a drug, with respect to
9 the approval under chapter V of the Fed-
10 eral Food, Drug, and Cosmetic Act (21
11 U.S.C. 351 et seq.) of the application sub-
12 mitted with respect to such product, for-
13 mulation, or ingredient; or

14 (ii) pursuant to requirements of a
15 Federal, State, or foreign regulatory au-
16 thority.

17 **SEC. 110. COUNTERFEIT COSMETICS.**

18 (a) COUNTERFEIT COSMETICS DEFINED.—Section
19 201(i) of the Federal Food, Drug, and Cosmetic Act (21
20 U.S.C. 321(i)) is amended—

21 (1) by striking “(i) The term” inserting “(i)(1)
22 The term”;

23 (2) by striking “(1) articles intended to be” and
24 inserting “(A) articles intended to be”;

1 (3) by striking “(2) articles intended for use”
2 and inserting “(B) articles intended for use”; and

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

4 “(2) The term ‘counterfeit cosmetic’ means a cos-
5 metic which, or the container or labeling of which, without
6 authorization—

7 “(A) bears the trademark, trade name, or other
8 identifying mark, imprint, or device, or any likeness
9 thereof, of a cosmetic manufacturer, processor, pack-
10 er, or distributor other than the person or persons
11 who in fact manufactured, processed, packed, or dis-
12 tributed such cosmetic; and

13 “(B) thereby falsely purports or is represented
14 to be the product of, or to have been packed or dis-
15 tributed by, such other cosmetic manufacturer, proc-
16 essor, packer, or distributor.”.

17 (b) PROHIBITED ACT.—Section 301(i) of the Federal
18 Food, Drug, and Cosmetic Act (21 U.S.C. 331(i)) is
19 amended—

20 (1) in subparagraph (2)—

21 (A) by inserting “digital printer,” after
22 “stone,”;

23 (B) by inserting “cosmetic” after “drug
24 or”; and

1 (C) by inserting before the period at the
2 end the following: “or such cosmetic a counter-
3 feit cosmetic”; and

4 (2) in subparagraph (3)—

5 (A) by inserting “or a cosmetic to be a
6 counterfeit cosmetic” after “to be a counterfeit
7 drug”; and

8 (B) by inserting “or counterfeit cosmetic”
9 before the period at the end.

10 (c) PENALTIES.—Section 303(c)(5) of the Federal
11 Food, Drug, and Cosmetic Act (21 U.S.C. 333(c)(5)) is
12 amended—

13 (1) by inserting “digital printer” after “stone,”;

14 (2) by inserting “or a cosmetic being a counter-
15 feit cosmetic” after “drug being a counterfeit drug”;

16 and

17 (3) by inserting before the period at the end the
18 following: “or the cosmetic was a counterfeit cos-
19 metic”.

20 (d) SEIZURE.—Section 304(a)(2) of the Federal
21 Food, Drug, and Cosmetic Act (21 U.S.C. 334(a)(2)) is
22 amended—

23 (1) by striking “(B) Any container” and all
24 that follows through “(D) Any adulterated” and in-
25 serting “(B) Any cosmetic that is a counterfeit cos-

1 metic, (C) Any container of a counterfeit drug or
2 counterfeit cosmetic, (D) Any punch, die, plate,
3 stone, labeling, container, digital printer, or other
4 thing used or designed for use in making a counter-
5 feit drug or drugs or a counterfeit cosmetic or cos-
6 metics, (E) Any adulterated”; and

7 (2) by striking “(E)” and inserting “(F)” be-
8 fore “Any adulterated or misbranded tobacco prod-
9 uct”.

10 (e) EXAMINATIONS AND INVESTIGATIONS.—Section
11 702(e) of the Federal Food, Drug, and Cosmetic Act (21
12 U.S.C. 372(e)) is amended—

13 (1) in the matter preceding paragraph (1), by
14 inserting “or counterfeit cosmetics” after “counter-
15 feit drugs”;

16 (2) in paragraph (4), by inserting “or cos-
17 metics” after “such drugs”; and

18 (3) in paragraph (5)—

19 (A) by striking “drugs or containers” and
20 inserting “drugs, cosmetics, or containers”; and

21 (B) by inserting “digital printers,” after
22 “labeling,”.

1 **SEC. 111. 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 product or cosmetic ingredient imported by the im-
13 porter (or agent thereof)—

14 “(A) has been manufactured according to
15 the cosmetic product good manufacturing prac-
16 tices established 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 product or cosmetic ingredient—

22 “(A) the United States owner or consignee
23 of the cosmetic product or cosmetic ingredient
24 at the time of entry of such cosmetic product
25 or cosmetic ingredient into the United States;
26 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 product or cosmetic ingredient at
6 the time of entry of such article into the United
7 States.

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

13 “(c) REGULATIONS.—

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

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

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

1 cosmetic product or cosmetic ingredient in com-
2 pliance 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 cosmetic products and cos-
10 metic ingredients imported into the United
11 States are as safe as cosmetic products and cos-
12 metic ingredients produced and sold within the
13 United States.

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

21 “(4) ACTIVITIES.—Verification activities under
22 a foreign supplier verification program under this
23 section may include monitoring records for ship-
24 ments, lot-by-lot certification of compliance, annual
25 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 cosmetic
14 products or cosmetic ingredients imported in small quan-
15 tities for research and evaluation purposes or for personal
16 consumption, provided that such cosmetic products or cos-
17 metic ingredients are not intended for retail sale and are
18 not sold or distributed 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 Cosmetic Act (21 U.S.C. 331), as
3 amended by section 113, is further amended by adding
4 at the end the following:

5 “(ggg) The importation or offering for importation
6 of a cosmetic product or cosmetic ingredient if the im-
7 porter (as defined in section 810) does not have in place
8 a foreign supplier verification program in compliance with
9 such section 810.”.

10 (c) IMPORTS.—Section 801(a) of the Federal Food,
11 Drug, and Cosmetic Act (21 U.S.C. 381(a)) is amended
12 by striking “or the importer (as defined in section 805)
13 is in violation of such section 805” and inserting “, or
14 being imported or offered for import into the United
15 States by an importer (as defined in section 805 or 810,
16 as applicable) that is in violation of section 805 or 810,
17 respectively”.

18 (d) EFFECTIVE DATE.—The amendments made by
19 this section shall take effect 2 years after the date of en-
20 actment of this Act.

21 **SEC. 112. APPLICABILITY WITH RESPECT TO CERTAIN COS-**
22 **METICS.**

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

1 **“SEC. 617. APPLICABILITY WITH RESPECT TO CERTAIN**
2 **COSMETICS.**

3 “In the case of a cosmetic product or a facility that
4 is subject to the requirements under this chapter and
5 chapter V, if any requirement under chapter V with re-
6 spect to such cosmetic or facility is substantially similar
7 to a requirement under this chapter, the cosmetic product
8 or facility shall be deemed to be in compliance with the
9 applicable requirement under this chapter if such product
10 or facility is in compliance with such substantially similar
11 requirement under chapter V, provided that the product
12 or facility has not obtained a waiver from the requirement
13 under chapter V.”.

14 **SEC. 113. SAVING CLAUSE.**

15 Chapter VI of the Federal Food, Drug, and Cosmetic
16 Act (21 U.S.C. 361 et seq.), as amended by section 112,
17 is further amended by adding the following:

18 **“SEC. 616. SAVINGS CLAUSE.**

19 “Nothing in the amendments to this Act made by the
20 Cosmetic Safety Enhancement Act of 2019, nor any
21 standard, rule, requirement, regulation, adverse event re-
22 port, safety assessment, safety determination, scientific
23 assessment, or order issued or implemented pursuant to
24 such amendments, shall be construed to modify or other-
25 wise affect, preempt, or displace any cause of action or
26 State or Federal law creating a remedy for civil relief or

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

3 **SEC. 114. ENFORCEMENT.**

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

7 (1) in paragraph (e)—

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

10 (B) by striking “519, 564,” and inserting
11 “519, 564, 609, 611,”;

12 (2) in paragraph (j) by inserting “607, 608,
13 610, 611” before “704”;

14 (3) in paragraph (ii)—

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

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

19 (4) in paragraph (xx), by inserting “or 613”
20 after “423”; and

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

22 “(fff) The failure to register in accordance with sec-
23 tion 605, the failure to submit a cosmetic ingredient state-
24 ment under section 606, the failure to provide information
25 required by section 605 or 606, or the failure to update

1 the information required by section 605 or 606, as re-
2 quired.”.

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

7 “(g) If it contains, after the date prescribed under
8 section 608(d)(3), an ingredient that the Secretary has de-
9 termined under section 608(d)(4) to be not safe, or not
10 safe under the conditions of use recommended or sug-
11 gested in the label based on an order issued by the Sec-
12 retary under section 608(d)(4).

13 “(h) If it is a cosmetic product for which any require-
14 ment of section 609 is not met.”.

15 (c) MISBRANDING.—Section 602 of the Federal
16 Food, Drug, and Cosmetic Act (21 U.S.C. 362), as
17 amended by section 106, is further amended—

18 (1) in paragraph (b)—

19 (A) by striking “and (2)” and inserting
20 “(2)”; and

21 (B) by inserting “; and (3) a domestic ad-
22 dress or a domestic telephone number, or elec-
23 tronic contact information, through which the
24 responsible person may receive a report of an

1 adverse event associated with the use of such
2 cosmetic product” after “numerical count”; and
3 (2) by adding at the end the following:

4 “(h) If it is a cosmetic product and it has been manu-
5 factured, processed, packed, or held in any factory, ware-
6 house, or establishment and the responsible person delays,
7 denies, or limits an inspection, or refuses to permit entry
8 or inspection.

9 “(i) If a fragrance ingredient described in section 615
10 is not disclosed to consumers through a method identified
11 by the Food and Drug Administration in the guidance doc-
12 ument issued under such section.

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

15 (d) GUIDANCE.—Not later than 1 year after the date
16 of enactment of this Act, the Secretary of Health and
17 Human Services, acting through the Commissioner of
18 Food and Drugs, shall issue guidance that defines the cir-
19 cumstances that would constitute delaying, denying, or
20 limiting inspection, or refusing to permit entry or inspec-
21 tion, for purposes of section 602(g) of the Federal Food,
22 Drug, and Cosmetic Act, as added by subsection (c)(2).

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

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

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

6 (f) FACILITY INSPECTION.—Section 704(a)(1) of the
7 Federal Food, Drug, and Cosmetic Act (21 U.S.C.
8 374(a)(1)) is amended by inserting after the third sen-
9 tence the following: “In the case of any person who manu-
10 factures, processes, packs, holds, distributes, or imports
11 a cosmetic product, or distributes a cosmetic product and
12 affixes its name on the cosmetic label, the inspection shall
13 extend to all records and other information described in
14 section 612 (regarding inspection of cosmetic records),
15 subject to the limitations under of such section.”.

16 **TITLE II—FEES RELATED TO** 17 **COSMETIC PRODUCTS**

18 **SEC. 201. FINDINGS.**

19 The Congress finds that the fees authorized by the
20 amendment made by section 202 of this Act will be dedi-
21 cated to cosmetic safety activities, as defined in section
22 744L of the Federal Food, Drug, and Cosmetic Act, as
23 added by such section 202. Such fees should supplement,
24 not supplant, funding dedicated to cosmetic safety activi-
25 ties of the Food and Drug Administration. Future fees

1 to be collected by the Secretary of Health and Human
2 Services should be dedicated to cosmetic safety activities
3 as set forth in the goals identified for purposes of part
4 10 of subchapter C of chapter VII of the Federal Food,
5 Drug, and Cosmetic Act, in the letters from the Secretary
6 of Health and Human Services to the Chairman of the
7 Committee on Health, Education, Labor, and Pensions of
8 the Senate and the Chairman of the Committee on Energy
9 and Commerce of the House of Representatives, as set
10 forth in the Congressional Record.

11 **SEC. 202. AUTHORITY TO ASSESS AND USE COSMETIC**
12 **PRODUCT FEES.**

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

16 **“PART 10—FEES RELATING TO COSMETIC**
17 **PRODUCTS**

18 **“SEC. 744L. DEFINITIONS.**

19 “For the purposes of this part:

20 “(1) **ADJUSTMENT FACTOR.**—The term ‘adjust-
21 ment factor’ applicable to a fiscal year means the
22 Consumer Price Index for all urban consumers (all
23 items; United States city average) for October of the
24 preceding fiscal year divided by such index for Octo-
25 ber 2018.

1 “(2) CONTRACT MANUFACTURER.—The term
2 ‘contract manufacturer’ means a cosmetic manufac-
3 turer where neither the owner, operator, or agent in
4 charge of such entity nor any affiliate of such owner,
5 operator, or agent in charge sells the cosmetic ingre-
6 dient, cosmetic formulation, or cosmetic product un-
7 less there is a specific contractual agreement in
8 place.

9 “(3) COSMETIC PRODUCT.—The term ‘cosmetic
10 product’ means a finished cosmetic comprised of a
11 specified set of ingredients, which may come in a
12 range of possible amounts for each ingredient and
13 which may include a variety of fragrances and col-
14 ors, and in some specific cosmetic applications, fla-
15 vors. Such term shall include tattoo ink whether or
16 not labeled as a finished cosmetic.

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

19 “(A) means activities of the Secretary re-
20 lated to compliance by responsible parties re-
21 quired to register under section 605 with re-
22 spect to cosmetics, including administrative ac-
23 tivities, such as—

1 “(i) information technology acquisi-
2 tion, management, maintenance, and sup-
3 port;

4 “(ii) the acquisition, administration,
5 and maintenance of the cosmetic registra-
6 tion system and the cosmetic ingredient
7 statement system under section 606;

8 “(iii) fee assessment and collection
9 under this part; and

10 “(iv) the acquisition, leasing, mainte-
11 nance, renovation and repair of facilities,
12 fixtures, furniture, scientific equipment,
13 and other necessary materials and supplies
14 for purposes of clauses (i) through (iii);

15 “(B) includes activities of the Secretary re-
16 lated to implementation of section 608, regard-
17 ing the review of cosmetic ingredients and non-
18 functional constituents;

19 “(C) includes activities of the Secretary re-
20 lated to implementation of section 606;

21 “(D) includes activities of the Secretary re-
22 lated to implementation and enforcement, such
23 as the establishment of good manufacturing
24 practices, the review of adverse event reports,

1 inspection planning and inspections, and use of
2 enforcement tools; and

3 “(E) includes activities of the Secretary re-
4 lated to meetings with regulated industry re-
5 garding determinations under section 608.

6 “(5) GROSS ANNUAL SALES.—The term ‘gross
7 annual sales’ means the average United States gross
8 annual sales for the previous 3 fiscal years of cos-
9 metic products for a responsible party as described
10 in paragraph (2), including the sales of cosmetic
11 products of all of its affiliates, as reported in the
12 registration under section 605.

13 “(6) LARGE MANUFACTURER.—The term ‘large
14 manufacturer’ means any entity that manufactures
15 cosmetic products or cosmetic formulations for sale
16 or distribution in the United States and has gross
17 annual sales of over \$500,000,000.

18 “(7) MID-SIZE MANUFACTURER .—The term
19 ‘mid-size manufacturer’ means any entity that man-
20 ufactures cosmetic products or cosmetic formulations
21 for sale or distribution in the United States and has
22 gross annual sales between \$499,000,000 and
23 \$31,000,000.

24 “(8) SMALL MANUFACTURER.—The term ‘small
25 manufacturer’ means any entity that manufactures

1 cosmetic products or cosmetic formulations for sale
2 or distribution in the United States and has gross
3 annual sales between \$30,000,000 and \$1,000,000.

4 “(9) RESPONSIBLE PARTY.—The term ‘respon-
5 sible party’ means the owner, operator, agent in
6 charge, or affiliate that owns the brand under which
7 a cosmetic product is sold.

8 **“SEC. 744M. REGISTRATION FEE.**

9 “(a) ASSESSMENT AND COLLECTION.—

10 “(1) IN GENERAL.—Beginning in fiscal year
11 2020, the Secretary shall in accordance with this
12 section assess and collect an annual fee from every
13 responsible party that manufactures or distributes
14 cosmetic products or cosmetic formulations in the
15 United States.

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

18 “(A) for fiscal year 2020, with respect to
19 responsible parties as described in paragraph
20 (1) for such first program year, on the date
21 that is 180 days after the identification in sub-
22 section (b); and

23 “(B) for fiscal year 2021 and each subse-
24 quent fiscal year, on the later of—

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

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

8 “(b) ONE-TIME IDENTIFICATION OF RESPONSIBLE
9 PARTIES FOR PURPOSES OF APPORTIONING FEES.—

10 “(1) REQUIRED IDENTIFICATION OF RESPON-
11 SIBLE PARTIES.—Not later than 120 days after en-
12 actment of the Cosmetic Safety Enhancement Act of
13 2019, each responsible party that markets or sells a
14 cosmetic product as defined in section 744L(4) shall
15 submit to the Secretary the information required
16 under this subsection.

17 “(2) INFORMATION REQUIRED TO BE SUB-
18 MITTED.—At a minimum, the submission required
19 by paragraph (1) shall include for each such respon-
20 sible party—

21 “(A) the gross annual sales of cosmetic
22 products or formulations as defined in section
23 744L for the previous 3 fiscal years and as will
24 be reported in the first registration under sec-
25 tion 605, and an assessment of whether such

1 responsible party qualifies as a small, mid-size,
2 or large manufacturer for the purposes of sub-
3 section (c)(3)(A);

4 “(B) identification of facilities where such
5 responsible party’s cosmetic products or cos-
6 metic formulations are manufactured, which
7 cosmetic products or cosmetic formulations are
8 manufactured there, and any other products
9 regulated under this Act that the facility manu-
10 factures;

11 “(C) the location of all such facilities iden-
12 tified in subparagraph (B); and

13 “(D) whether the facility is owned and op-
14 erated by a contract manufacturer.

15 “(3) NOTICE.—The Secretary may, by notice
16 published in the Federal Register, specify the means
17 and format for submission of the information under
18 paragraph (2) and may specify, as necessary for
19 purposes of this section, any additional information
20 relevant to setting the annual fee under this section
21 to be submitted.

22 “(c) FEE SETTING AND AMOUNTS.—

23 “(1) IN GENERAL.—Subject to subsection (d),
24 the Secretary shall establish the fees to be collected
25 under this section for each fiscal year beginning in

1 fiscal year 2020, based on the methodology de-
2 scribed in paragraph (3)(A), and shall publish such
3 fees in each fiscal year after fiscal year 2020 in a
4 Federal Register notice not later than 60 days be-
5 fore the beginning of each such fiscal year. For fis-
6 cal year 2020, the Food and Drug Administration
7 shall publish the fees 150 days after enactment of
8 the Cosmetic Safety Enhancement Act of 2019.

9 “(2) FEE EXEMPTION.—Any facility required to
10 register under section 605 whose average gross an-
11 nual sales of cosmetic products in the 3 fiscal years
12 immediately preceding the fiscal year for which the
13 annual fee will be paid was not more than
14 \$1,000,000, shall be exempt from registration fees
15 under this section for that fiscal year.

16 “(3) ANNUAL FEE SETTING.—

17 “(A) FEE SETTING.—For fiscal years
18 2020 to 2027 as described in subparagraph
19 (B), the amount of the registration fee under
20 subsection (a) shall be as follows:

21 “(i) Seventy percent shall be derived
22 from fees from large manufacturers.

23 “(ii) Twenty percent shall be derived
24 from fees from mid-size manufacturers.

1 “(iii) Ten percent shall be derived
2 from fees from small manufacturers.

3 “(B) TOTAL REVENUE.—The Food and
4 Drug Administration shall apportion the fees in
5 each fiscal year in accordance with subpara-
6 graph (A), in order to generate a total esti-
7 mated revenue of—

8 “(i) \$10,000,000 for fiscal year 2020;

9 “(ii) \$20,000,000 for fiscal year 2021;

10 “(iii) \$35,000,000 for fiscal year
11 2022; and

12 “(iv) \$46,000,000 for each of fiscal
13 years 2023 through 2027.

14 “(d) ADJUSTMENTS.—

15 “(1) INFLATION ADJUSTMENTS.—

16 “(A) ADJUSTMENT TO TOTAL REVENUE
17 AMOUNTS.—For fiscal year 2020 and each sub-
18 sequent fiscal year, the Secretary shall adjust
19 the total revenue amount specified in subsection
20 (c)(3) for such fiscal year by multiplying such
21 amount by the applicable inflation adjustment
22 under subparagraph (B) for such year.

23 “(B) APPLICABLE INFLATION ADJUST-
24 MENT.—The applicable inflation adjustment for

1 fiscal year 2020 and each subsequent fiscal
2 year is the product of—

3 “(i) the base inflation adjustment
4 under subparagraph (C) for such fiscal
5 year; and

6 “(ii) the product of the base inflation
7 adjustment under subparagraph (C) for
8 each of the fiscal years preceding such fis-
9 cal year, beginning with fiscal year 2020.

10 “(C) BASE INFLATION ADJUSTMENT.—

11 “(i) IN GENERAL.—Subject to further
12 adjustment under clause (ii), the base in-
13 flation adjustment for a fiscal year is the
14 sum of one plus—

15 “(I) the average annual percent
16 change in the cost, per full-time equiv-
17 alent position of the Food and Drug
18 Administration, of all personnel com-
19 pensation and benefits paid with re-
20 spect to such positions for the first 3
21 fiscal years of the preceding 4 fiscal
22 years, multiplied by 0.60; and

23 “(II) the average annual percent
24 change that occurred in the Consumer
25 Price Index for urban consumers

1 (Washington-Arlington-Alexandria;
2 Not Seasonally Adjusted; All items;
3 Annual Index) for the first 3 fiscal
4 years of the preceding 4 years of
5 available data multiplied by 0.40.

6 “(ii) LIMITATIONS.—For purposes of
7 subparagraph (B), if the base inflation ad-
8 justment for a fiscal year under clause
9 (i)—

10 “(I) is less than 1, such adjust-
11 ment shall be considered to be equal
12 to 1; or

13 “(II) is greater than 1, such ad-
14 justment shall be considered to be
15 equal to 1.

16 “(2) FINAL YEAR ADJUSTMENT.—For fiscal
17 year 2027, the Secretary may, in addition to adjust-
18 ments under paragraph (1), further increase the fee
19 revenues and fees established in subsection (c) if
20 such an adjustment is necessary to provide for not
21 more than 3 months of operating reserves of carry-
22 over fees for cosmetic safety activities for the first
23 3 months of fiscal year 2028. If such an adjustment
24 is necessary, the rationale for the increase, shall be
25 contained in the annual Federal Register notice es-

1 tablishing fees, in subsection (c)(1), for fiscal year
2 2027. If the Food and Drug Administration has car-
3 rryover balances for such activities in excess of 3
4 months of such operating reserves, the adjustment
5 under this paragraph shall not be made.

6 “(e) LIMITATIONS.—

7 “(1) IN GENERAL.—With respect to the amount
8 that, under the salaries and expenses account of the
9 Food and Drug Administration, is appropriated for
10 a fiscal year for the cosmetics program in the Center
11 for Food Safety and Applied Nutrition and related
12 field activities, fees may not be assessed under sub-
13 section (a) for the fiscal year unless the amount so
14 appropriated for the fiscal year (excluding the
15 amount of fees appropriated for the fiscal year), is
16 equal to or greater than that assessed for fiscal year
17 2019, multiplied by the adjustment factor applicable
18 to the fiscal year involved. If the amount so appro-
19 priated prevents the Secretary from assessing fees
20 under subsection (a), the Secretary is not required
21 to carry out any activities described in section 608
22 during that fiscal year.

23 “(2) AUTHORITY.—If the Secretary does not
24 assess fees under subsection (a) during any portion
25 of a fiscal year because of paragraph (1) and if at

1 a later date in such fiscal year the Secretary may as-
2 sess such fees, the Secretary may assess and collect
3 such fees, without any modification in the rate, for
4 registration under section 605 at any time in such
5 fiscal year.

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

7 “(1) IN GENERAL.—Fees authorized under sub-
8 section (a) shall be collected and available for obliga-
9 tion only to the extent and in the amount provided
10 in advance in appropriations Acts. Such fees are au-
11 thorized to remain available until expended. Such
12 sums as may be necessary may be transferred from
13 the Food and Drug Administration salaries and ex-
14 penses appropriation account without fiscal year lim-
15 itation to such appropriation account for salaries
16 and expenses with such fiscal year limitation. The
17 sums transferred shall be available solely for cos-
18 metic safety activities.

19 “(2) COLLECTIONS AND APPROPRIATIONS
20 ACTS.—The fees authorized by this section:

21 “(A) IN GENERAL.—Subject to subpara-
22 graphs (C) and (D), the fees authorized by this
23 section shall be collected and available in each
24 fiscal year in an amount not to exceed the
25 amount specified in appropriation Acts, or oth-

1 otherwise made available for obligation for such
2 fiscal year.

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

7 “(C) FEE COLLECTIONS DURING FIRST
8 PROGRAM YEAR.—Until the date of enactment
9 of an Act making appropriations through Sep-
10 tember 30, 2020, for the salaries and expenses
11 account of the Food and Drug Administration,
12 fees authorized by this section for fiscal year
13 2020 may be collected and shall be credited to
14 such account to remain available until ex-
15 pended. Fees collected under this subparagraph
16 shall be considered discretionary for purposes of
17 the Balanced Budget and Emergency Deficit
18 Control Act of 1985.

19 “(D) STARTUP COSTS.—Until one year
20 after the Secretary begins collecting user fees
21 under subsection (a), any amounts available for
22 the Center for Food Safety and Applied Nutri-
23 tion and related field activities (excluding user
24 fees) shall be available and allocated as needed
25 to pay the costs of any cosmetic safety activities

1 not authorized before enactment of the Cos-
2 metic Safety Enhancement Act of 2019.

3 “(E) REIMBURSEMENT OF STARTUP
4 AMOUNTS.—

5 “(i) IN GENERAL.—Any amounts allo-
6 cated for the startup period pursuant to
7 subparagraph (D) shall be reimbursed
8 through any appropriated fees collected
9 under subsection (a), in such manner as
10 the Secretary determines appropriate to
11 ensure that such allocation results in no
12 net change in the total amount of funds
13 otherwise available, for a period not to ex-
14 ceed two years after the Secretary begins
15 collecting user fees under subsection (a),
16 for the Center for Food Safety and Applied
17 Nutrition and related field activities (other
18 than cosmetic safety activities funded
19 through such allocation) for such period.

20 “(ii) TREATMENT OF REIMBURSED
21 AMOUNTS.—Amounts reimbursed under
22 clause (i) shall be available for the pro-
23 grams and activities for which funds allo-
24 cated for the startup period were available,
25 prior to such allocation, until 1 year after

1 the Secretary begins collecting user fees
2 under subsection (a), notwithstanding any
3 otherwise applicable limits on amounts for
4 such programs or activities for a fiscal
5 year.

6 “(3) AUTHORIZATION OF APPROPRIATIONS.—

7 There are authorized to be appropriated for fees
8 under this section the following:

9 “(A) \$10,000,000 for fiscal year 2020;

10 “(B) \$20,000,000 for fiscal year 2021;

11 “(C) \$35,000,000 for fiscal year 2022; and

12 “(D) \$46,000,000 for each of fiscal years

13 2023 through 2027.

14 “(g) EFFECT OF FAILURE TO PAY FEES.—The Sec-

15 retary shall not consider a registration by a responsible

16 party submitted under section 605 to be complete until

17 such fee under subsection (a) is paid. Until the fee is paid,

18 the registration is incomplete and the responsible party

19 is deemed to have failed to register in accordance with sec-

20 tion 605.

21 “(h) FALSE STATEMENTS.—Any statement or rep-

22 resentation made to the Food and Drug Administration

23 shall be subject to section 1001 of title 18, United States

24 Code.

1 “(i) COLLECTION OF UNPAID FEES.—In any case
2 where the Secretary does not receive payment of a fee as-
3 sessed under subsection (a), such fee shall be treated as
4 a claim of the United States Government subject to sub-
5 chapter II of chapter 37 of title 31, United States Code.

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

13 “(k) RECORDS.—Each responsible party that is re-
14 quired to register under section 605 shall retain all records
15 necessary to demonstrate gross annual sales for at least
16 2 fiscal years after such information is reported in its reg-
17 istration. Such records shall be made available to the Food
18 and Drug Administration for review and duplication upon
19 request of the Food and Drug Administration.

20 “(l) LIMITATION.—This part does not authorize the
21 assessment or collection of a fee for registration under sec-
22 tion 605 occurring after fiscal year 2027.”.

1 **SEC. 203. DIRECT HIRING AUTHORITY TO SUPPORT ACTIVI-**
2 **TIES RELATED TO COSMETICS.**

3 Part 10 of subchapter C of chapter VII, as added
4 by section 202, is amended by inserting after section
5 744M the following:

6 **“SEC. 744N. DIRECT HIRING AUTHORITY TO SUPPORT AC-**
7 **TIVITIES RELATED TO COSMETICS.**

8 “(a) IN GENERAL.—The Secretary shall have direct
9 hiring authority with respect to the appointment of em-
10 ployees into the competitive service or the excepted service
11 to administer the amendments made by title I of the Cos-
12 metic Safety Enhancement Act of 2019.

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

16 **“SEC. 744O. REPORTING REQUIREMENTS; REAUTHORIZA-**
17 **TION.**

18 “(a) PERFORMANCE REPORT.—Beginning with fiscal
19 year 2021, and not later than 120 calendar days after the
20 end of each fiscal year thereafter for which fees are col-
21 lected under this part, the Secretary shall prepare and
22 submit to the Committee on Energy and Commerce of the
23 House of Representatives and the Committee on Health,
24 Education, Labor, and Pensions of the Senate a report
25 concerning the progress of the Food and Drug Adminis-
26 tration on cosmetic safety activities, including implemen-

1 tation and enforcement activities as described in the Cos-
2 metic Safety Enhancement Act of 2019 during such fiscal
3 year and the future plans of the Food and Drug Adminis-
4 tration for such activities.

5 “(b) FISCAL REPORT.—Not later than 120 calendar
6 days after the end of fiscal year 2021 and each subsequent
7 fiscal year for which fees are collected under this part,
8 the Secretary shall prepare and submit to the Committee
9 on Energy and Commerce of the House of Representatives
10 and the Committee on Health, Education, Labor, and
11 Pensions of the Senate a report on the implementation
12 of the authority for such fees during such fiscal year and
13 the use, by the Food and Drug Administration, of the fees
14 collected for such fiscal year.

15 “(c) PUBLIC AVAILABILITY.—The Secretary shall
16 make the reports required under subsections (a) and (b)
17 available to the public on the internet website of the Food
18 and Drug Administration.

19 “(d) REAUTHORIZATION.—

20 “(1) CONSULTATION.—In developing rec-
21 ommendations to present to the Congress with re-
22 spect to performance goals developed by the Food
23 and Drug Administration, and plans for meeting the
24 goals, for cosmetic safety activities for the first 5 fis-
25 cal years after fiscal year 2027, and for the reau-

1 thorization of this part for such fiscal years, the Sec-
2 retary shall consult with—

3 “(A) the Committee on Energy and Com-
4 merce of the House of Representatives;

5 “(B) the Committee on Health, Education,
6 Labor, and Pensions of the Senate;

7 “(C) scientific and academic experts;

8 “(D) health care professionals;

9 “(E) representatives of public health and
10 consumer advocacy groups; and

11 “(F) the regulated industry.

12 “(2) PUBLIC REVIEW OF RECOMMENDA-
13 TIONS.—After negotiations with the regulated indus-
14 try, the Secretary shall—

15 “(A) present the recommendations devel-
16 oped under paragraph (1) to the congressional
17 committees specified in such paragraph;

18 “(B) publish such recommendations in the
19 Federal Register;

20 “(C) provide for a period of 30 calendar
21 days for the public to provide written comments
22 on such recommendations;

23 “(D) hold a meeting at which the public
24 may present its views on such recommenda-
25 tions; and

1 “(E) after consideration of such public
2 views and comments, revise such recommenda-
3 tions as necessary.

4 “(3) TRANSMITTAL OF RECOMMENDATIONS.—
5 Not later than January 15, 2026, the Secretary
6 shall transmit to the Congress the revised rec-
7 ommendations under paragraph (2), a summary of
8 the views and comments received under such para-
9 graph, and any changes made to the recommenda-
10 tions in response to such views and comments.”.

11 **SEC. 204. SUNSET DATES.**

12 (a) AUTHORIZATION.—Sections 744L and 744M of
13 the Federal Food, Drug, and Cosmetic Act, as added by
14 section 202, shall cease to be effective October 1, 2027.

15 (b) REPORTING REQUIREMENTS.—Section 744O of
16 the Federal Food, Drug, and Cosmetic Act, as added by
17 section 203, shall cease to be effective January 31, 2028.