117TH CONGRESS
1ST SESSION

S. 2100

To amend the Federal Food, Drug, and Cosmetic Act to ensure the safety of cosmetics.

IN THE SENATE OF THE UNITED STATES

JUNE 17, 2021

Mrs. FEINSTEIN (for herself and Ms. COLLINS) introduced the following bill; which was read twice and referred to the Committee on Health, Education, Labor, and Pensions

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A BILL

To amend the Federal Food, Drug, and Cosmetic Act to ensure the safety of cosmetics.

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 ''Personal Care Products Safety Act''.

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

TITLE I—COSMETIC SAFETY

SEC. 101. REGISTRATION OF COSMETICS FACILITIES AND COSMETIC INGREDIENT STATEMENTS.

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

"SEC. 604. DEFINITIONS.

''In this chapter:

''(1) COSMETIC FORMULATION.—The term 'cosmetic formulation' means a preparation of cosmetic raw materials with a qualitatively and quantitatively set composition.

''(2) COSMETIC PRODUCT.—The term 'cosmetic product' means a preparation of cosmetic raw ingredients, which may come in a range of possible

amounts for each ingredient, for purposes of introduction into interstate commerce as a finished product.

''(3) FACILITY.—The term 'facility' includes any factory, warehouse, or establishment (including a factory, warehouse, or establishment of an importer) that manufactures or processes cosmetic products or cosmetic formulations, or any other entity whose name and address appear on the label of a cosmetic product. Such term does not include—

''(A) beauty shops and salons that do not otherwise manufacture, process, or package cosmetics at that location;

''(B) cosmetic product retailers, including individual sales representatives, direct sellers, retail distribution facilities, and pharmacies, that do not otherwise manufacture, process, or package cosmetics at that location;

''(C) hospitals, physicians' offices, and health care clinics;

''(D) public health agencies and other nonprofit entities that provide cosmetics directly to the consumer;

''(E) hotels and other entities that provide complimentary cosmetics to guests;

''(F) trade shows and other venues where cosmetic product samples are provided free of charge;

''(G) a factory, warehouse, or establishment of—

''(i) domestic manufacturers with less than $500,000 in average gross annual sales of cosmetic products in the United States for the previous 3-year period, or less than $1,000,000 in such sales of cosmetic products produced in a private residence; or

''(ii) entities that manufacture or compound cosmetic products solely for use in research, teaching, or pilot plant production and not for sale; or

''(H) an establishment that solely performs one or more of the following with respect to cosmetic products: labeling, relabeling, packaging, repackaging, holding, or distributing.

''(4) FOREIGN FACILITY.—The term 'foreign facility' means a facility that manufactures or processes a cosmetic formulation or cosmetic product that is exported to the United States without further processing or packaging inside the United States. A

cosmetic is not considered to have undergone further processing or packaging for purposes of this definition solely on the basis that labeling was added or that any similar activity of a de minimis nature was carried out with respect to the cosmetic.

''(5) NON-FUNCTIONAL CONSTITUENT.—The term 'non-functional constituent' means any substance that is an incidental component of an ingredient, a breakdown product of an ingredient or a by-product of the manufacturing process that has not been intentionally added as a separate substance and serves no technical function in the cosmetic.

''(6) RESPONSIBLE PERSON.—The term 'responsible person' means—

''(A) the brand owner who is the domestic or foreign manufacturer or entity whose name appears on a cosmetic product label of a cosmetic product distributed in the United States, except for entities described in subparagraphs (A) through (H) of paragraph (3); or

''(B) a contract manufacturer who provides cosmetic products to the entities described in subparagraphs (A) through (H) of paragraph (3).''.

"SEC. 605. REGISTRATION OF COSMETIC FACILITIES.

"(a) REGISTRATION AND FEES FOR EXISTING MANUFACTURING OR PROCESSING OF COSMETICS.—

"(1) REGISTRATION, IN GENERAL.—Not later than 1 year after the date of enactment of the Personal Care Products Safety Act, and at a similar time in each subsequent year, as determined by the Food and Drug Administration, each responsible person engaged in manufacturing or processing a cosmetic product or a cosmetic formulation distributed in the United States shall register all of the responsible person's facilities with the Food and Drug Administration.

"(2) FEES.—If the average gross annual sales in the United States of cosmetic products of all of the responsible person's facilities registered under paragraph (1) for the previous 3-year period is greater than $10,000,000, a registration shall not be complete under this subsection until the responsible person has paid any registration fee required under section 744O.

"(b) REGISTRATION BY NEW FACILITIES.—Any facility first engaging after the date of enactment of the Personal Care Products Safety Act in an activity that would require it to register under subsection (a) shall register with the Food and Drug Administration within 60 days

of first engaging in such activity, and thereafter in accordance with subsection (a).

''(c) CONTRACT MANUFACTURERS.—If a facility manufactures or processes cosmetic products on behalf of a responsible person, the Food and Drug Administration shall require only a single registration for such facility even if such facility is manufacturing or processing its own cosmetic products or cosmetic products on behalf of more than 1 responsible person. Such single registration may be submitted to the Food and Drug Administration by such facility or any responsible person whose products are manufactured or processed at such facility.

''(d) CHANGES TO INFORMATION.—A registrant who has submitted a registration under this section shall notify the Food and Drug Administration of any change to the information required under subsection (a) or (b) not later than 60 days after the date of such change, unless otherwise specified by the Food and Drug Administration.

''(e) FORMAT; CONTENTS.—

''(1) ELECTRONIC FORMAT.—Each registration shall be submitted using an electronic format, as specified in a registration form provided by the Food and Drug Administration.

''(2) CONTENTS.—

"(A) IN GENERAL.—Except as provided in subparagraph (B), the registration shall contain the following information:

"(i) Each facility's name and full address, identifying the precise physical location of the facility.

"(ii) The identity of the facility, including the unique facility identifier, if any, previously assigned by the Food and Drug Administration to the facility under subsection (h).

"(iii) All business trading names used by the facility.

"(iv) The product category or categories of each cosmetic product or cosmetic formulation manufactured or processed at the facility or on whose label the facility's name and address appear.

"(v) The type of activity conducted at the facility (such as manufacturing or processing).

"(vi) The name, title, street address, telephone number, and electronic contact information of the emergency contact for the facility.

''(vii) In the case of a foreign facility, the name, street address, telephone number, emergency contact information, and name of the United States agent for the facility, and, if available, the electronic contact information of the United States agent.

''(viii) The name, title, street address, telephone number, and electronic contact information of the individual submitting the registration.

''(ix) An assurance that the Food and Drug Administration will be permitted to inspect such facility at the times and in the manner permitted by this Act.

''(x) Additional information pertaining to the facility or to the cosmetic products or cosmetic formulations manufactured or processed at the facility, or on whose label the facility's name and address appear, including all brand names known to consumers, as the Food and Drug Administration may require by regulation.

''(xi) An ingredient listing for all cosmetic products manufactured or processed

in such facility, in accordance with subsection (f), which, for each relevant cosmetic product, may be submitted to the Food and Drug Administration as part of such registration or separately.

''(xii) A written assurance that each cosmetic product manufactured or processed in such facility has been substantiated for safety or carries the warning required under section 740.10 of title 21, Code of Federal Regulations (or any successor regulations). The responsible person shall maintain records documenting any such substantiation of safety and the information on which such determination is based until 5 years after the finished product is no longer marketed, except that a responsible person for a domestic company whose sales are under $2,000,000 per year shall maintain such records for at least 2 years after the finished product is no longer marketed.

''(B) SMALL BUSINESSES.—

''(i) REQUIREMENTS.—In the case of a registrant described in clause (ii), the

registration shall contain the following information:

"(I) Each facility's name and full address, identifying the precise physical location of the facility.

"(II) The name, title, street address, telephone number, and electronic contact information of the emergency contact for the facility.

"(III) The consumer product category or categories of each cosmetic product or cosmetic formulation manufactured, processed, packed, or held at the facility or on whose label the facility's name and address appear.

"(ii) SMALL BUSINESS REGISTRANTS.—A registrant described in this clause is a domestic registrant—

"(I) whose average gross annual sales in the United States of cosmetic products for the previous 3-year period is between $500,000 and $2,000,000 (or between $1,000,000 and $2,000,000 in the case of sales of

cosmetic products produced in a private residence); and

"(II) who does not produce—

"(aa) products that are intended to go on the eye area;

"(bb) lip products with color;

"(cc) products that are injected;

"(dd) products that are intended for internal use; or

"(ee) products that are meant to alter appearance for more than 24 hours.

"(iii) GUIDANCE.—The Food and Drug Administration shall, after consultation with the Small Business Administration and small businesses that manufacture cosmetics, provide additional guidance for small businesses on compliance with the requirements of this section that would apply to small business registrants. Such guidance shall include specific examples of options for compliance that do not place an undue burden on small businesses.

''(3) ABBREVIATED REGISTRATION.—The Food and Drug Administration shall provide for an abbreviated registration renewal process for any registrant that has not had any changes to the required information with respect to the facility or facilities involved since the registrant submitted the preceding registration.

''(f) COSMETIC PRODUCT INGREDIENT LISTING.—

''(1) IN GENERAL.—The ingredient listing required pursuant to subsection (e)(2)(A)(xi) shall include—

''(A) the unique identifier assigned under section (h), as applicable, of—

''(i) each facility where the cosmetic product is manufactured or processed; and

''(ii) the facility whose name and address appear on the label, unless the statement is filed by a contract manufacturer described in section 604(6)(B);

''(B) the brand name and the full name for the cosmetic product as it appears on the label;

''(C) the cosmetic product listing number, if any, previously assigned to the cosmetic product by the Food and Drug Administration under paragraph (4);

''(D) the applicable cosmetic category for the cosmetic product;

''(E) a list of ingredients in the cosmetic product, including a range of possible amounts of each ingredient, identified by the name adopted in regulations promulgated by the Food and Drug Administration, if any, or by the common or usual name of the ingredient, which shall include—

''(i) a list of fragrances, flavors, and colors that may be included in the product, interchangeably, with ranges of possible amounts, which shall include—

''(I) in the case of fragrances that are purchased from a fragrance supplier, identification of the fragrances by the name or code provided by the supplier, including the name and contact information for the fragrance supplier; and

''(II) in the case of flavors that are purchased from a flavor supplier, identification of the flavors by the name or code provided by the supplier, including the name and contact

information for the flavor supplier; and

"(ii) other appropriate interchangeable ingredients as the Food and Drug Administration may specify in regulations or guidance that may be included in the product, with ranges of possible amounts;

"(F) the title and full contact information of each individual submitting the statement;

"(G) if applicable, information on the labeling required under section 612; and

"(H) if applicable, information showing that the cosmetic ingredient or ingredients in the product meet any specified conditions of use or tolerances required following a final determination of safety under section 607(d).

"(2) ADDITIONAL INFORMATION.—In the case of a cosmetic ingredient statement that includes a list of fragrances or flavors that are purchased from a fragrance or flavor supplier as described in paragraph (1)(E)(i), upon request by the Food and Drug Administration, the fragrance or flavor supplier shall submit to the Food and Drug Administration the complete list of ingredients in specific fragrances or

flavors, not later than 30 days after receiving such request.

''(3) COSMETIC PRODUCT INGREDIENT STATEMENT FOR NEW OR REFORMULATED COSMETIC PRODUCTS.—

''(A) IN GENERAL.—Except as provided under subparagraph (B), in the case of a cosmetic product that is first marketed after the date of enactment of the Personal Care Products Safety Act or a cosmetic product that is reformulated after such date of enactment, the responsible person shall submit a cosmetic ingredient statement to the Food and Drug Administration within 60 days of first marketing the new cosmetic product or reformulated cosmetic product, and annually thereafter.

''(B) SMALL BUSINESSES.—The Food and Drug Administration shall allow a responsible person that is a business that meets the applicable industry-based small business size standard established by the Administrator of the Small Business Administration under section 3 of the Small Business Act to have a period longer than 60 days to submit an initial new

cosmetic ingredient statement under subparagraph (A).

''(C) DEFINITION.—A cosmetic product shall not be considered first marketed or reformulated after the date of enactment under subparagraph (A) if the only change in such product is in—

''(i) the amount of an existing ingredient if it is within the range previously reported under paragraph (1)(E); or

''(ii) the addition or subtraction of a fragrance, flavor, or color, or such other interchangeable ingredients specified by the Food and Drug Administration in regulations or guidance, previously reported as a potential ingredient under paragraph (1)(E), if, in the case of such an addition, the amount is within the range previously reported.

''(4) COSMETIC PRODUCTS LIST.—At the time of the initial submission of any cosmetic ingredient statement under this section, the Food and Drug Administration shall assign a unique cosmetic product listing number to the cosmetic ingredient statement. Based on such cosmetic ingredient statements,

the Food and Drug Administration shall compile and maintain a list of cosmetic products distributed in the United States, including the ingredients of each such product, and shall make available such list to any State, upon request. Information disclosed to a State that is exempt from disclosure under section 552(b)(4) of title 5, United States Code, shall be treated as a trade secret and confidential information by the State.

''(g) INCOMPLETE OR INACCURATE REGISTRATION.—

''(1) IN GENERAL.—Not earlier than 10 days after providing notice of the intent to cancel a registration and the basis for such cancellation, the Food and Drug Administration may cancel a registration under this section if the Food and Drug Administration has reasonable grounds to believe that the registration was not properly completed or updated in accordance with this section or otherwise contains false, incomplete, or inaccurate information.

''(2) TIMELY UPDATE OR CORRECTION.—If, not later than 7 days after receipt of a notice of intent to cancel, the responsible person corrects the registration in accordance with the basis for the cancellation, and the required registration fee, if any, is

paid, the Food and Drug Administration shall not cancel such registration.

''(h) UNIQUE IDENTIFIER.—At the time of the initial registration of any cosmetic facility under this section, the Food and Drug Administration shall assign a unique identifier to the facility.

''(i) REGISTRY OF FACILITIES.—

''(1) IN GENERAL.—The Food and Drug Administration shall compile, maintain, and update a registry of facilities that are registered under this section, and shall remove from such registry the name of any facility whose registration under this section is cancelled. The registry shall be publicly available.

''(2) PUBLIC AVAILABILITY EXCEPTIONS.—Information derived from the registry or registration documents that discloses the residential address of a registrant or that discloses specific facilities where specific cosmetic products are manufactured or processed shall not be subject to disclosure under section 552 of title 5, United States Code.

''SEC. 606. SUSPENSION OF REGISTRATION OR COSMETIC INGREDIENT STATEMENT.

''(a) SUSPENSION OF REGISTRATION OF A FACILITY.—If the Food and Drug Administration determines

that a cosmetic formulation or cosmetic product manufactured or processed by a registered facility and distributed in the United States has a reasonable probability of causing serious adverse health consequences or death to humans, and the Food and Drug Administration has a reasonable belief that other products manufactured or processed by the facility may be similarly affected because of a failure that cannot be isolated to a single product or products or is sufficiently pervasive to raise concerns about other products manufactured in the facility, the Food and Drug Administration may suspend the registration of a facility.

''(b) SUSPENSION OF COSMETIC INGREDIENT STATEMENT.—If the Food and Drug Administration determines that a cosmetic product manufactured in a registered facility has a reasonable probability of causing serious adverse health consequences or death to humans, the Food and Drug Administration may suspend the cosmetic ingredient statement of that product.

''(c) NOTICE OF SUSPENSION.—Before suspending a facility registration or a cosmetic ingredient statement under this section, the Food and Drug Administration shall provide—

''(1) notice to the facility registrant of the cosmetic product or formulation or other responsible

person, as appropriate, of the intent to suspend the facility registration or the cosmetic ingredient statement, which shall specify the basis of the determination by the Food and Drug Administration that the facility or the cosmetic ingredient should be suspended and recommendations for specific actions to avoid suspension; and

''(2) an opportunity, within 2 business days of the notice provided under paragraph (1), for the responsible person to address the reasons for possible suspension of the facility registration or cosmetic ingredient statement.

''(d) REINSTATEMENT.—Upon a determination by the Food and Drug Administration that adequate grounds do not exist to continue the suspension actions, the Food and Drug Administration shall promptly vacate the suspension and reinstate the registration of the facility or the cosmetic ingredient statement.

''(e) EFFECT OF SUSPENSION.—

''(1) REGISTRATION.—If the registration of a facility is suspended under this section, no person shall introduce or deliver for introduction into interstate commerce cosmetics or cosmetic products from such facility.

''(2) COSMETIC INGREDIENT STATEMENT.—If the cosmetic ingredient statement for a cosmetic product is suspended under this section, no person shall introduce or deliver for introduction into interstate commerce any cosmetic product that is the subject of such statement.

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

SEC. 102. REVIEW OF INGREDIENTS AND NON-FUNCTIONAL CONSTITUENTS.

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

''SEC. 607. REVIEW OF INGREDIENTS AND NON-FUNCTIONAL CONSTITUENTS.

''(a) INGREDIENTS AND NON-FUNCTIONAL CONSTITUENTS SUBJECT TO REVIEW.—

''(1) IN GENERAL.—The Food and Drug Administration shall review the safety of the cosmetic ingredients and non-functional constituents listed under paragraph (3), as modified under subsection (c), if applicable, and issue an order under sub-

section (d) with respect to the use of each such ingredient and presence of each such non-functional constituent.

''(2) PUBLIC NOTICE AND COMMENT.—At the initiation of the review of each cosmetic ingredient or non-functional constituent, the Food and Drug Administration shall open a docket for the submission of public comment and additional data relevant to the safety of the ingredient or non-functional constituent. The Food and Drug Administration shall provide 60 days for public comment.

''(3) COSMETIC INGREDIENTS.—

''(A) IN GENERAL.—Beginning in fiscal year 2022, the Food and Drug Administration shall annually select and complete a safety review of at least 5 cosmetic ingredients or non-functional constituents that were not reviewed in the prior 3 years, from a list determined in consultation with the cosmetic industry and consumer and health groups. The Food and Drug Administration may combine selected cosmetics ingredients or non-functional constituents into categories for purposes of such review. The Food and Drug Administration may modify such list under subsection (c).

''(B) CONSIDERATIONS.—The determination of which ingredients or functional ingredients will be reviewed in a given year shall be publicized in annual reports to Congress and the public, in accordance with section 617. The review of any cosmetic ingredient or non-functional constituent shall commence with a public announcement by the Food and Drug Administration and the opening of a docket as required under paragraph (2).

''(4) COMMENT PERIOD.—As part of the annual reporting to Congress and the public under section 617, the Food and Drug Administration shall solicit public comment on which cosmetic ingredients or non-functional constituents on the list are of greatest interest to be reviewed next for early review and which additional cosmetic ingredients or non-functional constituents should be added to the list. The public may submit comments to the Food and Drug Administration at any time during the year regarding which cosmetic ingredients or non-functional constituents of interest the Food and Drug Administration may consider during that year or subsequent years.

''(b) LIST.—The Food and Drug Administration shall maintain a list, posted on the internet website of the Food and Drug Administration, of the cosmetic ingredients and non-functional constituents for which final orders have been issued under subsection (d)(3), the finding made for each such ingredient or non-functional constituent under subsection (d)(4), as modified by any order under subsection (f), if applicable, and, if applicable, compliance dates that are the subject of a final order under subsection (e).

''(c) INITIATIVE OF THE FDA.—The Food and Drug Administration may at any time propose the issuance of an order on the safety of a cosmetic ingredient or non-functional constituent that was not previously listed in subsection (a) or under section 617(a)(3). The Food and Drug Administration shall follow the same procedures and policies for review of any cosmetic ingredient or non-functional constituent so proposed as for the ingredients and constituents reviewed pursuant to subsection (a).

''(d) DETERMINATION ON SAFETY.—

''(1) INITIAL PROPOSED ADMINISTRATIVE ORDER.—Following consideration of data and comments to the public docket and any other information before the Food and Drug Administration, the Food and Drug Administration shall determine

whether there is adequate evidence to make an initial finding on the safety of the ingredient or non-functional constituent. If the Food and Drug Administration determines that there is adequate evidence, the Food and Drug Administration shall issue a proposed administrative order and shall post such order on the internet website of the Food and Drug Administration, notwithstanding subchapter II of chapter 5 of title 5, United States Code.

''(2) PUBLIC COMMENT.—Upon publication of the proposed administrative order described in paragraph (1), the Food and Drug Administration shall open a docket for the submission of public comment. The Food and Drug Administration shall provide 30 days for public comment following publication of the proposed administrative order.

''(3) FINAL ADMINISTRATIVE ORDER.—Following the public comment period described in paragraph (2) and consideration of comments to the public docket and any other information before the Food and Drug Administration, the Food and Drug Administration shall determine whether there is adequate evidence to make a final finding on the safety of the ingredient or non-functional constituent. If the Food and Drug Administration determines that

there is adequate evidence, the Food and Drug Administration shall issue a final administrative order and shall post such order on the internet website of the Food and Drug Administration, notwithstanding subchapter II of chapter 5 of title 5, United States Code.

''(4) DETERMINATIONS.—In the proposed administrative order or the final administrative order, as applicable, the Food and Drug Administration shall make a determination that the ingredient or non-functional constituent is—

''(A) safe in cosmetic products under specified conditions of use or tolerances;

''(B) safe in cosmetic products without the need for specified conditions of use or tolerances; or

''(C) not safe in cosmetic products.

''(5) CONDITIONS OF USE AND TOLERANCES.—An order under paragraph (4)(A) shall include such conditions on the use of an ingredient or such tolerances on the presence of a non-functional constituent as are necessary for the safety of cosmetic products containing such ingredient or non-functional constituent, including—

"(A) limits on the amount or concentration of the ingredient or non-functional constituent that may be present in a cosmetic product, including limits in products intended for children and other vulnerable populations, and limits on use near the eye or mucosal membranes;

"(B) warnings that are necessary or appropriate under section 612, including warnings related to use by children, pregnant women, populations with high exposure to the ingredient (such as workers who are exposed through production practices or handling of final products), or other vulnerable populations, to help ensure safe use of cosmetic products containing the ingredient or non-functional constituent; and

"(C) such other screening, safety protocol, or other similar conditions as are necessary for the safety of cosmetic products containing such ingredient or non-functional constituent.

"(6) PUBLIC NOTICE.—A final order under this subsection shall set forth the determination of the Food and Drug Administration on safety, any conditions of use or tolerances under subparagraph (A) or (B) of paragraph (4) and a summary of the valid scientific evidence supporting the finding. The order

shall be effective upon its publication on the internet website of the Food and Drug Administration and shall be considered final agency action.

''(e) ORDER.—

''(1) IN GENERAL.—If the Food and Drug Administration issues a final administrative order under subparagraph (A) or (C) of subsection (d)(4), the Food and Drug Administration shall, at the same time as publication of the notice under subsection (d)(6), publish a proposed order identifying dates by which use of the ingredient or non-functional constituent in cosmetic products shall comply with the final administrative order, and provide 60 days for public comment, including comment on whether compliance is feasible within the proposed dates. After considering comments on the proposed order, the Food and Drug Administration shall publish in the Federal Register a final order.

''(2) CONTENT.—The public notice information regarding the final order under paragraph (1) shall include a summary that is written in plain and understandable language that is comprehensible and meaningful for consumers. The summary shall include information on any conditions of use or warnings required under section 612, including the appli-

cation to vulnerable populations, the types of safety studies evaluated, and any additional relevant information that was part of the review process.

''(f) MODIFICATION OF AN ORDER.—An order issued under subsection (d) or (e) may be modified or revoked by the Food and Drug Administration on the initiative of the Food and Drug Administration or in response to a petition.

''(g) INADEQUATE EVIDENCE.—

''(1) NOTICE; EXTENSION.—If the Food and Drug Administration determines that the available data and information are not adequate to make a proposed or final determination regarding safety under subsection (d)(4), with respect to a cosmetic ingredient or non-functional constituent, the Food and Drug Administration shall—

''(A) publish such finding on the internet website of the Food and Drug Administration not later than 90 days after the close of the relevant comment period for the ingredient or non-functional constituent under subsection (a)(2), in the case of a proposed order, or subsection (d)(2), in the case of a final order; and

''(B)(i) include a notice providing interested persons an additional 30 days from the

notice date to provide additional data and information; and

''(ii) if, after the 30-day period under clause (i), the Food and Drug Administration determines that additional safety substantiation with respect to such ingredient or non-functional constituent is necessary to make a safety determination—

''(I) include a notice specifying an additional time period, not to exceed 18 months from the notice date, during which time the assurance made by a responsible person under section 605(e)(2)(A)(xii) with respect to the safety of such cosmetic ingredient or non-functional constituent shall be deemed to be in compliance with the requirements of this Act, but shall not affect final determinations of safety under subsection (d); and

''(II) plan to obtain such data and information.

''(2) DETERMINATION; ORDER.—

''(A) INADEQUATE DATA AND INFORMATION.—If the Food and Drug Administration determines, after considering any additional

data and information submitted under paragraph (1)(B), that the available data and information still are not adequate to make a determination regarding safety under subsection (d)(4), the Food and Drug Administration shall, within 90 days of the close of the additional time period provided under paragraph (1)(B), issue a proposed order or a final administrative order—

''(i) making a determination that the ingredient or non-functional constituent has not been shown to be safe in cosmetic products; and

''(ii) explaining why the available data and information are not adequate to assess the safety of the ingredient or non-functional constituent.

''(B) ADEQUATE DATA AND INFORMATION.—If the Food and Drug Administration determines, after considering any additional data and information submitted under paragraph (1)(B), that the available data and information are adequate to make a determination regarding safety under subsection (d)(4), the Food and Drug Administration shall, within

180 days of the close of the comment period, issue a proposed order, followed by a final order, on such cosmetic ingredient or non-functional constituent, in accordance with such subsection.

''(h) SAFETY ASSESSMENT.—

''(1) IN GENERAL.—In assessing the safety of an ingredient or non-functional constituent, the Food and Drug Administration shall consider whether there is adequate evidence to support a reasonable certainty among competent scientists that the ingredient is not harmful under the recommended or suggested conditions of use or customary or usual use, or that a non-functional constituent is not harmful under the recommended or suggested tolerance levels or the level at which it is customarily or usually present. The Food and Drug Administration may not consider an ingredient or non-functional constituent harmful solely because it can cause minor adverse health reactions, such as minor transient allergic reactions or minor transient skin irritations, in some users.

''(2) FACTORS.—In assessing the safety of an ingredient or non-functional constituent, the Food

and Drug Administration shall consider, among other relevant factors, the following:

"(A) The probable human exposure to the ingredient or non-functional constituent from expected use in cosmetics.

"(B) The probable cumulative and aggregate effect in humans of relevant exposure to the ingredient or non-functional constituent or to any chemically or pharmacologically related substances from use in cosmetics or other products with similar routes of exposure under recommended or suggested conditions of use or their customary use, to the extent adequate data is available for analysis. In appropriate cases, the Food and Drug Administration may consider available information on the total exposure to an ingredient or non-functional constituent from all sources.

"(C) Whether warnings or recommendations in a product label required under section 612, as part of any conditions of use or tolerances imposed by the Food and Drug Administration, would be necessary and appropriate to help ensure the safety of the ingredient or non-functional constituent.

''(3) DATA AND INFORMATION.—

''(A) REQUIRED INFORMATION.—A determination that an ingredient or non-functional constituent is safe in cosmetics shall be based upon adequate evidence submitted or otherwise known to the Food and Drug Administration, which shall include full reports of all available studies, published or unpublished, that are adequately designed to show whether the ingredient or non-functional constituent is safe. Such studies may include in vitro and in silico studies and epidemiological studies, biomonitoring studies, and studies focused on various points during the lifespan of the subject, that use scientifically valid methodology.

''(B) ADDITIONAL RELEVANT INFORMATION.—The Food and Drug Administration shall consider any other relevant information related to the safety of the ingredient or non-functional constituent, including—

''(i) adverse event reports;

''(ii) findings and information from State, Federal, national, and international entities and other bodies composed of scientific and medical experts;

"(iii) if the ingredient or non-functional constituent is lawfully used or present in other products regulated by the Food and Drug Administration, the scientific basis for such use; and

"(iv) experience with the ingredient or non-functional constituent in products that are distributed in the United States or in other countries, if such experience is well-documented and has resulted in substantial human exposure to the ingredient or non-functional constituent over time.

"(i) COAL-TAR HAIR DYE.—Coal-tar hair dye shall be subject to the conditions of section 601(a) unless the Food and Drug Administration has issued a final determination for a coal-tar hair dye ingredient under subsection (d)(4)(C).

"(j) CERTAIN INGREDIENTS IMPARTING PIGMENT.—Ingredients imparting pigment to cosmetic products that are subject to review and approval pursuant to section 721(b) shall not be subject to review under this section.".

(b) GAO REPORT.—The Comptroller General of the United States shall conduct a review of the program of review of cosmetic ingredients and non-functional constituents under section 607 of the Federal Food, Drug,

and Cosmetic Act, as added by subsection (a), and, not later than 5 years after the date of enactment of this Act, issue a report on such review.

SEC. 103. GOOD MANUFACTURING PRACTICES FOR COSMETICS.

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

"SEC. 608. GOOD MANUFACTURING PRACTICES FOR COSMETICS.

''(a) IN GENERAL.—The Food and Drug Administration shall review national and international standards for cosmetic good manufacturing practices that are in existence on the date of enactment of the Personal Care Products Safety Act and shall develop and implement, through regulations, standards consistent, to the extent the Food and Drug Administration determines practicable and appropriate, with such national and international standards for cosmetic good manufacturing practices to ensure that requirements of this chapter with respect to the manufacture of cosmetic products are in harmony.

''(b) CONSULTATION.—The standards under subsection (a) shall include simplified good manufacturing practices for small businesses that take into account the

size and scope of the business, developed in consultation with the Small Business Administration.

''(c) TIMEFRAME.—The Food and Drug Administration shall publish a proposed rule described in subsection (a) not later than 18 months after the date of enactment of the Personal Care Products Safety Act and shall publish a final such rule not later than 3 years after such date of enactment.''.

(b) EFFECTIVE DATE FOR COSMETIC MANUFACTURERS.—

(1) LARGE BUSINESSES.—For businesses of a size greater than the Small Business Administration's standard for a small business, section 608 of the Federal Food, Drug, and Cosmetic Act (as added by subsection (a)) shall take effect beginning 180 days after the date on which the Food and Drug Administration makes effective cosmetic good manufacturing practices.

(2) SMALL BUSINESSES.—For businesses of a size that meets the Small Business Administration's standard for a small business, section 608 of the Federal Food, Drug, and Cosmetic Act (as added by subsection (a)) shall take effect beginning 2 years after the date the Food and Drug Administration

makes effective cosmetic good manufacturing practices.

SEC. 104. ADVERSE EVENT REPORTS.

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

"SEC. 609. ADVERSE EVENT REPORTING FOR COSMETICS.

''(a) IN GENERAL.—With respect to any cosmetic product distributed in the United States, the responsible person shall submit to the Food and Drug Administration a report of any serious adverse event associated with such cosmetic product, when used in the United States, accompanied by a copy of the label on or with the retail packaging of the cosmetic, any new medical information, related to a submitted serious adverse event report that is received by the responsible person, and an annual report for all adverse events received by the responsible person.

''(b) DEFINITIONS.—In this section:

''(1) An 'adverse event' for a cosmetic product is a health-related event associated with the use of this product that is adverse.

''(2) A 'serious adverse event' for a cosmetic product is an adverse event that—

''(A) results in—

''(i) death;

''(ii) a life-threatening experience;

''(iii) inpatient hospitalization;

''(iv) a persistent or significant disability or incapacity;

''(v) congenital anomaly or birth defect; or

''(vi) significant disfigurement, including serious and persistent rashes or infections and significant hair loss; or

''(B) requires, based on appropriate medical judgment, a medical or surgical intervention to prevent an outcome described in subparagraph (A).

''(c) SUBMISSION OF REPORTS.—

''(1) SERIOUS ADVERSE EVENT REPORTS.—Except as provided in paragraph (2), with respect to a cosmetic product distributed in the United States, the responsible person shall submit a serious adverse event report to the Food and Drug Administration not later than 15 business days after information concerning the adverse event is received. If a serious adverse event report for a cosmetic with drug properties is filed using Form FDA 3500A (or any successor form developed for such purpose) or its elec-

tronic equivalent for over-the-counter drugs, the responsible person shall not have to submit a duplicative serious adverse event report under this section.

''(2) NEW MEDICAL INFORMATION.—The responsible person shall submit to the Food and Drug Administration any new medical information, related to a submitted serious adverse event report that is received by the responsible person within 1 year of the initial report, and shall submit such information not later than 15 business days after the new information is received by the responsible person.

''(3) CONSOLIDATION OF REPORTS.—The Food and Drug Administration shall provide for systems to enable the responsible person to submit a single report that includes duplicate reports of, or new medical information related to, a serious adverse event.

''(4) ANNUAL REPORT.—

''(A) IN GENERAL.—Not later than March 1 of each year, except as provided under subparagraph (C), the responsible person shall submit an electronic report for the prior calendar year for each cosmetic product marketed during that year.

"(B) CONTENTS.—Each report under this paragraph shall contain a summary of all adverse events received during the reporting period, a complete list of individual reports, and an estimate of the total number of product units estimated to have been distributed to consumers in the United States during such period. The report shall not include consumer complaints that are solely regarding efficacy and do not contain any information about an adverse event. The Food and Drug Administration shall further specify the contents of the annual electronic report by regulation or guidance.

"(C) SMALL BUSINESS EXCEPTION.—In the case of a domestic facility for which the average gross annual sales in cosmetic products in the United States over the previous 3-year period is not more than $2,000,000, the responsible person is not required to submit an annual report under this paragraph.

"(5) EXEMPTION.—The Food and Drug Administration may establish by regulation an exemption to any of the requirements under this subsection if the Food and Drug Administration determines that such exemption is supported by adequate

evidence and would have no adverse effect on public health.

''(d) REQUIREMENTS.—

''(1) IN GENERAL.—Each serious adverse event report under this section shall be submitted to the Food and Drug Administration using an electronic system of the Food and Drug Administration. The Food and Drug Administration shall make such electronic system available not later than 1 year after the date of enactment of the Personal Care Products Safety Act.

''(2) MODIFICATION.—The format of the reporting system may be modified by the Food and Drug Administration and the reports may include additional information. The Food and Drug Administration may, in guidance, further specify the format and contents of required reports.

''(3) SCOPE OF SERIOUS ADVERSE EVENT REPORT.—A serious adverse event report (including all information submitted in the initial report or added later) submitted to the Food and Drug Administration under subsection (a) includes—

''(A) a report under section 756 with respect to safety and related to a specific cosmetic product;

"(B) a record about an individual who suffered the serious adverse event under section 552a of title 5, United States Code;

"(C) a medical or similar file documenting the serious adverse event, the disclosure of which would constitute a violation of section 552(b)(6) of such title 5, and shall not be publicly disclosed unless all personally identifiable information is redacted; and

"(D) contact information for the individual reporting the serious adverse event.

"(4) RESPONSIBILITY TO GATHER INFORMATION.—After an individual initiates the reporting of a serious adverse event, the responsible person for the cosmetic product shall actively gather all of the information to complete and file the report with the Food and Drug Administration.

"(5) NO ADVERSE EVENTS TO REPORT.—The Food and Drug Administration shall provide an option as part of the electronic registration process for the responsible person to indicate if such responsible person had no adverse events to report over the previous year. With respect to a responsible person who received no adverse event reports for a year, the annual adverse event report requirement may be met

by indicating no such events on the annual registration form.

''(e) LIMITATION WITH RESPECT TO ADVERSE EVENT REPORTS.—The submission of an adverse event report in compliance with subsection (a) shall not constitute an admission that the cosmetic involved caused or contributed to the adverse event.

''(f) CONTACT INFORMATION.—The label of a cosmetic shall bear the domestic telephone number or electronic contact information, and it is encouraged that the label include both the telephone number and electronic contact information, through which the responsible person may receive a report of an adverse event.

''(g) MAINTENANCE OF RECORDS.—The responsible person shall maintain records related to each report of an adverse event received by the responsible person for a period of 6 years.

''(h) AVAILABILITY TO STATES.—The Food and Drug Administration shall make available records submitted under this section to any State, upon request. Information disclosed to a State that is exempt from disclosure under section 552(b)(4) of title 5, United States Code, shall be treated as a trade secret and confidential information by the State.

''(i) EFFECTIVE DATE OF REQUIREMENT WITH RESPECT TO SERIOUS ADVERSE EVENTS.—The requirement under this section to report serious adverse events shall become effective on the date that the Food and Drug Administration publicizes the availability of the electronic system described in subsection (d)(1).''.

SEC. 105. RECORDS INSPECTION; MANDATORY RECALL AUTHORITY.

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

''SEC. 610. INSPECTION OF COSMETIC RECORDS.

''(a) INSPECTION OF RECORDS.—Each manufacturer or processor of a cosmetic shall, at the request of an officer or employee duly designated by the Food and Drug Administration, permit such officer or employee, upon presentation of appropriate credentials and written notice to such person, at reasonable times and within reasonable limits and in a reasonable manner, to have access to and copy—

''(1) all records maintained under section 605(e)(2)(A)(xii) or 609 and in accordance with the rules promulgated by the Food and Drug Administration under section 608, as applicable; and

''(2) except as provided in subsection (b), all other records, if the Food and Drug Administration—

''(A) has a reasonable belief that the cosmetic—

''(i) is adulterated;

''(ii) has caused a reportable serious adverse event; or

''(iii) contains an ingredient that substantial new scientific information shows may be unsafe when present in a cosmetic; and

''(B) provides written notice of the basis for the Food and Drug Administration's reasonable belief described in subparagraph (A).

''(b) EXCLUSIONS.—No inspection authorized by this section shall extend to financial data, pricing data, personnel data (other than data as to qualification of technical and professional personnel performing functions subject to this Act), research data (other than safety data), or sales data other than shipment data.

''(c) SCOPE.—The requirements under subsection (a) apply to records maintained by or on behalf of such person in any format (including paper and electronic formats) and at any location.

''(d) PROTECTION OF SENSITIVE INFORMATION.—The Food and Drug Administration shall take appropriate measures to ensure that there are effective procedures to prevent the unauthorized disclosure of any trade secret or confidential information that is obtained by the Food and Drug Administration pursuant to this section. Information disclosed to a State that is exempt from disclosure under section 552(b)(4) of title 5, United States Code, shall be treated as a trade secret and confidential information by the State.

''(e) LIMITATIONS.—This section shall not be construed—

''(1) to limit the authority of the Food and Drug Administration to inspect records or to require establishment and maintenance of records under any other provision of this Act; or

''(2) to have any legal effect on section 552 of title 5, United States Code, or section 1905 of title 18, United States Code.

''(f) SUBMISSION OF RECORDS.—

''(1) IN GENERAL.—Any records required to be maintained by a responsible person under section 605(e)(2)(A)(xii) shall, upon the written request of the Food and Drug Administration to the responsible person, be provided to the Food and Drug Ad-

ministration within a reasonable timeframe not to exceed 60 days, in either electronic or paper form.

''(2) CRITERIA.—The Food and Drug Administration may require records under paragraph (1) if—

''(A) the Food and Drug Administration has a reasonable belief, described in written notice, that—

''(i) the finished product may be harmful based on adverse event reports or other scientific information; or

''(ii) scientific information raises credible and relevant questions about the safety of the product or any of its ingredients;

''(B) the Food and Drug Administration, an expert regulatory body, or an expert body composed of scientific and medical experts finds an ingredient in the product to be unsafe under the conditions of use of the product; or

''(C) the Food and Drug Administration concludes that submission of the records will serve the public health or otherwise enable the Food and Drug Administration to fulfill the cosmetic safety purposes of this section.''.

"SEC. 611. MANDATORY RECALL AUTHORITY.

"(a) VOLUNTARY PROCEDURES.—If the Food and Drug Administration determines that there is a reasonable probability that a cosmetic is adulterated under section 601 or misbranded under section 602 and the use of or exposure to such cosmetic is likely to cause serious adverse health consequences or death, the Food and Drug Administration shall provide the responsible person with an opportunity to voluntarily cease distribution and recall such article.

"(b) PREHEARING ORDER TO MANDATORILY CEASE DISTRIBUTION AND GIVE NOTICE.—

"(1) IN GENERAL.—If the responsible person refuses to or does not voluntarily cease distribution or recall such cosmetic within the time and in the manner prescribed by the Food and Drug Administration, the Food and Drug Administration may order such person to—

"(A) immediately cease distribution of such cosmetic; and

"(B) as applicable, immediately notify all persons—

"(i) manufacturing, processing, packing, transporting, holding, receiving, distributing, or importing and selling such cosmetic; and

"(ii) to which such cosmetic has been distributed, transported, or sold (except consumers),

to immediately cease distribution of such cosmetic.

"(2) REQUIRED ADDITIONAL INFORMATION.—

"(A) IN GENERAL.—If a cosmetic covered by a recall order issued under paragraph (1)(B) has been distributed to a warehouse-based third-party logistics provider without providing such provider sufficient information to know or reasonably determine the precise identity of such cosmetic covered by a recall order that is in its possession, the notice provided by the responsible person subject to the order issued under paragraph (1)(B) shall include such information as is necessary for the warehouse-based third-party logistics provider to identify the cosmetic.

"(B) RULES OF CONSTRUCTION.—Nothing in this paragraph shall be construed—

"(i) to exempt a warehouse-based third-party logistics provider from the requirements of this chapter, including the

requirements of this section and section 610; or

''(ii) to exempt a warehouse-based third-party logistics provider from being the subject of a mandatory recall order.

''(3) DETERMINATION TO LIMIT AREAS AFFECTED.—If the Food and Drug Administration requires a responsible person to cease distribution under paragraph (1)(A) of a cosmetic, the Food and Drug Administration may limit the size of the geographic area and the markets affected by such cessation if such limitation would not compromise the public health.

''(c) HEARING ON ORDER.—The Food and Drug Administration shall provide the responsible party subject to an order under subsection (b) with an opportunity for an informal hearing, to be held as soon as possible, but not later than 2 days after the issuance of the order, on the actions required by the order and on why the cosmetic that is the subject of the order should not be recalled.

''(d) POST-HEARING RECALL ORDER AND MODIFICATION OF ORDER.—

''(1) AMENDMENT OF ORDER.—If, after providing opportunity for an informal hearing under subsection (c), the Food and Drug Administration

determines that removal of the cosmetic from commerce is necessary, the Food and Drug Administration shall, as appropriate—

"(A) amend the order to require recall of such cosmetic or other appropriate action;

"(B) specify a timetable in which the recall shall occur;

"(C) require periodic reports to the Food and Drug Administration describing the progress of the recall; and

"(D) provide notice to consumers to whom such cosmetic was, or may have been, distributed.

"(2) VACATING OF ORDER.—If, after such hearing, the Food and Drug Administration determines that adequate grounds do not exist to continue the actions required by the order, or that such actions should be modified, the Food and Drug Administration shall vacate the order or modify the order.

"(e) COOPERATION AND CONSULTATION.—The Food and Drug Administration shall work with State and local public health officials in carrying out this section, as appropriate.

''(f) PUBLIC NOTIFICATION.—In conducting a recall under this section, the Food and Drug Administration shall—

''(1) ensure that a press release is published regarding the recall, and that alerts and public notices are issued, as appropriate, in order to provide notification—

''(A) of the recall to consumers and retailers to whom such cosmetic was, or may have been, distributed; and

''(B) that includes, at a minimum—

''(i) the name of the cosmetic subject to the recall;

''(ii) a description of the risk associated with such article; and

''(iii) to the extent practicable, information for consumers about similar cosmetics that are not affected by the recall; and

''(2) ensure publication on the internet website of the Food and Drug Administration of an image of the cosmetic that is the subject of the press release described in paragraph (1), if available.

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

not be delegated to any officer or employee other than the Commissioner.

''(h) EFFECT.—Nothing in this section shall affect the authority of the Food and Drug Administration to request or participate in a voluntary recall, or to issue an order to cease distribution or to recall under any other provision of this chapter or under the Public Health Service Act.''.

SEC. 106. LABELING.

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

''SEC. 612. LABELING.

''(a) SAFETY REVIEW AND LABELING.—Following a review of cosmetic ingredients that determines that warnings are required to help ensure safe use of cosmetic products under section 607(d)(5), the Food and Drug Administration shall require labeling of cosmetics that are not appropriate for use in the entire population, including warnings that vulnerable populations, such as children or pregnant women, should limit or avoid using the product.

''(b) COSMETIC PRODUCTS FOR PROFESSIONAL USE.—

''(1) DEFINITION OF PROFESSIONAL.—For purposes of this section, with respect to cosmetics, the term 'professional' means an individual who—

''(A) is licensed by an official State authority to practice in the field of cosmetology, nail care, barbering, or esthetics;

''(B) has complied with all requirements set forth by the State for such licensing; and

''(C) has been granted a license by a State board or legal agency or legal authority.

''(2) LISTING OF INGREDIENTS.—Cosmetic products used and sold by professionals shall list all ingredients and warnings, as required for other cosmetic products under this chapter.

''(3) PROFESSIONAL USE LABELING.—In the case of a cosmetic product intended to be used only by a professional on account of a specific ingredient or increased concentration of an ingredient that requires safe handling by trained professionals, the product shall bear a statement as follows: 'To be Administered Only by Licensed Professionals'.

''(c) REQUIREMENTS.—

''(1) DISPLAY.—A warning required under subsection (a) and a statement required under subsection (b)(3) shall be prominently displayed—

''(A) in the primary language used on the label; and

''(B) in conspicuous and legible type in contrast by typography, layout, or color with other material printed or displayed on the label.

''(2) MINIMUM WARNING REQUIREMENTS.—A responsible person may include on the labeling any additional warnings in addition to the minimum warnings required under subsection (a).

''(d) INTERNET SALES.—In the case of internet sales of cosmetics, each internet website offering a cosmetic product for sale to consumers shall provide the same information, in an electronically readable format, that is included on the packaging of the cosmetic product as regularly available through in-person sales, except information that is unique to a single cosmetic product sold in a retail facility, such as a lot number or expiration date, and the warnings and statements described in subsection (c) shall be prominently and conspicuously displayed on the website.

''(e) CONTACT INFORMATION.—The label on each cosmetic shall bear the manufacturer's toll-free domestic telephone number and electronic contact information, and it is encouraged that the label include both the telephone number and electronic contact information, that con-

sumers may use to contact the responsible person with respect to adverse events. The contact number shall provide a means for consumers to obtain additional information about ingredients in the designated cosmetic, including the ability to ask if a specific ingredient may be present that is not listed on the label and whether a specific ingredient may be contained in the fragrance or flavor used in the cosmetic. The manufacturer of the cosmetic is responsible for providing such information, including obtaining the information from suppliers if it is not readily available. Suppliers are required to release such information upon request of the cosmetic manufacturer.''.

(b) USE OF THE TERM ''NATURAL'' IN LABELING.—The Food and Drug Administration—

(1) in consultation with consumer protection stakeholders and the scientific community, shall establish a definition of the term ''natural'' with respect to the use of such term in the labeling of cosmetics;

(2) not later than 1 year after the date of enactment of this Act, shall issue proposed regulations setting forth such definition; and

(3) not later than 2 years after such date of enactment, issue final regulations setting forth such definition.

(c) EFFECTIVE DATE.—Section 612 of the Federal Food, Drug, and Cosmetic Act, as added by subsection (a), shall take effect on the date that is 1 year after the date of enactment of this Act.

SEC. 107. COAL TAR CHEMICALS.

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

"SEC. 613. COAL TAR CHEMICALS.

''Specific ingredients in coal tar hair dyes may be selected and reviewed under section 607. If the Food and Drug Administration reviews a coal-tar ingredient found in hair dye and makes a safety determination under section 607(d) for such ingredient, such determination shall include consideration for the safe use of such ingredient through appropriate conditions of use, which may include a specific label requirement, specified limits of concentrations, or other such conditions of use as the Food and Drug Administration determines appropriate, including a finding of not safe under any conditions if appropriate.''.

SEC. 108. FRAGRANCE ALLERGEN DISCLOSURE.

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

"SEC. 614. FRAGRANCE ALLERGENS.

''(a) FRAGRANCE ALLERGENS.—Not later than 2 years after the date of enactment of the Personal Care Products Safety Act, the responsible person shall include on the label of any cosmetic product containing one or more fragrance allergens, a list of each such fragrance allergen present in a rinse-off cosmetic at a concentration above 0.01 percent (100 ppm) or present in a leave-on cosmetic product at a concentration above .001 percent (10 ppm), in a form and manner as specified by the Food and Drug Administration.''.

''(b) IDENTIFIED FRAGRANCE ALLERGENS.—The fragrance allergens required to be identified on a label of a cosmetic product pursuant to subsection (a) include—

''(1) alpha-Isomethyl ionone;

''(2) amyl cinnamal;

''(3) amylcinnamyl alcohol;

''(4) anise alcohol;

''(5) benzyl alcohol;

''(6) benzyl benzoate;

''(7) benzyl cinnamate;

''(8) benzyl salicylate;

''(9) butylphenyl methylpropional;

''(10) cinnamal;

''(11) cinnamyl alcohol;

''(12) citral;

''(13) citronellol;

''(14) coumarin;

''(15) eugenol;

''(16) evernia prunastri (oak moss);

''(17) evernia furfuracea (tree moss);

''(18) farnesol;

''(19) geraniol;

''(20) hexyl cinnamal;

''(21) hydroxycitronellal;

''(22) hydroxyisohexyl 3-cyclohexene carboxaldehyde;

''(23) isoeugenol;

''(24) limonene;

''(25) linalool;

''(26) methyl 2-octynoate; and

''(27) other substances as identified by the Food and Drug Administration in guidance issued pursuant to this section.

''(c) GUIDANCE.—

''(1) ISSUANCE.—Not later than one year after the date of enactment of the Personal Care Products Safety Act, the Food and Drug Administration shall issue guidance specifying the form and manner of fragrance allergen listing on the label of cosmetic products pursuant to subsection (a).

''(2) CONTENT.—The guidance described in paragraph (1) shall—

''(A) specify the form and manner of fragrance allergen listing for cosmetic products where the package or label is too small or otherwise is unable to accommodate a label with sufficient space to bear the information required for compliance with this section; and

''(B) take into consideration requirements under international regulations for fragrance allergen labeling, as appropriate.

''(3) UPDATES.—The Food and Drug Administration may, as appropriate, update the list of fragrance allergens to include additional substances pursuant to guidance issued under this subsection and taking into consideration international regulations, as appropriate.

''(d) CONTACT INFORMATION.—

''(1) IN GENERAL.—The contact information on the label on a cosmetic product for consumers to report adverse events shall also provide a means for consumers to obtain additional information about the inclusion of any recognized fragrance allergen required to be included on such label under subsection (a).

''(2) RESPONSE.—

''(A) IN GENERAL.—The responsible person shall—

''(i) upon receipt of a request for information under paragraph (1), promptly obtain and provide such information to the requesting consumer; and

''(ii) in the case of information in the possession of a supplier, promptly obtain such information from such supplier, if reasonably available.

''(B) SUPPLIER.—A relevant supplier shall promptly provide information requested to a responsible person pursuant to subparagraph (A)(ii).''.

(b) INGREDIENT STATEMENT.—Section 602 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 362), as amended by section 114(c), is further amended by adding at the end the following:

''(i) If its labeling or packaging does not contain a listing of ingredients that meets the requirements of section 614.''.

(c) EFFECTIVE DATE.—The amendments made by this section shall apply with respect to cosmetics introduced or delivered for introduction into interstate com-

merce on or after the date that is 2 years after the date of enactment of this Act.

SEC. 109. SENSE OF THE SENATE ON ANIMAL TESTING.

(a) ANIMAL TESTING.—Chapter VI of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 361 et seq.), as amended by section 108, is further amended by adding the following:

"SEC. 615. ANIMAL TESTING.

''It is the sense of the Senate that animal testing should not be used for the purposes of safety testing on cosmetic products and should be phased out with the exception of appropriate allowances.''.

SEC. 110. PREEMPTION.

Chapter VI of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 361 et seq.), as amended by section 109, is further amended by adding the following:

"SEC. 616. PREEMPTION.

''(a) IN GENERAL.—No State or political subdivision of a State may establish or continue in effect any requirement for cosmetics, other than a requirement that is in full effect and implemented on the date of enactment of the Personal Care Products Safety Act—

''(1) with respect to registration, good manufacturing practices, mandatory recalls, or adverse event reporting; or

''(2) with respect to the safety of a cosmetic ingredient or non-functional constituent that is the subject of a final order on a determination of safety under this chapter, unless the requirement of the State or political subdivision is more restrictive than the final order under section 607(d)(3).

''(b) SAFETY OF COSMETIC INGREDIENTS AND NON-FUNCTIONAL CONSTITUENTS.—

''(1) DELAYED EFFECT OF NEW STATE REQUIREMENTS.—

''(A) IN GENERAL.—From the date that the Food and Drug Administration has made public the final selection of a cosmetic ingredient or non-functional constituent to be reviewed in the coming year under section 607(a)(3) and opened the public comment period under section 607(a)(2), until the date that is one year after the Food and Drug Administration has made public such selection, no State or political subdivision of a State may establish any new requirement related to such cosmetic ingredient or non-functional constituent.

''(B) INITIAL REVIEW.—With respect to the cosmetic ingredients to be reviewed in the first year, in accordance with section 607(a)(3),

for the 1-year period beginning on the date that is 6 months after the date of enactment of the Personal Care Products Safety Act, no State or political subdivision of a State may establish any new requirement related to such cosmetic ingredient or non-functional constituent.

''(2) SCOPE.—Subsection (a)(2) shall not be construed to affect the authority of a State or political subdivision of a State with respect to any requirement for the safety of a cosmetic ingredient or non-functional constituent that is unrelated to the scope of the safety assessment under section 607.

''(3) SENSE OF CONGRESS.—It is the sense of Congress that a State or political subdivision that regulates the safety of cosmetics with respect to the health of humans beyond the scope of section 607 should utilize the safety assessment criteria described in section 607(h).

''(c) STATE REQUIREMENT THAT IS IN FULL EFFECT AND IMPLEMENTED.—For purposes of this section:

''(1) STATE REQUIREMENT.—A State requirement includes a State requirement that is adopted by a State public initiative or referendum.

''(2) FULL EFFECT AND IMPLEMENTED.—The term 'full effect and implemented' includes require-

ments of States that are implemented after the date of enactment of the Personal Care Products Safety Act, if such requirements are under a law that was in effect, or a lawful program that was established and functioning, prior to the date of enactment of the Personal Care Products Safety Act.

''(d) LIMITATION.—Nothing in the amendments to this Act made by the Personal Care Products Safety Act shall be construed to preempt any State statute, public initiative, referendum, or other State action, except as expressly provided in this section.

''(e) SAVINGS.—Nothing in the amendments to this Act made by the Personal Care Products Safety Act, nor any standard, rule, requirement, regulation, adverse event report, safety assessment, safety determination, scientific assessment, or order issued or implemented pursuant to such amendments, shall be construed to modify or otherwise affect, preempt, or displace any cause of action or State or Federal law creating a remedy for civil relief or criminal cause of action, whether statutory or based in common law.

''(f) SENSE OF THE SENATE.—It is the sense of the Senate that subsection (e) does not negate the other provisions of this section.''.

SEC. 111. REPORTING.

Chapter VI of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 361 et seq.), as amended by section 110, is further amended by adding at the end the following:

"SEC. 617. REPORTING.

''(a) PERFORMANCE REPORT.—Not later than 1 year after the date of enactment of the Personal Care Products Safety Act, and not later than 60 days prior to the end of each fiscal year for which fees are collected under section 744O, the Food and Drug Administration shall prepare and submit to Congress a report concerning the progress of the Food and Drug Administration in achieving the objectives of the Personal Care Products Safety Act during such fiscal year and the future plans of the Food and Drug Administration for meeting the objectives. The annual report for a fiscal year shall include—

''(1) the number of registered facilities and cosmetic ingredient statements on file with the Food and Drug Administration;

''(2) identification of the cosmetic ingredients and non-functional constituents that have been fully reviewed for safety by the Food and Drug Administration in the prior fiscal year and for which a final administrative order has been released;

''(3) identification of at least 5 specific cosmetic ingredients and non-functional constituents that will

be reviewed by the Food and Drug Administration in the next fiscal year;

''(4) the number of facilities inspected and mandatory recalls that transpired during that fiscal year;

''(5) the number of serious adverse event reports received by the Food and Drug Administration during that fiscal year; and

''(6) any trends identified by the Food and Drug Administration about adverse event reports related to specific cosmetic ingredients or non-functional constituents.

''(b) PUBLIC AVAILABILITY.—The Food and Drug Administration shall make the reports required under subsection (a) available to the public on the internet website of the Food and Drug Administration on the date of submission of such reports to Congress.

''(c) PUBLIC INPUT ON SAFETY REVIEW.—Upon release of the report described in subsection (a), the Food and Drug Administration shall provide the public with an opportunity to provide feedback, at any time during the year, on the identification of ingredients under subsection (a)(3) by—

''(1) providing an electronic portal, upon release of the report, enabling the public to—

''(A) comment on the cosmetic ingredients or non-functional constituents under review for the current year;

''(B) recommend additional cosmetic ingredients and non-functional constituents to be considered for review for safety in future years; and

''(C) comment on the priorities for the specific cosmetic ingredients and non-functional constituents that the Food and Drug Administration anticipates will be reviewed in the next fiscal year;

''(2) announcing on the internet website of the Food and Drug Administration, within the first 30 days of the new fiscal year, any amendments to the list of cosmetic ingredients and non-functional constituents submitted pursuant to subsection (a)(3) based on public input, pursuant to paragraph (1); and

''(3) together with the final announcement of at least 5 specific cosmetic ingredients and non-functional constituents that will be reviewed in the coming year under section 607, providing a comment period for further public input, pursuant to section 607(a)(2).''.

SEC. 112. SMALL BUSINESSES.

Chapter VI of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 361 et seq.), as amended by section 111, is further amended by adding at the end the following:

''SEC. 618. SMALL BUSINESSES.

''The Commissioner, in coordination with the Administrator of the Small Business Administration, shall provide technical assistance, such as guidance and expertise, to small businesses regarding compliance with the Personal Care Products Safety Act, including the amendments made by such Act.''.

SEC. 113. APPLICABILITY WITH RESPECT TO CERTAIN COSMETICS.

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

''SEC. 619. APPLICABILITY WITH RESPECT TO CERTAIN COSMETICS.

''In the case of a cosmetic product or a facility that is subject to the requirements under this chapter and chapter V, if any requirement under chapter V with respect to such cosmetic or facility is substantially similar to a requirement under this chapter, the cosmetic product or facility shall be deemed to be in compliance with the applicable requirement under this chapter if such product or facility is in compliance with such substantially similar

requirement under chapter V, provided that the product or facility has not obtained a waiver from the requirement under chapter V. In the case of a cosmetic product or facility that is subject to, and in compliance with, a fee under subchapter C of chapter VII, other than a fee under part 11 of such subchapter, any fee under such part 11 shall be waived with respect to such cosmetic product or facility (with respect to cosmetic products).''.

SEC. 114. ENFORCEMENT.

(a) PROHIBITED ACTS.—Section 301 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 331) is amended—

(1) in paragraph (e)—

(A) by striking ''504, 564,'' and inserting ''504, 564, 609, 610,''; and

(B) by striking ''519, 564,'' and inserting ''519, 564, 609,'';

(2) in paragraph (j), by inserting ''606, 607, 608,'' before ''704'';

(3) in paragraph (ii)—

(A) by striking ''760 or 761) or'' and inserting ''604, 760, or 761) or''; and

(B) by striking ''761) submitted'' and inserting ''761 or as described in section 609) submitted'';

(4) in paragraph (xx) by inserting ''or 611'' after ''423''; and

(5) by adding at the end the following:

''(fff) The failure to register in accordance with section 605, the failure to provide any information required by section 605, or the failure to update the information required by section 605, as required.''.

(b) ADULTERATION.—Section 601 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 361) is amended by adding at the end the following:

''(f) If the methods used in, or the facilities or controls used for, its manufacture, processing, packing, or holding do not conform to current good manufacturing practice, as prescribed by the Food and Drug Administration in accordance with section 608.

''(g) If it contains, after the date prescribed under section 607(e), an ingredient that the Food and Drug Administration has determined under section 607(d)(4) to be not safe, or not safe under the conditions of use recommended or suggested in the label or a non-functional constituent that the Food and Drug Administration has determined under section 607(d)(4) to be not safe or not safe in the amount present in the cosmetic.

''(h) If it is a cosmetic product for which assurances regarding safety substantiation have not been supplied under section 605(e)(2)(A)(xii).''.

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

(1) in paragraph (b)—

(A) by striking ''and (2)'' and inserting ''(2)''; and

(B) by inserting ''; and (3) a domestic address or a domestic telephone number, and it is encouraged that the label include both a domestic address and a domestic telephone number, through which the responsible person may receive a report of an adverse event associated with the use of such cosmetic product'' after ''numerical count''; and

(2) by adding at the end the following:

''(g) If it has been manufactured or processed in any factory, warehouse, or establishment and the responsible person, operator, or agent of such factory, warehouse, or establishment delays, denies, or limits an inspection, or refuses to permit entry or inspection.

''(h) If its labeling does not conform with a requirement under section 612.''.

(d) GUIDANCE.—Not later than 1 year after the date of enactment of this Act, the Food and Drug Administration shall issue guidance that defines the circumstances that would constitute delaying, denying, or limiting inspection, or refusing to permit entry or inspection, for purposes of section 602(g) of the Federal Food, Drug, and Cosmetic Act, as added by subsection (c)(2).

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

(1) by striking ''section 760 or 761'' the first, third, and fourth place such term appears and inserting ''section 609, 760, or 761''; and

(2) by striking ''760 or 761)'' and inserting ''604, 760, or 761)''.

(f) FACTORY INSPECTION.—Section 704(a)(1) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 374(a)(1)) is amended by inserting after the third sentence the following: ''In the case of any person who manufactures, processes, distributes, or imports a cosmetic product, or distributes a cosmetic product and affixes its name on the cosmetic label, the inspection shall extend to all records and other information described in section 610 (regarding inspection of cosmetic records), when the standard for records inspections under paragraph (1) or (2) of subsection (a) of such section applies, subject to

the limitations under subsections (d) and (e) of such section.''.

SEC. 115. CONSUMER INFORMATION.

The Food and Drug Administration shall post on its internet website information for consumers regarding—

(1) final orders regarding the safety of a cosmetic ingredient or non-functional constituent under section 607(d)(3) of the Federal Food, Drug, and Cosmetic Act;

(2) cosmetic product recalls (including voluntary and mandatory recalls); and

(3) identified counterfeit cosmetic products.

SEC. 116. BAN ON PERFLUOROALKYL OR POLYFLUOROALKYL SUBSTANCES.

Not later than 6 months after the date of enactment of this Act, the Food and Drug Administration shall issue a proposed rule to ban the use of intentionally added perfluoroalkyl or polyfluoroalkyl substances in cosmetics.

SEC. 117. COUNTERFEIT COSMETICS.

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

(1) by striking ''(i) The term'' inserting ''(i)(1) The term'';

(2) by striking ''(1) articles intended to be'' and inserting ''(A) articles intended to be'';

(3) by striking ''(2) articles intended for use'' and inserting ''(B) articles intended for use''; and

(4) by adding at the end the following:

''(2) The term 'counterfeit cosmetic' means a cosmetic which, or the container or labeling of which, without authorization—

''(A) bears the trademark, trade name, or other identifying mark, imprint, or device, or any likeness thereof, of a cosmetic manufacturer, processor, packer, or distributor other than the person or persons who in fact manufactured, processed, packed, or distributed such cosmetic; and

''(B) thereby falsely purports or is represented to be the product of, or to have been packed or distributed by, such other cosmetic manufacturer, processor, packer, or distributor.''.

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

(1) in subparagraph (2)—

(A) by inserting ''digital printer,'' after ''stone,'';

(B) by inserting ''cosmetic'' after ''drug or''; and

(C) by inserting before the period at the end the following: ''or such cosmetic a counterfeit cosmetic''; and

(2) in subparagraph (3)—

(A) by inserting ''or a cosmetic to be a counterfeit cosmetic'' after ''to be a counterfeit drug''; and

(B) by inserting ''or counterfeit cosmetic'' before the period at the end.

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

(1) by inserting ''digital printer'' after ''stone,'';

(2) by inserting ''or a cosmetic being a counterfeit cosmetic'' after ''drug being a counterfeit drug''; and

(3) by inserting before the period at the end the following: ''or the cosmetic was a counterfeit cosmetic''.

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

(1) by striking ''(B) Any container'' and all that follows through ''(D) Any adulterated'' and inserting ''(B) Any cosmetic that is a counterfeit cosmetic, (C) Any container of a counterfeit drug or counterfeit cosmetic, (D) Any punch, die, plate, stone, labeling, container, digital printer, or other thing used or designed for use in making a counterfeit drug or drugs or a counterfeit cosmetic or cosmetics, (E) Any adulterated''; and

(2) by striking ''(E)'' and inserting ''(F)'' before ''Any adulterated or misbranded tobacco product''.

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

(1) in the matter preceding paragraph (1), by inserting ''or counterfeit cosmetics'' after ''counterfeit drugs'';

(2) in paragraph (4), by inserting ''or cosmetics'' after ''such drugs''; and

(3) in paragraph (5)—

(A) by striking ''drugs or containers'' and inserting ''drugs, cosmetics, or containers''; and

(B) by inserting ''digital printers,'' after ''labeling,''.

TITLE II—FEES RELATED TO COSMETIC SAFETY

SEC. 201. FINDINGS.

Congress finds that the fees authorized by the amendments made by this title will be dedicated to cosmetic safety activities, as set forth in the goals identified for purposes of part 11 of subchapter C of chapter VII of the Federal Food, Drug, and Cosmetic Act, in the letters from the Secretary of Health and Human Services to the Chairman of the Committee on Health, Education, Labor, and Pensions of the Senate and the Chairman of the Committee on Energy and Commerce of the House of Representatives, as set forth in the Congressional Record.

SEC. 202. AUTHORITY TO ASSESS AND USE COSMETIC SAFETY FEES.

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

"PART 11—FEES RELATING TO COSMETICS

"SEC. 744O. REGISTRATION FEE.

"(a) ASSESSMENT AND COLLECTION.—

"(1) IN GENERAL.—Beginning in fiscal year 2022, the Food and Drug Administration shall assess and collect an annual fee from every responsible

person (referred to in this section as a 'registrant') who owns or operates any facility (as defined in section 604(3)) engaged in manufacturing or processing, or whose name and address appear on the label of a cosmetic product distributed in the United States, except that this subsection shall not apply to contract manufacturers if a responsible person has already paid the appropriate fee with respect to the cosmetic product, to ensure no double fees are paid.

''(2) PAYABLE DATE.—A fee under this section shall be payable during the period of initial registration and on the date of registration each year thereafter as prescribed in section 605(a)(1).

''(b) DEFINITIONS.—In this section:

''(1) ADJUSTMENT FACTOR.—The term 'adjustment factor' applicable to a fiscal year means the Consumer Price Index for all urban consumers (all items; United States city average) for October of the preceding fiscal year divided by such index for October 2021.

''(2) AFFILIATE.—The term 'affiliate' means any business entity that has a relationship with a second business entity if, directly or indirectly—

''(A) one business entity controls, or has power to control, the other business entity; or

''(B) a third party controls, or has the power to control, both of the business entities.

''(3) COSMETIC PRODUCT.—The term 'cosmetic product' has the meaning given such term in section 604(2).

''(4) COSMETIC SAFETY ACTIVITIES.—The term 'cosmetic safety activities'—

''(A) means activities related to compliance by registrants under section 605 with the requirements of this Act with respect to cosmetics, including—

''(i) administrative activities, such as information technology support, human resources, financial management, the administration and maintenance of the cosmetic registration system and the cosmetic ingredient statement system under section 605, and fee assessment and collection under this section; and

''(ii) implementation and enforcement activities, such as the establishment of good manufacturing practices, the review of adverse event reports, inspection planning and inspections, and use of enforcement tools; and

''(B) includes activities related to implementation of section 607, regarding the review of cosmetic ingredients and non-functional constituents.

''(5) GROSS ANNUAL SALES.—The term 'gross annual sales' means the average United States gross annual sales for the previous 3-year period of cosmetics for a registrant, including the sales of all of its affiliates, as reported in the registration under section 605.

''(c) FEE SETTING AND AMOUNTS.—

''(1) IN GENERAL.—Subject to subsection (d), the Food and Drug Administration shall establish the fees to be collected under this section for each fiscal year after fiscal year 2022, based on the methodology described in paragraph (3), and shall publish such fees in a Federal Register notice not later than 60 days before the beginning of each such fiscal year.

''(2) FEE EXEMPTION.—Any registrant whose gross annual sales of cosmetic products in the 3-year period immediately preceding the fiscal year for which the annual fee will be paid was not more than $10,000,000, shall be exempt from registration fees under this section for that fiscal year.

''(3) ANNUAL FEE SETTING.—For fiscal years 2022 through 2027, to generate a total estimated annual revenue amount of $20,600,000, the amount of the registration fee under subsection (a) shall be as follows:

''(A) TIER I–A.—For a registrant that has gross annual sales of $5,000,000,000 or more in 2020, $1,350,000.

''(B) TIER I–B.—For a registrant that has gross annual sales of at least $4,000,000,000 per annum but less than $5,000,000,000 in 2020, $850,000.

''(C) TIER II–A.—For a registrant that has gross annual sales of at least $3,000,000,000 per annum but less than $4,000,000,000 in 2020, $730,000.

''(D) TIER II–B.—For a registrant that has gross annual sales of at least $2,000,000,000 per annum but less than $3,000,000,000 in 2020, $610,000.

''(E) TIER III–A.—For a registrant that has gross annual sales of at least $1,000,000,000 per annum but less than $2,000,000,000 in 2020, $500,000.

''(F) TIER III–B.—For a registrant that has gross annual sales of at least $500,000,000 per annum but less than $1,000,000,000 in 2020, $395,000.

''(G) TIER IV–A.—For a registrant that has gross annual sales of at least $200,000,000 per annum but less than $500,000,000 in 2020, $325,000.

''(H) TIER IV–B.—For a registrant that has gross annual sales of at least $100,000,000 per annum but less than $200,000,000 in 2020, $275,000.

''(I) TIER V–A.—For a registrant that has gross annual sales of at least $80,000,000 per annum but less than $100,000,000 in 2020, $185,000.

''(J) TIER V–B.—For a registrant that has gross annual sales of at least $60,000,000 per annum but less than $80,000,000 in 2020, $95,000.

''(K) TIER VI–A.—For a registrant that has gross annual sales of at least $40,000,000 per annum but less than $60,000,000 in 2020, $15,000.

''(L) TIER IV–B.—For a registrant that has gross annual sales of at least $20,000,000 per annum but less than $40,000,000 in 2020, $12,000.

''(M) TIER VII–A.—For a registrant that has gross annual sales of at least $10,000,000 per annum but less than $20,000,000 in 2020, $500.

''(d) ADJUSTMENTS.—

''(1) INFLATION ADJUSTMENT.—

''(A) IN GENERAL.—For fiscal year 2023 and each subsequent fiscal year, the revenues and fee amounts under subsection (c)(3) shall be adjusted by the Food and Drug Administration in the annual Federal Register notice establishing fees in subsection (c)(1), by an amount equal to the sum of—

''(i) one;

''(ii) the average annual percent change in the cost, per full-time equivalent position of the Food and Drug Administration, of all personnel compensation and benefits paid with respect to such positions for the first 3 of the preceding 4 fiscal years for which data are available, multi-

plied by the average proportion of personnel compensation and benefits costs to total Food and Drug Administration costs for the first 3 years of the preceding 4 fiscal years for which data are available; and

''(iii) the average annual percent change that occurred in the Consumer Price Index for urban consumers (Washington-Baltimore, DC6 MD–VA–WV; not seasonally adjusted; all items less food and energy; annual index) for the first 3 years of the preceding 4 years for which data are available multiplied by the average proportion of all costs other than personnel compensation and benefits costs to total Food and Drug Administration costs for the first 3 years of the preceding 4 fiscal years for which data are available.

''(B) COMPOUNDED BASIS.—The adjustment made each fiscal year under this subsection shall be added on a compounded basis to the sum of all adjustments made each fiscal year after fiscal year 2022 under this subsection.

''(2) FINAL YEAR ADJUSTMENT.—For fiscal year 2027, the Food and Drug Administration may, in addition to adjustments under paragraph (1), further increase the fee revenues and fees established in subsection (c) if such an adjustment is necessary to provide for not more than 3 months of operating reserves of carryover fees for cosmetic safety activities for the first 3 months of fiscal year 2028. If such an adjustment is necessary, the rationale for the increase, shall be contained in the annual Federal Register notice establishing fees, in subsection (c)(1), for fiscal year 2027. If the Food and Drug Administration has carryover balances for such activities in excess of 3 months of such operating reserves, the adjustment under this subparagraph shall not be made.

''(3) WORKLOAD ADJUSTMENT.—

''(A) IN GENERAL.—For fiscal year 2023 and each subsequent fiscal year, after fee revenues established in subsection (c)(3) are adjusted for a fiscal year for inflation in accordance with paragraph (1), the fee revenues shall be adjusted further for each fiscal year to reflect changes in the workload of the Food and Drug Administration for actual changes in

workload volume due to the process of reviewing cosmetic ingredients or non-functional constituents not listed under section 607(b).

"(B) DETERMINATION OF ADJUSTMENT.—The adjustment shall be determined by the Food and Drug Administration based on the workload in the most recent 1-year period for which workload data is available. The Food and Drug Administration shall publish in the Federal Register the fee revenues and fees resulting from the adjustment and the supporting methodologies.

"(C) MINIMUM REVENUES.—The adjustment shall not result in fee revenues for a fiscal year that are less than the sum of the amount under subsection (c)(3), as adjusted for inflation under subparagraph (1).

"(e) LIMITATIONS.—

"(1) IN GENERAL.—With respect to the amount that, under the salaries and expenses account of the Food and Drug Administration, is appropriated for a fiscal year for the cosmetics program in the Center for Food Safety and Applied Nutrition and related field activities, fees may not be assessed under subsection (a) for the fiscal year unless the amount so

appropriated for the fiscal year (excluding the amount of fees appropriated for the fiscal year), is equal to or greater than that assessed for fiscal year 2021, multiplied by the adjustment factor applicable to the fiscal year involved.

''(2) AUTHORITY.—If the Food and Drug Administration does not assess fees under subsection (a) during any portion of a fiscal year because of paragraph (1) and if at a later date in such fiscal year the Food and Drug Administration may assess such fees, the Food and Drug Administration may assess and collect such fees, without any modification in the rate, for registration under section 605 at any time in such fiscal year.

''(f) CREDITING AND AVAILABILITY OF FEES.—

''(1) IN GENERAL.—Fees authorized under subsection (a) shall be collected and available for obligation only to the extent and in the amount provided in advance in appropriations Acts. Such fees are authorized to remain available until expended. Such sums as may be necessary may be transferred from the Food and Drug Administration salaries and expenses appropriation account without fiscal year limitation to such appropriation account for salaries and expenses with such fiscal year limitation. The

sums transferred shall be available solely for cosmetic safety activities.

''(2) COLLECTIONS AND APPROPRIATIONS ACTS.—

''(A) IN GENERAL.—Subject to subparagraphs (C) and (D), the fees authorized by this section shall be collected and available in each fiscal year in an amount not to exceed the amount specified in appropriation Acts, or otherwise made available for obligation for such fiscal year.

''(B) USE OF FEES AND LIMITATION.—The fees authorized by this section shall be collected and available only to defray the costs of cosmetic safety activities.

''(C) FEE COLLECTIONS DURING FIRST PROGRAM YEAR.—Until the date of enactment of an Act making appropriations through September 30, 2020, for the salaries and expenses account of the Food and Drug Administration, fees authorized by this section for fiscal year 2022 may be collected and shall be credited to such account to remain available until expended. Fees collected under this subparagraph shall be considered discretionary for purposes of

the Balanced Budget and Emergency Deficit Control Act of 1985.

''(D) REIMBURSEMENT OF START-UP AMOUNTS.—Any amounts allocated to establish programs under section 605, prior to collection of fees, may be reimbursed through any appropriated fees collected under this section, in such manner as the Food and Drug Administration determines appropriate. Any amounts reimbursed under this subparagraph shall be available for the programs and activities for which funds allocated to establish the programs were available, prior to such allocation, until the end of the fiscal year in which the reimbursement occurs, notwithstanding any otherwise applicable limits on amounts for such program or activities for a fiscal year.

''(3) AUTHORIZATION OF APPROPRIATIONS.—For each of fiscal years 2022 through 2028, there are authorized to be appropriated for fees under this section $20,600,000, as adjusted by subsection (d).

''(4) OFFSET OF OVERCOLLECTIONS; RECOVERY OF COLLECTION SHORTFALLS.—

''(A) OFFSET OF OVERCOLLECTIONS.—If the sum of the cumulative amount of fees col-

lected under this section for the fiscal years 2022 through 2026 exceeds the cumulative amount appropriated pursuant to paragraph (3) for fiscal years 2022 through 2027, the excess amount shall be credited to the appropriation account of the Food and Drug Administration as provided in paragraph (1), and shall be subtracted from the amount of fees that would otherwise be authorized to be collected under this section pursuant to appropriation Acts for fiscal year 2028.

''(B) RECOVERY OF COLLECTION SHORTFALLS.—

''(i) 2024.—For fiscal year 2024, the amount of fees otherwise authorized to be collected under this section shall be increased by the amount, if any, by which the amount collected under this section and appropriated for fiscal year 2022 falls below the amount of fees authorized for fiscal year 2022 under paragraph (3).

''(ii) 2025.—For fiscal year 2025, the amount of fees otherwise authorized to be collected under this section shall be increased by the amount, if any, by which

the amount collected under this section and appropriated for fiscal year 221 falls below the amount of fees authorized for fiscal year 2023 under paragraph (3).

''(iii) 2026.—For fiscal year 2026, the amount of fees otherwise authorized to be collected under this section shall be increased by the amount, if any, by which the amount collected under this section and appropriated for fiscal year 2024 falls below the amount of fees authorized for fiscal year 2024 under paragraph (3).

''(iv) 2027.—For fiscal year 2027, the amount of fees otherwise authorized to be collected under this section shall be increased by the amount, if any, by which the amount collected under this section and appropriated for fiscal year 2025 falls below the amount of fees authorized for fiscal year 2025 under paragraph (3).

''(v) 2028.—For fiscal year 2028, the amount of fees otherwise authorized to be collected under this section shall be increased by the amount, if any, by which the amount collected under this section

and appropriated for fiscal year 2026 falls below the amount of fees authorized for fiscal year 2026 under paragraph (3).

''(g) EFFECT OF FAILURE TO PAY FEES.—The Food and Drug Administration shall not consider a registration submitted to be complete until such fee under subsection (a) is paid. Until the fee is paid, the registration is incomplete and the registrant is deemed to have failed to register in accordance with section 605.

''(h) FALSE STATEMENTS.—Any statement or representation made to the Food and Drug Administration shall be subject to section 1001 of title 18, United States Code.

''(i) COLLECTION OF UNPAID FEES.—In any case where the Food and Drug Administration does not receive payment of a fee assessed under subsection (a), such fee shall be treated as a claim of the United States Government subject to subchapter II of chapter 37 of title 31, United States Code.

''(j) CONSTRUCTION.—This section may not be construed to require that the number of full-time equivalent positions in the Department of Health and Human Services, for officers, employees, and advisory committees not engaged in cosmetic activities, be reduced to offset the

number of officers, employees, and advisory committees so engaged.

''(k) RECORDS.—Each facility shall retain all records necessary to demonstrate the facility's gross annual sales for at least 2 fiscal years after such information is reported in the facility's registration. Such records shall be made available to the Food and Drug Administration for review and duplication upon request of the Food and Drug Administration.''.

SEC. 203. DIRECT HIRING AUTHORITY TO SUPPORT ACTIVITIES RELATED TO COSMETICS.

Part 11 of subchapter C of chapter VII of the Federal Food, Drug, and Cosmetic Act, as added by section 202, is amended by inserting after section 744O the following:

''SEC. 744P. DIRECT HIRING AUTHORITY TO SUPPORT ACTIVITIES RELATED TO COSMETICS.

''(a) IN GENERAL.—The Food and Drug Administration shall have direct hiring authority with respect to the appointment of employees into the competitive service or the excepted service to administer the amendments made by title I of the Personal Care Products Safety Act.

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

○