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(Original Signature of Member)

116TH CONGRESS
1ST SESSION

H. R. _____

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

Ms. SCHAKOWSKY introduced the following bill; which was referred to the Committee on _____

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.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE; TABLE OF CONTENTS.

(a) SHORT TITLE.—This Act may be cited as the ''Safe Cosmetics and Personal Care Products Act of 2019''.

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

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

(2) by adding at the end the following:

"Subchapter B—Regulation Of Cosmetics

"SEC. 611. DEFINITIONS.

''In this subchapter:

''(1) BRAND OWNER.—The term 'brand owner' means the entity responsible for bringing a cosmetic to market.

''(2) CONTAMINANT.—The term 'contaminant' means unintended substances, such as those that can originate from sources outside the chemical pathway, chemical processes, storage of primary substances, instability of the packaging or harmful by-products of the manufacturing process.

''(3) DOMESTIC ESTABLISHMENT.—The term 'domestic establishment' means an establishment located in any State that brings a cosmetic to market.

''(4) FOREIGN ESTABLISHMENT.—The term 'foreign establishment' means an establishment that brings a cosmetic to market and exports those cosmetics to the United States.

''(5) INGREDIENT.—The term 'ingredient' means a chemical in a cosmetic, including—

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

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

''(B) substances that are present by reason of having been added to a cosmetic during processing for their technical or functional effect;

''(C) the components of a fragrance, flavor, preservative, or colorant; and

''(D) any individual component that the Secretary deems an ingredient for purposes of this chapter.

''(6) MANUFACTURER.—The term 'manufacturer' means the entity that produces ingredients or combines one or more ingredients to produce a cosmetic product.

''(7) MICROBUSINESS.—The term 'microbusiness' means a business—

''(A) that is a brand owner as defined in this subchapter; and

''(B) that has annual sales receipts for cosmetic products that do not exceed $1,000,000.

''(8) PROFESSIONAL USE.—The term 'professional use' means—

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

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

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

''(9) REASONABLE CERTAINTY OF NO HARM.—With respect to an ingredient or cosmetic, the term 'reasonable certainty of no harm' means that no harm will be caused to members of the general population or any vulnerable population by aggregate exposure to the cosmetic or ingredient, taking into account possible harmful effects from—

''(A) low-dose exposures to the cosmetic or ingredient;

''(B) additive effects resulting from repeated exposure to the cosmetic or ingredient over time; or

''(C) cumulative exposure resulting from all sources, including both the cosmetic or ingredient and environmental sources.

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

metic, the term 'reproductive or developmental toxicity' means that the ingredient or cosmetic can contribute to biologically adverse effects on the development of humans or animals, including effects on the female or male reproductive system, the endocrine system, fertility, pregnancy, pregnancy outcomes, or modifications in other functions of the body that are dependent on the integrity of the reproductive system as well as normal fetal development.

''(11) SERIOUS ADVERSE EVENT.—The term 'serious adverse event' means—

''(A) an acute or chronic response that results in death, a life-threatening experience, short- or long-term hospitalization, a persistent or significant disability or incapacity, a congenital anomaly or birth defect, serious and persistent rashes or infections, significant hair loss, permanent or significant alteration of appearance, or impacts to maternal health, including placentia previa, gestational diabetes, and miscarriage;

''(B) an event that requires, based on a reasonable medical judgment, a medical or surgical intervention; or

''(C) any other serious adverse health-related event associated with the use of the product.

''(12) SUPPLIER.—The term 'supplier' means the entity that supplies ingredients, raw materials, or specific components of a cosmetic or cosmetic packaging.

''(13) VULNERABLE POPULATIONS.—The term 'vulnerable populations' includes pregnant women, infants, children, the elderly, individuals with a compromised immune system, and highly exposed populations including workers in a hair salon, nail salon, beauty salon, spa, or cosmetic manufacturing plant.

"SEC. 612. REGISTRATION OF ESTABLISHMENTS AND REGISTRATION FEES.

''(a) REGISTRATION.—

''(1) IN GENERAL.—Beginning 1 year after the date of the enactment of this subchapter, and annually thereafter, any brand owner engaged in bringing a cosmetic to market for use in the United States shall register with the Secretary and pay to the Secretary the applicable fee, as established under the fee schedule in subsection (e).

''(2) EXCEPTION FOR MICROBUSINESSES.—The requirements of this section do not apply with respect to microbusinesses.

''(3) RULES FOR DOMESTIC AND FOREIGN ESTABLISHMENTS.—To be registered under paragraph (1)—

''(A) as a domestic establishment, the owner, operator, or agent in charge of the domestic establishment shall submit a registration to the Secretary; or

''(B) as a foreign establishment, the owner, operator, or agent in charge of the foreign establishment shall—

''(i) submit a registration to the Secretary; and

''(ii) include with the registration the name of the United States agent for the foreign establishment.

''(4) NEW ESTABLISHMENTS.—Any brand owner that initially brings a cosmetic to market after the date on which the requirements of paragraph (1) apply shall, not later than 60 days after the date on which the establishment brings a cosmetic to market, register with the Secretary and pay the applicable fee, as required under paragraph (1).

''(b) SUBMISSION OF REGISTRATION.—

''(1) IN GENERAL.—In order to register under subsection (a), an establishment (referred to in this section as the 'registrant') shall submit to the Secretary, with respect to any cosmetics that the establishment brings to market, all of the following:

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

''(B) A description of the establishment's activities with respect to cosmetics, including a list of all cosmetic products brought to market by the establishment and the functions of such cosmetics.

''(C) The gross receipts or sales for the establishment from cosmetics.

''(2) NOTIFICATION OF CHANGES.—When submitting the annual registration, the registrant shall notify the Secretary of changes to the information described in paragraph (1).

''(c) PROCEDURE.—Upon receipt of a completed registration submitted under subsection (a), the Secretary shall notify the registrant of the receipt of such registra-

tion and assign a registration number to each registered establishment.

''(d) LIST OF REGISTERED ESTABLISHMENTS.—

''(1) MAINTENANCE OF LIST.—The Secretary shall—

''(A) compile, maintain, and update as appropriate, a list of establishments that are registered under this section;

''(B) make such list publicly available, including by posting such list on the public website of the Food and Drug Administration;

''(C) remove from such list the name of any establishment that fails to register in accordance with this section; and

''(D) indicate on such list any establishment which has had its registration suspended or cancelled by the Secretary under this section.

''(2) APPLICATION OF FOIA.—

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

''(B) OTHER INFORMATION.—Information derived from—

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

''(ii) registration documents submitted pursuant to this section,

shall not be subject to disclosure under section 552 of title 5, United States Code, except to the extent that such information discloses the identity or location of a specific registrant.

''(e) FEE SCHEDULE.—A schedule of fees shall be developed by the Secretary to provide for oversight and enforcement of this subchapter. The fee structure shall—

''(1) be prorated based on the establishment's gross receipts or sales; and

''(2) only be assessed on companies with annual gross receipts or sales of cosmetics that exceed $5,000,000.

''(f) SUSPENSION AND CANCELLATION OF REGISTRATION.—

''(1) CRITERIA FOR SUSPENSION.—Registration under this section is subject to suspension if the Secretary finds—

''(A) the information submitted by the establishment for registration under subsection (a) is incomplete, inaccurate, or out of date;

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

''(C) the establishment fails to pay registration fees, as required under subsection (a), in a timely manner; or

''(D) the establishment violates any portion of this chapter.

''(2) SUSPENSION OF REGISTRATION.—If the Secretary determines that an establishment is subject to suspension under this subsection and that it is appropriate to suspend the registration of such establishment the Secretary shall—

''(A) suspend the registration of such establishment; and

''(B) provide a notice of suspension to such establishment.

''(3) CANCELLATION.—If the establishment fails to correct the issue that resulted in the suspension under paragraph (2) before the last day of the 30-day period beginning on the date that the establishment receives notice under such paragraph, the Secretary may cancel the registration of such establishment.

''(g) RECORDKEEPING.—All establishments that are required to register under this section shall maintain records that include a current list of suppliers and manufacturers if the registrant does not manufacture or package its own product. Those records shall be accessible by the Secretary upon request for review or audit.

''SEC. 613. INGREDIENTS LABELS AND WEBSITE DISCLOSURE FOR COSMETICS.

''(a) IN GENERAL.—Subject to subsections (b) and (c), the Secretary shall require that the label on each package of cosmetics (including cosmetics for retail sale and professional use) bears a declaration of the name of each ingredient in such cosmetic in descending order of predominance.

''(b) ADJUSTMENTS FOR LABEL SIZE.—

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

''(2) REQUIREMENTS FOR PUBLIC DISCLOSURE.—Such regulations shall establish requirements for listing ingredients on the label of such

cosmetics and additional requirements, as appropriate, for public disclosure of the ingredients in such cosmetics.

''(c) SPECIAL RULE FOR CONTAMINANTS.—The Secretary shall require, in the case of a contaminant (as defined by section 618), that a contaminant be declared on the label of a cosmetic, in the same manner as an ingredient under subsection (a), if the contaminant is present in a personal care product in any quantity exceeding one half of one percent of the content of the product by weight.

''(d) LABELING OF NANOMATERIALS IN COSMETICS.—The Secretary may require that—

''(1) minerals and other particulate ingredients be labeled as 'nano-scale' on a cosmetic ingredient label or list if not less than 1 percent of the ingredient particles in the cosmetic are 100 nanometers or smaller in not less than 1 dimension; and

''(2) other ingredients in a cosmetic be designated with scale-specific information on a cosmetic ingredient label or list if such ingredients possess scale-specific hazard properties.

''(e) WEBSITE DISCLOSURE OF COSMETIC INGREDIENTS.—The Secretary shall require that the website of a brand owner of a cosmetic include a declaration of the in-

gredients in the cosmetic in descending order of predominance, including the function of each ingredient.

''(f) LABELING OF INGREDIENTS IN COSMETICS SOLD THROUGH INTERNET COMMERCE.—The Secretary shall require—

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

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

''(g) PRODUCT LABELING OF FRAGRANCE AND FLAVOR INGREDIENTS.—

''(1) REQUIREMENTS.—The Secretary shall require that all fragrance and flavor ingredients in a cosmetic that are deemed hazardous to human health or the environment by paragraph (2) appear on the label of the cosmetic.

''(2) LIST OF INGREDIENTS DEEMED HAZARDOUS.—The following ingredients (including chemicals added by the relevant government agency or authoritative body subsequent to the date of en-

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

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

"(B) Chemicals classified by the European Union as carcinogens, mutagens, or reproductive toxicants pursuant to Category 1A or 1B in Annex VI to Regulation (EC) No. 1272/2008.

"(C) Chemicals included in the European Union Candidate List of Substances of Very High Concern in accordance with Article 59 of Regulation (EC) No. 1907/2006 on the basis of Article 57(f) for endocrine disrupting properties.

"(D) Chemicals for which a reference dose or reference concentration has been developed based on neurotoxicity in the Environmental Protection Agency's Integrated Risk Information System.

"(E) Chemicals that are identified as carcinogenic to humans, likely to be carcinogenic

to humans, or as Group A, B1, or B2 carcinogens, in the Environmental Protection Agency's Integrated Risk Information System.

''(F) Chemicals included in the European Chemicals Agency Candidate List of Substances of Very High Concern in accordance with Article 59 of Regulation (EC) No. 1907/2006 on the basis of Article 57(d), Article 57(e), or Article 57(f) of Regulation (EC) No. 1907/2006 for persistent, bioaccumulative and toxic, or very persistent and very bioaccumulative, properties.

''(G) Chemicals that are identified as persistent, bioaccumulative, and inherently toxic to the environment by the Canadian Environmental Protection Act Environmental Registry Domestic Substances List pursuant to subsection 66(1) of the Canadian Environmental Protection Act, 1999.

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

''(I) Group 1, 2A, or 2B carcinogens identified by the International Agency for Research on Cancer.

"(J) Neurotoxicants that are identified in the Agency for Toxic Substances and Disease Registry's Toxic Substances Portal.

"(K) Persistent bioaccumulative and toxic priority chemicals that are identified by the Environmental Protection Agency's National Waste Minimization Program as of February 22, 2016.

"(L) Reproductive and developmental toxicants identified by National Toxicology Program Center for the Evaluation of Risks monographs.

"(M) Chemicals identified as 'Persistent Bioaccumulative Toxic' by the Environmental Protection Agency on the Toxics Release Inventory under section 313 of the Emergency Planning and Community Right-to-Know Act of 1986 (42 U.S.C. 11023).

"(N) The State of Washington Department of Ecology's Persistent, Bioaccumulative, Toxic (PBT) Chemicals identified in Chapter 173–333 of Title 173 of the Washington Administrative Code.

"(O) Chemicals that are identified as known to be, or reasonably anticipated to be,

human carcinogens by the most recent Report on Carcinogens prepared by the Federal National Toxicology Program.

''(P) Chemicals for which primary maximum contaminant levels have been established for drinking water by the Environmental Protection Agency.

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

''(R) Toxic pollutants listed under section 307(a)(1) of the Federal Water Pollution Control Act (33 U.S.C. 1317) and priority pollutants identified in appendix A to part 423 of title 40, Code of Federal Regulations.

''(S) Chemicals that are identified on the Centers for Disease Control and Prevention's most recent Report on Human Exposure to Environmental Chemicals and Updated Tables Volume 1 and Volume 2.

''(T) Chemicals that are identified on Part A of the list of Chemicals for Priority Action prepared by the Oslo and Paris Conventions for

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

''(U) Chemicals identified as hazardous under section 101(14) or 102 of the Comprehensive Environmental Response, Compensation, and Liability Act of 1980 (42 U.S.C. 9601(14), 9602).

''(h) FRAGRANCE ALLERGENS.—The Secretary shall require that any fragrance allergen in a cosmetic be included on the label of the cosmetic and identified as a fragrance allergen if the fragrance allergen is—

''(1) included in Annex III of European Union Cosmetics Regulation No. 1223/2009, as required to be disclosed pursuant to European Union Detergents Regulation No. 21648/2004, and subsequent updates to those regulations; and

''(2) is present in—

''(A) a rinse-off cosmetic at a concentration at or above 0.01 percent; or

''(B) a leave-on cosmetic product at a concentration at or above 0.001 percent.

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

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

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

''(1) all cosmetics that are available for retail sale (including such cosmetics for professional use); and

''(2) brand owners and internet vendors of such cosmetics.

"SEC. 614. SAFETY STANDARD AND GOOD MANUFACTURING PRACTICES.

''(a) SAFETY STANDARD.—

''(1) IN GENERAL.—Taking into account the expected or reasonably foreseeable use of a cosmetic, the Secretary shall establish a safety standard that, with respect to a cosmetic or an ingredient in a cosmetic, provides a reasonable certainty of no harm (as such term is defined in section 611(9)) from exposure to the cosmetic or ingredient and protects the public from any known or anticipated adverse health effects associated with the cosmetic or ingredient.

''(2) STANDARDS FOR ESTABLISHING SAFETY STANDARD.—In establishing the safety standard

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

''(A) the likely level of exposure to all sources of the ingredient or cosmetic (including environmental sources) that will result under the safety standard presents not more than a one in a million risk for any adverse health effect in any vulnerable population at the lower 95th percentile confidence interval; or

''(B) the safety standard results in exposure to the amount or concentration of an ingredient or cosmetic that is shown to produce no adverse health effects, incorporating a margin of safety of at least 1,000 and considering the impact of cumulative exposure from all sources (including environmental sources).

''(3) USE OF OTHER FEDERAL STANDARDS.—If any Federal agency has promulgated a standard for an ingredient that satisfies the requirements of paragraph (1), the Secretary may treat such standard as the safety standard under paragraph (1) for purposes of such ingredient.

''(b) GOOD MANUFACTURING PRACTICES.—

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

for cosmetics and ingredients, including quality control procedures that the Secretary determines are necessary, and shall update such guidance as necessary.

''(2) CONSIDERATION OF SMALL BUSINESS.—In developing the guidance under paragraph (1), the Secretary shall consider how such practices will impact small businesses.

"SEC. 615. COSMETIC AND INGREDIENT SAFETY INFORMATION.

''(a) REQUIRED SUBMISSION OF ALL SAFETY INFORMATION.—

''(1) IN GENERAL.—Brand owners of cosmetics shall submit electronically to the Secretary all data and information that the brand owner can access regarding the safety of—

''(A) the ingredients listed on the cosmetic label and the brand owner's website under section 613 for a cosmetic; and

''(B) the cosmetic itself.

''(2) REQUIRED INFORMATION.—The required data and information under paragraph (1) shall include, for each ingredient in a cosmetic and for the cosmetic, the following:

''(A) Functions and uses.

''(B) Data and information on the physical, chemical, and toxicity properties of each such ingredient or cosmetic.

''(C) Exposure and fate information.

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

''(E) Any other information used to substantiate the safety of such ingredient and cosmetic.

''(3) DEADLINES.—

''(A) INITIAL SUBMISSION.—A brand owner shall submit the data and information required under paragraph (1)—

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

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

''(I) not later than the end of the 14-month period beginning on the date of the enactment of this subchapter; or

''(II) if the ingredient or cosmetic is first marketed for sale in interstate commerce after the end of the period described in subclause (I), not later than 60 days after the date on which such ingredient or cosmetic is first marketed for sale.

''(B) UPDATES.—

''(i) IN GENERAL.—Subject to clause (ii), a brand owner shall update the data and information submitted under subparagraph (A) annually.

''(ii) ADVERSE HEALTH EFFECTS.—In the case of information related to an adverse health effect that is suspected to be caused by an ingredient or a cosmetic, a brand owner shall update the information not later than 60 days after receiving such information.

''(4) SUPPLIER AND MANUFACTURER INFORMATION.—

''(A) USE OF SUPPLIER OR MANUFACTURER INFORMATION.—In order to meet the requirements of paragraph (1) with respect to an ingredient, a brand owner may submit safety

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

''(B) SUPPLIER OR MANUFACTURER PROVISION OF INFORMATION.—If a brand owner requests that a supplier or manufacturer of an ingredient provide to such brand owner any of the data and information described under paragraph (2) or under section 617, such supplier or manufacturer shall provide such data and information to such brand owner not later than 90 days after receiving such request.

''(b) DATABASE.—

''(1) INITIAL PUBLICATION.—Not later than 1 year after the date of the enactment of this subchapter, the Secretary shall publish a comprehensive database that—

''(A) is publicly accessible, including on the public website of the Food and Drug Administration; and

''(B) contains all nonconfidential information (as such term is used in section 623) submitted under subsection (a)(1).

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

date the database under paragraph (1) with such information.

''(c) REVIEW AND EVALUATION OF INFORMATION.—

''(1) IN GENERAL.—Based on the data and information submitted under subsection (a)(1), available from an authoritative source (as such term is defined in paragraph (3), including data described in section 627(b)), and such other information as the Secretary may have available, the Secretary shall review and evaluate the safety of cosmetics and ingredients of cosmetics that are marketed in interstate commerce.

''(2) CONSIDERATION OF NANOMATERIALS.—The Secretary shall—

''(A) monitor developments in the scientific understanding from any adverse health effects related to the use of nanotechnology in the formulation of cosmetics (including progress in the standardization of testing methods and specific size definitions for nanomaterials); and

''(B) consider scale-specific hazard properties of ingredients when reviewing and evaluating the safety of cosmetics and ingredients under paragraph (1).

''(3) AUTHORITATIVE SOURCE DEFINED.—For purposes of this subsection, the term 'authoritative source' means—

''(A) the Environmental Protection Agency;

''(B) the International Agency for Research on Cancer;

''(C) the National Institutes of Health;

''(D) the California Environmental Protection Agency; and

''(E) any other authoritative international, Federal, or State entity, as determined by the Secretary.

"SEC. 616. LISTS OF INGREDIENTS AND REQUIRED RESPONSES.

''(a) PLACEMENT ON LIST.—

''(1) IN GENERAL.—Based on an initial review and evaluation of the chronic health impacts associated with an ingredient that is used in one or more cosmetics, the Secretary shall create and periodically update a list of ingredients for safety review. From such list, the Secretary shall place ingredients on a priority assessment list and, after comprehensive safety review, place each ingredient on the priority assessment list on one of the following lists:

''(A) The prohibited and restricted lists under subsection (b).

''(B) The safe without limits list under subsection (c).

''(C) The insufficient data list under subsection (d).

''(2) INITIAL LIST.—The Secretary shall add 20 ingredients to the initial priority assessment list created under paragraph (1) immediately after the enactment of this subchapter.

''(3) CONSIDERATIONS.—In determining the placement of an ingredient on the priority assessment list under paragraph (1), the Secretary shall consider the scientific evidence linking that ingredient to harm and conduct further prioritization based on whether the ingredient—

''(A) is found to be present in the body through biomonitoring;

''(B) is found in drinking water or air;

''(C) is a known or suspected neurological or immunological toxicant, respiratory asthmagen, carcinogen, teratogen, or endocrine disruptor, or have other toxicity concerns (including reproductive or developmental toxicity);

''(D) is known to persist in the environment or bioaccumulate; or

''(E) is of particular concern to a community disproportionately impacted by cosmetic chemicals in products marketed to them because of their particular race, ethnicity, or occupation.

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

''(b) PROHIBITED AND RESTRICTED LISTS.—

''(1) IN GENERAL.—The Secretary shall issue, by regulation, two lists of ingredients that are identified by the Secretary—

''(A) in the first list, as prohibited for use in cosmetics because the Secretary determines that such ingredients are unsafe for use in cosmetics in any amount because such ingredients fail to meet the safety standard under section 614(a); or

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

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

''(2) INITIAL PROHIBITED LIST.—

''(A) IMMEDIATELY PROHIBITED INGREDIENTS.—Effective as of the date of enactment of this subchapter, the following ingredients are deemed to be listed pursuant to paragraph (1)(A) as prohibited for use:

''(i) Benzophenones, including benzophenone-1, benzophenone-3 (also known as ozybenzone), benzophenone-4, and benzophenone-5.

''(ii) Octinoxate.

''(iii) Butylated Hydroxyanisole and Butylated Hydroxyoluen.

''(iv) Coal tar dyes (P-phenylenediamine).

''(v) Cocamide Diethanolamine.

''(vi) Dibutyalated Phthalate (Phthalates DBP), Bis(2-ethylhexyl) Phthalate (DEHP).

''(vii) Toluene.

''(viii) Styrene or Styrene acrylates.

''(ix) Formaldehydes (Methylene glycol/methanediol/formaldehyde) and Form-

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

''(x) Triclosan.

''(xi) Lead acetate or other lead compounds.

''(xii) Parabens (isoproylparaben, isobutylparaben, pheylparaben, benzylparaben, pentylparaben, propylparaben and butylparaben).

''(B) FIRST INGREDIENTS LISTED BY REGULATION.—Not later than 2 years after the date of enactment of this subchapter, the Secretary shall promulgate by final regulation the lists required by subparagraphs (A) and (B) of paragraph (1), to supplement the ingredients deemed by subparagraph (A) of this paragraph to be listed pursuant to paragraph (1)(A).

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

''(4) UPDATES.—

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

"(i) updates to determinations under subsection (d)(3); or

"(ii) any updates prompted by new information that demonstrates that an ingredient fails to meet the safety standard, or requires restrictions on use to meet such standard.

"(B) CHEMICALS IDENTIFIED PURSUANT TO NIH-FUNDED RESEARCH.—The Secretary shall—

"(i) consult with the Director of the National Institute of Environmental Health Sciences to identify any chemicals that are determined to be of concern pursuant to investigations funded under section 463C of the Public Health Service Act; and

"(ii) review any such chemicals in accordance with this section to determine whether such chemicals should be prohib-

ited or subject to restrictions under this section.

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

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

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

''(c) SAFE WITHOUT LIMITS LIST.—

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

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

''(A) the type and form of cosmetic the ingredient is used in; and

''(B) the concentration of the ingredient that is used in a cosmetic.

''(3) UPDATES AND REDETERMINATIONS.—After promulgating the initial list pursuant to paragraph (1), the Secretary—

''(A) shall annually update the list under paragraph (1); and

''(B) may redetermine whether an ingredient distributed in commerce meets the safety standard under section 614(a) if, in the judgment of the Secretary, new information raises a credible question as to whether the ingredient continues to meet the safety standard.

''(d) PRIORITY ASSESSMENT LIST AND RELATED SAFETY DETERMINATIONS.—

''(1) IN GENERAL.—Not later than 1 year after the creation of the initial priority assessment list of ingredients for review under subsection (a)(1), the Secretary shall evaluate the safety of not less than 10 ingredients for which the Secretary has determined it is a priority to conduct a safety determination under paragraph (3).

''(2) ANNUAL ADDITION OF INGREDIENTS.—After the initial evaluation of 10 ingredients pursuant to paragraph (1), the Secretary shall annually

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

"(A) the prohibited and restricted lists under subsection (b);

"(B) the safe without limits list under subsection (c); or

"(C) the insufficient data list under this subsection.

"(3) DETERMINATION OF WHETHER INGREDIENT MEETS SAFETY STANDARD.—

"(A) REVIEW OF PRIORITY INGREDIENTS.—During the 2-year period following the date on which an ingredient is listed pursuant to paragraph (1) or (2), the Secretary shall—

"(i) collect data and information on such ingredient; and

"(ii) review and evaluate the safety of such ingredient.

"(B) DETERMINATION OF LIST PLACEMENT.—Not later than the end of the period under subparagraph (A), the Secretary shall issue a determination, based on the review and evaluation under such subparagraph, that the

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

''(C) GUIDANCE IN THE CASE OF INSUFFICIENT OR NO DATA.—If the Secretary determines under subparagraph (B) that, with respect to an ingredient, insufficient or no data exists to place such ingredient on either the prohibited and restricted list under subsection (b) or the safe without limits list under subsection (c), the Secretary shall provide guidance on the data and information (including minimum data requirements and safety testing protocols) that the Secretary requires to evaluate whether the ingredient meets the safety standard under section 614(a) for purposes of placing such ingredient on either such list.

''(D) COMMENT PERIOD.—Upon issuing the determination under subparagraph (B), and, if applicable, the guidance under subparagraph (C), the Secretary shall provide a period of not less than 60 days for public comment on the determination before applying such determination to an ingredient, except that a shorter

period for comment may be provided if the Secretary—

"(i) finds that it would be in the public interest to have a shorter period; and

"(ii) publicly declares the reasons for such finding.

"(4) RESPONSE TO INADEQUATE INFORMATION.—Not later than 18 months after the date that the Secretary issues guidance under paragraph (3)(C) with respect to an ingredient subject to a determination under paragraph (3)(B), a brand owner using such ingredient in a cosmetic shall—

"(A) reformulate such cosmetic to eliminate the use of the ingredient; or

"(B) provide the Secretary with the data and information specified in such guidance.

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

"(A) review such data and information; and

''(B) make a redetermination under paragraph (3)(B) for such ingredient, subject to the comment period under paragraph (3)(D).

"SEC. 617. TREATMENT OF COSMETICS BASED ON INGREDIENT LISTS.

''(a) IN GENERAL.—Subject to subsections (b)(5) and (d)(4) of section 616, a brand owner may only distribute in interstate commerce a cosmetic that meets the safety standard under section 614(a).

''(b) PRESUMPTION RELATED TO THE SAFETY OF COSMETICS.—

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

''(A) A cosmetic that is made solely of ingredients on the list under section 616(c)(1) (relating to ingredients that are safe without limits).

''(B) A cosmetic that is made solely of ingredients on the list under section 616(b)(1)(B) (relating to ingredients subject to restrictions) and the use of each of such ingredients in such cosmetic is in compliance with the restrictions

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

''(C) A cosmetic that is made solely of ingredients described in subparagraph (A) and subparagraph (B).

''(2) EXCEPTIONS.—The Secretary may require that a brand owner demonstrate that a cosmetic meets the safety standard under section 614(a) (including by requiring that the brand owner conduct safety testing, or request such safety testing from relevant suppliers and manufacturers, of a cosmetic described under paragraph (1)) if—

''(A) the cosmetic contains—

''(i) penetration enhancers, sensitizers, endocrine-disrupting compounds, or other similar ingredients; or

''(ii) ingredients that react with each other or with other substances to form harmful byproducts; or

''(B) the Secretary has any additional reason to believe that such cosmetic does not meet the safety standard under section 614(a).

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

tion 614(a), the Secretary shall provide the brand owner with guidance on the data and information that the Secretary requires to evaluate whether the cosmetic meets the safety standard under such section.

''(c) NOTIFICATION OF FAILURE OF SECRETARY TO ACT.—If the Secretary fails to act by an applicable deadline under section 616 or this section, brand owners and manufacturers of an ingredient or a cosmetic affected by such failure of the Secretary to act shall issue to the Secretary, the public, and each known customer of the ingredient or cosmetic, a written and electronic notice that a determination by the Secretary of the safety of the ingredient or cosmetic is pending.

''SEC. 618. TREATMENT OF CONTAMINANTS.

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

''(1) ingredients used in cosmetics that may contain contaminants of concern;

''(2) combinations of ingredients that may create contaminants of concern when such ingredients interact;

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

''(4) any other contaminant of concern identified by the Secretary that are present in cosmetics.

''(b) EVALUATION; LABELING.—The Secretary shall use the process described in sections 615 and 616 to evaluate contaminants of concern for possible elimination or restriction in cosmetics. The Secretary shall require that a contaminant on the list under subsection (a) be declared on the label of a cosmetic, in the same manner as an ingredient under section 613.

''(c) REQUIREMENTS FOR TESTING.—

''(1) IN GENERAL.—Not later than 1 year after the date of enactment of this subchapter, the Secretary shall establish, by rule, requirements for testing ingredients and cosmetics for contaminants listed under subsection (a).

''(2) CONTENTS.—The requirements under paragraph (1) shall include—

''(A) testing methods and applicable protocols; and

''(B) maximum allowable detection limits for each contaminant in an ingredient or cosmetic.

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

''(d) SUPPLIER REQUIREMENTS.—Beginning not later than 1 year after the promulgation of the rule under subsection (c)(1) with respect to an ingredient that is used in a cosmetic, a supplier of the ingredient shall, with respect to such ingredient—

''(1) comply with the requirements under subsection (c)(1) for any ingredient listed under subsection (a);

''(2) conduct similar testing on any ingredient that—

''(A) the supplier expects may be used in a cosmetic;

''(B) the supplier suspects may contain a contaminant of concern; and

''(C) is not listed under subsection (a); and

''(3) upon the sale of an ingredient to the manufacturer of a cosmetic, provide to the manufacturer specifications for the ingredient that—

''(A) include the levels of contaminants present in such ingredient; and

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

''(e) BRAND OWNER REQUIREMENTS.—Not later than 1 year after the promulgation of the rule under subsection (c)(1), a brand owner of a cosmetic shall, with respect to each ingredient that the brand owner uses in a cosmetic—

''(1) obtain, from each supplier or manufacturer of the ingredient, specifications for the ingredient that include—

''(A) the level of each contaminant present in the ingredient; and

''(B) the detection limits of the analytical test used to detect the contaminant; or

''(2) comply with the requirements under paragraphs (1) and (2) of subsection (d) for the ingredient, in the same manner as if the brand owner were a supplier.

''SEC. 619. COSMETIC AND INGREDIENT STATEMENTS.

''(a) IN GENERAL.—Beginning 1 year after the date of the enactment of this subchapter, each brand owner of a cosmetic intended to be marketed in the United States shall submit electronically to the Secretary, for each cosmetic that is intended to be marketed in the United States, a statement containing—

''(1) the registration number of the brand owner;

''(2) the brand name and the product name for the cosmetic;

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

''(4) a list of the ingredients in the product, including fragrance, flavorants, and the particle size range of any nanoscale cosmetic ingredients;

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

''(6) the name, title, and full contact information for the individual responsible for submitting and maintaining such statement.

''(b) NEW COSMETICS.—Any brand owner that begins to market a cosmetic after the date of the enactment of this subchapter shall comply with the requirements of subsection (a) beginning on the later of the following:

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

''(2) The end of the 6-month period after the date on which the establishment begins to manufacture such cosmetic.

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

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

shall notify the brand owner of the receipt of such statement and assign a cosmetic statement number.

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

''(f) ACCESS TO SAFETY INFORMATION.—The cosmetic and ingredient statements collected under this section shall be added to the publicly accessible database created by the Secretary under section 615(b).

''SEC. 620. NOTIFICATION, NONDISTRIBUTION, AND RECALL OF ADULTERATED OR MISBRANDED COSMETICS.

''(a) NOTIFICATION OF ADULTERATED OR MISBRANDED COSMETICS.—

''(1) IN GENERAL.—A responsible party that has reason to believe that a cosmetic, when introduced into or while in interstate commerce, or while held for sale (regardless of whether such sale is the first sale of such cosmetic) after shipment in interstate commerce, is adulterated or misbranded in a manner that presents a reasonable probability that the use or exposure to the cosmetic (or an ingredient or component used in any such cosmetic) will cause a threat of a serious adverse event shall notify the

Secretary of the identity and location of the cosmetic.

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

''(3) RESPONSIBLE PARTY DEFINED.—For purposes of this subsection, the term 'responsible party' means a brand owner, manufacturer, packager, retailer, or distributor of the cosmetic.

''(b) VOLUNTARY RECALL.—The Secretary may request that any person who distributes a cosmetic that the Secretary has reason to believe is adulterated, misbranded, or otherwise in violation of this Act voluntarily—

''(1) recall such cosmetic; and

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

''(c) ORDER TO CEASE DISTRIBUTION.—

''(1) IN GENERAL.—If the Secretary has reason to believe that—

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

''(B) the cosmetic is misbranded; or

''(C) the cosmetic is marketed, manufactured, packaged, or distributed by an unregistered brand owner,

the Secretary may issue an order requiring any person who distributes such cosmetic to immediately cease distribution of such cosmetic.

''(2) CEASE DISTRIBUTION AND NOTICE.—Any person who is subject to an order under paragraph (1) shall immediately cease distribution of such cosmetic and provide notification as required by such order.

''(3) APPEAL.—

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

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

''(C) INFORMAL HEARING.—Except as provided in subsection (d)(2), an informal hearing shall be held as soon as practicable, but not later than 5 calendar days (or less as deter-

mined by the Secretary) after such an appeal is filed, unless the parties jointly agree to an extension.

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

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

''(d) MANDATORY RECALL ORDERS.—

''(1) IN CONJUNCTION WITH ORDER TO CEASE DISTRIBUTION.—

''(A) AMENDMENT.—Except as provided under paragraph (2) and subject to subsection (c)(3)(D), if the Secretary determines that a recall of a cosmetic subject to an order under subsection (c) is appropriate, the Secretary shall amend the order to require a recall.

''(B) CONTENTS.—An amended order under subparagraph (A) shall—

''(i) specify a timetable in which the recall will occur;

''(ii) require periodic reports to the Secretary describing the progress of the recall; and

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

''(C) ASSISTANCE IN PROVIDING NOTICE.—In providing for notice under subparagraph (B), the Secretary may allow for the assistance of health professionals, State or local officials, or other individuals designated by the Secretary.

''(D) DETERMINATION.—If the Secretary determines that inadequate grounds exist to support the amendment made to the order under subparagraph (A), the Secretary shall remove such amendment from such order.

''(2) FOR IMMINENT THREAT OF A SERIOUS ADVERSE EVENT.—

''(A) IN GENERAL.—If the Secretary has credible evidence or information that a cosmetic subject to an order under subsection (c) presents an imminent threat of a serious adverse event, the Secretary shall issue an order requiring any person who distributes such cosmetic—

''(i) to immediately recall such cosmetic; and

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

''(B) RECALL AND NOTICE.—Any person who is subject to an emergency recall order under this subsection shall immediately recall such cosmetic and provide notification as required by such order.

''(3) APPEAL.—

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

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

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

such an appeal is filed, or fewer days (as determined by the Secretary), unless the parties jointly agree to an extension.

''(D) VACATION OF ORDER.—If the Secretary determines that inadequate grounds exist to support the actions required by the order under paragraph (1) or (2), the Secretary shall vacate the order.

''(4) NONDELEGATION.—An order (including an amended order) under paragraph (1) or (2) may only be issued by the Secretary or an official designated by the Secretary, and may not be delegated to another official or employee.

''(e) NOTICE TO CONSUMERS AND HEALTH OFFICIALS.—The Secretary shall post on the Food and Drug Administration's website and provide notice of a recall order under this section to consumers to whom the cosmetic was, or may have been, distributed and to appropriate State and local health officials.

''(f) SUPPLY CHAIN INFORMATION.—

''(1) IN GENERAL.—In the case of a cosmetic that the Secretary has reason to believe is adulterated, misbranded, or otherwise in violation of this Act, the Secretary shall request that the brand owner named on the label of such cosmetic (as re-

quired under section 602(b)(1)) submit all of the following information:

''(A) The name and place of business of the manufacturer, packager, supplier, or distributor from which such entity received the cosmetic or ingredients for manufacturing such cosmetic.

''(B) The name and place of business of any entity (including any retailer) that was provided with such cosmetic by the entity named on the label.

''(2) COLLECTION OF ADDITIONAL SUPPLY CHAIN INFORMATION.—In the case of a cosmetic that the Secretary has reason to believe is adulterated, misbranded, or otherwise in violation of this Act, to the extent necessary to protect the safety of the public, the Secretary may request that any entity (including a supplier of an ingredient, manufacturer, packer, distributor, or retailer) in the supply chain of such cosmetic submit to the Secretary information that is similar to the information described in subparagraphs (A) and (B) of paragraph (1).

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

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

''(A) maintain records sufficient to provide the information described in subparagraphs (A) and (B) of paragraph (1); and

''(B) provide such information to the Secretary upon the request of the Secretary.

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

''SEC. 621. PETITIONS.

''(a) IN GENERAL.—The Secretary shall complete and publish a review, and, if appropriate, immediately revise related, relevant information, including ingredient lists, ingredient restrictions or prohibitions, or ingredient or cosmetic safety determinations, not later than 6 months after the date on which the Secretary receives from any individual or entity a reasonable petition—

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

''(2) to remove an ingredient from the list of ingredients that are safe without limits under section 616(c);

''(3) to add an ingredient to the priority assessment list under section 616(d);

''(4) to add an ingredient to the list of ingredients with insufficient data under section 616(d); or

''(5) to add an ingredient to the list of contaminants under section 618.

''(b) REASONABLE PETITION.—Not later than 1 year after the date of enactment of this subchapter, the Secretary shall issue rules specifying the criteria which the Secretary will use to determine if a petition submitted under this section is a reasonable petition.

''SEC. 622. MANDATORY REPORTING OF SERIOUS ADVERSE EVENTS.

''(a) SUBMISSION OF REPORT ON SERIOUS ADVERSE EVENTS.—The Secretary shall require that the brand owner of a cosmetic whose name appears on the label of a cosmetic marketed in the United States submit to the Secretary a report containing information received concerning any serious adverse event associated with the use of the cosmetic.

''(b) TIMING OF REPORT.—A report under subsection (a) shall be submitted to the Secretary not later than 15 business days after information concerning the serious adverse event is received at the place of business of the brand owner.

''(c) CONTENT OF REPORT.—A report under subsection (a) shall include the following information, to the extent to which the brand owner submitting the report has been able to verify the information:

''(1) The identity of the individual experiencing the adverse health event.

''(2) An identifiable report of such effect.

''(3) The name of the cosmetic suspected of causing such effect.

''(4) A description of the adverse health event.

''(d) PUBLIC AVAILABILITY AND PRIVACY.—

''(1) PUBLIC AVAILABILITY.—Subject to paragraph (2), the serious adverse event reports collected by the Secretary under this section shall be submitted electronically and shall be made accessible to the public in a summary fashion on the Food and Drug Administration's website.

''(2) PRIVACY.—

''(A) PERSONALLY IDENTIFIABLE INFORMATION.—Notwithstanding any other provision of law, personally identifiable information in serious adverse event reports provided to the Secretary under this section, shall not—

''(i) be made publicly available pursuant to any State or other law requiring disclosure of information or records; or

''(ii) otherwise be disclosed or distributed to any party without the written consent of the Secretary and the person submitting such information to the Secretary.

''(B) TREATMENT OF INFORMATION UNDER PRIVACY ACT AND FOIA.—A report submitted to the Secretary under this section, shall be considered to be a record about an individual under section 552a of title 5, United States Code (commonly referred to as the 'Privacy Act of 1974') and a medical or similar file the disclosure of which would constitute a violation of section 552 of such title 5 (commonly referred to as the 'Freedom of Information Act'), and shall not be publicly disclosed unless all personally identifiable information is redacted.

''SEC. 623. NONCONFIDENTIAL INFORMATION.

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

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

''(2) All information concerning function, exposure, toxicity data, health hazards, and environmental hazards for a cosmetic.

''(3) The functions of ingredients in cosmetics.

''(4) Fragrance, flavor, and colorants in a cosmetic.

''(b) CONFIDENTIAL INFORMATION.—The concentration of cosmetic ingredients used in a finished cosmetic shall be considered confidential business information and may not be made available to the public under subsection (a).

''(c) PETITION FOR INFORMATION TO REMAIN CONFIDENTIAL.—

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

''(2) LIMITATION.—The Secretary may not approve a petition under paragraph (1) to the extent

that such petition would prevent the public disclosure of—

''(A) the name, identity, and structure of any chemical substance, contaminant, or impurity that is an ingredient;

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

''(C) any data used to substantiate the safety of that substance, contaminant, or impurity.

''SEC. 624. BAN ON USE OF ANIMAL TESTING.

''(a) BAN.—Beginning on the date of enactment of this subchapter, it shall be unlawful for any entity to conduct, directly or pursuant to contract, animal testing for the purpose of developing a cosmetic for sale in or affecting interstate commerce.

''(b) LIMITATION ON CONSIDERATION OF DATA.—The Secretary shall not take into consideration any animal testing on a finished cosmetic product or an ingredient that occurs on or after the date of enactment of this subchapter with respect to any determination as to whether a cosmetic or ingredient meets the safety standard under section 614(a).

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

''(1) the animal testing is for the purpose of determining whether an ingredient, or the relevant category of ingredients, meets the safety standard under section 614(a); and

''(2) the Secretary determines that the safety of the ingredient, or the relevant category of ingredients, cannot be established using a non-animal testing method that is validated by the Interagency Coordinating Committee on the Validation of Alternative Methods authorized by section 3 of the ICCVAM Authorization Act of 2000 (42 U.S.C. 285l–3) .

''(d) VALIDATED, ELIGIBLE NON-ANIMAL TESTING METHODS.—

''(1) LIST.—The Secretary shall develop, maintain, and make publicly available a list of non-animal testing methods that—

''(A) are validated by the Interagency Coordinating Committee on the Validation of Alternative Methods; and

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

''(2) INITIAL LIST; UPDATES.—The Secretary shall—

''(A) not later than 1 year after the date of enactment of this subchapter, publish the initial list under paragraph (1); and

''(B) annually thereafter, update such list.

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

''SEC. 625. PRODUCT TESTING AND REVIEW AUDIT.

''The Secretary shall conduct annual audits of random samples of cosmetics to assess or test for acute negative reactions, pathogen hazards, contaminants, leaching of packaging additives, mislabeling, or other relevant issues of concern (as determined by the Secretary).

''SEC. 626. RESOURCES FOR SMALL BUSINESSES.

''The Secretary shall provide technical support to assist small businesses in carrying out the requirements of this subchapter.

''SEC. 627. INTERAGENCY COOPERATION.

''(a) INTERAGENCY COUNCIL ON COSMETIC SAFETY.—There is established an Interagency Council on Cosmetic Safety for the purpose of sharing data and promoting collaboration on cosmetic safety between the Food and Drug Administration, the National Institute of Environmental Health Sciences, the Centers for Disease Con-

trol and Prevention, the Occupational Safety and Health Administration, and the Environmental Protection Agency.

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

''SEC. 628. SAVINGS CLAUSE.

''Nothing in this Act affects the right of a State or a political subdivision of a State to adopt or enforce any regulation, requirement, or standard of performance that is different from, or in addition to, a regulation, requirement, liability, or standard for performance established pursuant to this Act unless compliance with both this Act and the State or political subdivision of a State's regulation, requirement, liability, or standard of performance is impossible, in which case the applicable provisions of this Act shall control.

''SEC. 629. AUTHORIZATION OF APPROPRIATIONS.

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

SEC. 3. ADULTERATED AND MISBRANDED COSMETICS.

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

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

(2) by adding at the end the following:

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

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

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

"(2) it contains an ingredient on the list under section 616(b)(1)(B), such ingredient is being used in a manner that violates the limit on use or concentration of such ingredient under section 616(b)(3), and the manufacturer has not complied with section 616(b)(5) with respect to such ingredient and such cosmetic.

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

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

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

(1) in paragraph (a), by inserting ''or fails to meet the requirements of section 613 or 618(b)'' before the period; and

(2) by adding at the end the following:

''(g) If it—

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

''(2) is brought to market, manufactured, packaged, distributed, or sold in retail by a brand owner, manufacturer, packager, distributor, or retailer, respectively, who fails to notify the Secretary as required under section 620(a)(1);

''(3) is distributed in violation of an order under section 620(c);

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

''(5) is manufactured in a manner that fails to comply with good manufacturing practices prescribed by the Secretary under section 614(b); or

''(6) is brought to market by a brand owner who fails—

''(A) to submit the statement required under section 619; or

''(B) notify the Secretary of changes to information contained in such report, as required by such section.''.

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

(1) in paragraph (e), by inserting ''612,'' after ''564,'' each place it appears; and

(2) by adding at the end the following:

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

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

''(hhh) The failure of a supplier of an ingredient for use in a cosmetic—

''(1) to provide data and information as required by section 615(a)(4)(B); or

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

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

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

''(kkk) The conduct of animal testing in violation of section 624.''.

SEC. 4. SUPPORT FOR CREATING SAFER ALTERNATIVES.

(a) IN GENERAL.—The Secretary of Health and Human Services (in this section referred to as the ''Secretary''), acting through the Commissioner of Food and Drugs, in consultation with the Administrator of the Environmental Protection Agency, shall award grants to eligible entities to support research focused on the design of safer alternatives to chemicals in cosmetics with inherent toxicity or associated with chronic adverse health effects.

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

(1) be a public institution such as a university, a not-for-profit research institution, or a small business; and

(2) not benefit from a financial relationship with a cosmetics manufacturer, supplier, or trade association.

(c) PRIORITY.—In awarding grants under subsection (a), the Secretary shall give priority to applicants proposing to focus on—

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

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

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

SEC. 5. SUPPORT BY NATIONAL INSTITUTE OF ENVIRONMENTAL HEALTH SCIENCES FOR RESEARCH ON HEALTH DISPARITIES IMPACTING COMMUNITIES OF COLOR.

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

"SEC. 463C. RESEARCH ON HEALTH DISPARITIES RELATED TO COSMETICS IMPACTING COMMUNITIES OF COLOR.

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

"(1) to expand support for basic, epidemiological, and social scientific investigations into—

"(A) the chemicals linked to adverse health effects most commonly found in cosmetics marketed to women and girls of color, including beauty, personal hygiene, and intimate care products;

"(B) the marketing and sale of such cosmetics containing chemicals linked to adverse health effects to women and girls of color across their lifespans; or

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

"(2) to disseminate the results of any such research described in subparagraph (A) or (B) of paragraph (1) (conducted by the grantee pursuant to this section or otherwise) to help communities identify and address potentially unsafe chemical exposures in the use of cosmetics.

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

''(1) be a public institution such as a university, a not-for-profit research institution, or a small business; and

''(2) not benefit from a financial relationship with a cosmetics manufacturer, supplier, or trade association.

''(c) REPORT.—Not later than the end 1 year after awarding grants under this section, the Director of the Institute shall issue for the public and submit to the Committee on Energy and Commerce of the House of Representatives and the Committee on Health, Education, Labor, and Pensions of the Senate a report on the results of the investigations funded under subsection (a), including—

''(1) summary findings on—

''(A) marketing strategies, product categories, and specific cosmetics containing ingredients linked to adverse health effects; and

''(B) the demographics of the populations marketed to and using these cosmetics; and

''(2) recommended public health information strategies to reduce potentially unsafe exposures to cosmetics.

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

priated such sums as may be necessary for fiscal years 2020 through 2025.''.

SEC. 6. WORKER ISSUES.

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

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

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

(i) the manufacturer or importer produces or imports; and

(ii) includes a hazardous chemical, or a product ingredient associated with any chemical hazard, that is classified as a health hazard in accordance with the criteria found in section 1910.1200(d) of title 29 of the Code of Federal Regulations, and any successor regulations; and

(B) make the material safety data sheet available on the manufacturer or importer's 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-

tent and in the same manner as material safety data sheets are required to be made available under section 1910.1200(g) of title 29, Code of Federal Regulations, or any successor regulations; and

(C) upon request, provide employees with translations of such material safety data sheet in other languages, including Spanish, Vietnamese, Chinese, Korean, and upon request other languages.

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

(1) contain the information required in a material safety data sheet under section 1910.1200(g) of title 29, Code of Federal Regulations, or any successor regulations, for each hazardous chemical, or product ingredient associated with any chemical hazard, described in subsection (a)(1)(A)(ii); and

(2) include the following statement: ''This material safety data sheet is also available in multiple languages by contacting the manufacturer, using the contact information provided on this sheet.''.

(c) PROFESSIONAL USE DEFINED.—In this section, the term ''professional use'' has the meaning given such term in section 611 of the Federal Food, Drug, and Cosmetic Act, as added by this Act, except to the extent that such term applies to a product that is sold as a retail product in any of the establishments listed under such definition.