

**AMENDMENT IN THE NATURE OF A SUBSTITUTE
TO H.R. 5279
OFFERED BY MR. PALLONE OF NEW JERSEY**

Strike all after the enacting clause and insert the following:

1 SECTION 1. SHORT TITLE; TABLE OF CONTENTS.

2 (a) SHORT TITLE.—This Act may be cited as the
3 “Cosmetic Safety Enhancement Act of 2020”.

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

Sec. 1. Short title; table of contents.

TITLE I—COSMETIC SAFETY

Sec. 101. Registration of cosmetics facilities and cosmetic ingredient statements.

Sec. 102. Review of ingredients and nonfunctional constituents; safety of finished products.

Sec. 103. Good manufacturing practices for cosmetics.

Sec. 104. Adverse events.

Sec. 105. Records inspection; mandatory recall authority.

Sec. 106. Labeling and internet sales.

Sec. 107. Fragrance allergen disclosure.

Sec. 108. Consumer information.

Sec. 109. Small businesses.

Sec. 110. Animal testing restrictions.

Sec. 111. Counterfeit cosmetics.

Sec. 112. Foreign supplier verification and good importer practices.

Sec. 113. Applicability with respect to certain cosmetics.

Sec. 114. Saving clause.

Sec. 115. Enforcement.

TITLE II—FEES RELATED TO COSMETIC PRODUCTS

Sec. 201. Findings.

Sec. 202. Authority to assess and use cosmetic product fees.

Sec. 203. Direct hiring authority to support activities related to cosmetics.

Sec. 204. Sunset dates.

1 **TITLE I—COSMETIC SAFETY**

2 **SEC. 101. REGISTRATION OF COSMETICS FACILITIES AND**
3 **COSMETIC INGREDIENT STATEMENTS.**

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

7 **“SEC. 604. DEFINITIONS.**

8 “In this chapter:

9 “(1) ANIMAL TEST.—The term ‘animal test’
10 means the internal or external application or expo-
11 sure of a cosmetic product, cosmetic formulation, or
12 cosmetic ingredient to the skin, eyes, or other body
13 part of a live non-human vertebrate for the purpose
14 of evaluating the safety of a cosmetic product, cos-
15 metic formulation, or cosmetic ingredient.

16 “(2) CATEGORY OF INGREDIENTS OR NONFUNC-
17 TIONAL CONSTITUENTS.—The term ‘category of in-
18 gredients or nonfunctional constituents’ means a
19 group of ingredients or nonfunctional constituents,
20 the members of which are similar in molecular struc-
21 ture, in physical, chemical, or biological properties,
22 in use, or in mode of entrance into the human body
23 or the members of which are in some other way suit-
24 able for classification as such for purposes of this
25 chapter.

1 “(3) 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 “(4) 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 “(5) 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 cosmetic product or cosmetic formulation.

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

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

3 “(7) 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, beauty stores, retail
12 counters, and salons that do not otherwise man-
13 ufacture, process, or package cosmetic products
14 or cosmetic formulations at that location, in-
15 cluding those that offer customized or personal-
16 ized cosmetic products or cosmetic formulations
17 tailored to individual consumers for sale solely
18 in-person;

19 “(B) cosmetic product retailers, including
20 individual sales representatives, direct sellers
21 (as defined in section 3508 of the Internal Rev-
22 enue Code of 1986), retail distribution facilities,
23 retail franchises, retail warehouses, and phar-
24 macies, that do not otherwise manufacture,

1 process, or package cosmetic products or cos-
2 metic formulations at that location;

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

7 “(D) hospitals, physicians’ offices, and
8 health care clinics;

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

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

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

19 “(8) FOREIGN FACILITY.—The term ‘foreign fa-
20 cility’ means a facility that manufactures, processes,
21 packs, or holds, cosmetic products or cosmetic for-
22 mulations that are exported to the United States
23 without further processing or packaging inside the
24 United States. A cosmetic product or cosmetic for-
25 mulation is not considered to have undergone fur-

1 ther processing or packaging for purposes of this
2 definition solely on the basis that labeling was added
3 or that any similar activity of a de minimis nature
4 was carried out with respect to the cosmetic product
5 or cosmetic formulation.

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

13 “(10) PROFESSIONAL.—With respect to a cos-
14 metic product, the term ‘professional’ means—

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

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

22 “(11) PROFESSIONAL USE.—With respect to a
23 cosmetic product, the term ‘professional use’ means
24 a preparation of a cosmetic formulation intended
25 only for use by professionals in settings such as cos-

1 metology, nail care, barbering, esthetics, health care,
2 and other professions as determined by the Sec-
3 retary through regulation.

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

10 “(13) SOAP.—The term ‘soap’ means articles—

11 “(A) in which—

12 “(i) the bulk of the nonvolatile matter
13 in the product consists of an alkali salt of
14 fatty acids; and

15 “(ii) the detergent properties of the
16 article are due to the alkali-fatty acid com-
17 pounds; and

18 “(B) that are labeled, marketed, sold, and
19 represented only for use as soap.

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

21 “(a) REGISTRATION FOR MANUFACTURING AND
22 PROCESSING FACILITIES.—

23 “(1) IN GENERAL.—The owner, operator, or
24 agent in charge of (or an affiliate thereof) a facility
25 engaged in manufacturing, or processing, of a cos-

1 metic product or a cosmetic formulation distributed
2 in the United States shall register with the Sec-
3 retary.

4 “(2) ELECTRONIC REGISTRATION SYSTEM.—

5 “(A) REQUIRED MAINTENANCE.—The Sec-
6 retary shall—

7 “(i) maintain an electronic registra-
8 tion system for purposes of this section;
9 and

10 “(ii) not later than one year after the
11 date of enactment of the Cosmetic Safety
12 Enhancement Act of 2020, announce that
13 such system is operational.

14 “(B) TRANSFER FROM VOLUNTARY REG-
15 ISTRATION PROGRAM ALLOWED.—The Sec-
16 retary may transfer registrations of facilities
17 engaged in an activity described in paragraph
18 (1) and registered under the Food and Drug
19 Administration Voluntary Cosmetic Registra-
20 tion Program to the electronic registration sys-
21 tem referred to in subparagraph (A).

22 “(3) INITIAL REGISTRATION OF EXISTING FA-
23 CILITIES.—Not later than the date that is 6 months
24 after the date of the announcement required by
25 paragraph (2)(B), each facility engaged in an activ-

1 ity described in paragraph (1) shall be registered
2 under such paragraph.

3 “(4) INITIAL REGISTRATION OF NEW FACILI-
4 TIES.—In the case of a facility that first engages in
5 or resumes engaging in an activity described in
6 paragraph (1) on or after the date that is 18 months
7 after the date of enactment of the Cosmetic Safety
8 Enhancement Act of 2020, such facility shall reg-
9 ister with the Secretary immediately upon engaging
10 or reengaging in such activity, as applicable.

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

16 “(A) its own cosmetic products or cosmetic
17 formulations; or

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

21 “(b) ANNUAL REGISTRATION RENEWAL.—A facility
22 that continues to engage in any activity that would require
23 registration under subsection (a) shall submit to the Sec-
24 retary an annual registration during the first quarter of

1 the fiscal year for which such renewed registration shall
2 be effective.

3 “(c) FEES.—

4 “(1) IN GENERAL.—If the average gross annual
5 sales of cosmetic products in the United States of all
6 of the facilities of the responsible person registered
7 under subsection (a)(1) for the previous 3-fiscal-year
8 period is greater than \$1,000,000, a registration
9 shall not be complete under this subsection until the
10 responsible person has paid any registration fee re-
11 quired under section 744M.

12 “(2) USER FEE TIER IDENTIFICATION.—A re-
13 sponsible person required to register under this sub-
14 section shall identify annually the applicable cos-
15 metic product user fee tier based on the average
16 gross annual sales of cosmetic products in the
17 United States of all facilities of the responsible per-
18 son registered under subsection (a)(1) for the pre-
19 vious 3-fiscal-year period.

20 “(d) 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) not later than 30 days after the date of
24 such change, unless otherwise specified by the Secretary.

25 “(e) FORMAT; CONTENTS.—

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

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

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

11 “(B) The identity of the facility, including
12 the unique facility identifier, if any, previously
13 assigned by the Secretary to the facility under
14 subsection (g).

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

17 “(D) The product category (as identified
18 under section 720.4(e) of title 21, Code of Fed-
19 eral Regulations (or any successor regulation)),
20 or other cosmetic categories as determined ap-
21 propriate by the Secretary (including by guid-
22 ance) of each cosmetic product or cosmetic for-
23 mulation manufactured or processed at the fa-
24 cility or on whose label the facility’s name and
25 address appear.

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

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

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

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

17 “(I) The name, street address, telephone
18 number, and electronic contact information for
19 each facility that packs or holds cosmetic prod-
20 ucts or cosmetic formulations distributed by the
21 owner, operator, or agent in charge of a facility
22 required to register under this section.

23 “(J) An assurance that the Secretary will
24 be permitted to inspect such facility at the
25 times and in the manner permitted by this Act.

1 “(K) A written assurance that each cos-
2 metic product or cosmetic formulation manufac-
3 tured or processed in a facility required to reg-
4 ister under this section has been substantiated
5 for safety prior to marketing or carries the
6 warning required under section 740.10 of title
7 21, Code of Federal Regulations (or any suc-
8 cessor regulations). The responsible person shall
9 maintain records documenting such substan-
10 tiation and the data or information on which
11 such substantiation is based until 5 years after
12 the cosmetic product or cosmetic formulation is
13 no longer marketed.

14 “(L) Additional information pertaining to
15 the facility or to the cosmetic products or cos-
16 metic formulations manufactured or processed
17 at the facility, or on whose label the facility’s
18 name and address appear, including all brand
19 names known to consumers, as the Secretary
20 may require by regulation.

21 “(3) ABBREVIATED REGISTRATION.—The Sec-
22 retary shall provide for an abbreviated registration
23 renewal process for any facility that has not had any
24 changes to the information submitted by the facility
25 for the preceding registration.

1 “(f) INCOMPLETE OR INACCURATE REGISTRATION.—

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

5 “(A) the Secretary has reasonable grounds
6 to believe that the registration was not properly
7 completed or updated in accordance with this
8 section;

9 “(B) a required fee under section 744M
10 has not been paid within 30 days; or

11 “(C) the registration otherwise contains
12 false, incomplete, or inaccurate information.

13 “(2) NOTIFICATION.—The Secretary shall, at
14 least 10 days before canceling a registration pursu-
15 ant to paragraph (1), provide written notice to the
16 facility of the intent of the Secretary to cancel such
17 registration that contains the Secretary’s basis for
18 the determination to so cancel the registration.

19 “(3) TIMELY UPDATE OR CORRECTION.—If, not
20 later than 7 days after receipt of a notice of intent
21 to cancel under paragraph (2), the facility corrects
22 the registration in accordance with the basis for the
23 cancellation, and the required fee under section
24 744M, if any, is paid, the Secretary shall not cancel
25 such registration.

1 “(g) UNIQUE IDENTIFIER.—At the time of the initial
2 registration of any cosmetic facility under this section, the
3 Secretary shall assign a unique identifier to the facility
4 and provide such identifier to such facility in writing.

5 “(h) REGISTRY OF FACILITIES.—

6 “(1) IN GENERAL.—The Secretary shall com-
7 pile, maintain, and update a registry of facilities
8 that are registered under this section, and shall re-
9 move from such registry the name of any facility
10 whose registration under this section is cancelled.
11 The registry shall be publicly available.

12 “(2) PUBLIC AVAILABILITY EXCEPTIONS.—In-
13 formation derived from the registry or registration
14 documents that discloses the residential address of
15 an owner, operator, or agent in charge of (or an af-
16 filiate thereof) a facility engaged in manufacturing
17 or processing a cosmetic product or formulation, or
18 a facility owned by such person, or that discloses
19 specific facilities where specific brands of cosmetic
20 products are manufactured or processed shall not be
21 subject to disclosure under section 552 of title 5,
22 United States Code.

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

24 “(a) IN GENERAL.—For each cosmetic product, the
25 responsible person shall submit to the Secretary a cos-

1 metic ingredient statement, at such time and in such man-
2 ner as described under this section. A cosmetic ingredient
3 statement shall not be considered to be complete under
4 this section until the responsible person pays any applica-
5 ble fee required under section 744M.

6 “(b) SUBMISSION OF A COSMETIC INGREDIENT
7 STATEMENT.—

8 “(1) EXISTING COSMETIC PRODUCTS.—

9 “(A) IN GENERAL.—In the case of a cos-
10 metic product or cosmetic formulation that is
11 marketed on the date of enactment of the Cos-
12 metic Safety Enhancement Act of 2020, the re-
13 sponsible person shall—

14 “(i) not later than the date that is 6
15 months after the date of the announcement
16 of an electronic registration system re-
17 quired by section 605, submit to the Sec-
18 retary a cosmetic ingredient statement in
19 accordance with this section; and

20 “(ii) beginning one year after the in-
21 redient statement is submitted under
22 clause (i) and each year thereafter, submit
23 to the Secretary a renewal of such state-
24 ment, consistent with the requirements in
25 subsection (e), during the first quarter of

1 the fiscal year for which such renewed
2 statement is applicable.

3 “(B) TRANSFER TO ELECTRONIC REG-
4 ISTRATION SYSTEM ALLOWED.—The Secretary
5 may transfer to the electronic registration sys-
6 tem required by section 605 a cosmetic ingre-
7 dient statement with respect to a cosmetic prod-
8 uct or cosmetic formulation—

9 “(i) described in subparagraph (A);
10 and

11 “(ii) registered under the Food and
12 Drug Administration Voluntary Cosmetic
13 Registration Program.

14 “(2) COSMETIC INGREDIENT STATEMENT FOR
15 NEW COSMETIC PRODUCTS.—

16 “(A) IN GENERAL.—Except as provided
17 under subparagraph (B), in the case of a cos-
18 metic product or cosmetic formulation that is
19 first marketed after the date of enactment of
20 the Cosmetic Safety Enhancement Act of 2020
21 or a cosmetic product or cosmetic formulation
22 that is reformulated (or reintroduced to the
23 market) after such date of enactment, the re-
24 sponsible person shall—

1 “(i) submit to the Secretary a cos-
2 metic ingredient statement prior to first
3 marketing the new cosmetic product, new
4 cosmetic formulation, or the reformulated
5 (or reintroduced) cosmetic product or re-
6 formulated (or reintroduced) cosmetic for-
7 mulation; and

8 “(ii) beginning one year after the in-
9 gredient statement is submitted under
10 clause (i), submit to the Secretary annually
11 thereafter a renewal of such statement
12 during the first quarter of the fiscal year
13 for which the cosmetic ingredient state-
14 ment is applicable, consistent with the re-
15 quirements in subsection (e).

16 “(B) SMALL BUSINESSES.—In the case of
17 a responsible person that is a small business as
18 determined by the Secretary, the Secretary
19 shall allow such responsible person to have an
20 additional time period, of a duration to be de-
21 termined by the Secretary, in which to submit
22 the first cosmetic ingredient statement under
23 subparagraph (A). Such responsible person
24 shall, consistent with the requirements in sub-
25 section (e), submit a cosmetic ingredient state-

1 ment annually thereafter during the first quar-
2 ter of the applicable fiscal year.

3 “(3) ABBREVIATED RENEWAL.—The Secretary
4 shall provide for an abbreviated process for the re-
5 newal of any cosmetic ingredient statement under
6 this subsection with respect to which there has been
7 no change since the responsible person submitted the
8 previous cosmetic ingredient statement.

9 “(c) FORMAT; CONTENTS.—

10 “(1) FORM.—For each cosmetic ingredient
11 statement submitted with respect to a cosmetic prod-
12 uct or cosmetic formulation under this section, such
13 statement shall be submitted using an electronic for-
14 mat, in a form specified by the Secretary.

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

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

20 “(i) the facility or facilities where the
21 cosmetic product or cosmetic formulation
22 is manufactured, processed, packed, or
23 held or, if the same cosmetic product or
24 cosmetic formulation is manufactured,
25 processed, packed, or held in more than

1 one facility, the unique facility identifier of
2 each facility where it is manufactured,
3 processed, packed, or held; and

4 “(ii) the facility whose name and ad-
5 dress appear on the label, unless the state-
6 ment is filed by a contract manufacturer.

7 “(B) The brand name and the full name
8 for the cosmetic product or cosmetic formula-
9 tion as it appears on the label.

10 “(C) The listing number, if any, previously
11 assigned by the Secretary under subsection (f)
12 to the cosmetic product or cosmetic formula-
13 tion.

14 “(D) The applicable cosmetic category for
15 the cosmetic product or cosmetic formulation.

16 “(E) A list of ingredients in the cosmetic
17 product or cosmetic formulation including—

18 “(i) the name adopted in regulations
19 promulgated by the Secretary, if any, or by
20 the common or usual name of the ingre-
21 dient;

22 “(ii) information consistent with the
23 regulations promulgated by the Food and
24 Drug Administration related to cosmetic
25 labeling requirements;

1 “(iii) other appropriate interchange-
2 able ingredients as the Secretary may
3 specify in regulations or guidance that may
4 be included in the product; and

5 “(iv) in the case of an ingredient
6 (other than a fragrance, flavor, or color)
7 that has been designated for review under
8 section 608, includes potential ranges and
9 amounts of such ingredient.

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

12 “(G) If applicable, information on labeling
13 required under section 613.

14 “(H) Such additional information per-
15 taining to the cosmetic product as the Secretary
16 may require by regulation.

17 “(3) FRAGRANCE ALLERGENS, FRAGRANCES,
18 FLAVORS.—

19 “(A) IN GENERAL.—Any fragrance aller-
20 gen, fragrance, or flavor included in a cosmetic
21 product or cosmetic formulation shall be listed
22 in a cosmetic ingredient statement submitted
23 under this section.

24 “(B) FRAGRANCE ALLERGEN.—Any fra-
25 grance allergen identified under section 614

1 and included in a cosmetic product or cosmetic
2 formulation shall be listed in a cosmetic ingre-
3 dient statement.

4 “(C) FLAVORS.—With respect to a flavor
5 required to be included in a cosmetic ingredient
6 statement under subparagraph (A)—

7 “(i) in the case of a flavor purchased
8 from a flavor supplier, the cosmetic ingre-
9 dient statement shall include, with respect
10 to that flavor, the name or code provided
11 by the supplier; and

12 “(ii) in the case of any other flavor,
13 the cosmetic ingredient statement shall in-
14 clude, with respect to that flavor, the name
15 and contact information for the flavor
16 manufacturer or supplier.

17 “(D) FRAGRANCES.—With respect to a
18 fragrance required to be included in a cosmetic
19 ingredient statement under subparagraph (A)—

20 “(i) in the case of a fragrance pur-
21 chased from a fragrance supplier, the cos-
22 metic ingredient statement shall include,
23 with respect to that fragrance, the name or
24 code provided by the supplier; and

1 “(ii) in the case of any other fra-
2 grance, the cosmetic ingredient statement
3 shall include, with respect to that fra-
4 grance, the name and contact information
5 for the fragrance manufacturer or supplier.

6 “(4) CONFIDENTIALITY.—Fragrance ingredi-
7 ents included in a cosmetic ingredient statement
8 under paragraph (2)(E), other than fragrance aller-
9 gens identified pursuant to section 614, shall be
10 treated as trade secret or confidential commercial in-
11 formation.

12 “(5) CONTRACT MANUFACTURING ORGANIZA-
13 TION FACILITIES.—If a facility manufactures or
14 processes cosmetic products or cosmetic formulations
15 on behalf of an owner, operator, or agent in charge
16 whose name appears on the label of such products
17 or formulations, the Secretary shall require only a
18 single cosmetic ingredient statement for such cos-
19 metic product. Such single cosmetic ingredient state-
20 ment shall be submitted to the Secretary by the re-
21 sponsible person.

22 “(6) COSMETIC INGREDIENT STATEMENT FOR
23 CERTAIN SMALL BUSINESSES.—

24 “(A) IN GENERAL.—Notwithstanding any
25 other provision of this subsection, in the case of

1 a responsible person that has had an average of
2 less than \$1,000,000 in average gross annual
3 sales of cosmetic products in the United States
4 for the previous 3-fiscal-year period, the Sec-
5 retary may allow such responsible person—

6 “(i) to submit a simplified cosmetic
7 ingredient statement under this section;
8 and

9 “(ii) an additional time period, of a
10 duration to be determined by the Sec-
11 retary, in which to submit such simplified
12 cosmetic ingredient statement.

13 “(B) CONTENTS.—A responsible person
14 described in subparagraph (A) shall include in
15 each cosmetic ingredient statement submitted
16 under this section, at a minimum—

17 “(i) a list of ingredients in the cos-
18 metic product or cosmetic formulation, in-
19 cluding any fragrance allergens as de-
20 scribed in section 614;

21 “(ii) the applicable cosmetic category
22 for the cosmetic product or cosmetic for-
23 mulation; and

24 “(iii) in the case of a cosmetic product
25 or cosmetic formulation that includes a

1 fragrance or flavor purchased from a fra-
2 grance or flavor supplier, the contact infor-
3 mation for the fragrance or flavor supplier,
4 including the supplier's name, street ad-
5 dress, telephone number, and electronic
6 contact information.

7 “(d) ADDITIONAL REQUIREMENTS.—

8 “(1) SAFETY REQUIREMENTS.—In submitting a
9 cosmetic ingredient statement for each cosmetic
10 product or cosmetic formulation under this section,
11 a responsible person shall include an attestation that
12 the safety of the product or formulation, including
13 the individual ingredients of such product or formu-
14 lation, has been substantiated in accordance with
15 section 605(e)(2)(K).

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

23 “(e) COSMETIC PRODUCTS LIST.—

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

4 “(A) assign a unique cosmetic product list-
5 ing number to the cosmetic ingredient state-
6 ment; and

7 “(B) provide such number to the respon-
8 sible person who submitted such statement in
9 writing.

10 “(2) COSMETIC PRODUCTS LIST.—Using cos-
11 metic ingredient statements submitted under this
12 section, the Secretary shall—

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

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

19 “(3) CONFIDENTIALITY.—Information disclosed
20 to a State that is exempt from disclosure under sec-
21 tion 552(b)(4) of title 5, United States Code, shall
22 be treated as a trade secret and confidential com-
23 mercial information by the State. Such State and its
24 employees in possession of such information shall be
25 subject to the same laws governing information dis-

1 closure as employees of the Food and Drug Adminis-
2 tration.

3 “(f) EXEMPTION.—A responsible person shall be ex-
4 empt from the requirements of this section if such person
5 has had an average of less than \$500,000 in average gross
6 annual sales of cosmetic products in the United States for
7 the previous 3-fiscal-year period. Such exemption shall not
8 apply to cosmetic products that are intended to be injected
9 under the skin or into the eye, including tattoo ink, or
10 ingredients selected by the Food and Drug Administration
11 for review under section 608 if such ingredient is included
12 in a cosmetic product or cosmetic formulation distributed
13 by such person described.

14 **“SEC. 607. SUSPENSION OF REGISTRATION OR COSMETIC**
15 **INGREDIENT STATEMENT.**

16 “(a) SUSPENSION OF REGISTRATION OF A FACIL-
17 ITY.—If the Secretary determines that a cosmetic product
18 or cosmetic formulation manufactured or processed by a
19 facility registered under section 605 has a reasonable
20 probability of causing serious adverse health consequences
21 or death to humans, the Secretary may suspend the reg-
22 istration of such facility.

23 “(b) SUSPENSION OF COSMETIC INGREDIENT STATE-
24 MENT.—If the Secretary determines that a cosmetic prod-
25 uct or cosmetic formulation manufactured in a registered

1 facility has a reasonable probability of causing serious ad-
2 verse health consequences or death to humans, the Sec-
3 retary may suspend the cosmetic ingredient statement of
4 that product or formulation.

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

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

13 “(2) an opportunity for an informal hearing,
14 within 4 business days of the notice provided under
15 paragraph (1), for the facility or responsible person
16 that is the subject of such notice, as appropriate, to
17 address the reasons for possible suspension of the
18 registration of the facility or cosmetic ingredient
19 statement and the actions required for reinstatement
20 of the registration or cosmetic ingredient statement.

21 “(d) REINSTATEMENT.—Upon a determination by
22 the Secretary that adequate grounds do not exist to con-
23 tinue the suspension actions under subsection (a) or (b),
24 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. If the cosmetic ingredient statement is suspended
8 under this section, no person shall import, export, or oth-
9 erwise distribute any cosmetic product or cosmetic formu-
10 lation that is the subject of such cosmetic ingredient state-
11 ment.

12 “(f) NO DELEGATION.—The authority conferred by
13 this section to issue an order to suspend a registration
14 or cosmetic ingredient statement or vacate an order of sus-
15 pension shall not be delegated to any officer or employee
16 other than the Commissioner.

17 “(g) GUIDANCE.—Not later than 180 days after en-
18 actment of the Cosmetic Safety Enhancement Act of
19 2020, the Secretary shall issue guidance identifying the
20 procedures and criteria for a determination by the Sec-
21 retary that a cosmetic product or cosmetic formulation
22 manufactured, processed, packed, or held has a reasonable
23 probability of causing serious adverse health consequences
24 or death to humans that would result in a suspension.”.

1 **SEC. 102. REVIEW OF INGREDIENTS AND NONFUNCTIONAL**
2 **CONSTITUENTS; SAFETY OF FINISHED PROD-**
3 **UCTS.**

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

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

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

12 “(1) IN GENERAL.—Not later than 3 years
13 after the date of the enactment of the Cosmetic
14 Safety Enhancement Act of 2020, the Secretary
15 shall initiate reviews of the safety of no fewer than
16 three cosmetic ingredients or nonfunctional constitu-
17 ents (or categories thereof). Upon the completion of
18 each such review, the Secretary shall issue an order
19 under subsection (d) with respect to the use of each
20 such ingredient (or a category thereof) and presence
21 of each such nonfunctional constituent in cosmetic
22 products or cosmetic formulations (or a category
23 thereof).

24 “(2) INGREDIENTS AND NONFUNCTIONAL CON-
25 STITUENTS TO BE REVIEWED.—The Secretary shall
26 select and complete a review, on an ongoing basis,

1 of cosmetic ingredients or nonfunctional constituents
2 that were not reviewed in the prior 3 years. Such in-
3 gredients or nonfunctional constituents, including
4 any categories of ingredients or nonfunctional con-
5 stituents, should be selected after consultation with
6 stakeholders, including industry and consumer
7 groups.

8 “(3) INGREDIENTS NOT SUBJECT TO RE-
9 VIEW.—Ingredients imparting pigment to cosmetic
10 products that are already subject to review and ap-
11 proval by the Secretary pursuant to section 721(b)
12 shall not be subject to review under this section.

13 “(4) PROCESS FOR REVIEW.—

14 “(A) IN GENERAL.—The Secretary shall—

15 “(i) publish in the Federal Register a
16 list of the cosmetic ingredients and non-
17 functional constituents (or categories
18 thereof) identified for review under para-
19 graph (2); and

20 “(ii) open a public docket to solicit
21 public input and data relevant to the safe-
22 ty of the ingredients and nonfunctional
23 constituents (or categories thereof) so list-
24 ed for a period of not less than 60 days.

1 “(B) SELECTION OF NEXT INGREDIENT OR
2 NONFUNCTIONAL CONSTITUENT.—Upon
3 issuance of a final administrative order under
4 subsection (d)(3), the Secretary shall—

5 “(i) select a new cosmetic ingredient
6 or nonfunctional constituent, which may
7 include any category of ingredients or non-
8 functional constituents under subpara-
9 graph (A)(i); and

10 “(ii) open a docket under subpara-
11 graph (A)(ii).

12 “(5) CONTRACT AUTHORITY.—The Secretary
13 may contract with one or more qualified entities to
14 classify, compile, analyze, or aggregate data and in-
15 formation that is publicly available, provided by the
16 Secretary, or collected through the public docket
17 pursuant to paragraph (4) for purposes of review.

18 “(6) PUBLIC COMMENT.—Comments may be
19 submitted to the Secretary at any time with respect
20 to the safety of cosmetic ingredients or nonfunc-
21 tional constituents (or categories thereof), regardless
22 of whether such ingredients or constituents (or cat-
23 egories thereof) have been selected for review under
24 this subsection.

1 “(b) REVIEWED INGREDIENTS AND NONFUNCTIONAL
2 CONSTITUENTS.—The Secretary shall maintain a list,
3 posted on the internet website of the Food and Drug Ad-
4 ministration, of each cosmetic ingredient, nonfunctional
5 constituent, and category of ingredients or nonfunctional
6 constituents for which final orders have been issued under
7 subsection (d)(3), and with respect to each such ingredient
8 or nonfunctional constituent—

9 “(1) the finding made for each such ingredient,
10 nonfunctional constituent, or category under sub-
11 section (d)(4) or modified by any order under sub-
12 section (e); and

13 “(2) compliance dates that are the subject of a
14 final order under subsection (d)(3).

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

20 “(d) DETERMINATION ON SAFETY.—

21 “(1) PROPOSED ADMINISTRATIVE ORDER.—Fol-
22 lowing consideration of data and comments to the
23 public docket opened under subsection (a)(4) and
24 any other information before the Secretary with re-
25 spect to the safety of a cosmetic ingredient or non-

1 functional constituent (or category thereof), the Sec-
2 retary shall—

3 “(A) not later than 180 days following the
4 close of the docket under subsection (a)(4), de-
5 termine whether there is adequate evidence to
6 make an initial finding for purposes of making
7 a determination described in paragraph (4);

8 “(B) if the Secretary determines that there
9 is adequate evidence to make such a finding,
10 issue a proposed administrative order con-
11 taining the Secretary’s initial determination on
12 the safety of such ingredient or nonfunctional
13 constituent (or category thereof) as described in
14 paragraph (4) and publish such order in the
15 Federal Register not later than 2 years after
16 the close of the docket under subsection (a)(4),
17 notwithstanding subchapter II of chapter 5 of
18 title 5, United States Code; and

19 “(C) in the case of a proposed administra-
20 tive order in which the Secretary makes a de-
21 termination described in subparagraph (B) or
22 (C) of paragraph (4), include in such order a
23 compliance date.

24 “(2) PUBLIC COMMENT.—The Secretary shall
25 open a public docket for the submission of public

1 comments (including comments on whether any pro-
2 posed compliance date included in such order is fea-
3 sible) for a period of not less than 60 days, begin-
4 ning on the date of the issuance of the order.

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

10 “(A) determine whether there is adequate
11 evidence to make a final determination de-
12 scribed in paragraph (4);

13 “(B) if the Secretary determines that there
14 is adequate evidence to make such a final find-
15 ing, issue a final administrative order not later
16 than 90 days following the close of the com-
17 ment period under paragraph (2), publish such
18 order in the Federal Register, and post such
19 order on the internet website of the Food and
20 Drug Administration, notwithstanding sub-
21 chapter II of chapter 5 of title 5, United States
22 Code; and

23 “(C) in the case of a final administrative
24 order in which the Secretary makes the deter-
25 mination described in subparagraph (B) or (C)

1 of paragraph (4), include in such order a com-
2 pliance date.

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 613, 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 “(7) COMPLIANCE DATES.—A final order issued
7 under this subsection shall include a compliance date
8 by which use of the ingredient or nonfunctional con-
9 stituent in cosmetic products may no longer be mar-
10 keted. Such date shall be no later than 2 years after
11 publication of the final order.

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

16 “(f) INADEQUATE EVIDENCE.—

17 “(1) NOTICE; EXTENSION.—If the Secretary de-
18 termines that available data and information are not
19 adequate to make a proposed or final determination
20 under subsection (d), with respect to the safety of a
21 cosmetic ingredient or nonfunctional constituent (or
22 a category thereof), the Secretary shall—

23 “(A) convene a meeting with manufactur-
24 ers of the relevant cosmetic ingredient or non-
25 functional constituent (or a category thereof) or

1 their representatives and provide such manufac-
2 turers the opportunity to provide additional
3 data and information;

4 “(B) publish such determination in the
5 Federal Register not later than 180 days after
6 the close of the comment period for the ingre-
7 dient or nonfunctional constituent (or category
8 thereof) under subsection (a)(6) or under sub-
9 section (d)(1), as applicable; and

10 “(C) include in such publication a notice
11 providing interested persons an additional 30
12 days from the date on which the notice is pub-
13 lished to provide additional data and informa-
14 tion and an opportunity for a confidential meet-
15 ing pursuant to paragraph (2).

16 “(2) MEETINGS.—The Secretary may offer a
17 responsible person of such cosmetic ingredient or
18 nonfunctional constituent (or category thereof) a
19 confidential meeting with respect to a finding under
20 paragraph (1), to discuss matters relating to the
21 data and information requirements to support a de-
22 termination of safety of such ingredient or nonfunc-
23 tional constituent (or category thereof), which may
24 involve confidential information. Such meeting
25 should be convened in a reasonable time period

1 agreed upon between the responsible person and the
2 Secretary.

3 “(3) INADEQUATE DATA AND INFORMATION.—
4 If the Secretary determines, after providing an op-
5 portunity for a meeting pursuant to paragraphs (1)
6 or (2) and considering any additional data and infor-
7 mation pursuant to paragraph (1) that the available
8 data and information are still not adequate to make
9 a proposed or final determination under subsection
10 (d) with respect to the safety of a cosmetic ingre-
11 dient or nonfunctional constituent (or category
12 thereof), the Secretary shall—

13 “(A) publish such finding in the Federal
14 Register not later than 180 days after the close
15 of the comment period for the ingredient or
16 nonfunctional constituent (or category thereof)
17 under paragraph (1)(B); and

18 “(B) include in such publication—

19 “(i) a summary of the data and infor-
20 mation needed to make a proposed or final
21 determination;

22 “(ii) a proposed timeframe for the
23 generation and submission of such data
24 and information, which timeframe shall be

1 as soon as practicable and not exceed two
2 years; and

3 “(iii) an opportunity for a confidential
4 meeting pursuant to paragraph (2) regard-
5 ing the development of such data and in-
6 formation.

7 “(4) DETERMINATION; ORDER.—

8 “(A) DETERMINATION.—Not later than
9 180 days after the close of the docket under
10 paragraph (1)(B) or the receipt of data and in-
11 formation generated and submitted pursuant to
12 paragraph (3)(B), the Secretary shall make a
13 determination whether there is adequate data
14 and information to make a proposed or final de-
15 termination under subsection (d).

16 “(B) INADEQUATE DATA AND INFORMA-
17 TION.—If the Secretary determines after con-
18 sidering any additional data and information
19 generated and submitted pursuant to paragraph
20 (3)(B), or if the needed data and information
21 identified pursuant to paragraph (3)(B) is not
22 generated and submitted to the Secretary, the
23 Secretary shall—

24 “(i) within 90 days of the close of the
25 additional time period provided under

1 paragraph (3)(B) issue a proposed admin-
2 istrative order making a determination
3 that the ingredient or nonfunctional con-
4 stituent has not been shown to be safe in
5 cosmetic products;

6 “(ii) identify in such proposed order
7 the reasons why the available data and in-
8 formation are not adequate to assess the
9 safety of the ingredient or nonfunctional
10 constituent;

11 “(iii) include in such proposed order a
12 timeline identifying the date by which the
13 cosmetic ingredient or nonfunctional con-
14 stituent (or category thereof) may no
15 longer be marketed;

16 “(iv) provide for a period of not less
17 than 60 days for public comment on the
18 proposed administrative order; and

19 “(v) issue a final administrative order
20 not later than 60 days following the close
21 of the public comment period under clause
22 (iv).

23 “(C) ADEQUATE DATA AND INFORMA-
24 TION.—If the Secretary determines, after con-
25 sidering any additional data and information

1 submitted pursuant to paragraph (1)(B) or
2 generated and submitted pursuant to paragraph
3 (3)(B), that the available data and information
4 are adequate to make a determination with re-
5 spect to the safety of a cosmetic ingredient or
6 nonfunctional constituent (or category thereof),
7 the Secretary shall—

8 “(i) in the case of a determination de-
9 scribed in subparagraph (A) of subsection
10 (d)(4), within 180 days of the close of the
11 applicable comment period under para-
12 graph (1)(B) or the end of the timeframe
13 identified under paragraph (3)(B), issue a
14 final administrative order, with respect to
15 such cosmetic ingredient or nonfunctional
16 constituent (or category thereof), in ac-
17 cordance with subsection (d)(3);

18 “(ii) in the case of a determination
19 described in subparagraph (B) of sub-
20 section (d)(4), within 180 days of the close
21 of the applicable comment period under
22 paragraph (1)(B) or the end of the time-
23 frame identified under paragraph (3)(B),
24 issue a proposed administrative order,
25 allow for a period of not less than 60 days

1 for public comment, and issue a final ad-
2 ministrative order, with respect to such
3 cosmetic ingredient or nonfunctional con-
4 stituent (or category thereof), in accord-
5 ance with subsection (d)(3); and

6 “(iii) in the case of a determination
7 described in subparagraph (C) of sub-
8 section (d)(4), within 180 days of the close
9 of the applicable comment period under
10 paragraph (1)(B) or the end of the time-
11 frame identified under paragraph (3)(B),
12 issue a final administrative order, with re-
13 spect to such cosmetic ingredient or non-
14 functional constituent (or category there-
15 of), in accordance with subsection (d)(3)
16 specifying the date by which sale of such
17 ingredient or nonfunctional constituent
18 must cease.

19 “(D) INFORMAL HEARING.—Following
20 issuance of a final administrative order under
21 this section, the manufacturer or manufacturers
22 of a cosmetic product or cosmetic formulation
23 utilizing an ingredient or nonfunctional con-
24 stituent (or category thereof) may request an
25 informal hearing with the Chief Scientist of the

1 Food and Drug Administration. Such hearing
2 shall be held within 60 calendar days of such
3 request and provide an opportunity for such
4 manufacturer or manufacturers to seek changes
5 to the findings of the Food and Drug Adminis-
6 tration included in such order. The Chief Sci-
7 entist may not delegate such hearing to employ-
8 ees other than those in the Office of the Com-
9 missioner of the Food and Drug Administration
10 and shall issue a revised order, if applicable,
11 within 60 calendar days of such hearing. Such
12 revised order shall be considered final agency
13 action subject to judicial review.

14 “(g) SAFETY ASSESSMENT STANDARDS.—

15 “(1) IN GENERAL.—In assessing the safety of
16 an ingredient or nonfunctional constituent (or cat-
17 egory thereof) under this section, the Secretary shall
18 consider—

19 “(A) whether there is adequate evidence to
20 support a reasonable certainty among com-
21 petent scientists that—

22 “(i) in the case of a cosmetic ingre-
23 dient (or category thereof), the ingredient
24 (or category thereof) is not harmful under

1 the recommended or suggested conditions
2 of use or customary or usual use; or

3 “(ii) in the case of a nonfunctional
4 constituent (or category thereof), that the
5 nonfunctional constituent (or category
6 thereof) is not harmful under the rec-
7 ommended or suggested tolerance levels or
8 the level at which it is customarily or usu-
9 ally present;

10 “(B) the probable human exposure to the
11 cosmetic ingredient or nonfunctional constituent
12 (or category thereof) from expected use in cos-
13 metic products and cosmetic formulations;

14 “(C) the probable cumulative and aggre-
15 gate effect in humans of relevant exposure to
16 the cosmetic ingredient or nonfunctional con-
17 stituent (or category thereof) or to any chemi-
18 cally or pharmacologically related substances
19 from use in cosmetic products or cosmetic for-
20 mulations or other products with similar routes
21 of exposure under recommended or suggested
22 conditions of use or their customary use, to the
23 extent adequate data are available for analysis,
24 and if appropriate, available information on the
25 total exposure to a cosmetic ingredient or non-

1 functional constituent (or category thereof)
2 from all sources; and

3 “(D) whether warnings or recommenda-
4 tions in a cosmetic product label, as part of any
5 conditions of use or tolerances imposed by the
6 Secretary in a determination described in sub-
7 paragraph (B) of subsection (d)(4), would be
8 necessary and appropriate to help ensure the
9 safety of the ingredient or nonfunctional con-
10 stituent (or category thereof).

11 “(2) MINOR ADVERSE REACTIONS.—The Sec-
12 retary may not consider a cosmetic ingredient or
13 nonfunctional constituent (or category thereof)
14 harmful under paragraph (1) solely because it can
15 cause minor adverse health reactions, such as minor
16 transient allergic reactions or minor transient skin
17 irritations, in some users.

18 “(3) DATA AND INFORMATION.—

19 “(A) REQUIRED INFORMATION.—A deter-
20 mination under subsection (d)(4) shall be based
21 upon adequate evidence submitted or otherwise
22 known to the Secretary, which shall include full
23 reports of all available studies, published or un-
24 published, that are adequately designed to show
25 whether the ingredient or nonfunctional con-

1 stituent (or category thereof) is safe. Such
2 studies may include in vitro and in silico studies
3 and epidemiological studies, biomonitoring stud-
4 ies, and studies focused on various points dur-
5 ing the lifespan of the subject, that use scientif-
6 ically valid methodology.

7 “(B) ADDITIONAL RELEVANT INFORMA-
8 TION.—The Secretary shall consider any other
9 relevant information related to the safety of a
10 cosmetic ingredient or nonfunctional constituent
11 (or category thereof), including—

12 “(i) adverse event reports;

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

17 “(iii) if the cosmetic ingredient or
18 nonfunctional constituent (or category
19 thereof) is lawfully used or present in other
20 products regulated by the Secretary, the
21 scientific basis for such use; and

22 “(iv) experience with the cosmetic in-
23 gredient or nonfunctional constituent (or
24 category thereof) in products that are dis-
25 tributed in the United States or in other

1 countries, if such experience is well-docu-
2 mented and has resulted in substantial
3 human exposure to the cosmetic ingredient
4 or nonfunctional constituent over time.

5 “(h) COAL TAR HAIR DYE.—In assessing for pur-
6 poses of this section the safety of coal tar hair dye or any
7 ingredient or nonfunctional constituent therein, the Sec-
8 retary shall not make a determination that the dye, ingre-
9 dient, or nonfunctional constituent is not safe for use in
10 cosmetic products solely because the dye, ingredient, or
11 nonfunctional constituent can cause allergic reactions.

12 “(i) RULE OF CONSTRUCTION.—Nothing in this sec-
13 tion shall be construed to affect the ability of a responsible
14 person to introduce into commerce a cosmetic product that
15 contains a cosmetic ingredient or nonfunctional con-
16 stituent (or category thereof) while such ingredient or non-
17 functional constituent (or category thereof) is under re-
18 view, being considered for review for safety, or subject of
19 a public docket seeking additional information.”.

20 (b) PUBLIC MEETING AND GUIDANCE.—

21 (1) PUBLIC MEETING.—Not later than 12
22 months after the date of the enactment of this Act,
23 the Secretary of Health and Human Services (in this
24 subsection referred to as the “Secretary”) shall con-
25 vene a public meeting to describe and solicit public

1 input regarding the ingredient review process under
2 section 608 of the Federal Food, Drug, and Cos-
3 metic Act (as added by subsection (a)). Such meet-
4 ing shall include representatives from the cosmetics
5 industry, medical practitioners and scientific experts
6 with cosmetic expertise, and consumer and public
7 health advocacy organizations.

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

15 (A) the types of scientific evidence, clinical
16 studies, data, or other information needed to
17 support the review of cosmetic ingredients or
18 nonfunctional constituents (or categories there-
19 of) selected for review under such section;

20 (B) the recommended format in which to
21 submit to the Secretary such data and informa-
22 tion, including any applicable foreign data and
23 information, related to a cosmetic ingredient or
24 nonfunctional constituent (or category thereof)
25 that has been selected for such review;

1 (C) the manner and the number of days by
2 which the Secretary intends to review and re-
3 spond to such data and information, including
4 with respect to providing a scientific rationale
5 for any additional data and information;

6 (D) the process for communication be-
7 tween the Secretary and industry related to an
8 ingredient or nonfunctional constituent (or a
9 category thereof) that has been selected for re-
10 view; and

11 (E) includes such other information as the
12 Secretary determines appropriate.

13 (3) TIMING.—Not later than 24 months after
14 the date of the enactment of this Act, the Secretary
15 shall issue draft guidance under paragraph (1) on
16 the implementation of section 608 of the Federal
17 Food, Drug, and Cosmetic Act (as added by sub-
18 section (a)). The Secretary shall issue final guidance
19 on the implementation of such section not later than
20 6 months after the date on which the comment pe-
21 riod for the draft guidance closes.

22 (c) GAO STUDY.—Not later than 6 years after the
23 date of the enactment of this Act, the Comptroller General
24 of the United States shall submit to the Committee on
25 Energy and Commerce of the House of Representatives

1 and the Committee on Health, Education, Labor, and
2 Pensions of the Senate a report addressing the effective-
3 ness and overall impact of the ingredient review program
4 established under section 608 of the Federal Food, Drug,
5 and Cosmetic Act (as added by subsection (a)), including
6 with respect to its impact on the safety of cosmetic ingre-
7 dients—

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

10 (A) whether the ingredient or nonfunc-
11 tional constituent (or category thereof) was de-
12 termined—

13 (i) to be safe in cosmetic products
14 without the need for specified conditions of
15 use or tolerances;

16 (ii) to be safe in cosmetic products
17 under specified conditions of use of toler-
18 ances; or

19 (iii) to be not safe in cosmetic prod-
20 ucts;

21 (B) the timeline for such review;

22 (C) the types of scientific evidence, clinical
23 studies, data, or other information used to
24 make such a determination;

1 (D) whether, and to what extent, the re-
2 view of the ingredient or nonfunctional con-
3 stituent (or category thereof) resulted in cos-
4 metic products being reformulated or removed
5 from the market; and

6 (E) the impact the review and determina-
7 tion had on consumer use and access to such
8 product; and

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

12 (A) the resources used by the Secretary in
13 reviewing ingredients and nonfunctional con-
14 stituents (or categories thereof), including the
15 effects of the program on other cosmetic safety
16 activities of the Secretary;

17 (B) the impact of such section on innova-
18 tion and consumer access to cosmetic products;
19 and

20 (C) whether any improvements to the pro-
21 gram under such section 608 are necessary for
22 increasing the efficiency and effectiveness of the
23 review of cosmetic ingredients, nonfunctional
24 constituents, or categories thereof.

1 **SEC. 103. GOOD MANUFACTURING PRACTICES FOR COS-**
2 **METICS.**

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

7 **“SEC. 609. GOOD MANUFACTURING PRACTICES FOR COS-**
8 **METICS.**

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

10 “(1) review national and international stand-
11 ards for cosmetic good manufacturing practices that
12 are in effect on the date of enactment of the Cos-
13 metic Safety Enhancement Act of 2020; and

14 “(2) issue a rule establishing requirements for
15 current good manufacturing practices consistent, to
16 the extent the Secretary determines practicable and
17 appropriate, with such national and international
18 standards.

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

21 “(1) shall require facilities subject to require-
22 ments of this chapter to have adequate procedures
23 in place to ensure the integrity of cosmetic ingredi-
24 ents and other raw materials used in the manufac-
25 ture of cosmetic products or cosmetic formulations;

1 “(2) may specify requirements for the use of
2 certain analytical or recordkeeping methods by a
3 manufacturer as may be necessary to ensure that a
4 cosmetic product or cosmetic formulation is not inju-
5 rious to health under the recommended or suggested
6 conditions of use, or customary or usual use of the
7 product or formulation; and

8 “(3) shall not—

9 “(A) impose standards for which there is
10 no current and generally available analytic
11 method; or

12 “(B) apply to facilities meeting the criteria
13 to be considered excluded from the definition of
14 a facility under section 604, including those of-
15 fering customized or personalized cosmetics to
16 consumers, or to entities that are in compliance
17 with the good manufacturing practice regula-
18 tions specified in parts 210 and 211 of title 21,
19 Code of Federal Regulations (or any successor
20 regulations).

21 “(c) TIMEFRAME.—

22 “(1) PROPOSED RULE.—Not later than 24
23 months after the date of enactment of the Cosmetic
24 Safety Enhancement Act of 2020, the Secretary

1 shall publish a proposed rule described in subsection
2 (a).

3 “(2) PUBLIC COMMENT PERIOD.—Before pro-
4 mulgating a final rule under paragraph (3), the Sec-
5 retary shall provide for a public comment period on
6 the proposed rule issued under paragraph (1) for a
7 period of not less than 60 days.

8 “(3) FINAL RULES.—

9 “(A) PUBLICATION.—Not later than 36
10 months after the date of enactment of the Cos-
11 metic Safety Enhancement Act of 2020, the
12 Secretary shall publish a final rule described in
13 subsection (a).

14 “(B) EFFECTIVE DATE.—Such final rule
15 shall be published not less than 30 days before
16 the effective date of the final rule.”

17 (b) EFFECTIVE DATE FOR COSMETIC MANUFACTUR-
18 ERS.—Regulations issued pursuant to section 609 of the
19 Federal Food, Drug, and Cosmetic Act (as added by sub-
20 section (a)) shall apply with respect to—

21 (1) large manufacturers (as determined by the
22 Secretary) beginning 180 days after the date on
23 which the final rule described in subsection (a) is ef-
24 fective;

1 (2) midsize manufacturers (as determined by
2 the Secretary), beginning 210 days after such date;
3 and

4 (3) small manufacturers (as determined by the
5 Secretary), beginning 2 years after such date.

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

9 “(f) If it is a cosmetic product or cosmetic formula-
10 tion and it has been manufactured, processed, packed, or
11 held under conditions that do not meet current good man-
12 ufacturing practice regulations issued by the Secretary.”.

13 **SEC. 104. ADVERSE EVENTS.**

14 Chapter VI of the Federal Food, Drug, and Cosmetic
15 Act (21 U.S.C. 361 et seq.), as amended by section
16 103(a), is further amended by adding at the end the fol-
17 lowing:

18 **“SEC. 610. ADVERSE EVENT REPORTING FOR COSMETICS.**

19 “(a) SUBMISSION OF SERIOUS ADVERSE EVENT RE-
20 PORTS.—

21 “(1) IN GENERAL.—With respect to any cos-
22 metic product distributed in the United States, the
23 responsible person shall submit, not later than 15
24 days after the receipt by the responsible person,
25 using an electronic system developed under sub-

1 section (b), to the Secretary any report of a serious
2 adverse event associated with the use of such cos-
3 metic product, accompanied by a copy of the label on
4 or with the retail packaging of the cosmetic product.

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

16 “(3) PUBLICATION.—The Secretary shall make
17 publicly available on the internet website of the Food
18 and Drug Administration reports submitted under
19 paragraph (1).

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

1 required to submit a serious adverse event report
2 under paragraph (1) with respect to that cosmetic
3 product.

4 “(b) REQUIREMENTS FOR SERIOUS ADVERSE EVENT
5 REPORTS.—

6 “(1) ELECTRONIC SYSTEM.—

7 “(A) IN GENERAL.—The Secretary shall,
8 not later than 1 year after the date of enact-
9 ment of the Cosmetic Safety Enhancement Act
10 of 2020, develop and implement an electronic
11 system for use for the submission of serious ad-
12 verse event reports under this section.

13 “(B) MODIFICATION.—The format of the
14 electronic system developed and implemented
15 under paragraph (1) may be modified by the
16 Secretary. The Secretary may, in guidance, fur-
17 ther specify the format and contents of required
18 reports.

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

1 “(A) any report by the responsible person
2 under section 756 with respect to the safety of
3 the cosmetic product that is the subject of the
4 report;

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

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

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

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

1 “(4) NO ADVERSE EVENTS TO REPORT.—The
2 Secretary shall provide an option as part of the elec-
3 tronic registration process for the responsible person
4 to indicate if such responsible person had no adverse
5 events to report over the previous year. With respect
6 to a responsible person who received no adverse
7 event reports for a year, the annual adverse event
8 report requirement may be met by indicating no
9 such events on the annual registration form.

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

16 “(c) REQUIREMENTS FOR OTHER ADVERSE
17 EVENTS.—

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

1 reasonable times and within reasonable limits and in
2 a reasonable manner, including allowing electronic
3 access and to copy such records.

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

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

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

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

22 “(D) such other information as may be
23 specified in regulation or guidance issued by the
24 Secretary.

1 “(3) RULE OF CONSTRUCTION.—This section
2 shall not be construed to require the inclusion in any
3 report or record under this section any consumer
4 complaint that concerns solely efficacy and does not
5 contain any information about an adverse event.

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

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

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

1 mation disclosure as employees of the Food and Drug Ad-
2 ministration.

3 “(g) PROTECTION OF INFORMATION.—A serious ad-
4 verse event report submitted to the Secretary under this
5 section, including any new medical information submitted
6 under subsection (a)(2), or an adverse event report volun-
7 tarily submitted to the Secretary—

8 “(1) shall be considered to be a safety report
9 under section 756 and may be accompanied by a
10 statement, which shall be a part of any report that
11 is released for public disclosure, that denies that the
12 report or the records constitute an admission that
13 the product involved caused or contributed to the ad-
14 verse event; and

15 “(2)(A) shall be considered to be—

16 “(i) a record about an individual under
17 section 552a of title 5, United States Code
18 (commonly referred to as the ‘Privacy Act of
19 1974’); and

20 “(ii) a medical or similar file the disclosure
21 of which would constitute a violation of section
22 552 of such title 5 (commonly referred to as the
23 ‘Freedom of Information Act’); and

24 “(B) shall not be publicly disclosed unless all
25 personally identifiable information is redacted.

1 “(h) EFFECTIVE DATES.—

2 “(1) SERIOUS ADVERSE EVENTS.—The require-
3 ment under this section to report serious adverse
4 events shall become effective on the date that the
5 Secretary publicizes the availability of the electronic
6 system described in subsection (b)(1).

7 “(2) OTHER ADVERSE EVENTS.—The require-
8 ment under this section to maintain records relating
9 to adverse events which are not serious adverse
10 events shall become effective 18 months after the
11 date of the enactment of the Cosmetic Safety En-
12 hancement Act of 2020.

13 “(i) DEFINITIONS.—In this section:

14 “(1) ADVERSE EVENT.—The term ‘adverse
15 event’ means, with respect to a cosmetic product, a
16 health-related event associated with the use of such
17 product that is adverse, including a risk of illness or
18 injury. Such term does not include any instance of
19 a consumer complaint related to efficacy, such as the
20 cosmetic product did not work as advertised or mar-
21 keted.

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

25 “(A) results in—

- 1 “(i) death;
- 2 “(ii) a life-threatening experience;
- 3 “(iii) inpatient hospitalization;
- 4 “(iv) a persistent or significant ad-
- 5 verse health condition, disability, or inca-
- 6 pacity;
- 7 “(v) congenital anomaly or birth de-
- 8 fect; or
- 9 “(vi) significant disfigurement, includ-
- 10 ing serious or persistent rashes and infec-
- 11 tions, burns, or significant hair loss; or
- 12 “(B) requires, based on reasonable medical
- 13 judgment, a medical or surgical intervention to
- 14 prevent an outcome described in subparagraph
- 15 (A).”.

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

17 **THORITY.**

18 Chapter VI of the Federal Food, Drug, and Cosmetic

19 Act (21 U.S.C. 361 et seq.), as amended by section 104,

20 is further amended by adding at the end the following:

21 **“SEC. 611. INSPECTION OF COSMETIC RECORDS.**

22 “(a) INSPECTION OF RECORDS.—For purposes of

23 section 704, each facility owned or operated by a respon-

24 sible person for a cosmetic product shall, at the request

25 of an officer or employee duly designated by the Secretary,

1 permit such officer or employee, upon presentation of ap-
2 propriate credentials and written notice to such person,
3 at reasonable times and within reasonable limits and in
4 a reasonable manner, to have access to and copy, or re-
5 ceive electronically records maintained by or on behalf of
6 such person in any format (including paper and electronic
7 formats) and at any location related to such cosmetic
8 product, including—

9 “(1) all records required to be maintained
10 under section 610 and in accordance with the rules
11 promulgated by the Secretary under section 609, as
12 applicable;

13 “(2) all records maintained under section
14 605(e)(2)(K);

15 “(3) any records relating to an ingredient or in-
16 gredients in specific fragrances or flavors of a cos-
17 metic product or cosmetic formulation, if requested
18 by the Secretary by means of a written notification
19 issued pursuant to this subsection; and

20 “(4) except as provided in subsection (b), all
21 other records relating to the cosmetic product or
22 cosmetic formulation and to any other cosmetic
23 product or cosmetic formulation the Secretary rea-
24 sonably believes is likely to be affected in a similar
25 manner, if the Secretary—

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

3 “(i) is adulterated;

4 “(ii) has caused a reportable serious
5 adverse event; or

6 “(iii) contains an ingredient for which
7 new scientific information shows may be
8 unsafe when present in a cosmetic product
9 or cosmetic formulation; and

10 “(B) provides written notice to the respon-
11 sible person of the basis for the Secretary’s rea-
12 sonable belief described in subparagraph (A), as
13 applicable.

14 “(b) EXCLUSIONS.—

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

17 “(A) recipes, financial data, pricing data,
18 personnel data (other than data as to qualifica-
19 tion of technical and professional personnel per-
20 forming functions subject to this Act), research
21 data (other than safety data) or sales data
22 other than shipment and distribution data; or

23 “(B) except as provided in paragraph (2),
24 information related to ingredients in fragrances

1 or flavors of a cosmetic product or cosmetic for-
2 mulation.

3 “(2) EXCEPTION.—The Secretary may obtain
4 information related to an ingredient or ingredients
5 in fragrances or flavors in an identified cosmetic
6 product or cosmetic formulation only by a request in
7 a written notification provided to the manufacturer
8 pursuant to a for-cause inspection. In response to
9 such written notification, the manufacturer of such
10 fragrance or flavor shall provide information about
11 an ingredient or ingredients in the specified fra-
12 grance or flavor that the Secretary determines is
13 necessary to assist its investigation, in the manufac-
14 turer’s preferred electronic or written format, to the
15 Secretary upon receipt of such notification. Any in-
16 formation provided in response to such written noti-
17 fication shall be considered a trade secret under sec-
18 tion 301(j) and, notwithstanding such section, shall
19 only be disclosed if the Secretary determines such
20 disclosure is necessary to protect the public health.
21 The authority to determine such disclosure is nec-
22 essary to protect the public health shall not be dele-
23 gated to any officer or employee other than the Di-
24 rector of the Office of Cosmetics and Colors within

1 the Center for Food Safety and Applied Nutrition,
2 or any successor office.

3 “(c) PROTECTION OF SENSITIVE INFORMATION.—

4 The Secretary shall take appropriate measures to ensure
5 that there are effective procedures to prevent the unau-
6 thorized disclosure of any trade secret or confidential com-
7 mercial information that is obtained by the Secretary pur-
8 suant to this section. Information disclosed to a State
9 shall be pursuant to the laws governing disclosure of infor-
10 mation. Confidential commercial information disclosed to
11 the State that is exempt from disclosure under section
12 552(b)(4) of title 5, United States Code, shall be treated
13 as confidential commercial information by the State. Such
14 State and its employees in possession of such information
15 under this section shall be subject to the same laws gov-
16 erning information disclosure as employees of the Food
17 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 “(e) SUBMISSION OF RECORDS.—

4 “(1) IN GENERAL.—Any records required to be
5 maintained by a facility registered under section
6 605(a) shall, upon the written request by the Sec-
7 retary to the owner, operator, or agent in charge (or
8 an affiliate thereof) of such facility, provide such
9 records to the Secretary within a reasonable time-
10 frame not to exceed 60 days, in either electronic or
11 paper form.

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

14 “(A) the Secretary has a reasonable belief,
15 described in written notice, that—

16 “(i) the cosmetic product or cosmetic
17 formulation may be harmful based on ad-
18 verse event reports or other scientific infor-
19 mation; or

20 “(ii) scientific information raises cred-
21 ible and relevant questions about the safe-
22 ty of the cosmetic product or any of its in-
23 gredients;

24 “(B) the Secretary, an expert regulatory
25 body, or an expert body composed of scientific

1 and medical experts finds an ingredient in the
2 cosmetic product to be unsafe under the condi-
3 tions of use of the product; or

4 “(C) the Secretary concludes that submis-
5 sion of the records are necessary for purposes
6 of protecting the public health.

7 “(f) DEFINITIONS.—For purposes of this section, the
8 term ‘for-cause inspection’ means an inspection that is
9 carried out in response to specific information that—

10 “(1) raises questions, concerns, or problems as-
11 sociated with a facility regulated under this chapter,
12 or a cosmetic product, cosmetic formulation, or cos-
13 metic ingredient, regulated firm, or commodity; and

14 “(2) may include the results of a sample anal-
15 ysis, observations made during prior inspections, re-
16 call or market withdrawal, consumer or employee
17 complaint, adverse event report, or suspicion of
18 fraud.

19 **“SEC. 612. MANDATORY RECALL AUTHORITY.**

20 “(a) VOLUNTARY PROCEDURES.—If the Secretary
21 determines that there is a reasonable probability that a
22 cosmetic product is adulterated under section 601 or mis-
23 branded under section 602 and there is a reasonable prob-
24 ability that the use of, and exposure to, such cosmetic
25 product is likely to cause serious adverse health con-

1 sequences or death, the Secretary shall provide the respon-
2 sible person with an opportunity to voluntarily cease dis-
3 tribution and recall such article. The Secretary shall pro-
4 vide such responsible person with an opportunity in writ-
5 ing to voluntarily provide to the Secretary a list of any
6 known distributors, packers, or holders in the United
7 States that received such cosmetic product directly from
8 such responsible person.

9 “(b) PREHEARING ORDER TO MANDATORILY CEASE
10 DISTRIBUTION AND GIVE NOTICE.—

11 “(1) IN GENERAL.—If the responsible person
12 refuses to or does not voluntarily cease distribution
13 or recall such cosmetic product within the time and
14 in the manner prescribed by the Secretary, the Sec-
15 retary may order such person to—

16 “(A) immediately cease distribution of
17 such cosmetic product; and

18 “(B) as applicable, immediately order all
19 facilities—

20 “(i) manufacturing, processing, pack-
21 ing, transporting, holding, receiving, dis-
22 tributing, or importing and selling such
23 cosmetic product; and

24 “(ii) to which such cosmetic product
25 has been distributed, transported, or sold,

1 to immediately cease distribution of such cos-
2 metic product.

3 “(2) REQUIRED ADDITIONAL INFORMATION.—

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

18 “(B) RULES OF CONSTRUCTION.—Nothing
19 in this paragraph shall be construed to exempt
20 a warehouse-based, third-party logistics pro-
21 vider from—

22 “(i) the requirements of this chapter,
23 including the requirements of this section
24 and section 611; or

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

3 “(3) DETERMINATION TO LIMIT AREAS AF-
4 FECTED.—If the Secretary requires a responsible
5 person to cease distribution under paragraph (1)(A)
6 of a cosmetic product, the Secretary may limit the
7 size of the geographic area and the markets affected
8 by such cessation if such limitation would not com-
9 promise the public health.

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

17 “(d) POSTHEARING RECALL ORDER AND MODIFICA-
18 TION OF ORDER.—

19 “(1) AMENDMENT OF ORDER.—If, after pro-
20 viding opportunity for an informal hearing under
21 subsection (c), the Secretary determines that re-
22 moval of the cosmetic product from commerce is
23 necessary, the Secretary shall, as appropriate—

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

4 “(B) specify a timetable in which the recall
5 shall occur;

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

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

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

16 “(e) COOPERATION AND CONSULTATION.—The Sec-
17 retary shall work with State and local public health offi-
18 cials in carrying out this section, as appropriate, and shall
19 ensure trade secret and confidential commercial informa-
20 tion remain subject to the applicable laws governing disclo-
21 sure of information, unless disclosure is necessary to pro-
22 tect public health.

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

1 “(1) ensure that a press release or other means
2 for public notification is published regarding the re-
3 call in order to provide notification—

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

7 “(B) that includes, at a minimum—

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

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

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

17 “(2) ensure publication on the internet website
18 of the Food and Drug Administration of an image
19 of the cosmetic product that is the subject of the
20 press release described in paragraph (1), if available
21 and the Secretary determines such publication is
22 necessary.

23 “(g) NO DELEGATION.—The authority conferred by
24 this section to order a recall or vacate a recall order shall

1 not be delegated to any officer or employee other than the
2 Commissioner of Food and Drugs.

3 “(h) **RULE OF CONSTRUCTION.**—Nothing in this sec-
4 tion shall affect the authority of the Secretary to request
5 or participate in a voluntary recall, or to issue an order
6 to cease distribution or to recall any article under any
7 other provision of this Act or under the Public Health
8 Service Act.”.

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

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

14 **“SEC. 613. LABELING AND INTERNET SALES.**

15 “(a) **SAFETY REVIEW AND LABELING.**—If a warning
16 or condition of use is required pursuant to section
17 608(d)(5) to ensure the safe use of a cosmetic ingredient,
18 the Secretary shall require appropriate labeling of any cos-
19 metic product that contains such ingredient. Such labeling
20 shall also indicate whether such ingredient—

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

23 “(2) requires warnings that children, pregnant
24 women, and other vulnerable populations should
25 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 internet
12 website, including the responsible person.”.

13 **SEC. 107. FRAGRANCE ALLERGEN DISCLOSURE.**

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

18 **“SEC. 614. FRAGRANCE ALLERGENS.**

19 “(a) FRAGRANCE ALLERGENS.—Not later than 2
20 years after the date of enactment of the Cosmetic Safety
21 Enhancement Act of 2020, the responsible person shall
22 include on the label of any cosmetic product containing
23 one or more fragrance allergens, a list of each such fra-
24 grance allergen included in such cosmetic product in a
25 form and manner as specified by the Secretary.

1 “(b) IDENTIFIED FRAGRANCE ALLERGENS.—The
2 fragrance allergens to be identified on a label of a cosmetic
3 product include—

4 “(1) Alpha-Isomethyl ionone;

5 “(2) Amyl cinnamal;

6 “(3) Amylcinnamyl alcohol;

7 “(4) Anise alcohol;

8 “(5) Benzyl alcohol;

9 “(6) Benzyl benzoate;

10 “(7) Benzyl cinnamate;

11 “(8) Benzyl salicylate;

12 “(9) Butylphenyl methylpropional;

13 “(10) Cinnamal;

14 “(11) Cinnamyl alcohol;

15 “(12) Citral;

16 “(13) Citronellol;

17 “(14) Coumarin;

18 “(15) Eugenol;

19 “(16) Evernia prunastri (oak moss);

20 “(17) Evernia furfuracea (tree moss);

21 “(18) Farnesol;

22 “(19) Geraniol;

23 “(20) Hexyl cinnamal;

24 “(21) Hydroxycitronellal;

1 “(22) Hydroxyisohexyl 3-cyclohexene
2 carboxaldehyde;

3 “(23) Isoeugenol;

4 “(24) Limonene;

5 “(25) Linalool;

6 “(26) Methyl 2-octynoate; and

7 “(27) other substances as identified by the Sec-
8 retary in guidance issued pursuant to this section.

9 “(c) GUIDANCE.—

10 “(1) ISSUANCE.—Not later than one year after
11 the date of enactment of the Cosmetic Safety En-
12 hancement Act of 2020, the Secretary shall issue
13 one or more guidances specifying the form and man-
14 ner of fragrance allergen listing on the label of cos-
15 metic products.

16 “(2) CONTENTS.—Such guidance shall—

17 “(A) specify the form and manner of fra-
18 grance allergen listing for cosmetic products
19 where the package or label is too small or oth-
20 erwise is unable to accommodate a label with
21 sufficient space to bear the information re-
22 quired for compliance with this section;

23 “(B) specify thresholds for rinse-off and
24 leave-on cosmetic formulations; and

1 “(C) take into consideration requirements
2 under international regulations for fragrance al-
3 lergen labeling, as appropriate.

4 “(3) UPDATES.—The Secretary may, as needed,
5 update the list of fragrance allergens to include ad-
6 ditional substances pursuant to guidance issued
7 under this subsection and taking into consideration
8 international regulations, as appropriate.

9 “(d) CONTACT INFORMATION.—

10 “(1) IN GENERAL.—The contact information on
11 the label on a cosmetic product for consumers to re-
12 port adverse events shall also provide a means for
13 consumers to obtain additional information about
14 the inclusion of any recognized fragrance allergen
15 required to be included on such label under sub-
16 section (a).

17 “(2) RESPONSE.—

18 “(A) IN GENERAL.—The responsible per-
19 son shall—

20 “(i) upon receipt of a request for in-
21 formation under paragraph (1), promptly
22 obtain and provide such information to the
23 requesting consumer; and

24 “(ii) in the case of information in the
25 possession of a supplier, promptly obtain

1 such information from such supplier, if
2 reasonably available.

3 “(B) SUPPLIER.—A relevant supplier shall
4 promptly provide information requested to a re-
5 sponsible person pursuant to subparagraph
6 (A)(ii).”.

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

10 “(g) If its labeling or packaging does not contain a
11 listing of ingredients that meets the requirements of part
12 701 of title 21, Code of Federal Regulations (as in effect
13 on date of enactment of the Cosmetic Safety Enhancement
14 Act of 2020) (or any successor regulations).”.

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

20 **SEC. 108. CONSUMER INFORMATION.**

21 The Secretary of Health and Human Services, acting
22 through the Commissioner of Food and Drugs, shall post
23 on its internet website information for consumers regard-
24 ing—

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

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

6 (3) identified counterfeit cosmetic products.

7 **SEC. 109. SMALL BUSINESSES.**

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

11 **“SEC. 615. SMALL BUSINESSES.**

12 “(a) IN GENERAL.—The Secretary, in coordination
13 with the Administrator of the Small Business Administra-
14 tion, shall provide technical assistance, such as guidance
15 and expertise, to small businesses regarding compliance
16 with the Cosmetic Safety Enhancement Act of 2020, in-
17 cluding the amendments made by such Act.

18 “(b) COMPLIANCE GUIDE.—Not later than 180 days
19 after the date of the enactment of Cosmetic Safety En-
20 hancement Act of 2020, the Secretary shall issue a small
21 business guide setting forth in plain language the require-
22 ments of sections 605, 606, 609, and 810, as added by
23 the Cosmetic Safety Enhancement Act of 2020, in order
24 to assist small businesses in complying with such require-
25 ments.”.

1 **SEC. 110. ANIMAL TESTING RESTRICTIONS.**

2 (a) IN GENERAL.—Section 601 of the Federal Food,
3 Drug, and Cosmetic Act (21 U.S.C. 361), as amended by
4 section 103, is further amended by adding at the end the
5 following:

6 “(g) If the cosmetic product, cosmetic formulation,
7 or cosmetic ingredient was developed or manufactured
8 using an animal test that was conducted or contracted by
9 the manufacturer, or any affiliate or supplier of the manu-
10 facturer, unless one of the following applies:

11 “(1) With respect to a cosmetic ingredient of
12 the cosmetic product or cosmetic formulation, an
13 animal test is required by the Secretary to evaluate
14 the safety of such ingredient or formulation.

15 “(2) With respect to a cosmetic ingredient of
16 the cosmetic product or cosmetic formulation, the
17 cosmetic ingredient or cosmetic formulation is in
18 wide use and cannot be replaced by another ingre-
19 dient that is capable of performing a similar func-
20 tion without posing a potentially greater risk to
21 human health and there is not an alternative method
22 for testing the cosmetic ingredient that is accepted
23 by the Secretary and the Interagency Coordinating
24 Committee on Validation of Alternative Methods.

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

4 “(4) In the case of a cosmetic product, cosmetic
5 formulation, or cosmetic ingredient that is also a
6 drug, the animal test was conducted with respect to
7 the approval under chapter V of the application sub-
8 mitted with respect to such product, formulation, or
9 ingredient.

10 “(5) The animal test was conducted for pur-
11 poses not related to developing or manufacturing the
12 cosmetic product, cosmetic formulation, or cosmetic
13 ingredient, and in response to a requirement of a
14 Federal, State, or foreign regulatory authority.”.

15 (b) APPLICABILITY.—The amendment made by sub-
16 section (a) shall apply with respect to cosmetic products
17 or cosmetic formulations introduced or delivered for intro-
18 duction into interstate commerce on or after the date that
19 is two years after the date of enactment of this Act.

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

1 (d) RESOURCES REGARDING ANIMAL TESTING AL-
2 TERNATIVES.—Not later than 180 days after the date of
3 enactment of this Act, the Secretary shall publish informa-
4 tion on the internet website of the Food and Drug Admin-
5 istration regarding resources available for information
6 about non-animal methods, and methods that reduce ani-
7 mal usage, in testing for the safety of cosmetic products,
8 cosmetic formulations, and cosmetic ingredients.

9 (e) RULES OF CONSTRUCTION.—

10 (1) USE OF EVIDENCE.—Nothing in this sec-
11 tion, or the amendment made by this section, shall
12 be construed to prohibit any entity from reviewing,
13 assessing, or retaining evidence generated from ani-
14 mal testing.

15 (2) ACCEPTANCE OF DATA BY SECRETARY.—
16 Nothing in this section, or the amendment made by
17 this section, shall be construed to prohibit the Sec-
18 retary from accepting data from animal testing con-
19 ducted—

20 (A) prior to the date specified in sub-
21 section (b); or

22 (B) on or after such date—

23 (i) in the case of a cosmetic product,
24 cosmetic formulation, or cosmetic ingre-
25 dient that is also a drug, with respect to

1 the approval under chapter V of the Fed-
2 eral Food, Drug, and Cosmetic Act (21
3 U.S.C. 351 et seq.) of the application sub-
4 mitted with respect to such product, for-
5 mulation, or ingredient; or

6 (ii) pursuant to requirements of a
7 Federal, State, or foreign regulatory au-
8 thority.

9 **SEC. 111. COUNTERFEIT COSMETICS.**

10 (a) COUNTERFEIT COSMETICS DEFINED.—Section
11 201(i) of the Federal Food, Drug, and Cosmetic Act (21
12 U.S.C. 321(i)) is amended—

13 (1) by striking “(i) The term” inserting “(i)(1)
14 The term”;

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

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

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

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

23 “(A) bears the trademark, trade name, or other
24 identifying mark, imprint, or device, or any likeness
25 thereof, of a cosmetic manufacturer, processor, pack-

1 er, or distributor other than the person or persons
2 who in fact manufactured, processed, packed, or dis-
3 tributed such cosmetic; and

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

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

11 (1) in subparagraph (2)—

12 (A) by inserting “digital printer or tech-
13 nology,” after “stone,”;

14 (B) by inserting “cosmetic” after “drug
15 or”;

16 (C) by inserting before the period at the
17 end the following: “or such cosmetic a counter-
18 feit cosmetic”;

19 (2) in subparagraph (3)—

20 (A) by inserting “or a cosmetic to be a
21 counterfeit cosmetic” after “to be a counterfeit
22 drug”;

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

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

4 (1) by inserting “digital printer or technology”
5 after “stone,”;

6 (2) by inserting “or a cosmetic being a counter-
7 feit cosmetic” after “drug being a counterfeit drug”;
8 and

9 (3) by inserting before the period at the end the
10 following: “or the cosmetic was a counterfeit cos-
11 metic”.

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

15 (1) by striking “(B) Any container” and all
16 that follows through “(D) Any adulterated” and in-
17 serting “(B) Any cosmetic that is a counterfeit cos-
18 metic, (C) Any container of a counterfeit drug or
19 counterfeit cosmetic, (D) Any punch, die, plate,
20 stone, labeling, container, digital printer or tech-
21 nology, or other thing used or designed for use in
22 making a counterfeit drug or drugs or a counterfeit
23 cosmetic or cosmetics, (E) Any adulterated”; and

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

4 (e) EXAMINATIONS AND INVESTIGATIONS.—Section
5 702(e) of the Federal Food, Drug, and Cosmetic Act (21
6 U.S.C. 372(e)) is amended—

7 (1) in the matter preceding paragraph (1), by
8 inserting “or counterfeit cosmetics” after “counter-
9 feit drugs”;

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

12 (3) in paragraph (5)—

13 (A) by striking “drugs or containers” and
14 inserting “drugs, cosmetics, or containers”; and

15 (B) by inserting “digital printers or tech-
16 nologies,” after “labeling.”.

17 **SEC. 112. COSMETIC FOREIGN SUPPLIER VERIFICATION.**

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

21 **“SEC. 810. COSMETIC FOREIGN SUPPLIER VERIFICATION**
22 **PROGRAM.**

23 “(a) IN GENERAL.—

24 “(1) VERIFICATION REQUIREMENT.—Except as
25 provided under subsection (e), each importer shall

1 perform risk-based foreign supplier verification ac-
2 tivities for the purpose of verifying that the cosmetic
3 product or cosmetic ingredient imported by the im-
4 porter (or agent thereof)—

5 “(A) has been manufactured according to
6 the cosmetic product good manufacturing prac-
7 tices established under section 609; and

8 “(B) is not adulterated under section 601
9 or misbranded under section 602.

10 “(2) APPLICABILITY.—The requirements of this
11 subsection apply only to cosmetic products or cos-
12 metic ingredients that do not undergo furthering
13 manufacturing or processing according to cosmetic
14 product good manufacturing processes established
15 under section 609 following import into the United
16 States.

17 “(2) IMPORTER DEFINED.—For purposes of
18 this section, the term ‘importer’ means, with respect
19 to a cosmetic product or cosmetic ingredient—

20 “(A) the United States owner or consignee
21 of the cosmetic product or cosmetic ingredient
22 at the time of entry of such cosmetic product
23 or cosmetic ingredient into the United States;
24 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 into the United States.

7 “(b) GUIDANCE.—Not later than 1 year after the
8 date of enactment of the Cosmetic Safety Enhancement
9 Act of 2020, the Secretary shall issue guidance to assist
10 importers in developing cosmetic foreign supplier
11 verification programs, including to assist importers—

12 “(1) in identifying the cosmetic products and
13 cosmetic ingredients subject to the requirements of
14 subsection (a); and

15 “(2) in complying with the streamlined mecha-
16 nisms for compliance.

17 “(c) REGULATIONS.—

18 “(1) IN GENERAL.—Not later than 1 year after
19 the date of enactment of Cosmetic Safety Enhance-
20 ment Act of 2020, the Secretary shall promulgate
21 regulations to provide for the content of the foreign
22 supplier verification program established under sub-
23 section (a).

24 “(2) REQUIREMENTS.—The regulations promul-
25 gated under paragraph (1) shall require that the for-

1 eign supplier verification program of each importer
2 be adequate to provide assurances that each foreign
3 supplier to the importer produces the imported cos-
4 metic product or cosmetic ingredient in compliance
5 with—

6 “(A) cosmetic good manufacturing prac-
7 tices established under section 609; and

8 “(B) sections 601 and 602.

9 “(3) CONSIDERATIONS; STREAMLINED MECHA-
10 NISMS.—

11 “(A) IN GENERAL.—In promulgating regu-
12 lations under this subsection, the Secretary
13 shall, as appropriate—

14 “(i) take into account differences
15 among importers and types of imported
16 cosmetic products and cosmetic ingredi-
17 ents, including based on the level of risk
18 posed by the imported cosmetic product or
19 cosmetic ingredient;

20 “(ii) include streamlined mechanisms
21 for compliance for manufacturers and
22 processors whose name appears on the
23 label of a cosmetic product pursuant to
24 section 602 and that act as an importer of
25 their own products.

1 “(B) STREAMLINED MECHANISMS.—The
2 streamlined mechanisms of compliance referred
3 to in subparagraph (A)(ii) shall apply to cos-
4 metic products that are manufactured pursuant
5 to the requirements of section 609 and—

6 “(i) whose importer has retained an
7 export certificate from a country with a
8 regulatory system that the Secretary has
9 determined to be equivalent to that of the
10 United States pursuant to the Federal
11 Register notice described in subsection (e);

12 “(ii) whose importer has retained a
13 record of inspection of the facility where
14 the cosmetic products were manufactured
15 by a foreign regulatory authority of a
16 country with a regulatory system that the
17 Secretary has determined to be equivalent
18 to that of the United States in such a no-
19 tice,

20 “(iii) whose importer retains records
21 in compliance with section 609 and makes
22 such records available upon request by the
23 Secretary; or

1 “(iv) that satisfies such other criteria
2 as the Secretary determines appropriate to
3 document compliance with section 609.

4 “(4) ACTIVITIES.—Verification activities under
5 a cosmetic foreign supplier verification program
6 under this section may include review of third-party
7 facility audits or regulatory inspection history, moni-
8 toring records for shipments, lot-by-lot certification
9 of compliance, annual onsite inspections, review of
10 records demonstrating compliance with cosmetic
11 good manufacturing practices and other safety proc-
12 esses, and periodically testing and sampling ship-
13 ments.

14 “(d) RECORD MAINTENANCE AND ACCESS.—Records
15 of an importer related to a cosmetic foreign supplier
16 verification program shall—

17 “(1) be maintained for a period of not less than
18 2 years; and

19 “(2) be made available promptly to a duly au-
20 thorized representative of the Secretary upon re-
21 quest.

22 “(e) EXEMPTIONS.—The Secretary, by notice pub-
23 lished in the Federal Register—

24 “(1) shall establish an exemption from the re-
25 quirements of this section for cosmetic products or

1 cosmetic ingredients imported in small quantities for
2 research and evaluation purposes or for personal
3 consumption, provided that such cosmetic products
4 or cosmetic ingredients are not intended for retail
5 sale and are not sold or distributed to the public;
6 and

7 “(2) may exempt other cosmetic products or
8 cosmetic ingredients from the requirements of this
9 section if such products or ingredients are imported
10 from a country determined by the Secretary to have
11 a cosmetic regulatory system equivalent to that of
12 the United States.

13 “(f) PUBLICATION OF LIST OF PARTICIPANTS.—The
14 Secretary shall publish and maintain on the internet
15 website of the Food and Drug Administration a current
16 list that includes the name of, location of, and other infor-
17 mation deemed necessary by the Secretary about, import-
18 ers participating under this section.”.

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

23 “(ggg) The importation or offering for importation
24 of a cosmetic product or cosmetic ingredient if the im-
25 porter (as defined in section 810) does not have in place

1 a foreign supplier verification program in compliance with
2 such section 810.”.

3 (c) IMPORTS.—Section 801(a) of the Federal Food,
4 Drug, and Cosmetic Act (21 U.S.C. 381(a)) is amended
5 by striking “or the importer (as defined in section 805)
6 is in violation of such section 805” and inserting “, or
7 being imported or offered for import into the United
8 States by an importer (as defined in section 805 or 810,
9 as applicable) that is in violation of section 805 or 810,
10 respectively”.

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

14 **SEC. 113. APPLICABILITY WITH RESPECT TO CERTAIN COS-**
15 **METICS.**

16 Chapter VI of the Federal Food, Drug, and Cosmetic
17 Act (21 U.S.C. 361 et seq.), as amended by section 107,
18 is further amended by adding at the end the following:

19 **“SEC. 616. APPLICABILITY WITH RESPECT TO CERTAIN**
20 **PRODUCTS.**

21 “(a) DRUGS.—In the case of a cosmetic product or
22 a facility that is subject to the requirements under this
23 chapter and chapter V, if any requirement under chapter
24 V with respect to such cosmetic or facility is substantially
25 similar to a requirement under this chapter, the cosmetic

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

7 “(b) SOAP.—In the case of a product that meets the
8 definition of a soap under section 604, the requirements
9 of this chapter shall not apply with respect to that product
10 so long as the product continues to meet that definition.”.

11 **SEC. 114. SAVING CLAUSE.**

12 Chapter VI of the Federal Food, Drug, and Cosmetic
13 Act (21 U.S.C. 361 et seq.), as amended by section 113,
14 is further amended by adding the following:

15 **“SEC. 617. SAVINGS CLAUSE.**

16 “Nothing in the amendments to this Act made by the
17 Cosmetic Safety Enhancement Act of 2020, nor any
18 standard, rule, requirement, regulation, adverse event re-
19 port, safety assessment, safety determination, scientific
20 assessment, or order issued or implemented pursuant to
21 such amendments, shall be construed to modify or other-
22 wise affect, preempt, or displace any cause of action or
23 State or Federal law creating a remedy for civil relief or
24 criminal cause of action, whether statutory or based in
25 common law.”.

1 **SEC. 115. ENFORCEMENT.**

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

5 (1) in paragraph (e)—

6 (A) by striking “504, 564,” and inserting
7 “504, 564, 610, 611”; and

8 (B) by striking “519, 564,” and inserting
9 “519, 564, 609, 610,”;

10 (2) in paragraph (j) by inserting “607, 608,
11 609, 610” before “704”;

12 (3) in paragraph (ii)—

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

15 (B) by striking “760 or 761) submitted”
16 and inserting “610, 760, or 761) submitted”;

17 (4) in paragraph (xx), by inserting “or 612”
18 after “423”; and

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

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

1 (b) ADULTERATION.—Section 601 of the Federal
2 Food, Drug, and Cosmetic Act (21 U.S.C. 361), as
3 amended by section 110, is further amended by adding
4 at the end the following:

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

11 “(i) If it is a cosmetic product or cosmetic formula-
12 tion for which assurances regarding safety substantiation
13 have not been submitted under section 605(e)(2)(K).”.

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

17 (1) in paragraph (b)—

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

20 (B) by inserting “; and (3) a domestic ad-
21 dress or a domestic telephone number, or elec-
22 tronic contact information, through which the
23 responsible person may receive a report of an
24 adverse event associated with the use of such
25 cosmetic product” after “numerical count”; and

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

2 “(h) If it is a cosmetic product or cosmetic formula-
3 tion for which assurances regarding safety substantiation
4 have not been submitted under section 605(e)(2)(K) .

5 “(i) If a fragrance ingredient described in section 614
6 is not disclosed to consumers through a method identified
7 by the Food and Drug Administration in the guidance doc-
8 ument issued under such section.

9 “(j) If its labeling does not conform with a require-
10 ment under section 613.”.

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

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

21 (1) by striking “section 760 or 761” the first,
22 third, and fourth place such term appears and in-
23 serting “section 610, 760, or 761”; and

24 (2) by striking “760 or 761)” and inserting
25 “604, 760, or 761)”.

1 (f) FACILITY INSPECTION.—Section 704(a)(1) of the
2 Federal Food, Drug, and Cosmetic Act (21 U.S.C.
3 374(a)(1)) is amended by inserting after the third sen-
4 tence the following: “In the case of any person who manu-
5 factures, processes, packs, holds, distributes, or imports
6 a cosmetic product, or distributes a cosmetic product and
7 affixes its name on the cosmetic label, the inspection shall
8 extend to all records and other information described in
9 section 611 (regarding inspection of cosmetic records),
10 subject to the limitations under of such section.”.

11 **TITLE II—FEES RELATED TO** 12 **COSMETIC PRODUCTS**

13 **SEC. 201. FINDINGS.**

14 The Congress finds that the fees authorized by the
15 amendment made by section 202 of this Act will be dedi-
16 cated to cosmetic safety activities, as defined in section
17 744L of the Federal Food, Drug, and Cosmetic Act, as
18 added by such section 202. Such fees should supplement,
19 not supplant, funding dedicated to cosmetic safety activi-
20 ties of the Food and Drug Administration. Future fees
21 authorized by the reauthorization of part 10 of subchapter
22 C of chapter VII of the Federal Food, Drug, and Cosmetic
23 Act to be collected by the Secretary of Health and Human
24 Services should be dedicated to cosmetic safety activities
25 as set forth in the goals identified for purposes of such

1 part 10, in the letters from the Secretary of Health and
2 Human Services to the Chairman of the Committee on
3 Energy and Commerce of the House of Representatives
4 and the Chairman of the Committee on Health, Edu-
5 cation, Labor, and Pensions of the Senate, as set forth
6 in the Congressional Record.

7 **SEC. 202. AUTHORITY TO ASSESS AND USE COSMETIC**
8 **PRODUCT FEES.**

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

12 **“PART 10—FEES RELATING TO COSMETIC**
13 **PRODUCTS**

14 **“SEC. 744L. DEFINITIONS.**

15 “For the purposes of this part:

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

22 “(2) **COSMETIC FORMULATION.**—The term ‘cos-
23 metic formulation’ has the meaning given to such
24 term in section 604.

1 “(3) 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 “(4) COSMETIC PRODUCT.—The term ‘cosmetic
10 product’ has the meaning given to such term in sec-
11 tion 604.

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

14 “(A) means activities of the Secretary re-
15 lated to compliance by responsible persons re-
16 quired to register under section 605 with re-
17 spect to cosmetics, including administrative ac-
18 tivities, such as—

19 “(i) information technology acquisi-
20 tion, management, maintenance, and sup-
21 port;

22 “(ii) the acquisition, administration,
23 and maintenance of the cosmetic registra-
24 tion system under section 605 and the cos-

1 metic ingredient statement system under
2 section 606;

3 “(iii) fee assessment and collection
4 under this part; and

5 “(iv) the acquisition, leasing, mainte-
6 nance, renovation, and repair of facilities,
7 fixtures, furniture, scientific equipment,
8 and other necessary materials and supplies
9 for purposes of clauses (i) through (iii);

10 “(B) includes activities of the Secretary re-
11 lated to implementation of section 608, regard-
12 ing the review of cosmetic ingredients and non-
13 functional constituents and related meetings
14 with regulated industry regarding determination
15 made under such section;

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

18 “(D) includes activities of the Secretary re-
19 lated to implementation and enforcement, such
20 as the establishment of good manufacturing
21 practices, the review of adverse event reports,
22 inspection planning and inspections, and use of
23 enforcement tools; and

1 “(E) includes activities of the Secretary re-
2 lated other issues related to implementation of
3 the Cosmetic Safety Enhancement Act of 2020.

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

10 “(7) MANUFACTURER.—The term ‘manufac-
11 turer’ means the manufacturer, packer, or dis-
12 tributor whose name appears on the label of a cos-
13 metic product marketed in the United States pursu-
14 ant to section 602. If more than one name of a man-
15 ufacturer, packer, or distributor appears on the label
16 of such cosmetic product, the ‘manufacturer’ shall be
17 the brand owner. All affiliates shall be considered
18 one manufacturer for the purpose of this term. Sub-
19 ject to the exemption in the subsequent sentence,
20 each cosmetic product marketed in the United
21 States shall have a ‘manufacturer’ for the purposes
22 of this section. Such term does not include—

23 “(A) beauty shops, beauty stores, retail
24 counters, and salons that do not otherwise man-
25 ufacture or process cosmetic products or cos-

1 metic formulations at that location, including
2 those that offer customized or personalized cos-
3 metic products or cosmetic formulations tai-
4 lored to individual consumers for sale solely in-
5 person;

6 “(B) cosmetic product retailers, including
7 individual sales representatives, direct sellers
8 (as defined in section 3508 of the Internal Rev-
9 enue Code of 1986), retail distribution facilities,
10 retail franchises, retail warehouses, and phar-
11 macies, that do not otherwise manufacture or
12 process cosmetic products or cosmetic formula-
13 tions at that location;

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

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

20 “(E) hotels, airlines, and other entities
21 that provide complimentary cosmetic products
22 to guests;

23 “(F) public health agencies and other non-
24 profit entities that provide cosmetic products or

1 cosmetic formulations directly to the consumer;
2 and

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

6 “(8) TIER 6 MANUFACTURER.—The term ‘Tier
7 6 manufacturer’ means any entity that manufactures
8 cosmetic products for sale or distribution in the
9 United States and has gross annual sales of over
10 \$4,000,000,000.

11 “(9) TIER 5 MANUFACTURER.—The term ‘Tier
12 5 manufacturer’ means any entity that manufac-
13 tures cosmetic products for sale or distribution in
14 the United States and has gross annual sales that
15 are not more than \$4,000,000,000 and over
16 \$1,000,000,000.

17 “(10) TIER 4 MANUFACTURER.—The term ‘Tier
18 4 manufacturer’ means any entity that manufac-
19 tures cosmetic products for sale or distribution in
20 the United States and has gross annual sales that
21 are not more than \$1,000,000,000 and over
22 \$500,000,000.

23 “(11) TIER 3 MANUFACTURER.—The term ‘Tier
24 3 manufacturer’ means any entity that manufac-
25 tures cosmetic products for sale or distribution in

1 the United States and has gross annual sales that
2 are not more than \$500,000,000 and over
3 \$100,000,000.

4 “(12) TIER 2 MANUFACTURER.—The term ‘Tier
5 2 manufacturer’ means any entity that manufac-
6 tures cosmetic products for sale or distribution in
7 the United States and has gross annual sales that
8 are not more than \$100,000,000 and over
9 \$30,000,000.

10 “(13) TIER 1 MANUFACTURER.—The term ‘Tier
11 1 manufacturer’ means any entity that manufac-
12 tures cosmetic products for sale or distribution in
13 the United States and has gross annual sales that
14 are not more than \$30,000,000 and over
15 \$1,000,000.

16 **“SEC. 744M. COSMETIC PRODUCT FEE.**

17 “(a) ASSESSMENT AND COLLECTION.—

18 “(1) IN GENERAL.—Beginning in fiscal year
19 2020 and ending in fiscal year 2027, the Secretary
20 shall in accordance with this section assess and col-
21 lect an annual fee from every manufacturer that
22 markets cosmetic products in the United States dur-
23 ing the relevant fiscal year.

24 “(2) PAYABLE DATE.—An annual fee under
25 this section shall be paid only once for each manu-

1 manufacturer, including all affiliates of such manufac-
2 turer, for a fiscal year in which the fee is payable.

3 Fees under this section shall be due and payable—

4 “(A) for fiscal year 2020, with respect to
5 manufacturers as described in paragraph (1)
6 for such first program year, on the date during
7 such fiscal year as set forth by the Secretary in
8 the Federal Register; and

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

11 “(i) the first business day on or after
12 October 1 of such fiscal year; or

13 “(ii) the first business day after the
14 enactment of an appropriations Act pro-
15 viding for the collection and obligation of
16 fees for such fiscal year under this section.

17 “(b) ONE-TIME IDENTIFICATION OF MANUFACTUR-
18 ERS FOR PURPOSES OF APPORTIONING FEES.—

19 “(1) REQUIRED IDENTIFICATION OF MANUFAC-
20 TURERS.—Not later than the date that is 120 days
21 after enactment of the Cosmetic Safety Enhance-
22 ment Act of 2020, each manufacturer that markets
23 a cosmetic product in the United States on such
24 date shall submit to the Secretary the information
25 required under this notification.

1 “(2) INFORMATION REQUIRED TO BE SUB-
2 MITTED.—At a minimum, the submission required
3 by paragraph (1) shall include for each such respon-
4 sible person—

5 “(A) the gross annual sales of such manu-
6 facturer. of cosmetic products or cosmetic for-
7 mulations for the previous 3 fiscal years as will
8 be reported in the first registration under sec-
9 tion 605 for such responsible person, and an as-
10 sessment of which tier as defined in subsection
11 (a) such manufacturer qualifies for the pur-
12 poses of subsection (c)(3)(A);

13 “(B) identification of facilities where such
14 responsible person’s cosmetic products or cos-
15 metic formulations are manufactured, which
16 cosmetic products or cosmetic formulations are
17 manufactured there, and any other products
18 regulated under this Act that the facility manu-
19 factures;

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

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

24 “(2) NOTICE.—The Secretary may, by notice
25 published in the Federal Register, specify the means

1 and format for submission of the information under
2 paragraph (1) and may specify, as necessary for
3 purposes of this section, any additional information
4 relevant to setting the annual fee under this section
5 to be submitted.

6 “(c) FEE SETTING AND AMOUNTS.—

7 “(1) IN GENERAL.—Subject to subsection (d),
8 the Secretary shall establish the fees to be collected
9 under this section for each of fiscal years 2020 to
10 2027, based on the methodology described in para-
11 graph (3), and shall publish such fees in each fiscal
12 year after fiscal year 2020 in a Federal Register no-
13 tice not later than 60 days before the beginning of
14 each such fiscal year. For fiscal year 2020, the Sec-
15 retary shall publish the fees 150 days after the date
16 of enactment of the Cosmetic Safety Enhancement
17 Act of 2020.

18 “(2) FEE EXEMPTION.—Any manufacturer
19 whose average gross annual sales of cosmetic prod-
20 ucts in the 3 fiscal years immediately preceding the
21 fiscal year for which the annual fee will be paid was
22 not more than \$1,000,000, shall be exempt from
23 fees under this section for that fiscal year.

24 “(3) ANNUAL FEE SETTING.—

1 “(A) FEE SETTING.—For each of fiscal
2 years 2020 to 2027, the amount of the registra-
3 tion fee under subsection (a) shall be appor-
4 tioned as follows:

5 “(i) Thirty-five percent shall be de-
6 rived from fees from Tier 6 and Tier 5
7 manufacturers.

8 “(ii) Fifty percent shall be derived
9 from fees from Tier 3 and 4 manufactur-
10 ers.

11 “(iii) Fifteen percent shall be derived
12 from fees from Tier 1 and 2 manufactur-
13 ers.

14 “(B) TOTAL REVENUE.—The Secretary
15 shall establish the fee amounts for each fiscal
16 year in accordance with subparagraph (A), in
17 order to generate a total estimated revenue of—

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

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

20 “(iii) \$ 35,000,000 for fiscal years
21 2022 to 2023; and

22 “(iv) \$46,000,000 for each of fiscal
23 years through 2027.

24 “(d) ADJUSTMENTS.—

25 “(1) INFLATION ADJUSTMENTS.—

1 “(A) ADJUSTMENT TO TOTAL REVENUE
2 AMOUNTS.—For fiscal year 2022 and each sub-
3 sequent fiscal year, the Secretary shall adjust
4 the total revenue amount specified in subsection
5 (c)(3) for such fiscal year by multiplying such
6 amount by the applicable inflation adjustment
7 under subparagraph (B) for such year.

8 “(B) APPLICABLE INFLATION ADJUST-
9 MENT.—The applicable inflation adjustment for
10 fiscal year 2022 and each subsequent fiscal
11 year through fiscal year 2027 is the product
12 of—

13 “(i) the base inflation adjustment
14 under subparagraph (C) for such fiscal
15 year; and

16 “(ii) the product of the base inflation
17 adjustment under subparagraph (C) for
18 each of the fiscal years preceding such fis-
19 cal year, beginning with fiscal year 2020.

20 “(C) BASE INFLATION ADJUSTMENT.—

21 “(i) IN GENERAL.—Subject to further
22 adjustment under clause (ii), the base in-
23 flation adjustment for a fiscal year is the
24 sum of one plus—

1 “(I) the average annual percent
2 change in the cost, per full-time equiv-
3 alent position of the Food and Drug
4 Administration, of all personnel com-
5 pensation and benefits paid with re-
6 spect to such positions for the first
7 fiscal years of the preceding fiscal
8 years, multiplied by 0.60; and

9 “(II) the average annual percent
10 change that occurred in the Consumer
11 Price Index for urban consumers
12 (Washington-Arlington-Alexandria;
13 Not Seasonally Adjusted; All items;
14 Annual Index) for the first 3 fiscal
15 years of the preceding 4 years of
16 available data multiplied by 0.40.

17 “(ii) LIMITATIONS.—For purposes of
18 subparagraph (B), if the base inflation ad-
19 justment for a fiscal year under clause
20 (i)—

21 “(I) is less than 1, such adjust-
22 ment shall be considered to be equal
23 to 1; or

1 “(II) is greater than 1.04, such
2 adjustment shall be considered to be
3 equal to 1.04.

4 “(2) FINAL YEAR ADJUSTMENT.—For fiscal
5 year 2027, the Secretary may, in addition to adjust-
6 ments under paragraph (1), further increase the fee
7 revenues and fees established in subsection (c) if
8 such an adjustment is necessary to provide for not
9 more than 3 months of operating reserves of carry-
10 over fees for cosmetic safety activities for the first
11 3 months of fiscal year 2028. If such an adjustment
12 is necessary, the rationale for the increase shall be
13 contained in the annual Federal Register notice es-
14 tablishing fees for fiscal year 2027. If the Food and
15 Drug Administration has carryover balances for
16 such activities in excess of 3 months of such oper-
17 ating reserves, the adjustment under this paragraph
18 shall not be made.

19 “(e) LIMITATIONS.—

20 “(1) IN GENERAL.—With respect to the amount
21 that is appropriated for a fiscal year for the cos-
22 metics program of the Center for Food Safety and
23 Applied Nutrition of the Food and Drug Administra-
24 tion and related field activities, fees may not be as-
25 sessed under subsection (a) for the fiscal year unless

1 the amount so appropriated (excluding the amount
2 of fees appropriated for the fiscal year), is equal to
3 or greater than the amount that is appropriated for
4 such program for fiscal year 2019, multiplied by the
5 adjustment factor applicable to the fiscal year in-
6 volved. If the amount so appropriated prevents the
7 Secretary from assessing fees under subsection (a),
8 the Secretary is not required to carry out any activi-
9 ties described in section 608 until such time the Sec-
10 retary again assesses fees in a fiscal year under sub-
11 section (a).

12 “(2) AUTHORITY.—If the Secretary does not
13 assess fees under subsection (a) during any portion
14 of a fiscal year because of paragraph (1) and if at
15 a later date in such fiscal year the Secretary may as-
16 sess such fees, the Secretary may assess and collect
17 such fees, without any modification in the rate, at
18 any time in such fiscal year by providing notice of
19 no less than 60 days in the Federal Register.

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

21 “(1) IN GENERAL.—Fees authorized under sub-
22 section (a) shall be collected and available for obliga-
23 tion only to the extent and in the amount provided
24 in advance in appropriations Acts. Such fees are au-
25 thorized to remain available until expended. Such

1 sums as may be necessary may be transferred from
2 the Food and Drug Administration salaries and ex-
3 penses appropriation account without fiscal year lim-
4 itation to such appropriation account for salaries
5 and expenses with such fiscal year limitation. The
6 sums transferred shall be available solely for cos-
7 metic safety activities.

8 “(2) COLLECTIONS AND APPROPRIATIONS
9 ACTS.—

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

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

21 “(C) FEE COLLECTIONS DURING FIRST
22 PROGRAM YEAR.—Until the date of enactment
23 of appropriations through September 30, 2020,
24 for the ‘Food and Drug Administration—Sala-
25 ries and Expenses’ account, fees authorized by

1 this section for fiscal year 2020 may be col-
2 lected, and any fees so collected shall be cred-
3 ited to such account, to remain available until
4 expended.

5 “(D) STARTUP COSTS.—Until one year
6 after the Secretary begins collecting user fees
7 under subsection (a), any amounts available for
8 the Center for Food Safety and Applied Nutri-
9 tion and related field activities (excluding user
10 fees) shall be available and allocated as needed
11 to pay the costs of any cosmetic safety activities
12 not authorized before enactment of the Cos-
13 metic Safety Enhancement Act of 2020.

14 “(E) REIMBURSEMENT OF STARTUP
15 AMOUNTS.—

16 “(i) IN GENERAL.—Any amounts allo-
17 cated for the startup period pursuant to
18 subparagraph (D) shall be reimbursed
19 through any appropriated fees collected
20 under subsection (a), in such manner as
21 the Secretary determines appropriate to
22 ensure that such allocation results in no
23 net change in the total amount of funds
24 otherwise available, for a period not to ex-
25 ceed two years after the Secretary begins

1 collecting user fees under subsection (a),
2 for the Center for Food Safety and Applied
3 Nutrition and related field activities (other
4 than cosmetic safety activities and related
5 field activities funded through such alloca-
6 tion) for such period. This paragraph shall
7 not be construed to authorize the Secretary
8 to assess any fees in any amounts greater
9 than otherwise authorized under subsection
10 (c)(3).

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

22 “(3) AUTHORIZATION OF APPROPRIATIONS.—
23 There are authorized to be appropriated for fees
24 under this section the following:

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

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

2 “(C) \$ 35,000,000 for fiscal years 2022
3 through 2023; and

4 “(D) \$46,000,000 for each of fiscal years
5 2024 through 2027.

6 “(g) EFFECT OF FAILURE TO PAY FEES.—The Sec-
7 retary shall not consider a registration by a manufacturer
8 submitted under section to be complete until all fees owed
9 by such manufacturer under subsection (a) are paid. Until
10 the fees are paid, the registration is incomplete and the
11 responsible person is deemed to have failed to register in
12 accordance with section 605.

13 “(h) COLLECTION OF UNPAID FEES.—In any case
14 where the Secretary does not receive payment of a fee as-
15 sessed under subsection (a), such fee shall be treated as
16 a claim of the United States Government subject to sub-
17 chapter II of chapter 37 of title 31, United States Code.

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

1 “(j) RECORDS.—Each responsible person that is re-
2 quired to register under section 605 shall retain all records
3 necessary to demonstrate gross annual sales for at least
4 2 fiscal years after such information is reported in its reg-
5 istration. Such records shall be made available to the Sec-
6 retary for review and duplication upon request of the Sec-
7 retary.

8 “(k) LIMITATION.—This part does not authorize the
9 assessment or collection of a fee for registration under sec-
10 tion 605 occurring after fiscal year 2025.”.

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

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

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

18 “The Secretary shall have direct hiring authority with
19 respect to the appointment of employees into the competi-
20 tive service or the excepted service to administer the Cos-
21 metic Safety Enhancement Act of 2020 and the amend-
22 ments made thereby.

1 **“SEC. 7440. REPORTING REQUIREMENTS; REAUTHORIZA-**
2 **TION.**

3 “(a) **PERFORMANCE REPORT.**—Beginning with fiscal
4 year 2021, and not later than 120 calendar days after the
5 end of each fiscal year thereafter for which fees are col-
6 lected under this part, the Secretary shall prepare and
7 submit to the Committee on Energy and Commerce of the
8 House of Representatives and the Committee on Health,
9 Education, Labor, and Pensions of the Senate a report
10 concerning the progress of the Food and Drug Adminis-
11 tration on cosmetic safety activities during such fiscal
12 year, including the future plans of the Food and Drug Ad-
13 ministration for such activities.

14 “(b) **FISCAL REPORT.**—Not later than 120 calendar
15 days after the end of fiscal year 2021 and each subsequent
16 fiscal year for which fees are collected under this part,
17 the Secretary shall prepare and submit to the Committee
18 on Energy and Commerce of the House of Representatives
19 and the Committee on Health, Education, Labor, and
20 Pensions of the Senate a report on the implementation
21 of the authority for such fees during such fiscal year and
22 the use, by the Food and Drug Administration, of the fees
23 collected for such fiscal year.

24 “(c) **PUBLIC AVAILABILITY.**—The Secretary shall
25 make the reports required under subsections (a) and (b)

1 available to the public on the internet website of the Food
2 and Drug Administration.

3 “(d) REAUTHORIZATION.—

4 “(1) CONSULTATION.—In developing rec-
5 ommendations to present to the Congress with re-
6 spect to performance goals developed by the Food
7 and Drug Administration, and plans for meeting the
8 goals, for cosmetic safety activities for the first 5 fis-
9 cal years after fiscal year 2027, and for the reau-
10 thORIZATION of this part for such fiscal years, the Sec-
11 retary shall consult with—

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

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

16 “(C) scientific and academic experts;

17 “(D) health care professionals;

18 “(E) representatives of public health and
19 consumer advocacy groups; and

20 “(F) the regulated industry.

21 “(2) PUBLIC REVIEW OF RECOMMENDA-
22 TIONS.—After negotiations with the regulated indus-
23 try, the Secretary shall—

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

4 “(B) publish such recommendations in the
5 Federal Register;

6 “(C) provide for a period of 30 calendar
7 days for the public to provide written comments
8 on such recommendations;

9 “(D) hold a meeting at which the public
10 may present its views on such recommenda-
11 tions; and

12 “(E) after consideration of such public
13 views and comments, revise such recommenda-
14 tions as necessary.

15 “(3) TRANSMITTAL OF RECOMMENDATIONS.—
16 Not later than January 15, 2026, the Secretary
17 shall transmit to the Congress the revised rec-
18 ommendations under paragraph (2), a summary of
19 the views and comments received under such para-
20 graph, and any changes made to the recommenda-
21 tions in response to such views and comments.”.

22 **SEC. 204. SUNSET DATES.**

23 (a) AUTHORIZATION.—Sections 744L, 744M, and
24 744N of the Federal Food, Drug, and Cosmetic Act, as

1 added by section 202, shall cease to be effective October
2 1, 2027.

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

