[DISCUSSION DRAFT]

114TH CONGRESS
2D SESSION

H. R. _____

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

IN THE HOUSE OF REPRESENTATIVES

Mr. PALLONE (for himself and Mr. LANCE) introduced the following bill; which was referred to the Committee on _____

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 "_____ Act of 2016".

(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 cosmetic comprised of a specified set of ingredients, which may come in a range of

possible amounts for each ingredient and which may include a variety of fragrances, flavors, and colors.

''(3) FACILITY.—The term 'facility' includes any factory, warehouse, or establishment (including a factory, warehouse, or establishment of an importer) that manufactures, processes, packs, or holds 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, retail distribution facilities, retail warehouses, 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) domestic manufacturers with less than **[**$100,000**]** in gross annual sales of cosmetic products; or

"(H) entities that manufacture or compound cosmetic products solely for use in research, teaching, or pilot plant production and not for sale.

"(4) FOREIGN FACILITY.—The term 'foreign facility' means a facility that manufactures, processes, packs, or holds, 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) NONFUNCTIONAL CONSTITUENT.—The term 'nonfunctional 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, processor, or entity whose name appears on the label of a cosmetic product or a cosmetic formulation 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.—Each responsible person engaged in manufacturing, or processing, or whose name appears on the label of 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 Ad-

ministration. Each facility required to register under this subsection shall, not later than 90 days after the Secretary establishes an electronic registration system for purposes of this section, submit a registration utilizing such system which shall be effective for fiscal year **[**2017**]**.

''(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 **[**$500,000**]**, a registration shall not be complete under this subsection until the responsible person has paid any registration fee required under section 744L.

''(b) REGISTRATION FOR EXISTING PACKING OR HOLDING FACILITIES.—Each facility engaged in packing or holding a cosmetic product distributed in the United States shall register with the Food and Drug Administration. Each facility required to register under this subsection shall, not later than 90 days after the Secretary establishes an electronic registration system for purposes of this section, submit a registration utilizing such system which shall be effective for fiscal year **[**2017**]**.

''(c) REGISTRATION BY NEW FACILITIES.—Any facility first engaging after the date of enactment of the

[_____] in an activity that would require it to register under subsection (a) or (b) shall register with the Food and Drug Administration immediately upon engaging in such activity, and thereafter in accordance with subsection (a) or (b).

''(d) CHANGES TO INFORMATION.—A facility that 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 30 days after the date of such change, unless otherwise specified by the Food and Drug Administration.

''(e) ANNUAL REGISTRATION RENEWAL.—Any facility that continues to engage in any activity that would require registration under subsection (a) or (b) shall submit to the Secretary an annual registration during the first quarter of the fiscal year for which such renewed registration shall be effective.

''(f) 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.—The registration shall contain the following information:

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

"(B) 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 (g).

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

"(D) The 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.

"(E) The type or types of activities conducted at the facility (such as manufacturing, processing, packing, or holding).

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

"(G) In the case of a foreign facility, the name, street address, telephone number, emergency contact information for the facility, the name of the United States agent for the facil-

ity, and the phone number and electronic contact information of the United States agent.

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

"(I) 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.

"(J) Additional information pertaining to the facility or to the cosmetic products or cosmetic formulations manufactured, processed, packed, or held 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.

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

''(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, if a required registration fee has not been paid within 30 days, or if the registration 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 facility 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 responsible person, facility, 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. COSMETIC INGREDIENT STATEMENTS.

''(a) IN GENERAL.—For each cosmetic product, the responsible person shall submit to the Food and Drug Administration a cosmetic ingredient statement, at such time and in such manner as the Food and Drug Administration may prescribe. The cosmetic ingredient statement shall not become effective until the responsible person pays any applicable fee required under section 744L.

''(b) SUBMISSION OF A COSMETIC INGREDIENT STATEMENT.—

''(1) EXISTING COSMETIC PRODUCTS.—In the case of a cosmetic product that is marketed on the date of enactment of the **[**_____**]**, the responsible person shall submit a cosmetic ingredient statement not later than December 1, **[**2016**]**. The responsible person shall submit to the Food and Drug Administration an annual renewal of such statement during the first quarter of the fiscal year for which such renewed statement is applicable.

''(2) COSMETIC INGREDIENT STATEMENT FOR NEW 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 **[**_____**]** 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 prior to first marketing the new cosmetic product or the reformulated cosmetic product, and annually thereafter during the first quarter of the fiscal year for which the cosmetic ingredient statement is applicable.

"(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 an additional time period, as determined by the Secretary, to submit an initial new cosmetic ingredient statement under subparagraph (A). Such responsible person shall submit a cosmetic ingredient statement annually thereafter during the first quarter of the fiscal year.

"(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 subsection (c)(2)(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 reg-

ulations or guidance, previously reported as a potential ingredient under subsection (c)(2)(E), if, in the case of such an addition, the amount is within the range previously reported.

''(c) FORMAT; CONTENTS.—

''(1) FORM.—For each cosmetic product, the cosmetic ingredient statement shall be submitted using an electronic format, as specified in a cosmetic and ingredient form provided by the Food and Drug Administration.

''(2) CONTENTS.—The cosmetic ingredient statement shall include the following information:

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

''(i) the facility or facilities where the cosmetic product is manufactured, processed, packed, or held or, if the same cosmetic product is manufactured, processed, packed, or held in more than one facility, the unique facility identifier of each facility where it is manufactured, processed, packed, or held; and

''(ii) the facility whose name and address appear on the label, unless the state-

ment 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 by the Food and Drug Administration under subsection (f) to the cosmetic product.

"(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, and with 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. The cosmetic ingredient statement shall contain—

"(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, the fragrances shall be identified by the name or code provided by the supplier, and include the name and contact information for the fragrance supplier;

''(II) in the case of flavors that are purchased from a flavor supplier, the flavors shall be identified by the name or code provided by the supplier, and include the name and contact information for the flavor supplier; and

''(III) in the case of a notification provided by the Food and Drug Administration to the responsible person for the cosmetic manufacturer, the Food and Drug Administration may request, from the fragrance or flavor supplier, the complete list of ingredients in specific fragrances or flavors and the supplier shall have 30 days to provide such list to the Food and Drug Administration; and

''(ii) other appropriate interchangeable ingredients as the Food and Drug Ad-

ministration 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 614.

"(H) Such additional information pertaining to the cosmetic product as the Food and Drug Administration may require.

"(3) COSMETIC INGREDIENT STATEMENT FOR CERTAIN SMALL BUSINESSES.—

"(A) IN GENERAL.—Notwithstanding any other provision of this subsection, the Food and Drug Administration may permit a simplified cosmetic ingredient statement under this section for a responsible person that—

"(i) 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; and

"(ii) has had an average of less than [$500,000] in annual domestic cosmetic sales over the previous 3 years.

"(B) CONTENTS.—A responsible person described in subparagraph (A) shall include in each cosmetic ingredient statement under this section, at a minimum, a list of ingredients in the cosmetic product and the applicable cosmetic category for the cosmetic product. If a cosmetic product includes a fragrance or flavor purchased from a fragrance or flavor supplier, the responsible person must, at a minimum, include a list of all fragrances and flavors contained in the cosmetic product and contact information for the fragrance or flavor supplier, including the supplier's name, street address, telephone number, and electronic contact information. In the case of a notification provided by the Food and Drug Administration to the responsible person for the cosmetic manufacturer, the Food and Drug Administration may request, from the fragrance or flavor supplier, the complete list of ingredients in specific fragrances or flavors and the supplier shall have

30 days to provide such list to the Food and Drug Administration.

''(d) INCOMPLETE OR INACCURATE COSMETIC INGREDIENT STATEMENT.—

''(1) IN GENERAL.—Not earlier than 10 days after providing notice under paragraph (2), the Food and Drug Administration may nullify a cosmetic ingredient statement filed under this section if the Food and Drug Administration has reasonable grounds to believe that the cosmetic ingredient statement was not completed or updated in accordance with this section or otherwise contains false, incomplete, or inaccurate information.

''(2) NOTICE OF NULLIFICATION.—A nullification under paragraph (1) shall be preceded by notice to the responsible person of the intent to cancel the cosmetic ingredient statement and the basis for such cancellation.

''(3) TIMELY UPDATE OR CORRECTION.—If the cosmetic ingredient statement is appropriately updated or corrected not later than 7 days after notice is provided under paragraph (1), the Food and Drug Administration shall not nullify such cosmetic ingredient statement.

''(4) EFFECT OF NULLIFICATION.—If a cosmetic ingredient statement is nullified under this section, no person shall import, export, or otherwise distribute the cosmetic product that was the subject of the cosmetic ingredient statement.

''(e) ADDITIONAL REQUIREMENTS.—

''(1) SAFETY REQUIREMENTS.—In filing each cosmetic ingredient statement for each cosmetic product, the responsible person shall include an attestation that the safety of the product, including the individual ingredients of such product and the product as a whole, has been substantiated in accordance with section 609. In the case of a cosmetic ingredient statement that includes a range of possible amounts (as described in subsection (c)(2)(E)), the responsible person shall include an attestation that the safety of the full range in the finished product has been substantiated, in accordance with section 609.

''(2) ABBREVIATED FILING.—The Food and Drug Administration shall provide for an abbreviated renewal process for any such filing with respect to which there has been no change since the responsible person submitted the previous filing.

''(3) CHANGES TO INFORMATION.—

"(A) IN GENERAL.—Except as provided in subparagraph (B), the responsible person shall notify the Food and Drug Administration within 60 days of any change to the information required to be in a cosmetic ingredient statement, including discontinuation of the manufacture of a cosmetic product, except that notification under this paragraph is not required for a change in—

"(i) the amount of an existing ingredient if it is within the range previously reported under subsection (c)(2)(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 subsection (c)(2)(E), if, in the case of an addition of such an ingredient, the amount is within the range previously reported.

"(B) SMALL BUSINESS.—The Food and Drug Administration shall allow a responsible person that is a business that meets the applicable industry-based small business size stand-

ard established by the Administrator of the Small Business Administration under section 3 of the Small Business Act to have an additional time period, as determined by the Secretary, to submit any change to the information required to be in a cosmetic ingredient statement as described in subparagraph (A).

''(f) 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.

''SEC. 607. 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, processed, packed, or held by 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 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 or 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 registration or the cosmetic ingredient statement should be suspended; and

''(2) an opportunity, within 2 business days of the notice provided under paragraph (1), for the facility or responsible person, as appropriate, 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 import or export cosmetics or otherwise distribute cosmetics from such facility.

''(2) COSMETIC INGREDIENT STATEMENT.—If the cosmetic ingredient statement for a cosmetic product is suspended under this section, no person shall import or export such cosmetic product or otherwise distribute in the United States such 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 NONFUNCTIONAL CONSTITUENTS; SAFETY OF FINISHED PRODUCTS.

(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. 608. REVIEW OF INGREDIENTS AND NONFUNCTIONAL CONSTITUENTS.

''(a) INGREDIENTS AND NONFUNCTIONAL CONSTITUENTS SUBJECT TO REVIEW.—

''(1) IN GENERAL.—Beginning one year after the date of enactment of [_____], the Food and Drug Administration shall review the safety of the cosmetic ingredients and nonfunctional constituents under paragraph (3), as modified under subsection (c), if applicable, and issue an order under subsection (d) with respect to the use of each such ingredient and presence of each such nonfunctional constituent.

''(2) PUBLIC NOTICE AND COMMENT.—At the initiation of the review of each cosmetic ingredient or nonfunctional 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 nonfunctional constituent. The Food and Drug Administration shall provide 60 days for public comment.

''(3) COSMETIC INGREDIENTS.—

''(A) INGREDIENTS TO BE CONSIDERED IN FIRST YEAR.—Not later than one year after the Secretary begins collecting user fees under this section, the Food and Drug Administration shall initiate the review for safety of the following cosmetic ingredients:

''(i) [Diazolidinyl urea].

''(ii) Lead acetate.

''(iii) Methylene glycol/methanediol/formaldehyde.

''(iv) Propyl paraben.

''(v) Quaternium-15.

''(B) INGREDIENTS TO BE CONSIDERED IN SUBSEQUENT YEARS.—

''(i) IN GENERAL.—No later than two years after the Secretary begins collecting user fees under this section, and on a [triennial] basis thereafter, the Food and Drug Administration shall select and com-

plete a review of at least [10] cosmetic ingredients or nonfunctional constituents that were not reviewed in the prior [3 years] from a list determined in consultation with industry and consumer groups for review of safety. The Food and Drug Administration may combine selected cosmetics ingredients or nonfunctional constituents into categories for purposes of its review. The Food and Drug Administration may modify such list under subsection (c).

''(ii) CONSIDERATIONS.—The determination of which ingredients or functional ingredients will be reviewed within a 3-year period shall be publicized in annual reports to Congress and the public, in accordance with section 618, and subject to consultation as provided for in clause (iii). The review of any cosmetic ingredient or nonfunctional constituent shall commence with a public announcement by the Food and Drug Administration and the opening of a docket as required under paragraph (2).

"(iii) ADVISORY COMMITTEE.—Not later than one year after the date of enactment of the _____ Act of 2016, the Secretary shall—

"(I) rename the Food Advisory Committee of the Food and Drug Administration, as in existence on such date of enactment, the Food and Cosmetic Advisory Committee (in this clause referred to as the 'Advisory Committee');

"(II) expand the responsibilities of the Advisory Committee to include evaluating and making recommendations on broad scientific and technical cosmetic-related issues, advising on cosmetic ingredients and nonfunctional constituents to be considered for review, summarizing public comments received by the Food and Drug Administration related to cosmetic ingredient review, recommending cosmetic ingredients or nonfunctional constituents to be reviewed for safety **[**triennially**]**, and advising on other

matters pertaining to the safety of new cosmetics and cosmetic ingredients; and

''(III) include in the membership of the Advisory Committee equal numbers of individuals from the cosmetics industry and cosmetics consumer groups, together with such additional members as the Secretary determines appropriate, which additional members may include medical practitioners with an expertise in cosmetics issues.

''(4) COMMENT PERIOD.—The Food and Drug Administration shall solicit public comment on which cosmetic ingredients or nonfunctional constituents on the list are of greatest interest to be reviewed next for early review and which additional cosmetic ingredients or nonfunctional 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 nonfunctional constituents of interest that 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 nonfunctional constituents for which final orders have been issued under subsection (d)(3), the finding made for each such ingredient or nonfunctional constituent under subsection (d)(4), as modified by any order under subsection (e), and, if applicable, compliance dates that are the subject of a final order under subsection (d)(3).

''(c) INITIATIVE OF THE FDA.—The Food and Drug Administration may at any time, after consultation with the Food Advisory Committee, propose the issuance of an order on the safety of a cosmetic ingredient or nonfunctional constituent that was not previously listed in subsection (a) or under section 618(a)(3).

''(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 nonfunctional constituent. If the Food and Drug Ad-

ministration 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. If the Food and Drug Administration issues a proposed administrative order under subparagraph (C) of subsection (d)(4), the proposed administrative order shall include a compliance date by which use of the ingredient or nonfunctional constituent in cosmetic products shall comply with the final administrative order, when effective.

''(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, including comment on whether any proposed compliance date is feasible. 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 pub-

lic 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 nonfunctional 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. If the Food and Drug Administration issues a final administrative order under subparagraph (C) of subsection (d)(4), the final administrative order shall include a compliance date by which use of the ingredient or nonfunctional constituent in cosmetic products shall comply with the final administrative order.

''(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 nonfunctional 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 nonfunctional constituent as are necessary for the safety of cosmetic products containing such ingredient or nonfunctional constituent, including—

"(A) limits on the amount or concentration of the ingredient or nonfunctional 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 614, 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 nonfunctional constituent; and

"(C) such other conditions as are necessary for the safety of cosmetic products containing such ingredient or nonfunctional constituent.

"(6) PUBLIC NOTICE.—A final administrative 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 subsection (d)(4) and a summary of the valid scientific evidence supporting the finding. If the final administrative order does not identify a compliance date, 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) MODIFICATION OF AN ORDER.—An order issued under subsection (d) 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.

"(f) 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 nonfunctional constituent, the Food and Drug Administration shall—

"(A) publish such finding on the Internet website of the Food and Drug Administration not later than 180 days after the close of the relevant comment period for the ingredient or nonfunctional 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) include a notice providing interested persons an additional 30 days from the notice date to provide additional 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 180 days of the close of the addi-

tional time period provided under paragraph (1)(B), issue a final administrative order—

"(i) making a determination that the ingredient or nonfunctional 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 nonfunctional 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)(A), 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 nonfunctional constituent, in accordance with such subsection. If the Food and Drug Administration determines, after considering any additional data and information submitted under para-

graph (1)(B), that the available data and information are adequate to make a determination regarding safety under subsection (d)(4)(B), the Food and Drug Administration shall, within 180 days of the close of the comment period, issue a final order.

''(g) SAFETY ASSESSMENT.—

''(1) IN GENERAL.—In assessing the safety of an ingredient or nonfunctional 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 nonfunctional 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 nonfunctional 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 nonfunctional constituent, the Sec-

retary shall consider the following, among other relevant factors, to the extent the Secretary determines adequate data are available for such analyses:

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

"(B) The probable cumulative and aggregate effect in humans of relevant exposure to the ingredient or nonfunctional 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 nonfunctional constituent from all sources.

"(C) Whether warnings or recommendations in a product label, 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 nonfunctional constituent.

''(3) DATA AND INFORMATION.—

''(A) REQUIRED INFORMATION.—A determination that an ingredient or nonfunctional 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 nonfunctional 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 nonfunctional 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 nonfunctional 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 nonfunctional 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 nonfunctional constituent over time.''.

''SEC. 609. SAFETY OF FINISHED COSMETIC PRODUCTS.

''(a) DETERMINATION.—

''(1) IN GENERAL.—Each responsible person for a finished cosmetic product shall, before first distributing the product for sale, make a written determination that the product is safe under the conditions of use recommended in the labeling of the product. Such determination shall be based on adequate evidence that each ingredient in the finished product is safe for the use recommended or suggested in the labeling of the product and that the finished product is safe.

''(2) NEW INFORMATION.—If new information relevant to the determination becomes available, the responsible person shall promptly update the determination to address that information.

''(3) SAFETY WITH RESPECT TO RANGES OF POSSIBLE AMOUNTS.—In the case of a cosmetic product for which there is a range of possible amounts of cosmetic ingredients included in the cosmetic ingredient statement, as described in section 606(c)(2)(E), the safety determination under paragraph (1) shall include substantiation of the safety of the full range in the finished product.

''(b) PRESUMPTION OF ADEQUATE EVIDENCE.—

''(1) IN GENERAL.—Except as provided in subsection (c), a determination made under subsection (a) shall be presumed to be based on adequate evidence if it is supported by—

''(A) with respect to each ingredient in the finished product—

''(i) references to an official statement by one or more expert medical or scientific bodies that the ingredient is safe under the conditions of use recommended or suggested in the product's labeling; or

"(ii) appropriate safety testing of the ingredient; and

"(B) appropriate safety substantiation of the finished product beyond the safety substantiation of individual ingredients and consideration of the combination of ingredients.

"(2) STATEMENT OF AN EXPERT MEDICAL OR SCIENTIFIC BODY.—For purposes of this section, a statement of an expert medical or scientific body is an official statement of that body, if—

"(A) the medical or scientific body is a Federal, State, national, or international entity with recognized expertise in chemical or cosmetic safety, or other similarly recognized body composed of scientific and medical experts;

"(B) the statement is based upon adequate data to support the finding of safety, and such data are available to the Food and Drug Administration; and

"(C) the statement is published and endorsed by the medical or scientific body and is not a statement of an employee of such body made in the individual capacity of the employee.

"(c) REBUTTAL OF PRESUMPTION.—Notwithstanding subsection (b), a determination under subsection

(a) will not be presumed to be based on adequate evidence if—

''(1) the Food and Drug Administration issues an order under section 608 that an ingredient or nonfunctional constituent in the finished product is not safe under the product's conditions of use or customary or usual use; or

''(2) the Food and Drug Administration has provided the manufacturer with notice that—

''(A) the manufacturer has not met the criteria under subsection (b); or

''(B) the Food and Drug Administration has information that raises significant questions about the safety of the product or any of its ingredients.

''(d) TIMELY UPDATE.—Upon notice of inadequate evidence under subsection (c), the responsible person shall have 10 days to submit additional evidence to the Food and Drug Administration regarding the safety of an ingredient, nonfunctional constituent, or the entire cosmetic product, and the Food and Drug Administration shall have 30 days from the date of receipt of such additional evidence to provide the responsible person with notice that the criteria under subsection (b) have been met or not met.

''(e) RECORDS MAINTENANCE.—The responsible person shall maintain records documenting the determination required under this section and the information on which it is based until 5 years after the finished product is no longer marketed.

''(f) SUBMISSION OF RECORDS.—

''(1) IN GENERAL.—The records required under subsection (e) shall, upon the written request of the Food and Drug Administration to the responsible person, be provided to the Food and Drug Administration within a reasonable timeframe not to exceed 30 days, in electronic 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;

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

"(iii) the determination required under subsection (a) is not supported by adequate evidence; or

"(iv) one or more of the criteria to establish a presumption of adequate evidence of safety in subsection (b) has not been satisfied;

"(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.

"(g) GUIDANCE AND REGULATIONS.—

"(1) IN GENERAL.—The Food and Drug Administration shall issue guidance describing the evidence necessary to support a determination under subsection (a), and may, by regulation, establish exemptions to the requirements of this section, if the Food and Drug Administration determines that such

exemptions are supported by adequate evidence and would have no adverse effect on public health.

''(2) SMALL BUSINESSES.—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. Such guidance shall include specific examples of options for compliance that do not place an undue burden on small businesses.''.

(b) EFFECTIVE DATE.—Section 609 of the Federal Food, Drug, and Cosmetic Act, as added by subsection (a), shall take effect 180 days after the date of enactment of this Act.

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. 610. 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 **[**_____**]** and shall develop and implement, through regulations, United States 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) 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 **[**_____**]** 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 610 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 publishes the final rule described in subsection (a).

(2) SMALL BUSINESSES.—For businesses of a size that meets the Small Business Administration's standard for a small business, section 610 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 the final rule described in subsection (a).

(c) ENFORCEMENT.—Section 601 of Chapter VI 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.''.

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. 611. ADVERSE EVENT REPORTING FOR COSMETICS.

''(a) IN GENERAL.—With respect to any cosmetic product distributed in the United States, the responsible person shall submit, in electronic format, 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 adverse health condition, disability or incapacity;

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

"(vi) significant disfigurement, including serious and persistent rashes and infections; 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), 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 electronic 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) SEMIANNUAL REPORT.—**]**

["(A) IN GENERAL.—Not later than January 1 and July 1 of each year, 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 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.**]**

"(4) EXEMPTION.—The Food and Drug Administration may establish by regulation an exemption to any of the requirements under this sub-

section 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 **[**_____**]**.

"(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 pre-

vious 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. 612. INSPECTION OF COSMETIC RECORDS.

''(a) INSPECTION OF RECORDS.—Each manufacturer, processor, packer, holder, distributor, transporter, or person whose name and address appear on the label 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 611 and in accordance with the rules promulgated by the

Food and Drug Administration under section 610, as applicable;

''(2) all records maintained under section 609; and

''(3) 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), as applicable.

''(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 sub-

ject 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.''.

"SEC. 613. 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,

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 612; 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) POSTHEARING 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 com-

merce 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 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. 614. 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 608(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.—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, and 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, 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) DISPLAY.—The warning required under subsection (a) and the statement required under subsection (b)(3) shall be prominently displayed—

"(1) in the primary language used on the label; and

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

''(d) INTERNET SALES.—In the case of Internet sales of cosmetics, each Internet website offering cosmetic products for sale to consumers shall provide the same information that is included on the packaging of the cosmetic products as regularly available, such as warnings, ingredient list, and contact information, 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 domestic telephone number or electronic contact information, and it is encouraged that the label include both the telephone number and electronic contact information, that consumers 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 a cosmetic, including the ability to ask if a specific ingredient may be present that is not listed on the label, including whether a specific ingredient may be contained in the fragrance or flavor used in the cosmetic. The responsible person whose contact information appears on the cosmetic product label is responsible for providing such information

to consumers and is charged with promptly obtaining the information from suppliers if it is not readily available. Suppliers are required to promptly release such information upon request of the cosmetic manufacturer.''.

(b) EFFECTIVE DATE.—Section 614 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. 615. COAL TAR CHEMICALS.

''(a) IN GENERAL.—Under section 608, the Food and Drug Administration may review any cosmetic ingredient in order to determine if it is safe in cosmetic products without the need for specified conditions of use or tolerances, safe in cosmetic products under specified conditions of use or tolerances, or not safe in cosmetic products.

''(b) COAL TAR HAIR DYES.—Specific ingredients in coal tar hair dyes may be selected and reviewed under section 608(a)(3).''.

SEC. 108. ANIMAL TESTING ALTERNATIVES.

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 the following:

"SEC. 616. ANIMAL TESTING ALTERNATIVES.

"(a) IN GENERAL.—To minimize the use of animal testing for safety of cosmetic ingredients, nonfunctional constituents, and finished cosmetic products, the Food and Drug Administration shall—

"(1) encourage the use of alternative testing methods that provide information that is equivalent or superior in scientific quality to the animal testing method to—

"(A) not involve the use of an animal to test a chemical substance for safe use in cosmetics; or

"(B) use fewer animals than conventional animal-based tests for safe use in cosmetics when nonanimal methods are impracticable; and

"(2) encourage—

"(A) the sharing of data across companies and organizations that are testing for safety in cosmetics, so as to avoid duplication of animal tests; and

"(B) funding for research and validation of alternative testing methods.

''(b) GUIDANCE.—Not later than 3 years after the date of enactment of the **[**_____**]**, the Food and Drug Administration shall issue guidance on the acceptability of scientifically reliable and relevant alternatives to animal testing for the safety of cosmetic ingredients, nonfunctional constituents, and finished cosmetic products, and encouraging the use of such methods. The Food and Drug Administration shall update such guidance on an annual basis.

''(c) RESOURCES REGARDING ANIMAL TESTING ALTERNATIVES.—Not later than 180 days after the date of enactment of the **[**_____**]**, the Food and Drug Administration shall provide information on the Internet website of the Food and Drug Administration regarding resources available for information about non-animal methods, and methods that reduce animal usage, in testing for the safety of cosmetic ingredients, nonfunctional constituents, and finished cosmetic products.''.

SEC. 109. PREEMPTION.

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. 617. SAVINGS.

"(a) NO PREEMPTION OF COMMON LAW OR STATUTORY CAUSES OF ACTION FOR CIVIL RELIEF OF CRIMINAL CONDUCT.—

"(1) IN GENERAL.—Nothing in this Act [this chapter? the _____ Act of 2016?], nor any amendment made by the [_____], nor any rules, regulations, requirements, risk evaluations, scientific assessments, or orders issued pursuant to this Act shall be construed to preempt, displace, or supplant any State or Federal common law rights or any State or Federal statute creating a remedy for civil relief, including those for civil damage, or penalty for criminal conduct.

"(2) CLARIFICATION OF NO PREEMPTION.—Notwithstanding any other provision of this Act, nothing in this Act, nor any amendment made by the [_____], shall preempt or preclude any cause of action for personal injury, wrongful death, property damage, or other injury based on negligence, strict liability, products liability, failure to warn, or any other legal theory of liability under any State law, maritime law, or Federal common law or statutory theory.

"(b) NO EFFECT ON PRIVATE REMEDIES.—

''(1) IN GENERAL.—Nothing in this Act, nor any amendment made by the **[**_____**]**, nor any rules, regulations, requirements, risk evaluations, scientific assessments, or orders issued pursuant to this Act shall be interpreted as, in either the plaintiff's or defendant's favor, dispositive in any civil action.

''(2) AUTHORITY OF COURTS.—This Act does not affect the authority of any court to make a determination in an adjudicatory proceeding under applicable State or Federal law with respect to the admission into evidence or any other use of this Act or rules, regulations, requirements, standards of performance, risk evaluations, scientific assessments, or orders issued pursuant to this Act.''.

SEC. 110. REPORTING.

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 at the end the following:

''SEC. 618. REPORTING.

''(a) PERFORMANCE REPORT.—Beginning with fiscal year **[**2018**]**, and not later than 60 days prior to the end of each fiscal year for which fees are collected under section 744L, 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 **[**_____**]** 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 nonfunctional 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 the cosmetic ingredients and nonfunctional constituents identified by the Food and Drug Administration for review under section 608(a)(3)(B) during the relevant time period and identify which, if any, reviews are complete;

''(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) efforts of the Food and Drug Administration to reduce animal testing for safety of cosmetic ingredients, nonfunctional constituents, and cosmetic products.

''(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.''.

SEC. 111. SMALL BUSINESSES.

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. 619. SMALL BUSINESSES.

''(a) IN GENERAL.—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 _____ Act of 2016, including the amendments made by such Act.

''(b) COMPLIANCE GUIDE.—Not later than 180 days after enactment of **[**_____**]**, the Secretary shall issue a small business guide setting forth in plain language the requirements of sections 605 and 606 in order to assist small businesses in complying.''.

SEC. 112. 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 111, is further amended by adding at the end the following:

"SEC. 620. 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.".

SEC. 113. ENFORCEMENT.

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

(1) in subsection (e)—

(A) by striking "504, 564" and inserting "504, 564, 611, or 612"; and

(B) by striking ''519, 564'' and inserting ''519, 564, 611,'';

(2) in subsection (j) by inserting ''607, 608, 610,'' before ''704'';

(3) in subsection (ii)—

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

(B) by striking ''760 or 761) submitted'' and inserting ''611, 760, or 761) submitted'';

(4) in subsection (xx) by inserting ''or 613'' after ''423''; and

(5) by adding at the end the following:

''(ddd) The failure to register in accordance with section 605, the failure to submit a cosmetic ingredient statement under section 606, the failure to provide any information required by section 605 or 606, or the failure to update the information required by section 605 or 606, as required.''.

(b) ADULTERATION.—Section 601 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 361), as amended by section 103, is further amended by adding at the end the following:

''(g) If it contains, after the date prescribed under section 608(e), an ingredient that the Food and Drug Administration has determined under section 608(d)(4) to be

not safe, or not safe under the conditions of use recommended or suggested in the label or a nonfunctional constituent that the Food and Drug Administration has determined under section 608(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 any requirement of section 609 (relating to safety substantiation) is not met.''.

(c) MISBRANDING.—Section 602 is amended—

(1) in subsection (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, processed, packed, or held 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 614.''.

(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) is amended—

(1) by striking ''section 760 or 761'' the first, third, and fourth place such term appears and inserting ''section 611, 760, or 761''; and

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

(f) FACTORY INSPECTION.—Section 704(a)(1) is amended by inserting after the third sentence the following: ''In the case of any person who manufactures, processes, packs, holds, 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 612 (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 subsection (d) of such section.''.

SEC. 114. 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 nonfunctional constituent under section 608(d)(3);

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

(3) identified counterfeit cosmetic products.

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 10 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 10—FEES RELATING TO COSMETICS

"SEC. 744L. REGISTRATION FEE.

''(a) ASSESSMENT AND COLLECTION.—

''(1) IN GENERAL.—Beginning in fiscal year [2017], the Secretary shall in accordance with this section assess and collect an annual fee from every responsible person required to register under section 605(a).

''(2) PAYABLE DATE.—Fees under this section shall be due and payable—

''(A) for fiscal year [2017], with respect to responsible parties required to register under section 605 for such first program year, on the date of registration; and

''(B) for fiscal year [2017] and each subsequent fiscal year, on the later of—

''(i) the date of registration or registration renewal, as applicable, under section 605; or

''(ii) the date of enactment of an appropriations Act providing for the collection and obligation of fees under this section for the fiscal year involved.

''(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 2015.

''(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 SAFETY ACTIVITIES.—The term 'cosmetic safety activities'—

''(A) means activities related to compliance by responsible parties required to register under

section 605 with the requirements of this Act with respect to cosmetics, including—

"(i) administrative activities, such as—

"(I) information technology acquisition, management, maintenance, and support;

"(II) the acquisition, administration, and maintenance of the cosmetic registration system and the cosmetic ingredient statement system under section 606;

"(III) fee assessment and collection under this section; and

"(IV) the acquisition, leasing, maintenance, renovation and repair of facilities, fixtures, furniture, scientific equipment, and other necessary materials and supplies for purposes of subclauses (I) through (III); and

"(ii) implementation and enforcement activities, such as the establishment of good manufacturing practices, the review of adverse event reports, inspection plan-

ning and inspections, and use of enforcement tools;

"(B) includes activities related to implementation of section 608, regarding the review of cosmetic ingredients and nonfunctional constituents; and

"(C) activities of the Secretary related to implementation of section 606.

"(4) 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 responsible party, 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 **[**2016**]**, based on the methodology described in paragraph (3)(B), 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 responsible party required to register under section 605 whose average

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 **[**$500,000**]**, shall be exempt from registration fees under this section for that fiscal year.

''(3) ANNUAL FEE SETTING.—

''(A) FISCAL YEAR **[**2017**]**.—For fiscal year **[**2017**]**, to generate a total estimated revenue amount of $20,600,000, the amount of the registration fee under subsection (a) shall be as follows:

''(i) TIER I–A.—For a responsible party required to register under section 605 that has gross annual sales of $5,000,000,000 or more in 2015, $1,100,000.

''(ii) TIER I–B.—For a responsible party required to register under section 605 that has gross annual sales of at least $4,000,000,000 per annum but less than $5,000,000,000 in 2015, $840,000.

''(iii) TIER II–A.—For a responsible party required to register under section 605 that has gross annual sales of at least

$3,000,000,000 per annum but less than $4,000,000,000 in 2015, $720,000.

''(iv) TIER II–B.—For a responsible party required to register under section 605 that has gross annual sales of at least $2,000,000,000 per annum but less than $3,000,000,000 in 2015, $600,000.

''(v) TIER III–A.—For a responsible party required to register under section 605 that has gross annual sales of at least $1,000,000,000 per annum but less than $2,000,000,000 in 2015, $500,000.

''(vi) TIER III–B.—For a responsible party required to register under section 605 that has gross annual sales of at least $500,000,000 per annum but less than $1,000,000,000 in 2015, $395,000.

''(vii) TIER IV–A.—For a responsible party required to register under section 605 that has gross annual sales of at least $200,000,000 per annum but less than $500,000,000 in 2015, $325,000.

''(viii) TIER IV–B.—For a responsible party required to register under section 605 that has gross annual sales of at least

$100,000,000 per annum but less than $200,000,000 in 2015, $275,000.

''(ix) TIER V–A.—For a responsible party required to register under section 605 that has gross annual sales of at least $80,000,000 per annum but less than $100,000,000 in 2015, $185,000.

''(x) TIER V–B.—For a responsible party required to register under section 605 that has gross annual sales of at least $60,000,000 per annum but less than $80,000,000 in 2015, $95,000.

''(xi) TIER VI–A.—For a responsible party required to register under section 605 that has gross annual sales of at least $40,000,000 per annum but less than $60,000,000 in 2015, $15,000.

''(xii) TIER IV–B.—For a responsible party required to register under section 605 that has gross annual sales of at least $20,000,000 per annum but less than $40,000,000 in 2015, $12,000.

''(xiii) TIER VII–A.—For a responsible party required to register under section 605 that has gross annual sales of at least

$2,500,000 per annum but less than $20,000,000 in 2015, $500.

''(xiv) TIER VII–B.—For a responsible party required to register under section 605 that has gross annual sales of at least **[**$500,000**]** per annum but less than $2,500,000 in 2015, $250.

''(B) FISCAL YEARS **[**2017**]**–2022.—For fiscal years **[**2017**]**–2022, fees under subsection (a) shall be established to generate a total estimated revenue amount of $20,600,000, as adjusted by subsection (d). Of that amount:

''(i) TIER I–A.—Responsible parties required to register under section 605 that have gross annual sales of $5,000,000,000 or more in the fiscal year immediately preceding the fiscal year in which the annual fee will be paid, shall be responsible, collectively, for 10.7 percent.

''(ii) TIER I–B.—Responsible parties required to register under section 605 that have gross annual sales of at least $4,000,000,000 per annum but less than $5,000,000,000 in the fiscal year immediately preceding the fiscal year in which

the annual fee will be paid, shall be responsible, collectively, for 4.1 percent.

''(iii) TIER II–A.—Responsible parties required to register under section 605 that have gross annual sales of at least $3,000,000,000 per annum but less than $4,000,000,000 in the fiscal year immediately preceding the fiscal year in which the annual fee will be paid, shall be responsible, collectively, for 3.5 percent.

''(iv) TIER II–B.—Responsible parties required to register under section 605 that have gross annual sales of at least $2,000,000,000 per annum but less than $3,000,000,000 in the fiscal year immediately preceding the fiscal year in which the annual fee will be paid, shall be responsible, collectively, for 2.9 percent.

''(v) TIER III–A.—Responsible parties required to register under section 605 that have gross annual sales of at least $1,000,000,000 per annum but less than $2,000,000,000 in the fiscal year immediately preceding the fiscal year in which

the annual fee will be paid, shall be responsible, collectively, for 7.3 percent.

''(vi) TIER III–B.—Responsible parties required to register under section 605 that have gross annual sales of at least $500,000,000 per annum but less than $1,000,000,000 in the fiscal year immediately preceding the fiscal year in which the annual fee will be paid, shall be responsible, collectively, for 13.4 percent.

''(vii) TIER IV–A.—Responsible parties required to register under section 605 that have gross annual sales of at least $200,000,000 per annum but less than $500,000,000 in the fiscal year immediately preceding the fiscal year in which the annual fee will be paid, shall be responsible, collectively, for 15.8 percent.

''(viii) TIER IV–B.—Responsible parties required to register under section 605 that have gross annual sales of at least $100,000,000 per annum but less than $200,000,000 in the fiscal year immediately preceding the fiscal year in which

the annual fee will be paid, shall be responsible, collectively, for 13.3 percent.

''(ix) TIER V–A.—Responsible parties required to register under section 605 that have gross annual sales of at least $80,000,000 per annum but less than $100,000,000 in the fiscal year immediately preceding the fiscal year in which the annual fee will be paid, shall be responsible, collectively, for 9 percent.

''(x) TIER V–B.—Responsible parties required to register under section 605 that have gross annual sales of at least $60,000,000 per annum but less than $80,000,000 in the fiscal year immediately preceding the fiscal year in which the annual fee will be paid, shall be responsible, collectively, for 6.9 percent.

''(xi) TIER VI–A.—Responsible parties required to register under section 605 that have gross annual sales of at least $40,000,000 per annum but less than $60,000,000 in the fiscal year immediately preceding the fiscal year in which the an-

nual fee will be paid, shall be responsible, collectively, for 5.1 percent.

''(xii) TIER VI–B.—Responsible parties required to register under section 605 that have gross annual sales of at least $20,000,000 per annum but less than $40,000,000 in the fiscal year immediately preceding the fiscal year in which the annual fee will be paid, shall be responsible, collectively, for 4.4 percent.

''(xiii) TIER VII–A.—Responsible parties required to register under section 605 that have gross annual sales of at least $2,500,000 per annum but less than $20,000,000 in the fiscal year immediately preceding the fiscal year in which the annual fee will be paid, shall be responsible, collectively, for 1.2 percent.

''(xiv) TIER VII–B.—Responsible parties required to register under section 605 that have gross annual sales of at least [$500,000] per annum but less than $2,500,000 in the fiscal year immediately preceding the fiscal year in which the annual fee will be paid, shall be responsible,

collectively, for 2.4 percent, except that no such responsible party shall be responsible for more than $250 per fiscal year.

''(d) ADJUSTMENTS.—

''(1) INFLATION ADJUSTMENT.—

''(A) IN GENERAL.—For fiscal year **[**2018**]** and each subsequent fiscal year, the revenues and fee amounts under subsection (c)(3)(B) 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, multiplied 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 [2017] under this subsection.

"(C) ADJUSTMENT TO BASE FEE AMOUNTS.—For each of fiscal years [2017] through 2022, the base fee amounts specified in subsection (c)(3) shall be adjusted as needed, on a uniform proportionate basis, to generate the total revenue amounts under subsection

(c)(3), as adjusted for inflation under subparagraph (A).

''(2) FINAL YEAR ADJUSTMENT.—For fiscal year 2022, 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 2023. 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 2022. 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 paragraph shall not be made.

''(3) WORKLOAD ADJUSTMENT.—

''(A) IN GENERAL.—For fiscal year [2018] and each subsequent fiscal year, after fee revenues established in subsection (c)(3)(B) 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 nonfunctional constituents not listed under section 608(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 are 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)(B), as adjusted for inflation under paragraph (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 **[**2017**]**, multiplied by the adjustment factor applicable to the fiscal year involved. If the amount so appropriated prevents the Food and Drug Administration from assessing fees under subsection (a), the Food and Drug Administration is not required to carry out any activities described in section 608 during that fiscal year.

''(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.—The fees authorized by this section—

''(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 Sep-

tember 30, [2016], for the salaries and expenses account of the Food and Drug Administration, fees authorized by this section for fiscal year [2017] 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) STARTUP COSTS.—Until one year after the Food and Drug Administration begins collecting user fees under subsection(a), any amounts available to the Center for Food Safety and Applied Nutrition (excluding user fees) may be available and allocated as needed to pay the costs of cosmetic regulation activities described in this Act.

''(E) REIMBURSEMENT OF STARTUP AMOUNTS.—

''(i) IN GENERAL.—Any amounts allocated for the startup period pursuant to subparagraph (B)(ii) shall be reimbursed through any appropriated fees collected under subsection (a), in such manner as the Secretary determines appropriate to

ensure that such allocation results in no net change in the total amount of funds otherwise available, for a period not to exceed one year after the Food and Drug Administration begins collecting user fees under subsection (a), for Food and Drug Administration programs and activities (other than cosmetic regulation activities) for such period.

''(ii) TREATMENT OF REIMBURSED AMOUNTS.—Amounts reimbursed under clause (i) shall be available for the programs and activities for which funds allocated for the startup period were available, prior to such allocation, until 1 year after the Food and Drug Administration begins collecting user fees under subsection (a), notwithstanding any otherwise applicable limits on amounts for such programs or activities for a fiscal year.

''(3) AUTHORIZATION OF APPROPRIATIONS.—For each of fiscal years **[**2017**]**–2022, there are authorized to be appropriated for fees under this section $20,600,000, as adjusted by subsection (d).

''(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 responsible party 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 responsible party required to register under section 605 shall retain all records nec-

essary to demonstrate gross annual sales for at least 2 fiscal years after such information is reported in its 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.

''(l) SUNSET DATE.—Section 744 of the Federal Food, Drug, and Cosmetic Act does not authorize the assessment or collection of a fee for registration under section 605 of such Act occurring after fiscal year 2022. The amendments made by this title cease to be effective on October 1, 2022.''.

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

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

''SEC. 744M. 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 **[**_____**]**.

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