

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”.

1 (b) TABLE OF CONTENTS.—The table of contents of  
 2 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 mis-  
     branded 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 re-  
     search 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.**

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

6 (1) by inserting before section 601 the fol-  
 7 lowing:

8 **“Subchapter A—Adulterated and Misbranded**  
 9 **Cosmetics”;**

10 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        metic, 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 ingredients 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 toxi-  
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) AUTHORITY 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 ENIENT 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 (e)(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 (e)(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-

1           ner of making such sheet available) to distribu-  
2           tors and employers, including owners of hair,  
3           nail, and beauty salons or spas or other estab-  
4           lishments that provide cosmetic services for hu-  
5           mans, in English, Spanish, Vietnamese, Chi-  
6           nese, Korean, and upon request other lan-  
7           guages.

8           (2) DISTRIBUTORS.—Each distributor of a cos-  
9           metic or personal care product for professional use  
10          shall distribute and provide material safety data  
11          sheets described in subsection (b) in the same man-  
12          ner as a distributor of a chemical hazard is required  
13          to distribute and provide material safety data sheets  
14          under section 1910.1200(g) of title 29, Code of Fed-  
15          eral Regulations, or any successor regulations.

16          (3) EMPLOYERS.—Each employer, including  
17          any operator of a salon or other establishment de-  
18          scribed in paragraph (1)(B), shall—

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

23                (B) make such material safety data sheet  
24                available to all employees of the employer who  
25                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 nameese, 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.

○