

116TH CONGRESS
1ST SESSION

H. R. 4296

To amend title VI of the Federal Food, Drug, and Cosmetic Act to ensure the safe use of cosmetics, and for other purposes.

IN THE HOUSE OF REPRESENTATIVES

SEPTEMBER 12, 2019

Ms. SCHAKOWSKY (for herself, Mr. SEAN PATRICK MALONEY of New York, Ms. LEE of California, Mr. TED LIEU of California, Mr. GRIJALVA, Ms. DELAURO, Mr. HUFFMAN, Ms. PRESSLEY, Mr. HASTINGS, Mr. LOWENTHAL, Ms. JUDY CHU of California, Ms. SPEIER, Ms. JAYAPAL, Ms. DEGETTE, Ms. PINGREE, Ms. MATSUI, and Ms. WASSERMAN SCHULTZ) introduced the following bill; which was referred to the Committee on Energy and Commerce, and in addition to the Committee on Education and Labor, for a period to be subsequently determined by the Speaker, in each case for consideration of such provisions as fall within the jurisdiction of the committee concerned

A BILL

To amend title VI of the Federal Food, Drug, and Cosmetic Act to ensure the safe use of cosmetics, and for other purposes.

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

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

4 (a) SHORT TITLE.—This Act may be cited as the
5 “Safe Cosmetics and Personal Care Products Act of
6 2019”.

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

Sec. 1. Short title; table of contents.

Sec. 2. Cosmetic regulation.

“SUBCHAPTER A—ADULTERATED AND MISBRANDED COSMETICS

“SUBCHAPTER B—REGULATION OF COSMETICS

“Sec. 611. Definitions.

“Sec. 612. Registration of establishments and registration fees.

“Sec. 613. Ingredients labels and website disclosure for cosmetics.

“Sec. 614. Safety standard and good manufacturing practices.

“Sec. 615. Cosmetic and ingredient safety information.

“Sec. 616. Lists of ingredients and required responses.

“Sec. 617. Treatment of cosmetics based on ingredient lists.

“Sec. 618. Treatment of contaminants.

“Sec. 619. Cosmetic and ingredient statements.

“Sec. 620. Notification, nondistribution, and recall of adulterated or misbranded cosmetics.

“Sec. 621. Petitions.

“Sec. 622. Mandatory reporting of serious adverse events.

“Sec. 623. Nonconfidential information.

“Sec. 624. Ban on use of animal testing.

“Sec. 625. Product testing and review audit.

“Sec. 626. Resources for small businesses.

“Sec. 627. Interagency cooperation.

“Sec. 628. Savings clause.

“Sec. 629. Authorization of appropriations.

Sec. 3. Adulterated and misbranded cosmetics.

Sec. 4. Support for creating safer alternatives.

Sec. 5. Support by National Institute of Environmental Health Sciences for research on health disparities impacting communities of color.

“Sec. 463C. Research on health disparities related to cosmetics impacting communities of color.

Sec. 6. Worker issues.

3 SEC. 2. COSMETIC REGULATION.

Chapter VI of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 361 et seq.) is amended—

(1) by inserting before section 601 the following:

“Subchapter A—Adulterated and Misbranded Cosmetics”;

and

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

2 **“Subchapter B—Regulation of Cosmetics**

3 **“SEC. 611. DEFINITIONS.**

4 “In this subchapter:

5 “(1) BRAND OWNER.—The term ‘brand owner’
6 means the entity responsible for bringing a cosmetic
7 to market.

8 “(2) CONTAMINANT.—The term ‘contaminant’
9 means unintended substances, such as those that
10 can originate from sources outside the chemical
11 pathway, chemical processes, storage of primary sub-
12 stances, instability of the packaging or harmful by-
13 products of the manufacturing process.

14 “(3) DOMESTIC ESTABLISHMENT.—The term
15 ‘domestic establishment’ means an establishment lo-
16 cated in any State that brings a cosmetic to market.

17 “(4) FOREIGN ESTABLISHMENT.—The term
18 ‘foreign establishment’ means an establishment that
19 brings a cosmetic to market and exports those cos-
20 metics to the United States.

21 “(5) INGREDIENT.—The term ‘ingredient’
22 means a chemical in a cosmetic, including—

23 “(A) chemicals that have a technical or
24 functional effect in the cosmetic, including the
25 breakdown products of an intentionally added

1 chemical that also have a functional or technical
2 effect in the cosmetic;

3 “(B) substances that are present by reason
4 of having been added to a cosmetic during proc-
5 essing for their technical or functional effect;

6 “(C) the components of a fragrance, flavor,
7 preservative, or colorant; and

8 “(D) any individual component that the
9 Secretary deems an ingredient for purposes of
10 this chapter.

11 “(6) MANUFACTURER.—The term ‘manufac-
12 turer’ means the entity that produces ingredients or
13 combines one or more ingredients to produce a cos-
14 metic product.

15 “(7) MICROBUSINESS.—The term ‘microbusi-
16 ness’ means a business—

17 “(A) that is a brand owner as defined in
18 this subchapter; and

19 “(B) that has annual sales receipts for cos-
20 metic products that do not exceed \$1,000,000.

21 “(8) PROFESSIONAL USE.—The term ‘profes-
22 sional use’ means—

23 “(A) the application of a cosmetic to a
24 human customer or client by an employee or
25 contractor of a hair salon, nail salon, beauty

1 salon, spa, or other establishment within the
2 scope of the work conducted by such employee
3 or contractor; or

4 “(B) the use by or application to a human
5 of a cosmetic purchased from a hair salon, nail
6 salon, beauty salon, spa, or other establishment
7 that provides cosmetic treatment services for
8 humans.

9 “(9) REASONABLE CERTAINTY OF NO HARM.—
10 With respect to an ingredient or cosmetic, the term
11 ‘reasonable certainty of no harm’ means that no
12 harm will be caused to members of the general popu-
13 lation or any vulnerable population by aggregate ex-
14 posure to the cosmetic or ingredient, taking into ac-
15 count possible harmful effects from—

16 “(A) low-dose exposures to the cosmetic or
17 ingredient;

18 “(B) additive effects resulting from re-
19 peated exposure to the cosmetic or ingredient
20 over time; or

21 “(C) cumulative exposure resulting from
22 all sources, including both the cosmetic or in-
23 gredient and environmental sources.

24 “(10) REPRODUCTIVE OR DEVELOPMENTAL
25 TOXICITY.—With respect to an ingredient or cos-

1 metetic, the term ‘reproductive or developmental tox-
2 icity’ means that the ingredient or cosmetic can con-
3 tribute to biologically adverse effects on the develop-
4 ment of humans or animals, including effects on the
5 female or male reproductive system, the endocrine
6 system, fertility, pregnancy, pregnancy outcomes, or
7 modifications in other functions of the body that are
8 dependent on the integrity of the reproductive sys-
9 tem as well as normal fetal development.

10 “(11) SERIOUS ADVERSE EVENT.—The term
11 ‘serious adverse event’ means—

12 “(A) an acute or chronic response that re-
13 sults in death, a life-threatening experience,
14 short- or long-term hospitalization, a persistent
15 or significant disability or incapacity, a con-
16 genital anomaly or birth defect, serious and
17 persistent rashes or infections, significant hair
18 loss, permanent or significant alteration of ap-
19 pearance, or impacts to maternal health, includ-
20 ing placenta previa, gestational diabetes, and
21 miscarriage;

22 “(B) an event that requires, based on a
23 reasonable medical judgment, a medical or sur-
24 gical intervention; or

1 “(C) any other serious adverse health-re-
2 lated event associated with the use of the prod-
3 uct.

4 “(12) SUPPLIER.—The term ‘supplier’ means
5 the entity that supplies ingredients, raw materials,
6 or specific components of a cosmetic or cosmetic
7 packaging.

8 “(13) VULNERABLE POPULATIONS.—The term
9 ‘vulnerable populations’ includes pregnant women,
10 infants, children, the elderly, individuals with a com-
11 promised immune system, and highly exposed popu-
12 lations including workers in a hair salon, nail salon,
13 beauty salon, spa, or cosmetic manufacturing plant.

14 **“SEC. 612. REGISTRATION OF ESTABLISHMENTS AND REG-**
15 **ISTRATION FEES.**

16 “(a) REGISTRATION.—

17 “(1) IN GENERAL.—Beginning 1 year after the
18 date of the enactment of this subchapter, and annu-
19 ally thereafter, any brand owner engaged in bringing
20 a cosmetic to market for use in the United States
21 shall register with the Secretary and pay to the Sec-
22 retary the applicable fee, as established under the
23 fee schedule in subsection (e).

1 “(2) EXCEPTION FOR MICROBUSINESSES.—The
2 requirements of this section do not apply with re-
3 spect to microbusinesses.

4 “(3) RULES FOR DOMESTIC AND FOREIGN ES-
5 TABLISHMENTS.—To be registered under paragraph
6 (1)—

7 “(A) as a domestic establishment, the
8 owner, operator, or agent in charge of the do-
9 mestic establishment shall submit a registration
10 to the Secretary; or

11 “(B) as a foreign establishment, the owner,
12 operator, or agent in charge of the foreign es-
13 tablishment shall—

14 “(i) submit a registration to the Sec-
15 retary; and

16 “(ii) include with the registration the
17 name of the United States agent for the
18 foreign establishment.

19 “(4) NEW ESTABLISHMENTS.—Any brand
20 owner that initially brings a cosmetic to market
21 after the date on which the requirements of para-
22 graph (1) apply shall, not later than 60 days after
23 the date on which the establishment brings a cos-
24 metic to market, register with the Secretary and pay
25 the applicable fee, as required under paragraph (1).

1 “(b) SUBMISSION OF REGISTRATION.—

2 “(1) IN GENERAL.—In order to register under
3 subsection (a), an establishment (referred to in this
4 section as the ‘registrant’) shall submit to the Sec-
5 retary, with respect to any cosmetics that the estab-
6 lishment brings to market, all of the following:

7 “(A) Any information necessary to notify
8 the Secretary of the name, address, and legal
9 status of each establishment at which, and all
10 trade names under which, the registrant brings
11 cosmetics to market.

12 “(B) A description of the establishment’s
13 activities with respect to cosmetics, including a
14 list of all cosmetic products brought to market
15 by the establishment and the functions of such
16 cosmetics.

17 “(C) The gross receipts or sales for the es-
18 tablishment from cosmetics.

19 “(2) NOTIFICATION OF CHANGES.—When sub-
20 mitting the annual registration, the registrant shall
21 notify the Secretary of changes to the information
22 described in paragraph (1).

23 “(c) PROCEDURE.—Upon receipt of a completed reg-
24 istration submitted under subsection (a), the Secretary
25 shall notify the registrant of the receipt of such registra-

1 tion and assign a registration number to each registered
2 establishment.

3 “(d) LIST OF REGISTERED ESTABLISHMENTS.—

4 “(1) MAINTENANCE OF LIST.—The Secretary
5 shall—

6 “(A) compile, maintain, and update as ap-
7 propriate, a list of establishments that are reg-
8 istered under this section;

9 “(B) make such list publicly available, in-
10 cluding by posting such list on the public
11 website of the Food and Drug Administration;

12 “(C) remove from such list the name of
13 any establishment that fails to register in ac-
14 cordance with this section; and

15 “(D) indicate on such list any establish-
16 ment which has had its registration suspended
17 or cancelled by the Secretary under this section.

18 “(2) APPLICATION OF FOIA.—

19 “(A) REGISTRATION DOCUMENTS.—Any
20 registration documents submitted pursuant to
21 this section shall not be subject to disclosure
22 under section 552 of title 5, United States
23 Code.

24 “(B) OTHER INFORMATION.—Information
25 derived from—

1 “(i) the list under paragraph (1); or

2 “(ii) registration documents submitted

3 pursuant to this section,

4 shall not be subject to disclosure under section

5 552 of title 5, United States Code, except to the

6 extent that such information discloses the iden-

7 tity or location of a specific registrant.

8 “(e) FEE SCHEDULE.—A schedule of fees shall be de-

9 veloped by the Secretary to provide for oversight and en-

10 forcement of this subchapter. The fee structure shall—

11 “(1) be prorated based on the establishment’s

12 gross receipts or sales; and

13 “(2) only be assessed on companies with annual

14 gross receipts or sales of cosmetics that exceed

15 \$5,000,000.

16 “(f) SUSPENSION AND CANCELLATION OF REGISTRA-

17 TION.—

18 “(1) CRITERIA FOR SUSPENSION.—Registration

19 under this section is subject to suspension if the

20 Secretary finds—

21 “(A) the information submitted by the es-

22 tablishment for registration under subsection

23 (a) is incomplete, inaccurate, or out of date;

1 “(B) the establishment fails to notify the
2 Secretary of changes required under subsection
3 (b)(2);

4 “(C) the establishment fails to pay reg-
5 istration fees, as required under subsection (a),
6 in a timely manner; or

7 “(D) the establishment violates any portion
8 of this chapter.

9 “(2) SUSPENSION OF REGISTRATION.—If the
10 Secretary determines that an establishment is sub-
11 ject to suspension under this subsection and that it
12 is appropriate to suspend the registration of such es-
13 tablishment the Secretary shall—

14 “(A) suspend the registration of such es-
15 tablishment; and

16 “(B) provide a notice of suspension to such
17 establishment.

18 “(3) CANCELLATION.—If the establishment
19 fails to correct the issue that resulted in the suspen-
20 sion under paragraph (2) before the last day of the
21 30-day period beginning on the date that the estab-
22 lishment receives notice under such paragraph, the
23 Secretary may cancel the registration of such estab-
24 lishment.

1 “(g) RECORDKEEPING.—All establishments that are
2 required to register under this section shall maintain
3 records that include a current list of suppliers and manu-
4 facturers if the registrant does not manufacture or pack-
5 age its own product. Those records shall be accessible by
6 the Secretary upon request for review or audit.

7 **“SEC. 613. INGREDIENTS LABELS AND WEBSITE DISCLO-**
8 **SURE FOR COSMETICS.**

9 “(a) IN GENERAL.—Subject to subsections (b) and
10 (c), the Secretary shall require that the label on each pack-
11 age of cosmetics (including cosmetics for retail sale and
12 professional use) bears a declaration of the name of each
13 ingredient in such cosmetic in descending order of pre-
14 dominance.

15 “(b) ADJUSTMENTS FOR LABEL SIZE.—

16 “(1) RULES FOR SMALL PRODUCTS.—Not later
17 than 6 months after the date of the enactment of
18 this subchapter, the Secretary shall issue regulations
19 that apply to any cosmetic for which the product
20 packaging is not of sufficient size to bear or contain
21 a label that meets the requirements of subsection
22 (a).

23 “(2) REQUIREMENTS FOR PUBLIC DISCLO-
24 SURE.—Such regulations shall establish require-
25 ments for listing ingredients on the label of such

1 cosmetics and additional requirements, as appro-
2 priate, for public disclosure of the ingredients in
3 such cosmetics.

4 “(c) SPECIAL RULE FOR CONTAMINANTS.—The Sec-
5 retary shall require, in the case of a contaminant (as de-
6 fined by section 618), that a contaminant be declared on
7 the label of a cosmetic, in the same manner as an ingre-
8 dient under subsection (a), if the contaminant is present
9 in a personal care product in any quantity exceeding one
10 half of one percent of the content of the product by weight.

11 “(d) LABELING OF NANOMATERIALS IN COS-
12 METICS.—The Secretary may require that—

13 “(1) minerals and other particulate ingredients
14 be labeled as ‘nano-scale’ on a cosmetic ingredient
15 label or list if not less than 1 percent of the ingre-
16 dient particles in the cosmetic are 100 nanometers
17 or smaller in not less than 1 dimension; and

18 “(2) other ingredients in a cosmetic be des-
19 ignated with scale-specific information on a cosmetic
20 ingredient label or list if such ingredients possess
21 scale-specific hazard properties.

22 “(e) WEBSITE DISCLOSURE OF COSMETIC INGREDI-
23 ENTS.—The Secretary shall require that the website of a
24 brand owner of a cosmetic include a declaration of the in-

1 gredients in the cosmetic in descending order of predomi-
2 nance, including the function of each ingredient.

3 “(f) LABELING OF INGREDIENTS IN COSMETICS
4 SOLD THROUGH INTERNET COMMERCE.—The Secretary
5 shall require—

6 “(1) in the case of a cosmetic sold on the
7 website of an internet vendor, that the brand owner
8 of such cosmetic provide to such internet vendor a
9 list of the ingredients in the cosmetic; and

10 “(2) that each internet vendor display the list
11 of ingredients in a cosmetic sold by such vendor on
12 the web page that is the primary web page providing
13 information relating to the sale of such cosmetic on
14 the website of the vendor.

15 “(g) PRODUCT LABELING OF FRAGRANCE AND FLA-
16 VOR INGREDIENTS.—

17 “(1) REQUIREMENTS.—The Secretary shall re-
18 quire that all fragrance and flavor ingredients in a
19 cosmetic that are deemed hazardous to human
20 health or the environment by paragraph (2) appear
21 on the label of the cosmetic.

22 “(2) LIST OF INGREDIENTS DEEMED HAZ-
23 ARDOUS.—The following ingredients (including
24 chemicals added by the relevant government agency
25 or authoritative body subsequent to the date of en-

1 actment of this subchapter) are deemed hazardous
2 to human health or the environment for purposes of
3 paragraph (1)(A):

4 “(A) Chemicals known to cause cancer or
5 reproductive toxicity that are listed pursuant to
6 California Health & Safety Code Section
7 25249.5 et seq.

8 “(B) Chemicals classified by the European
9 Union as carcinogens, mutagens, or reproduc-
10 tive toxicants pursuant to Category 1A or 1B
11 in Annex VI to Regulation (EC) No. 1272/
12 2008.

13 “(C) Chemicals included in the European
14 Union Candidate List of Substances of Very
15 High Concern in accordance with Article 59 of
16 Regulation (EC) No. 1907/2006 on the basis of
17 Article 57(f) for endocrine disrupting prop-
18 erties.

19 “(D) Chemicals for which a reference dose
20 or reference concentration has been developed
21 based on neurotoxicity in the Environmental
22 Protection Agency’s Integrated Risk Informa-
23 tion System.

24 “(E) Chemicals that are identified as car-
25 cinogenic to humans, likely to be carcinogenic

1 to humans, or as Group A, B1, or B2 carcino-
2 gens, in the Environmental Protection Agency's
3 Integrated Risk Information System.

4 “(F) Chemicals included in the European
5 Chemicals Agency Candidate List of Substances
6 of Very High Concern in accordance with Arti-
7 cle 59 of Regulation (EC) No. 1907/2006 on
8 the basis of Article 57(d), Article 57(e), or Arti-
9 cle 57(f) of Regulation (EC) No. 1907/2006 for
10 persistent, bioaccumulative and toxic, or very
11 persistent and very bioaccumulative, properties.

12 “(G) Chemicals that are identified as per-
13 sistent, bioaccumulative, and inherently toxic to
14 the environment by the Canadian Environ-
15 mental Protection Act Environmental Registry
16 Domestic Substances List pursuant to sub-
17 section 66(1) of the Canadian Environmental
18 Protection Act, 1999.

19 “(H) Chemicals classified by the European
20 Union in Annex VI to Regulation (EC) No.
21 1272/2008 as respiratory sensitizer category 1.

22 “(I) Group 1, 2A, or 2B carcinogens iden-
23 tified by the International Agency for Research
24 on Cancer.

1 “(J) Neurotoxicants that are identified in
2 the Agency for Toxic Substances and Disease
3 Registry’s Toxic Substances Portal.

4 “(K) Persistent bioaccumulative and toxic
5 priority chemicals that are identified by the En-
6 vironmental Protection Agency’s National
7 Waste Minimization Program as of February
8 22, 2016.

9 “(L) Reproductive and developmental tox-
10 cants identified by National Toxicology Pro-
11 gram Center for the Evaluation of Risks mono-
12 graphs.

13 “(M) Chemicals identified as ‘Persistent
14 Bioaccumulative Toxic’ by the Environmental
15 Protection Agency on the Toxics Release Inven-
16 tory under section 313 of the Emergency Plan-
17 ning and Community Right-to-Know Act of
18 1986 (42 U.S.C. 11023).

19 “(N) The State of Washington Depart-
20 ment of Ecology’s Persistent, Bioaccumulative,
21 Toxic (PBT) Chemicals identified in Chapter
22 173–333 of Title 173 of the Washington Ad-
23 ministrative Code.

24 “(O) Chemicals that are identified as
25 known to be, or reasonably anticipated to be,

1 human carcinogens by the most recent Report
2 on Carcinogens prepared by the Federal Na-
3 tional Toxicology Program.

4 “(P) Chemicals for which primary max-
5 imum contaminant levels have been established
6 for drinking water by the Environmental Pro-
7 tection Agency.

8 “(Q) Chemicals identified as hazardous air
9 pollutants by the Environmental Protection
10 Agency pursuant to section 112 of the Clean
11 Air Act (42 U.S.C. 7412).

12 “(R) Toxic pollutants listed under section
13 307(a)(1) of the Federal Water Pollution Con-
14 trol Act (33 U.S.C. 1317) and priority pollut-
15 ants identified in appendix A to part 423 of
16 title 40, Code of Federal Regulations.

17 “(S) Chemicals that are identified on the
18 Centers for Disease Control and Prevention’s
19 most recent Report on Human Exposure to En-
20 vironmental Chemicals and Updated Tables
21 Volume 1 and Volume 2.

22 “(T) Chemicals that are identified on Part
23 A of the list of Chemicals for Priority Action
24 prepared by the Oslo and Paris Conventions for

1 the Protection of the Marine Environment of
2 the North-East Atlantic.

3 “(U) Chemicals identified as hazardous
4 under section 101(14) or 102 of the Com-
5 prehensive Environmental Response, Compensa-
6 tion, and Liability Act of 1980 (42 U.S.C.
7 9601(14), 9602).

8 “(h) FRAGRANCE ALLERGENS.—The Secretary shall
9 require that any fragrance allergen in a cosmetic be in-
10 cluded on the label of the cosmetic and identified as a fra-
11 grance allergen if the fragrance allergen is—

12 “(1) included in Annex III of European Union
13 Cosmetics Regulation No. 1223/2009, as required to
14 be disclosed pursuant to European Union Deter-
15 gents Regulation No. 21648/2004, and subsequent
16 updates to those regulations; and

17 “(2) is present in—

18 “(A) a rinse-off cosmetic at a concentra-
19 tion at or above 0.01 percent; or

20 “(B) a leave-on cosmetic product at a con-
21 centration at or above 0.001 percent.

22 “(i) TRADE SECRETS.—Notwithstanding any other
23 provision of law, an ingredient required to be listed on a
24 product label or on a brand owner or internet commerce

1 website under this section shall not be treated as a trade
2 secret.

3 “(j) APPLICATION.—Beginning 18 months after the
4 date of the enactment of this subchapter, the requirements
5 of this section shall apply to—

6 “(1) all cosmetics that are available for retail
7 sale (including such cosmetics for professional use);
8 and

9 “(2) brand owners and internet vendors of such
10 cosmetics.

11 **“SEC. 614. SAFETY STANDARD AND GOOD MANUFACTURING**
12 **PRACTICES.**

13 “(a) SAFETY STANDARD.—

14 “(1) IN GENERAL.—Taking into account the ex-
15 pected or reasonably foreseeable use of a cosmetic,
16 the Secretary shall establish a safety standard that,
17 with respect to a cosmetic or an ingredient in a cos-
18 metic, provides a reasonable certainty of no harm
19 (as such term is defined in section 611(9)) from ex-
20 posure to the cosmetic or ingredient and protects the
21 public from any known or anticipated adverse health
22 effects associated with the cosmetic or ingredient.

23 “(2) STANDARDS FOR ESTABLISHING SAFETY
24 STANDARD.—In establishing the safety standard

1 under paragraph (1), the Secretary shall ensure
2 that—

3 “(A) the likely level of exposure to all
4 sources of the ingredient or cosmetic (including
5 environmental sources) that will result under
6 the safety standard presents not more than a
7 one in a million risk for any adverse health ef-
8 fect in any vulnerable population at the lower
9 95th percentile confidence interval; or

10 “(B) the safety standard results in expo-
11 sure to the amount or concentration of an in-
12 gredient or cosmetic that is shown to produce
13 no adverse health effects, incorporating a mar-
14 gin of safety of at least 1,000 and considering
15 the impact of cumulative exposure from all
16 sources (including environmental sources).

17 “(3) USE OF OTHER FEDERAL STANDARDS.—If
18 any Federal agency has promulgated a standard for
19 an ingredient that satisfies the requirements of
20 paragraph (1), the Secretary may treat such stand-
21 ard as the safety standard under paragraph (1) for
22 purposes of such ingredient.

23 “(b) GOOD MANUFACTURING PRACTICES.—

24 “(1) IN GENERAL.—The Secretary shall issue
25 guidance prescribing good manufacturing practices

1 for cosmetics and ingredients, including quality con-
 2 trol procedures that the Secretary determines are
 3 necessary, and shall update such guidance as nec-
 4 essary.

5 “(2) CONSIDERATION OF SMALL BUSINESS.—In
 6 developing the guidance under paragraph (1), the
 7 Secretary shall consider how such practices will im-
 8 pact small businesses.

9 **“SEC. 615. COSMETIC AND INGREDIENT SAFETY INFORMA-**
 10 **TION.**

11 “(a) REQUIRED SUBMISSION OF ALL SAFETY INFOR-
 12 MATION.—

13 “(1) IN GENERAL.—Brand owners of cosmetics
 14 shall submit electronically to the Secretary all data
 15 and information that the brand owner can access re-
 16 garding the safety of—

17 “(A) the ingredients listed on the cosmetic
 18 label and the brand owner’s website under sec-
 19 tion 613 for a cosmetic; and

20 “(B) the cosmetic itself.

21 “(2) REQUIRED INFORMATION.—The required
 22 data and information under paragraph (1) shall in-
 23 clude, for each ingredient in a cosmetic and for the
 24 cosmetic, the following:

25 “(A) Functions and uses.

1 “(B) Data and information on the phys-
2 ical, chemical, and toxicity properties of each
3 such ingredient or cosmetic.

4 “(C) Exposure and fate information.

5 “(D) Results of all safety tests that the
6 brand owner can access or has conducted.

7 “(E) Any other information used to sub-
8 stantiate the safety of such ingredient and cos-
9 metic.

10 “(3) DEADLINES.—

11 “(A) INITIAL SUBMISSION.—A brand
12 owner shall submit the data and information re-
13 quired under paragraph (1)—

14 “(i) in the case of an ingredient or
15 cosmetic which is marketed for sale in
16 interstate commerce on or before the date
17 of the enactment of this subchapter, not
18 later than 1 year after such date; and

19 “(ii) in the case of an ingredient or
20 cosmetic which is not marketed for sale on
21 or before such date—

22 “(I) not later than the end of the
23 14-month period beginning on the
24 date of the enactment of this sub-
25 chapter; or

1 “(II) if the ingredient or cosmetic
2 is first marketed for sale in interstate
3 commerce after the end of the period
4 described in subclause (I), not later
5 than 60 days after the date on which
6 such ingredient or cosmetic is first
7 marketed for sale.

8 “(B) UPDATES.—

9 “(i) IN GENERAL.—Subject to clause
10 (ii), a brand owner shall update the data
11 and information submitted under subpara-
12 graph (A) annually.

13 “(ii) ADVERSE HEALTH EFFECTS.—In
14 the case of information related to an ad-
15 verse health effect that is suspected to be
16 caused by an ingredient or a cosmetic, a
17 brand owner shall update the information
18 not later than 60 days after receiving such
19 information.

20 “(4) SUPPLIER AND MANUFACTURER INFORMA-
21 TION.—

22 “(A) USE OF SUPPLIER OR MANUFAC-
23 TURER INFORMATION.—In order to meet the re-
24 quirements of paragraph (1) with respect to an
25 ingredient, a brand owner may submit safety

1 data and information provided by the supplier
2 or manufacturer of the ingredient or cosmetic.

3 “(B) SUPPLIER OR MANUFACTURER PRO-
4 VISION OF INFORMATION.—If a brand owner re-
5 quests that a supplier or manufacturer of an in-
6 gredient provide to such brand owner any of the
7 data and information described under para-
8 graph (2) or under section 617, such supplier
9 or manufacturer shall provide such data and in-
10 formation to such brand owner not later than
11 90 days after receiving such request.

12 “(b) DATABASE.—

13 “(1) INITIAL PUBLICATION.—Not later than 1
14 year after the date of the enactment of this sub-
15 chapter, the Secretary shall publish a comprehensive
16 database that—

17 “(A) is publicly accessible, including on the
18 public website of the Food and Drug Adminis-
19 tration; and

20 “(B) contains all nonconfidential informa-
21 tion (as such term is used in section 623) sub-
22 mitted under subsection (a)(1).

23 “(2) UPDATES.—Not later than 90 days after
24 the Secretary receives new or updated information
25 under subsection (a)(3)(B), the Secretary shall up-

1 date the database under paragraph (1) with such in-
2 formation.

3 “(c) REVIEW AND EVALUATION OF INFORMATION.—

4 “(1) IN GENERAL.—Based on the data and in-
5 formation submitted under subsection (a)(1), avail-
6 able from an authoritative source (as such term is
7 defined in paragraph (3), including data described in
8 section 627(b)), and such other information as the
9 Secretary may have available, the Secretary shall re-
10 view and evaluate the safety of cosmetics and ingre-
11 dients of cosmetics that are marketed in interstate
12 commerce.

13 “(2) CONSIDERATION OF NANOMATERIALS.—

14 The Secretary shall—

15 “(A) monitor developments in the scientific
16 understanding from any adverse health effects
17 related to the use of nanotechnology in the for-
18 mulation of cosmetics (including progress in the
19 standardization of testing methods and specific
20 size definitions for nanomaterials); and

21 “(B) consider scale-specific hazard prop-
22 erties of ingredients when reviewing and evalu-
23 ating the safety of cosmetics and ingredients
24 under paragraph (1).

1 “(3) AUTHORITATIVE SOURCE DEFINED.—For
 2 purposes of this subsection, the term ‘authoritative
 3 source’ means—

4 “(A) the Environmental Protection Agen-
 5 cy;

6 “(B) the International Agency for Re-
 7 search on Cancer;

8 “(C) the National Institutes of Health;

9 “(D) the California Environmental Protec-
 10 tion Agency; and

11 “(E) any other authoritative international,
 12 Federal, or State entity, as determined by the
 13 Secretary.

14 **“SEC. 616. LISTS OF INGREDIENTS AND REQUIRED RE-**
 15 **SPONSES.**

16 “(a) PLACEMENT ON LIST.—

17 “(1) IN GENERAL.—Based on an initial review
 18 and evaluation of the chronic health impacts associ-
 19 ated with an ingredient that is used in one or more
 20 cosmetics, the Secretary shall create and periodically
 21 update a list of ingredients for safety review. From
 22 such list, the Secretary shall place ingredients on a
 23 priority assessment list and, after comprehensive
 24 safety review, place each ingredient on the priority
 25 assessment list on one of the following lists:

1 “(A) The prohibited and restricted lists
2 under subsection (b).

3 “(B) The safe without limits list under
4 subsection (c).

5 “(C) The insufficient data list under sub-
6 section (d).

7 “(2) INITIAL LIST.—The Secretary shall add 20
8 ingredients to the initial priority assessment list cre-
9 ated under paragraph (1) immediately after the en-
10 actment of this subchapter.

11 “(3) CONSIDERATIONS.—In determining the
12 placement of an ingredient on the priority assess-
13 ment list under paragraph (1), the Secretary shall
14 consider the scientific evidence linking that ingre-
15 dient to harm and conduct further prioritization
16 based on whether the ingredient—

17 “(A) is found to be present in the body
18 through biomonitoring;

19 “(B) is found in drinking water or air;

20 “(C) is a known or suspected neurological
21 or immunological toxicant, respiratory
22 asthmagen, carcinogen, teratogen, or endocrine
23 disruptor, or have other toxicity concerns (in-
24 cluding reproductive or developmental toxicity);

1 “(D) is known to persist in the environ-
2 ment or bioaccumulate; or

3 “(E) is of particular concern to a commu-
4 nity disproportionately impacted by cosmetic
5 chemicals in products marketed to them be-
6 cause of their particular race, ethnicity, or oc-
7 cupation.

8 “(4) PRIORITIZATION OF INGREDIENTS THAT
9 ARE FOOD.—In placing ingredients on the lists
10 under paragraph (1), the Secretary shall prioritize
11 the placement of ingredients that are food (as such
12 term is defined under section 201(f)) on such lists.

13 “(b) PROHIBITED AND RESTRICTED LISTS.—

14 “(1) IN GENERAL.—The Secretary shall issue,
15 by regulation, two lists of ingredients that are iden-
16 tified by the Secretary—

17 “(A) in the first list, as prohibited for use
18 in cosmetics because the Secretary determines
19 that such ingredients are unsafe for use in cos-
20 metics in any amount because such ingredients
21 fail to meet the safety standard under section
22 614(a); or

23 “(B) in the second list, as being subject to
24 necessary restrictions in use or concentration to

1 allow the use of the ingredient in a cosmetic to
2 satisfy the safety standard.

3 “(2) INITIAL PROHIBITED LIST.—

4 “(A) IMMEDIATELY PROHIBITED INGREDI-
5 ENTS.—Effective as of the date of enactment of
6 this subchapter, the following ingredients are
7 deemed to be listed pursuant to paragraph
8 (1)(A) as prohibited for use:

9 “(i) Benzophenones, including benzo-
10 phenone-1, benzophenone-3 (also known as
11 ozybenzone), benzophenone-4, and benzo-
12 phenone-5.

13 “(ii) Octinoxate.

14 “(iii) Butylated Hydroxyanisole and
15 Butylated Hydroxytoluen.

16 “(iv) Coal tar dyes (P-phenylenedia-
17 mine).

18 “(v) Cocamide Diethanolamine.

19 “(vi) Dibutylated Phthalate (Phtha-
20 lates DBP), Bis(2-ethylhexyl) Phthalate
21 (DEHP).

22 “(vii) Toluene.

23 “(viii) Styrene or Styrene acrylates.

24 “(ix) Formaldehydes (Methylene gly-
25 col/methanediol/formaldehyde) and Form-

1 aldehyde-releasing preservatives (DMDM
2 hydantoin, diazolidinyl urea, imidazolidinyl
3 urea, methenamine, quaternium-15, and
4 sodium hydroxymethylglycinate).

5 “(x) Triclosan.

6 “(xi) Lead acetate or other lead com-
7 pounds.

8 “(xii) Parabens (isopropylparaben, iso-
9 butylparaben, phenylparaben, benzylpara-
10 ben, pentylparaben, propylparaben, and
11 butylparaben).

12 “(B) FIRST INGREDIENTS LISTED BY REG-
13 ULATION.—Not later than 2 years after the
14 date of enactment of this subchapter, the Sec-
15 retary shall promulgate by final regulation the
16 lists required by subparagraphs (A) and (B) of
17 paragraph (1), to supplement the ingredients
18 deemed by subparagraph (A) of this paragraph
19 to be listed pursuant to paragraph (1)(A).

20 “(3) SPECIFICATION OF RESTRICTIONS.—In the
21 case of any ingredient listed under paragraph
22 (1)(B), the Secretary shall specify the restrictions on
23 use or concentration that are necessary to satisfy the
24 safety standard for such ingredient.

25 “(4) UPDATES.—

1 “(A) IN GENERAL.—After promulgating
2 the initial list pursuant to paragraph (2)(B),
3 the Secretary shall update the lists under para-
4 graph (1) at a minimum annually, including—

5 “(i) updates to determinations under
6 subsection (d)(3); or

7 “(ii) any updates prompted by new in-
8 formation that demonstrates that an ingre-
9 dient fails to meet the safety standard, or
10 requires restrictions on use to meet such
11 standard.

12 “(B) CHEMICALS IDENTIFIED PURSUANT
13 TO NIH-FUNDED RESEARCH.—The Secretary
14 shall—

15 “(i) consult with the Director of the
16 National Institute of Environmental
17 Health Sciences to identify any chemicals
18 that are determined to be of concern pur-
19 suant to investigations funded under sec-
20 tion 463C of the Public Health Service
21 Act; and

22 “(ii) review any such chemicals in ac-
23 cordance with this section to determine
24 whether such chemicals should be prohib-

1 ited or subject to restrictions under this
2 section.

3 “(5) MANUFACTURER REQUIREMENTS.—Not
4 later than 1 year after the date on which an ingre-
5 dient is placed on a list under this subsection, any
6 manufacturer using such ingredient in a cosmetic
7 shall reformulate such cosmetic to—

8 “(A) eliminate the use of the ingredient, if
9 it is listed under paragraph (1)(A); or

10 “(B) modify the use of the ingredient if it
11 is listed under paragraph (1)(B), to meet the
12 restrictions specified under paragraph (3).

13 “(c) SAFE WITHOUT LIMITS LIST.—

14 “(1) IN GENERAL.—Not later than 2 years
15 after the date of the enactment of this subchapter,
16 the Secretary shall issue, by regulation, a list of in-
17 gredients that the Secretary has determined are safe
18 for use in cosmetics, without limits or restrictions.

19 “(2) STANDARD FOR INCLUSION IN LIST.—The
20 Secretary may only include an ingredient on the list
21 under paragraph (1) if the Secretary determines
22 that the ingredient meets the safety standard under
23 section 614(a), regardless of—

24 “(A) the type and form of cosmetic the in-
25 gredient is used in; and

1 “(B) the concentration of the ingredient
2 that is used in a cosmetic.

3 “(3) UPDATES AND REDETERMINATIONS.—
4 After promulgating the initial list pursuant to para-
5 graph (1), the Secretary—

6 “(A) shall annually update the list under
7 paragraph (1); and

8 “(B) may redetermine whether an ingre-
9 dient distributed in commerce meets the safety
10 standard under section 614(a) if, in the judg-
11 ment of the Secretary, new information raises a
12 credible question as to whether the ingredient
13 continues to meet the safety standard.

14 “(d) PRIORITY ASSESSMENT LIST AND RELATED
15 SAFETY DETERMINATIONS.—

16 “(1) IN GENERAL.—Not later than 1 year after
17 the creation of the initial priority assessment list of
18 ingredients for review under subsection (a)(1), the
19 Secretary shall evaluate the safety of not less than
20 10 ingredients for which the Secretary has deter-
21 mined it is a priority to conduct a safety determina-
22 tion under paragraph (3).

23 “(2) ANNUAL ADDITION OF INGREDIENTS.—
24 After the initial evaluation of 10 ingredients pursu-
25 ant to paragraph (1), the Secretary shall annually

1 add at least 10 additional ingredients to such list
2 until all ingredients that are used in the formulation
3 or manufacture of cosmetics have been evaluated for
4 safety and added to—

5 “(A) the prohibited and restricted lists
6 under subsection (b);

7 “(B) the safe without limits list under sub-
8 section (c); or

9 “(C) the insufficient data list under this
10 subsection.

11 “(3) DETERMINATION OF WHETHER INGREDI-
12 DIENT MEETS SAFETY STANDARD.—

13 “(A) REVIEW OF PRIORITY INGREDI-
14 ENTS.—During the 2-year period following the
15 date on which an ingredient is listed pursuant
16 to paragraph (1) or (2), the Secretary shall—

17 “(i) collect data and information on
18 such ingredient; and

19 “(ii) review and evaluate the safety of
20 such ingredient.

21 “(B) DETERMINATION OF LIST PLACE-
22 MENT.—Not later than the end of the period
23 under subparagraph (A), the Secretary shall
24 issue a determination, based on the review and
25 evaluation under such subparagraph, that the

1 ingredient meets the requirements for inclusion
2 on a list specified in subparagraph (A), (B), or
3 (C) of paragraph (2).

4 “(C) GUIDANCE IN THE CASE OF INSUFFI-
5 CIENT OR NO DATA.—If the Secretary deter-
6 mines under subparagraph (B) that, with re-
7 spect to an ingredient, insufficient or no data
8 exists to place such ingredient on either the
9 prohibited and restricted list under subsection
10 (b) or the safe without limits list under sub-
11 section (c), the Secretary shall provide guidance
12 on the data and information (including min-
13 imum data requirements and safety testing pro-
14 tocols) that the Secretary requires to evaluate
15 whether the ingredient meets the safety stand-
16 ard under section 614(a) for purposes of plac-
17 ing such ingredient on either such list.

18 “(D) COMMENT PERIOD.—Upon issuing
19 the determination under subparagraph (B),
20 and, if applicable, the guidance under subpara-
21 graph (C), the Secretary shall provide a period
22 of not less than 60 days for public comment on
23 the determination before applying such deter-
24 mination to an ingredient, except that a shorter

1 period for comment may be provided if the Sec-
2 retary—

3 “(i) finds that it would be in the pub-
4 lic interest to have a shorter period; and

5 “(ii) publicly declares the reasons for
6 such finding.

7 “(4) RESPONSE TO INADEQUATE INFORMA-
8 TION.—Not later than 18 months after the date that
9 the Secretary issues guidance under paragraph
10 (3)(C) with respect to an ingredient subject to a de-
11 termination under paragraph (3)(B), a brand owner
12 using such ingredient in a cosmetic shall—

13 “(A) reformulate such cosmetic to elimi-
14 nate the use of the ingredient; or

15 “(B) provide the Secretary with the data
16 and information specified in such guidance.

17 “(5) EVALUATION OF ADDITIONAL DATA AND
18 INFORMATION.—With respect to an ingredient, not
19 later than 6 months after the Secretary receives the
20 data and information under paragraph (4)(B), the
21 Secretary shall—

22 “(A) review such data and information;
23 and

1 “(B) make a redetermination under para-
 2 graph (3)(B) for such ingredient, subject to the
 3 comment period under paragraph (3)(D).

4 **“SEC. 617. TREATMENT OF COSMETICS BASED ON INGRE-**
 5 **DIENT LISTS.**

6 “(a) IN GENERAL.—Subject to subsections (b)(5)
 7 and (d)(4) of section 616, a brand owner may only dis-
 8 tribute in interstate commerce a cosmetic that meets the
 9 safety standard under section 614(a).

10 “(b) PRESUMPTION RELATED TO THE SAFETY OF
 11 COSMETICS.—

12 “(1) IN GENERAL.—Subject to paragraph (2),
 13 for purposes of subsection (a), the Secretary shall
 14 presume that the following cosmetics meet the safety
 15 standard under section 614(a):

16 “(A) A cosmetic that is made solely of in-
 17 gredients on the list under section 616(c)(1)
 18 (relating to ingredients that are safe without
 19 limits).

20 “(B) A cosmetic that is made solely of in-
 21 gredients on the list under section 616(b)(1)(B)
 22 (relating to ingredients subject to restrictions)
 23 and the use of each of such ingredients in such
 24 cosmetic is in compliance with the restrictions

1 on the use of such ingredients specified under
2 section 616(b)(3).

3 “(C) A cosmetic that is made solely of in-
4 gredients described in subparagraph (A) and
5 subparagraph (B).

6 “(2) EXCEPTIONS.—The Secretary may require
7 that a brand owner demonstrate that a cosmetic
8 meets the safety standard under section 614(a) (in-
9 cluding by requiring that the brand owner conduct
10 safety testing, or request such safety testing from
11 relevant suppliers and manufacturers, of a cosmetic
12 described under paragraph (1)) if—

13 “(A) the cosmetic contains—

14 “(i) penetration enhancers, sensi-
15 tizers, endocrine-disrupting compounds, or
16 other similar ingredients; or

17 “(ii) ingredients that react with each
18 other or with other substances to form
19 harmful byproducts; or

20 “(B) the Secretary has any additional rea-
21 son to believe that such cosmetic does not meet
22 the safety standard under section 614(a).

23 “(3) GUIDANCE.—If, under paragraph (2), the
24 Secretary requires that a brand owner demonstrate
25 that a cosmetic meets the safety standard under sec-

1 tion 614(a), the Secretary shall provide the brand
2 owner with guidance on the data and information
3 that the Secretary requires to evaluate whether the
4 cosmetic meets the safety standard under such sec-
5 tion.

6 “(c) NOTIFICATION OF FAILURE OF SECRETARY TO
7 ACT.—If the Secretary fails to act by an applicable dead-
8 line under section 616 or this section, brand owners and
9 manufacturers of an ingredient or a cosmetic affected by
10 such failure of the Secretary to act shall issue to the Sec-
11 retary, the public, and each known customer of the ingre-
12 dient or cosmetic, a written and electronic notice that a
13 determination by the Secretary of the safety of the ingre-
14 dient or cosmetic is pending.

15 **“SEC. 618. TREATMENT OF CONTAMINANTS.**

16 “(a) PUBLICATION OF LIST.—Not later than 1 year
17 after the date of the enactment of this subchapter, and
18 annually thereafter, the Secretary shall publish a list of
19 contaminants of concern linked to severe acute reactions
20 or chronic adverse health effects, including—

21 “(1) ingredients used in cosmetics that may
22 contain contaminants of concern;

23 “(2) combinations of ingredients that may cre-
24 ate contaminants of concern when such ingredients
25 interact;

1 “(3) contaminants of concern that may leech
2 from product packaging into a cosmetic; and

3 “(4) any other contaminant of concern identi-
4 fied by the Secretary that are present in cosmetics.

5 “(b) EVALUATION; LABELING.—The Secretary shall
6 use the process described in sections 615 and 616 to evalu-
7 ate contaminants of concern for possible elimination or re-
8 striction in cosmetics. The Secretary shall require that a
9 contaminant on the list under subsection (a) be declared
10 on the label of a cosmetic, in the same manner as an ingre-
11 dient under section 613.

12 “(c) REQUIREMENTS FOR TESTING.—

13 “(1) IN GENERAL.—Not later than 1 year after
14 the date of enactment of this subchapter, the Sec-
15 retary shall establish, by rule, requirements for test-
16 ing ingredients and cosmetics for contaminants list-
17 ed under subsection (a).

18 “(2) CONTENTS.—The requirements under
19 paragraph (1) shall include—

20 “(A) testing methods and applicable proto-
21 cols; and

22 “(B) maximum allowable detection limits
23 for each contaminant in an ingredient or cos-
24 metic.

1 “(3) UPDATE.—The Secretary shall annually
2 update the requirements under paragraph (1).

3 “(d) SUPPLIER REQUIREMENTS.—Beginning not
4 later than 1 year after the promulgation of the rule under
5 subsection (c)(1) with respect to an ingredient that is used
6 in a cosmetic, a supplier of the ingredient shall, with re-
7 spect to such ingredient—

8 “(1) comply with the requirements under sub-
9 section (c)(1) for any ingredient listed under sub-
10 section (a);

11 “(2) conduct similar testing on any ingredient
12 that—

13 “(A) the supplier expects may be used in
14 a cosmetic;

15 “(B) the supplier suspects may contain a
16 contaminant of concern; and

17 “(C) is not listed under subsection (a); and

18 “(3) upon the sale of an ingredient to the man-
19 ufacturer of a cosmetic, provide to the manufacturer
20 specifications for the ingredient that—

21 “(A) include the levels of contaminants
22 present in such ingredient; and

23 “(B) are based on the results of the tests
24 under paragraph (1) and paragraph (2).

1 “(e) BRAND OWNER REQUIREMENTS.—Not later
2 than 1 year after the promulgation of the rule under sub-
3 section (c)(1), a brand owner of a cosmetic shall, with re-
4 spect to each ingredient that the brand owner uses in a
5 cosmetic—

6 “(1) obtain, from each supplier or manufac-
7 turer of the ingredient, specifications for the ingre-
8 dient that include—

9 “(A) the level of each contaminant present
10 in the ingredient; and

11 “(B) the detection limits of the analytical
12 test used to detect the contaminant; or

13 “(2) comply with the requirements under para-
14 graphs (1) and (2) of subsection (d) for the ingre-
15 dient, in the same manner as if the brand owner
16 were a supplier.

17 **“SEC. 619. COSMETIC AND INGREDIENT STATEMENTS.**

18 “(a) IN GENERAL.—Beginning 1 year after the date
19 of the enactment of this subchapter, each brand owner of
20 a cosmetic intended to be marketed in the United States
21 shall submit electronically to the Secretary, for each cos-
22 metic that is intended to be marketed in the United
23 States, a statement containing—

24 “(1) the registration number of the brand
25 owner;

1 “(2) the brand name and the product name for
2 the cosmetic;

3 “(3) the applicable use for the cosmetic;

4 “(4) a list of the ingredients in the product, in-
5 cluding fragrance, flavorants, and the particle size
6 range of any nanoscale cosmetic ingredients;

7 “(5) any warnings and directions for use from
8 the cosmetic label or insert; and

9 “(6) the name, title, and full contact informa-
10 tion for the individual responsible for submitting and
11 maintaining such statement.

12 “(b) NEW COSMETICS.—Any brand owner that be-
13 gins to market a cosmetic after the date of the enactment
14 of this subchapter shall comply with the requirements of
15 subsection (a) beginning on the later of the following:

16 “(1) The end of the 18-month period beginning
17 on the date of the enactment of this subchapter.

18 “(2) The end of the 6-month period after the
19 date on which the establishment begins to manufac-
20 ture such cosmetic.

21 “(c) NOTIFICATION OF CHANGES.—The brand owner
22 shall notify the Secretary annually of any change to the
23 information required under subsection (a).

24 “(d) PROCEDURE.—Upon receipt of a completed
25 statement described under subsection (a), the Secretary

1 shall notify the brand owner of the receipt of such state-
 2 ment and assign a cosmetic statement number.

3 “(e) LIST.—The Secretary shall compile, maintain,
 4 and update as appropriate, a list of cosmetics for which
 5 statements are submitted under this section.

6 “(f) ACCESS TO SAFETY INFORMATION.—The cos-
 7 metic and ingredient statements collected under this sec-
 8 tion shall be added to the publicly accessible database cre-
 9 ated by the Secretary under section 615(b).

10 **“SEC. 620. NOTIFICATION, NONDISTRIBUTION, AND RECALL**
 11 **OF ADULTERATED OR MISBRANDED COS-**
 12 **METICS.**

13 “(a) NOTIFICATION OF ADULTERATED OR MIS-
 14 BRANDED COSMETICS.—

15 “(1) IN GENERAL.—A responsible party that
 16 has reason to believe that a cosmetic, when intro-
 17 duced into or while in interstate commerce, or while
 18 held for sale (regardless of whether such sale is the
 19 first sale of such cosmetic) after shipment in inter-
 20 state commerce, is adulterated or misbranded in a
 21 manner that presents a reasonable probability that
 22 the use or exposure to the cosmetic (or an ingredient
 23 or component used in any such cosmetic) will cause
 24 a threat of a serious adverse event shall notify the

1 Secretary of the identity and location of the cos-
2 metic.

3 “(2) MANNER OF NOTIFICATION.—Notification
4 under paragraph (1) shall be made in such manner
5 and by such means as the Secretary may require by
6 regulation or guidance.

7 “(3) RESPONSIBLE PARTY DEFINED.—For pur-
8 poses of this subsection, the term ‘responsible party’
9 means a brand owner, manufacturer, packager, re-
10 tailer, or distributor of the cosmetic.

11 “(b) VOLUNTARY RECALL.—The Secretary may re-
12 quest that any person who distributes a cosmetic that the
13 Secretary has reason to believe is adulterated, misbranded,
14 or otherwise in violation of this Act voluntarily—

15 “(1) recall such cosmetic; and

16 “(2) provide for notice, including to individuals
17 as appropriate, to persons who may be affected by
18 the recall.

19 “(c) ORDER TO CEASE DISTRIBUTION.—

20 “(1) IN GENERAL.—If the Secretary has reason
21 to believe that—

22 “(A) the use of, or exposure to, a cosmetic
23 may cause a serious adverse event;

24 “(B) the cosmetic is misbranded; or

1 “(C) the cosmetic is marketed, manufac-
2 tured, packaged, or distributed by an unregis-
3 tered brand owner,
4 the Secretary may issue an order requiring any per-
5 son who distributes such cosmetic to immediately
6 cease distribution of such cosmetic.

7 “(2) CEASE DISTRIBUTION AND NOTICE.—Any
8 person who is subject to an order under paragraph
9 (1) shall immediately cease distribution of such cos-
10 metic and provide notification as required by such
11 order.

12 “(3) APPEAL.—

13 “(A) 24 HOURS.—A person subject to an
14 order under paragraph (1) may appeal such
15 order to the Secretary within 24 hours of the
16 issuance of such order.

17 “(B) CONTENTS OF APPEAL.—Such appeal
18 may include a request for an informal hearing
19 and a description of any efforts to recall such
20 cosmetic undertaken voluntarily by the person,
21 including after a request under subsection (b).

22 “(C) INFORMAL HEARING.—Except as pro-
23 vided in subsection (d)(2), an informal hearing
24 shall be held as soon as practicable, but not
25 later than 5 calendar days (or less as deter-

1 mined by the Secretary) after such an appeal is
2 filed, unless the parties jointly agree to an ex-
3 tension.

4 “(D) IMPACT ON RECALL.—If an appeal is
5 filed under subparagraph (A), the Secretary
6 may not amend the order to require a recall
7 under subsection (d) until after the conclusion
8 of the hearing under subparagraph (C).

9 “(4) VACATION OF ORDER.—If the Secretary
10 determines that inadequate grounds exist to support
11 the actions required by the order under paragraph
12 (1), the Secretary shall vacate the order.

13 “(d) MANDATORY RECALL ORDERS.—

14 “(1) IN CONJUNCTION WITH ORDER TO CEASE
15 DISTRIBUTION.—

16 “(A) AMENDMENT.—Except as provided
17 under paragraph (2) and subject to subsection
18 (c)(3)(D), if the Secretary determines that a re-
19 call of a cosmetic subject to an order under
20 subsection (c) is appropriate, the Secretary
21 shall amend the order to require a recall.

22 “(B) CONTENTS.—An amended order
23 under subparagraph (A) shall—

24 “(i) specify a timetable in which the
25 recall will occur;

1 “(ii) require periodic reports to the
2 Secretary describing the progress of the re-
3 call; and

4 “(iii) provide for notice, including to
5 individuals as appropriate, to persons who
6 may be affected by the recall.

7 “(C) ASSISTANCE IN PROVIDING NO-
8 TICE.—In providing for notice under subpara-
9 graph (B), the Secretary may allow for the as-
10 sistance of health professionals, State or local
11 officials, or other individuals designated by the
12 Secretary.

13 “(D) DETERMINATION.—If the Secretary
14 determines that inadequate grounds exist to
15 support the amendment made to the order
16 under subparagraph (A), the Secretary shall re-
17 move such amendment from such order.

18 “(2) FOR IMMINENT THREAT OF A SERIOUS AD-
19 VERSE EVENT.—

20 “(A) IN GENERAL.—If the Secretary has
21 credible evidence or information that a cosmetic
22 subject to an order under subsection (c) pre-
23 sents an imminent threat of a serious adverse
24 event, the Secretary shall issue an order requir-
25 ing any person who distributes such cosmetic—

1 “(i) to immediately recall such cos-
2 metic; and

3 “(ii) to provide for notice, including to
4 individuals as appropriate, to persons who
5 may be affected by the recall.

6 “(B) RECALL AND NOTICE.—Any person
7 who is subject to an emergency recall order
8 under this subsection shall immediately recall
9 such cosmetic and provide notification as re-
10 quired by such order.

11 “(3) APPEAL.—

12 “(A) 24 HOURS.—Any person subject to
13 such an order (including an amended order)
14 under paragraph (1) or (2) may appeal such
15 order to the Secretary within 24 hours of the
16 issuance of such order.

17 “(B) CONTENTS OF APPEAL.—Such appeal
18 may include a request for an informal hearing
19 and a description of any efforts to recall such
20 cosmetic undertaken voluntarily by the person,
21 including after a request under subsection (b).

22 “(C) INFORMAL HEARING.—An informal
23 hearing shall be held as soon as practicable
24 after the appeal is filed under subparagraph
25 (A), but not later than 5 calendar days after

1 such an appeal is filed, or fewer days (as deter-
2 mined by the Secretary), unless the parties
3 jointly agree to an extension.

4 “(D) VACATION OF ORDER.—If the Sec-
5 retary determines that inadequate grounds exist
6 to support the actions required by the order
7 under paragraph (1) or (2), the Secretary shall
8 vacate the order.

9 “(4) NONDELEGATION.—An order (including
10 an amended order) under paragraph (1) or (2) may
11 only be issued by the Secretary or an official des-
12 ignated by the Secretary, and may not be delegated
13 to another official or employee.

14 “(e) NOTICE TO CONSUMERS AND HEALTH OFFI-
15 CIALS.—The Secretary shall post on the Food and Drug
16 Administration’s website and provide notice of a recall
17 order under this section to consumers to whom the cos-
18 metic was, or may have been, distributed and to appro-
19 priate State and local health officials.

20 “(f) SUPPLY CHAIN INFORMATION.—

21 “(1) IN GENERAL.—In the case of a cosmetic
22 that the Secretary has reason to believe is adulter-
23 ated, misbranded, or otherwise in violation of this
24 Act, the Secretary shall request that the brand
25 owner named on the label of such cosmetic (as re-

1 quired under section 602(b)(1)) submit all of the fol-
2 lowing information:

3 “(A) The name and place of business of
4 the manufacturer, packager, supplier, or dis-
5 tributor from which such entity received the
6 cosmetic or ingredients for manufacturing such
7 cosmetic.

8 “(B) The name and place of business of
9 any entity (including any retailer) that was pro-
10 vided with such cosmetic by the entity named
11 on the label.

12 “(2) COLLECTION OF ADDITIONAL SUPPLY
13 CHAIN INFORMATION.—In the case of a cosmetic
14 that the Secretary has reason to believe is adulter-
15 ated, misbranded, or otherwise in violation of this
16 Act, to the extent necessary to protect the safety of
17 the public, the Secretary may request that any entity
18 (including a supplier of an ingredient, manufacturer,
19 packer, distributor, or retailer) in the supply chain
20 of such cosmetic submit to the Secretary information
21 that is similar to the information described in sub-
22 paragraphs (A) and (B) of paragraph (1).

23 “(3) MAINTENANCE OF RECORDS.—Any entity
24 in the supply chain of a cosmetic (including the

1 brand owner named on the label of a cosmetic)
2 shall—

3 “(A) maintain records sufficient to provide
4 the information described in subparagraphs (A)
5 and (B) of paragraph (1); and

6 “(B) provide such information to the Sec-
7 retary upon the request of the Secretary.

8 “(g) SAVINGS CLAUSE.—Nothing contained in this
9 section shall be construed as limiting the authority of the
10 Secretary to issue an order to cease distribution of, or to
11 recall, a cosmetic under any other provision of this Act.

12 **“SEC. 621. PETITIONS.**

13 “(a) IN GENERAL.—The Secretary shall complete
14 and publish a review, and, if appropriate, immediately re-
15 vise related, relevant information, including ingredient
16 lists, ingredient restrictions or prohibitions, or ingredient
17 or cosmetic safety determinations, not later than 6 months
18 after the date on which the Secretary receives from any
19 individual or entity a reasonable petition—

20 “(1) to prohibit or restrict an ingredient for use
21 in cosmetics and list such ingredient on the list
22 under section 616(b);

23 “(2) to remove an ingredient from the list of in-
24 gredients that are safe without limits under section
25 616(c);

1 “(3) to add an ingredient to the priority assess-
2 ment list under section 616(d);

3 “(4) to add an ingredient to the list of ingredi-
4 ents with insufficient data under section 616(d); or

5 “(5) to add an ingredient to the list of contami-
6 nants under section 618.

7 “(b) REASONABLE PETITION.—Not later than 1 year
8 after the date of enactment of this subchapter, the Sec-
9 retary shall issue rules specifying the criteria which the
10 Secretary will use to determine if a petition submitted
11 under this section is a reasonable petition.

12 **“SEC. 622. MANDATORY REPORTING OF SERIOUS ADVERSE**
13 **EVENTS.**

14 “(a) SUBMISSION OF REPORT ON SERIOUS ADVERSE
15 EVENTS.—The Secretary shall require that the brand
16 owner of a cosmetic whose name appears on the label of
17 a cosmetic marketed in the United States submit to the
18 Secretary a report containing information received con-
19 cerning any serious adverse event associated with the use
20 of the cosmetic.

21 “(b) TIMING OF REPORT.—A report under subsection
22 (a) shall be submitted to the Secretary not later than 15
23 business days after information concerning the serious ad-
24 verse event is received at the place of business of the brand
25 owner.

1 “(c) CONTENT OF REPORT.—A report under sub-
2 section (a) shall include the following information, to the
3 extent to which the brand owner submitting the report has
4 been able to verify the information:

5 “(1) The identity of the individual experiencing
6 the adverse health event.

7 “(2) An identifiable report of such effect.

8 “(3) The name of the cosmetic suspected of
9 causing such effect.

10 “(4) A description of the adverse health event.

11 “(d) PUBLIC AVAILABILITY AND PRIVACY.—

12 “(1) PUBLIC AVAILABILITY.—Subject to para-
13 graph (2), the serious adverse event reports collected
14 by the Secretary under this section shall be sub-
15 mitted electronically and shall be made accessible to
16 the public in a summary fashion on the Food and
17 Drug Administration’s website.

18 “(2) PRIVACY.—

19 “(A) PERSONALLY IDENTIFIABLE INFOR-
20 MATION.—Notwithstanding any other provision
21 of law, personally identifiable information in se-
22 rious adverse event reports provided to the Sec-
23 retary under this section, shall not—

1 “(i) be made publicly available pursu-
 2 ant to any State or other law requiring dis-
 3 closure of information or records; or

4 “(ii) otherwise be disclosed or distrib-
 5 uted to any party without the written con-
 6 sent of the Secretary and the person sub-
 7 mitting such information to the Secretary.

8 “(B) TREATMENT OF INFORMATION
 9 UNDER PRIVACY ACT AND FOIA.—A report sub-
 10 mitted to the Secretary under this section, shall
 11 be considered to be a record about an individual
 12 under section 552a of title 5, United States
 13 Code (commonly referred to as the ‘Privacy Act
 14 of 1974’) and a medical or similar file the dis-
 15 closure of which would constitute a violation of
 16 section 552 of such title 5 (commonly referred
 17 to as the ‘Freedom of Information Act’), and
 18 shall not be publicly disclosed unless all person-
 19 ally identifiable information is redacted.

20 **“SEC. 623. NONCONFIDENTIAL INFORMATION.**

21 “(a) INFORMATION AVAILABLE TO PUBLIC.—Subject
 22 to subsection (c) and section 622(d)(2), all nonconfidential
 23 information submitted pursuant to this subchapter shall
 24 be made available to the public, including the following
 25 types of information:

1 “(1) The name, identity, and structure of a
2 chemical substance, contaminant, or impurity that is
3 an ingredient.

4 “(2) All information concerning function, expo-
5 sure, toxicity data, health hazards, and environ-
6 mental hazards for a cosmetic.

7 “(3) The functions of ingredients in cosmetics.

8 “(4) Fragrance, flavor, and colorants in a cos-
9 metic.

10 “(b) CONFIDENTIAL INFORMATION.—The concentra-
11 tion of cosmetic ingredients used in a finished cosmetic
12 shall be considered confidential business information and
13 may not be made available to the public under subsection
14 (a).

15 “(c) PETITION FOR INFORMATION TO REMAIN CON-
16 FIDENTIAL.—

17 “(1) IN GENERAL.—The Secretary shall create
18 a process for an entity to petition for nonconfidential
19 information described in subsection (a) to remain
20 confidential if the entity shows that there would be
21 a serious negative impact to the entity’s commercial
22 interests if such information were disclosed to the
23 public.

24 “(2) LIMITATION.—The Secretary may not ap-
25 prove a petition under paragraph (1) to the extent

1 that such petition would prevent the public disclo-
2 sure of—

3 “(A) the name, identity, and structure of
4 any chemical substance, contaminant, or impu-
5 rity that is an ingredient;

6 “(B) all health and safety data related to
7 that substance, contaminant, or impurity; or

8 “(C) any data used to substantiate the
9 safety of that substance, contaminant, or impu-
10 rity.

11 **“SEC. 624. BAN ON USE OF ANIMAL TESTING.**

12 “(a) BAN.—Beginning on the date of enactment of
13 this subchapter, it shall be unlawful for any entity to con-
14 duct, directly or pursuant to contract, animal testing for
15 the purpose of developing a cosmetic for sale in or affect-
16 ing interstate commerce.

17 “(b) LIMITATION ON CONSIDERATION OF DATA.—
18 The Secretary shall not take into consideration any animal
19 testing on a finished cosmetic product or an ingredient
20 that occurs on or after the date of enactment of this sub-
21 chapter with respect to any determination as to whether
22 a cosmetic or ingredient meets the safety standard under
23 section 614(a).

24 “(c) EXCEPTION.—Subsections (a) and (b) shall not
25 apply with respect to animal testing if—

1 “(1) the animal testing is for the purpose of de-
2 termining whether an ingredient, or the relevant cat-
3 egory of ingredients, meets the safety standard
4 under section 614(a); and

5 “(2) the Secretary determines that the safety of
6 the ingredient, or the relevant category of ingredi-
7 ents, cannot be established using a non-animal test-
8 ing method that is validated by the Interagency Co-
9 ordinating Committee on the Validation of Alter-
10 native Methods authorized by section 3 of the
11 ICCVAM Authorization Act of 2000 (42 U.S.C.
12 285l-3) .

13 “(d) VALIDATED, ELIGIBLE NON-ANIMAL TESTING
14 METHODS.—

15 “(1) LIST.—The Secretary shall develop, main-
16 tain, and make publicly available a list of non-animal
17 testing methods that—

18 “(A) are validated by the Interagency Co-
19 ordinating Committee on the Validation of Al-
20 ternative Methods; and

21 “(B) are eligible for use pursuant to the
22 exception described in subsection (c).

23 “(2) INITIAL LIST; UPDATES.—The Secretary
24 shall—

1 “(A) not later than 1 year after the date
2 of enactment of this subchapter, publish the ini-
3 tial list under paragraph (1); and

4 “(B) annually thereafter, update such list.

5 “(e) GRANTS.—The Secretary shall award grants for
6 the development of testing methods that may be used to
7 replace animal testing pursuant to the exception described
8 in subsection (c).

9 **“SEC. 625. PRODUCT TESTING AND REVIEW AUDIT.**

10 “The Secretary shall conduct annual audits of ran-
11 dom samples of cosmetics to assess or test for acute nega-
12 tive reactions, pathogen hazards, contaminants, leaching
13 of packaging additives, mislabeling, or other relevant
14 issues of concern (as determined by the Secretary).

15 **“SEC. 626. RESOURCES FOR SMALL BUSINESSES.**

16 “The Secretary shall provide technical support to as-
17 sist small businesses in carrying out the requirements of
18 this subchapter.

19 **“SEC. 627. INTERAGENCY COOPERATION.**

20 “(a) INTERAGENCY COUNCIL ON COSMETIC SAFE-
21 TY.—There is established an Interagency Council on Cos-
22 metic Safety for the purpose of sharing data and pro-
23 moting collaboration on cosmetic safety between the Food
24 and Drug Administration, the National Institute of Envi-
25 ronmental Health Sciences, the Centers for Disease Con-

1 trol and Prevention, the Occupational Safety and Health
2 Administration, and the Environmental Protection Agen-
3 cy.

4 “(b) USE OF DATA FROM FEDERAL SOURCES.—For
5 purposes of this subchapter, the Secretary, as appropriate,
6 shall request and utilize ingredient and cosmetic toxicity,
7 use, and exposure data from other Federal agencies.

8 **“SEC. 628. SAVINGS CLAUSE.**

9 “Nothing in this Act affects the right of a State or
10 a political subdivision of a State to adopt or enforce any
11 regulation, requirement, or standard of performance that
12 is different from, or in addition to, a regulation, require-
13 ment, liability, or standard for performance established
14 pursuant to this Act unless compliance with both this Act
15 and the State or political subdivision of a State’s regula-
16 tion, requirement, liability, or standard of performance is
17 impossible, in which case the applicable provisions of this
18 Act shall control.

19 **“SEC. 629. AUTHORIZATION OF APPROPRIATIONS.**

20 “There are authorized to be appropriated such sums
21 as may be necessary to carry out this subchapter for each
22 of the fiscal years 2020 through 2024.”.

1 **SEC. 3. ADULTERATED AND MISBRANDED COSMETICS.**

2 (a) ADULTERATED COSMETICS.—Section 601 of the
3 Federal Food, Drug, and Cosmetic Act (21 U.S.C. 361)
4 is amended—

5 (1) in paragraph (a), by striking “, except that
6 this provision shall not apply to coal-tar hair dye”
7 and all that follows through “or eyebrow dyes”; and

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

9 “(f) If it is manufactured in a manner that fails to
10 comply with section 617(a).

11 “(g) If it is imported, distributed, or marketed and—

12 “(1) it contains an ingredient on the list under
13 section 616(b)(1)(A), and the manufacturer has not
14 complied with section 616(b)(5) with respect to such
15 ingredient and such cosmetic; or

16 “(2) it contains an ingredient on the list under
17 section 616(b)(1)(B), such ingredient is being used
18 in a manner that violates the limit on use or con-
19 centration of such ingredient under section
20 616(b)(3), and the manufacturer has not complied
21 with section 616(b)(5) with respect to such ingre-
22 dient and such cosmetic.

23 “(h) If it is marketed by a brand owner that, with
24 respect to such cosmetic, is required to demonstrate,
25 under section 617(b)(2), that the cosmetic meets the safe-

1 ty standard and the brand owner has not yet submitted
2 the required data under section 617(b)(3).”.

3 (b) MISBRANDED COSMETICS.—Section 602 of the
4 Federal Food, Drug, and Cosmetic Act (21 U.S.C. 362)
5 is amended—

6 (1) in paragraph (a), by inserting “or fails to
7 meet the requirements of section 613 or 618(b)” be-
8 fore the period; and

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

10 “(g) If it—

11 “(1) was brought to market by a brand owner
12 that failed to register and pay the applicable fee as
13 required under section 612;

14 “(2) is brought to market, manufactured, pack-
15 aged, distributed, or sold in retail by a brand owner,
16 manufacturer, packager, distributor, or retailer, re-
17 spectively, who fails to notify the Secretary as re-
18 quired under section 620(a)(1);

19 “(3) is distributed in violation of an order
20 under section 620(c);

21 “(4) is not recalled as required by an order
22 under section 620(d);

23 “(5) is manufactured in a manner that fails to
24 comply with good manufacturing practices pre-
25 scribed by the Secretary under section 614(b); or

1 “(6) is brought to market by a brand owner
2 who fails—

3 “(A) to submit the statement required
4 under section 619; or

5 “(B) notify the Secretary of changes to in-
6 formation contained in such report, as required
7 by such section.”.

8 (c) ADDITIONAL PROHIBITIONS.—Section 301 of the
9 Federal Food, Drug, and Cosmetic Act (21 U.S.C. 331)
10 is amended—

11 (1) in paragraph (e), by inserting “612,” after
12 “564,” each place it appears; and

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

14 “(fff) The failure of a brand owner, manufacturer,
15 or supplier of a cosmetic or an ingredient for use in a
16 cosmetic to submit and update data and information as
17 required under section 615(a).

18 “(ggg) The manufacture, importation, distribution,
19 or marketing of an ingredient for use in a cosmetic that
20 is on the list under section 616(b)(1)(A).

21 “(hhh) The failure of a supplier of an ingredient for
22 use in a cosmetic—

23 “(1) to provide data and information as re-
24 quired by section 615(a)(4)(B); or

1 “(2) to comply with the testing requirements
2 under section 618(d).

3 “(iii) The failure of a manufacturer to comply with
4 the requirements of section 618(e).

5 “(jjj) The failure of a brand owner of a cosmetic to
6 comply with the requirement of reporting serious adverse
7 events under section 622.

8 “(kkk) The conduct of animal testing in violation of
9 section 624.”.

10 **SEC. 4. SUPPORT FOR CREATING SAFER ALTERNATIVES.**

11 (a) IN GENERAL.—The Secretary of Health and
12 Human Services (in this section referred to as the “Sec-
13 retary”), acting through the Commissioner of Food and
14 Drugs, in consultation with the Administrator of the Envi-
15 ronmental Protection Agency, shall award grants to eligi-
16 ble entities to support research focused on the design of
17 safer alternatives to chemicals in cosmetics with inherent
18 toxicity or associated with chronic adverse health effects.

19 (b) ELIGIBLE ENTITIES.—To be eligible to receive a
20 grant under subsection (a), an entity shall—

21 (1) be a public institution such as a university,
22 a not-for-profit research institution, or a small busi-
23 ness; and

1 (2) not benefit from a financial relationship
2 with a cosmetics manufacturer, supplier, or trade as-
3 sociation.

4 (c) PRIORITY.—In awarding grants under subsection
5 (a), the Secretary shall give priority to applicants pro-
6 posing to focus on—

7 (1) replacing chemicals in professional cosmetic
8 products used by nail and hair and beauty salon
9 workers with safer alternatives; or

10 (2) replacing chemicals in cosmetic products
11 marketed to women and girls of color, including any
12 such beauty, personal hygiene, and intimate care
13 products, with safer alternatives.

14 (d) AUTHORIZATION OF APPROPRIATIONS.—To carry
15 out this section, there are authorized to be appropriated
16 such sums as may be necessary for fiscal years 2020
17 through 2025.

18 **SEC. 5. SUPPORT BY NATIONAL INSTITUTE OF ENVIRON-**
19 **MENTAL HEALTH SCIENCES FOR RESEARCH**
20 **ON HEALTH DISPARITIES IMPACTING COM-**
21 **MUNITIES OF COLOR.**

22 Subpart 12 of part C of title IV of the Public Health
23 Service Act (42 U.S.C. 285l et seq.) is amended by adding
24 at the end the following new section:

1 **“SEC. 463C. RESEARCH ON HEALTH DISPARITIES RELATED**
2 **TO COSMETICS IMPACTING COMMUNITIES OF**
3 **COLOR.**

4 “(a) IN GENERAL.—The Director of the Institute
5 shall award grants to eligible entities—

6 “(1) to expand support for basic, epidemiolog-
7 ical, and social scientific investigations into—

8 “(A) the chemicals linked to adverse health
9 effects most commonly found in cosmetics mar-
10 keted to women and girls of color, including
11 beauty, personal hygiene, and intimate care
12 products;

13 “(B) the marketing and sale of such cos-
14 metics containing chemicals linked to adverse
15 health effects to women and girls of color across
16 their lifespans; or

17 “(C) the use of such cosmetics by women
18 and girls of color across their lifespans; and

19 “(2) to disseminate the results of any such re-
20 search described in subparagraph (A) or (B) of
21 paragraph (1) (conducted by the grantee pursuant
22 to this section or otherwise) to help communities
23 identify and address potentially unsafe chemical ex-
24 posures in the use of cosmetics.

25 “(b) ELIGIBLE ENTITIES.—To be eligible to receive
26 a grant under subsection (a), an entity shall—

1 “(1) be a public institution such as a university,
2 a not-for-profit research institution, or a small busi-
3 ness; and

4 “(2) not benefit from a financial relationship
5 with a cosmetics manufacturer, supplier, or trade as-
6 sociation.

7 “(c) REPORT.—Not later than the end 1 year after
8 awarding grants under this section, the Director of the
9 Institute shall issue for the public and submit to the Com-
10 mittee on Energy and Commerce of the House of Rep-
11 resentatives and the Committee on Health, Education,
12 Labor, and Pensions of the Senate a report on the results
13 of the investigations funded under subsection (a), includ-
14 ing—

15 “(1) summary findings on—

16 “(A) marketing strategies, product cat-
17 egories, and specific cosmetics containing ingre-
18 dients linked to adverse health effects; and

19 “(B) the demographics of the populations
20 marketed to and using these cosmetics; and

21 “(2) recommended public health information
22 strategies to reduce potentially unsafe exposures to
23 cosmetics.

24 “(d) AUTHORIZATION OF APPROPRIATIONS.—To
25 carry out this section, there are authorized to be appro-

1 priated such sums as may be necessary for fiscal years
2 2020 through 2025.”.

3 **SEC. 6. WORKER ISSUES.**

4 (a) IN GENERAL.—The Secretary of Labor shall pro-
5 mulgate an occupational safety and health standard under
6 section 6 of the Occupational Safety and Health Act of
7 1970 (29 U.S.C. 655) that requires the following:

8 (1) MANUFACTURERS AND IMPORTERS.—Each
9 manufacturer or importer selling any cosmetic for
10 professional use shall—

11 (A) obtain or develop a material safety
12 data sheet described in subsection (b) for each
13 such cosmetic or personal care product that—

14 (i) the manufacturer or importer pro-
15 duces or imports; and

16 (ii) includes a hazardous chemical, or
17 a product ingredient associated with any
18 chemical hazard, that is classified as a
19 health hazard in accordance with the cri-
20 teria found in section 1910.1200(d) of title
21 29 of the Code of Federal Regulations, and
22 any successor regulations; and

23 (B) make the material safety data sheet
24 available on the manufacturer or importer’s
25 website (in addition to any other required man-

ner of making such sheet available) to distributors and employers, including owners of hair, nail, and beauty salons or spas or other establishments that provide cosmetic services for humans, in English, Spanish, Vietnamese, Chinese, Korean, and upon request other languages.

(2) DISTRIBUTORS.—Each distributor of a cosmetic or personal care product for professional use shall distribute and provide material safety data sheets described in subsection (b) in the same manner as a distributor of a chemical hazard is required to distribute and provide material safety data sheets under section 1910.1200(g) of title 29, Code of Federal Regulations, or any successor regulations.

(3) EMPLOYERS.—Each employer, including any operator of a salon or other establishment described in paragraph (1)(B), shall—

(A) have a material safety data sheet in the workplace for each cosmetic or personal care product for professional use that is used in the course of the employer's business;

(B) make such material safety data sheet available to all employees of the employer who are exposed or use the product to the same ex-

1 tent and in the same manner as material safety
2 data sheets are required to be made available
3 under section 1910.1200(g) of title 29, Code of
4 Federal Regulations, or any successor regula-
5 tions; and

6 (C) upon request, provide employees with
7 translations of such material safety data sheet
8 in other languages, including Spanish, Viet-
9 namese, Chinese, Korean, and upon request
10 other languages.

11 (b) CONTENTS OF MATERIAL SAFETY DATA
12 SHEET.—A material safety data sheet for a cosmetic or
13 personal care product for professional use described in this
14 section shall—

15 (1) contain the information required in a mate-
16 rial safety data sheet under section 1910.1200(g) of
17 title 29, Code of Federal Regulations, or any suc-
18 cessor regulations, for each hazardous chemical, or
19 product ingredient associated with any chemical haz-
20 ard, described in subsection (a)(1)(A)(ii); and

21 (2) include the following statement: “This ma-
22 terial safety data sheet is also available in multiple
23 languages by contacting the manufacturer, using the
24 contact information provided on this sheet.”.

1 (c) PROFESSIONAL USE DEFINED.—In this section,
2 the term “professional use” has the meaning given such
3 term in section 611 of the Federal Food, Drug, and Cos-
4 metic Act, as added by this Act, except to the extent that
5 such term applies to a product that is sold as a retail prod-
6 uct in any of the establishments listed under such defini-
7 tion.

