S.

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

IN THE SENATE OF THE UNITED STATES

Mrs. FEINSTEIN (for herself and Ms. COLLINS) introduced the following bill; which was read twice and 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 Representa-}

tives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE; TABLE OF CONTENTS.

(a) SHORT TITLE.—This Act may be cited as the “Personal Care Products Safety Act”.

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

Sec. 1. Short title; table of contents.

TITLE I—COSMETIC SAFETY

Sec. 101. Registration of cosmetics facilities and cosmetic ingredient state-
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, 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 non-profit 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) NON-FUNCTIONAL CONSTITUENT.—The term ‘non-functional constituent’ means any substance that is an incidental component of an ingredient, a breakdown product of an ingredient or a by-
product of the manufacturing process that has not been intentionally added as a separate substance and serves no technical function in the cosmetic.

“(6) RESPONSIBLE PERSON.—The term ‘responsible person’ means—

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

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

“SEC. 605. REGISTRATION OF COSMETIC FACILITIES.

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

“(1) REGISTRATION, IN GENERAL.—Not later than December 1, 2015, and at a similar time in each subsequent year, as determined by the Food and Drug Administration, each responsible person engaged in manufacturing or processing a cosmetic product or a cosmetic formulation distributed in the
United States shall register all of the responsible person’s facilities with the Food and Drug Administration.

“(2) Fees.—If the average gross annual sales in the United States of cosmetic products of all of the responsible person’s facilities registered under paragraph (1) for the previous 3-year period is greater than $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 of Cosmetics.—Not later than December 1, 2015, and at a similar time once every 3 years thereafter, as determined by the Food and Drug Administration, each person who owns or operates a cosmetic facility or facilities engaged in packing or holding a cosmetic product distributed in the United States shall register each such facility with the Food and Drug Administration.

“(c) Registration by New Facilities.—Any facility first engaging after the date of enactment of the Personal Care Products Safety Act in an activity that would require it to register under subsection (a) or (b) shall register with the Food and Drug Administration within 60
days of first engaging in such activity, and thereafter in
accordance with subsection (a) or (b).

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

“(e) FORMAT; CONTENTS.—

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

“(2) CONTENTS.—The registration shall con-
tain 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 of activity 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 facility, and, if available, the 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 registrant that has not had any changes to such information with respect to the facility or facilities involved since the registrant submitted the preceding registration.

“(f) Incomplete or Inaccurate Registration.—

“(1) In general.—Not earlier than 10 days after providing notice of the intent to cancel a registration and the basis for such cancellation, the Food and Drug Administration may cancel a registration under this section if the Food and Drug Administration has reasonable grounds to believe that the registration was not properly completed or updated in accordance with this section or otherwise contains false, incomplete, or inaccurate information.
“(2) TIMELY UPDATE OR CORRECTION.—If, not later than 7 days after receipt of a notice of intent to cancel, the sponsor 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.

“(g) 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.

“(h) REGISTRY OF FACILITIES.—

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

“(2) PUBLIC AVAILABILITY EXCEPTIONS.—Information derived from the registry or registration documents that discloses the residential address of a registrant or that discloses specific facilities where specific cosmetic products are manufactured or proc-
essed 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 Ad-
ministration 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 Personal Care Products
Safety Act, the responsible person shall submit a
cosmetic ingredient statement not later than December
1, 2015. The responsible person shall submit to
the Food and Drug Administration a renewal of
such statement on a yearly basis.

“(2) Cosmetic Ingredient Statement for
New Cosmetic Products.—

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

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

“(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 regulations 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 cos-
metic 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 statement is filed by a contract manufacturer, described in section 604(6)(B).

“(B) The brand name and the full name for the cosmetic product as it appears on the label.

“(C) The cosmetic product listing number, if any, previously assigned 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 Administra-

(continued...
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 in-
gredients in specific fragrances or fla-
vors and the supplier shall have 30
days to provide such list to the Food
and Drug Administration; and

“(ii) other appropriate interchange-
able ingredients as the Food and Drug Ad-
ministration may specify in regulations or
guidance that may be included in the prod-

tect, with ranges of possible amounts.

“(F) The title and full contact information
of each individual submitting the statement.

“(G) If applicable, information on the la-
beling required under section 614.

“(H) Such additional information per-
taining 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 sec-
tion 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.

“(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.

“(e) ADDITIONAL REQUIREMENTS.—

“(1) SAFETY REQUIREMENTS.—In filing each cosmetic ingredient statement 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 (e)(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 abbre-
viated renewal process for any such filing with re-
spect 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 with-
in 60 days of any change to the information re-
quired 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 ingre-
dient if it is within the range previously re-
ported 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 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 standard established by the Administrator of the Small Business Administration under section 3 of the Small Business Act to have a period longer than 60 days, but not longer than the next annual registration deadline under section 605(a)(1), 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 manufac-
tured, processed, packed, or held by a registered facility
has a reasonable probability of causing serious adverse
health consequences or death to humans, and there is rea-
son to believe that other formulations or products manu-
factured, processed, packed, or held by the facility may
be similarly affected because of a failure affecting multiple
products in that facility, the Food and Drug Administra-
tion 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 fa-
cility has a reasonable probability of causing serious ad-
verse health consequences or death to humans, the Food
and Drug Administration may suspend the cosmetic ingre-
dient statement of that product.
“(c) Notice of Suspension.—Before suspending a facility registration or a cosmetic ingredient statement under this section, the Food and Drug Administration shall provide—

“(1) notice to the facility registrant of the cosmetic product or formulation or other responsible person, as appropriate, of the intent to suspend the facility registration or the cosmetic ingredient statement, which shall specify the basis of the determination by the Food and Drug Administration that the facility or the cosmetic ingredient should be suspended and recommendations for specific actions to avoid suspension; and

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

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

“(e) Effect of Suspension.—
“(1) **Registration.**—If the registration of a facility is suspended under this section, no person shall 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 NON-FUNCTIONAL 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 NON-FUNCTIONAL CONSTITUENTS.**

“(a) **Ingredients and Non-Functional Constituents Subject to Review.**—

“(1) IN GENERAL.—Beginning in fiscal year 2016, the Food and Drug Administration shall re-
view the safety of the cosmetic ingredients and non-
functional 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 non-functional constituent.

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

“(3) COSMETIC INGREDIENTS.—

“(A) INGREDIENTS TO BE CONSIDERED IN FIRST YEAR.—During fiscal year 2016, the Food and Drug Administration shall initiate the review for safety of the following cosmetic in-
gredients:

“(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.—Beginning in fiscal year 2017, the Food and Drug Administration shall annually select and complete review of at least 5 cosmetic ingredients or non-functional constituents that were not reviewed in the prior 3 years from a list determined in consultation with industry and consumer groups for review of safety. 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 in a given year 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 non-functional constituent shall commence with
a public announcement by the Food and Drug Administration and the opening of a docket as required under paragraph (2).

“(iii) CONSULTATION.—The Food and Drug Administration shall establish a Cosmetics Safety Advisory Committee, which shall include equal numbers of individuals from the cosmetics industry and consumer groups, and other individuals, as the Food and Drug Administration determines appropriate, including medical practitioners. Such advisory committee shall advise the Food and Drug Administration on cosmetic ingredients and non-functional constituents to be considered for review, summarize public comments received pursuant to paragraph (4), and recommend 5 cosmetic ingredients or non-functional constituents to be reviewed for safety each year, as described in clause (i). The Food and Drug Administration may consult with the Cosmetics Safety Advisory Committee on other matters pertaining to cosmetic safety.
“(4) COMMENT PERIOD.—As part of the annual reporting to Congress and the public under section 618, the Food and Drug Administration shall solicit public comment on which cosmetic ingredients or non-functional constituents on the list are of greatest interest to be reviewed next for early review and which additional cosmetic ingredients or non-functional constituents should be added to the list. The public may submit comments to the Food and Drug Administration at any time during the year regarding which cosmetic ingredients or non-functional constituents of interest 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 non-functional constituents for which final orders have been issued under subsection (d)(3), the finding made for each such ingredient or non-functional constituent under subsection (d)(4), as modified by any order under subsection (f), and, if applicable, compliance dates that are the subject of a final order under subsection (e).

“(c) INITIATIVE OF THE FDA.—The Food and Drug Administration may at any time, after consultation with
the Cosmetics Safety Advisory Committee, propose the issuance of an order on the safety of a cosmetic ingredient or non-functional constituent that was not previously listed in subsection (a) or under section 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 non-functional constituent. If the Food and Drug Administration determines that there is adequate evidence, the Food and Drug Administration shall issue a proposed administrative order and shall post such order on the Internet website of the Food and Drug Administration, notwithstanding subchapter II of chapter 5 of title 5, United States Code.

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

“(3) Final Administrative Order.—Following the public comment period described in paragraph (2) and consideration of comments to the public docket and any other information before the Food and Drug Administration, the Food and Drug Administration shall determine whether there is adequate evidence to make a final finding on the safety of the ingredient or non-functional constituent. If the Food and Drug Administration determines that there is adequate evidence, the Food and Drug Administration shall issue a final administrative order and shall post such order on the Internet website of the Food and Drug Administration, notwithstanding subchapter II of chapter 5 of title 5, United States Code.

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

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

“(C) not safe in cosmetic products.

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

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

“(B) warnings that are necessary or appropriate under section 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 non-functional constituent; and

“(C) such other conditions as are necessary for the safety of cosmetic products containing such ingredient or non-functional constituent.

“(6) PUBLIC NOTICE.—A final order under this subsection shall set forth the determination of the Food and Drug Administration on safety, any conditions of use or tolerances under subparagraph (A) or (B) of paragraph (4) and a summary of the valid scientific evidence supporting the finding. The order shall be effective upon its publication on the Internet website of the Food and Drug Administration and shall be considered final agency action.

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

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

“(g) INADEQUATE EVIDENCE.—

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

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

“(B)(i) include a notice providing interested persons an additional 30 days from the
notice date to provide additional data and information; and

“(ii) if, after the 30-day period under clause (i), the Food and Drug Administration determines that additional safety substantiation with respect to such ingredient or non-functional constituent is necessary to make a safety determination, include a notice specifying an additional time period, not to exceed 18 months from the notice date, and plan to obtain such data and information.

“(2) Determination; order.—

“(A) Inadequate data and information.—If the Food and Drug Administration determines, after considering any additional data and information submitted under paragraph (1)(B), that the available data and information still are not adequate to make a determination regarding safety under subsection (d)(4), the Food and Drug Administration shall, within 90 days of the close of the additional time period provided under paragraph (1)(B), issue a proposed order or a final administrative order—
“(i) making a determination that the
ingredient or non-functional constituent
has not been shown to be safe in cosmetic
products; and

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

“(B) Adequate data and information.—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 infor-
mation are adequate to make a determination
regarding safety under subsection (d)(4), the
Food and Drug Administration shall, within
180 days of the close of the comment period,
issue a proposed order, followed by a final
order, on such cosmetic ingredient or non-func-
tional constituent, in accordance with such sub-
section.

“(h) Safety assessment.—

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

“(2) FACTORS.—In assessing the safety of an ingredient or non-functional constituent, the Food and Drug Administration shall consider, among other relevant factors, the following:

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

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

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

“(3) DATA AND INFORMATION.—

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

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

“(i) adverse event reports;

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

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

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

“SEC. 609. SAFETY OF FINISHED COSMETIC PRODUCTS.

“(a) Determination.—

“(1) In general.—Each responsible person
for a finished cosmetic product shall, before first dis-
tributing the product for sale, make a written deter-
mination that the product is safe under the condi-
tions of use recommended in the labeling of the
product. Such determination shall be based on ade-
quate evidence that each ingredient in the finished
product is safe for the use recommended or sug-
gested 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 deter-
mination 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 cos-
metic ingredient statement, as described in section
606(c)(2)(E), the safety determination under para-
graph (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 non-functional 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, non-functional 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 Adminis-
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tration within a reasonable timeframe not to exceed
60 days, in either electronic or paper form.

“(2) CRITERIA.—The Food and Drug Adminis-
tration may require records under paragraph (1) if—

“(A) the Food and Drug Administration
has a reasonable belief, described in written no-
tice, that—

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

“(ii) scientific information raises cred-
ible and relevant questions about the safe-
ty of the product or any of its ingredients;

“(iii) the responsible person has not
made the determination required under
subsection (a), or such determination is
not supported by adequate evidence; or

“(iv) one or more of the criteria to es-
tablish 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 Ad-
ministration shall issue guidance describing the evi-
dence necessary to support a determination under
subsection (a), and may, by regulation, establish ex-
emptions 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 guid-
ance for small businesses on compliance with the re-
quirements of this section. Such guidance shall in-
clude specific examples of options for compliance
that do not place an undue burden on small busi-
nesses.”.
(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 Personal Care Products Safety Act 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 Administra-
tion shall publish a proposed rule described in subsection
(a) not later than 18 months after the date of enactment
of the Personal Care Products Safety Act and shall pub-
lish a final such rule not later than 3 years after such
date of enactment.”.

(b) EFFECTIVE DATE FOR COSMETIC MANUFACTU-
ERS.—

(1) LARGE BUSINESSES.—For businesses of a
size greater than the Small Business Administra-
tion’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 makes effective cosmetic good
manufacturing practices.

(2) SMALL BUSINESSES.—For businesses of a
size that meets the Small Business Administration’s
standard for a small business, section 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 cosmetic good manufacturing prac-
tices.
(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 to the Food and Drug Administration a report of any serious adverse event associated with such cosmetic product, when used in the United States, accompanied by a copy of the label on or with the retail packaging of the cosmetic, any new medical information, related to a submitted serious adverse event report that is received by the responsible person, and an annual report for all adverse events received by the responsible person.

“(b) **DEFINITIONS.**—In this section:
“(1) An ‘adverse event’ for a cosmetic product is a health-related event associated with the use of this product that is adverse.

“(2) A ‘serious adverse event’ for a cosmetic product is an adverse event that—

“(A) results in—

“(i) death;

“(ii) a life-threatening experience;

“(iii) inpatient hospitalization;

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

“(v) congenital anomaly or birth defect; or

“(vi) significant disfigurement, including serious and persistent rashes 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) ANNUAL REPORT.—

“(A) IN GENERAL.—Not later than March 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 pe-
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 subsection if the Food and Drug Administration determines that such exemption is supported by adequate evidence and would have no adverse effect on public health.

“(d) REQUIREMENTS.—

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

“(2) MODIFICATION.—The format of the re-
porting system may be modified by the Food and
Drug Administration and the reports may include
additional information. The Food and Drug Admin-
istration may, in guidance, further specify the for-
mat and contents of required reports.

“(3) SCOPE OF SERIOUS ADVERSE EVENT RE-
PORT.—A serious adverse event report (including all
information submitted in the initial report or added
later) submitted to the Food and Drug Administra-
tion under subsection (a) includes—

“(A) a report under section 756 with re-
spect to safety and related to a specific cos-
metic product;

“(B) a record about an individual who suf-
f ered 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 pub-
licly disclosed unless all personally identifiable
information is redacted; and
“(D) contact information for the individual reporting the serious adverse event.

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

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

“(e) Limitation With Respect to Adverse Event Reports.—The submission of an adverse event report in compliance with subsection (a) shall not constitute an admission that the cosmetic involved caused or contributed to the adverse event.

“(f) Contact Information.—The label of a cosmetic shall bear the domestic telephone number or elec-
tronic 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 pe-
riod of 6 years.

“(h) AVAILABILITY TO STATES.—The Food and
Drug Administration shall make available records sub-
mitted under this section to any State, upon request. In-
formation disclosed to a State that is exempt from disclo-
sure 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 RE-
spect 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 Ad-
ministration 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, or holder 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; and

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

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

“(i) is adulterated;

“(ii) has caused a reportable serious adverse event; or
“(iii) contains an ingredient that substantial new scientific information shows may be unsafe when present in a cosmetic; and

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

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

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

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

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

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

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

“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 respon-
sible 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) POST-HEARING RECALL ORDER AND MODIFICA-
TION OF ORDER.—

“(1) AMENDMENT OF ORDER.—If, after pro-
viding 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 Administra-
tion 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, distrib-
uted.

“(2) VACATING OF ORDER.—If, after such hear-
ing, 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 Administra-
tion 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 ap-
propriate.

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

“(1) ensure that a press release is published re-

outside the recall, and that alerts and public notices
are issued, as appropriate, in order to provide notifi-
cation—

“(A) of the recall to consumers and retail-
ers 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 associ-
ated with such article; and

“(iii) to the extent practicable, infor-
mation for consumers about similar cos-
metics 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 prod-
ucts under section 608(d)(5), the Food and Drug Admin-
istration 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 re-
spect to cosmetics, the term ‘professional’ means an
individual who—

“(A) is licensed by an official State author-
ity 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 re-
quires 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, 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 manufacturer of the cosmetic is responsible for providing such information, including obtaining the information from suppliers if it is not readily available. Suppliers are required to release such information upon request of the cosmetic manufacturer.”

(b) 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 chemicals 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, non-functional 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 Personal Care Products Safety
Act, the Food and Drug Administration shall issue guid-
ance on the acceptability of scientifically reliable and rel-
evant alternatives to animal testing for the safety of cos-
metic ingredients, non-functional constituents, and fin-
ished 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 AL-
TERNATIVES.—Not later than 180 days after the date of
enactment of the Personal Care Products Safety Act, the
Food and Drug Administration shall provide information
on the Internet website of the Food and Drug Administra-
tion regarding resources available for information about
non-animal methods, and methods that reduce animal
usage, in testing for the safety of cosmetic ingredients,
non-functional constituents, and finished cosmetic prod-
ucts.”.
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. PREEMPTION.

"(a) Registration, Good Manufacturing Practices, Recalls, Adverse Event Reporting.—Except for a State requirement that is in full effect and implemented on the date of enactment of the Personal Care Products Safety Act, no State or political subdivision of a State may establish or continue in effect any requirement for cosmetics with respect to registration, good manufacturing practices, mandatory recalls, or adverse event reporting.

"(b) Safety of Cosmetic Ingredients and Non-Functional Constituents.—

"(1) In general.—Except for a State requirement that is more restrictive than a final order issued under section 608(d)(3) and that is in full effect and implemented on the date of enactment of the Personal Care Products Safety Act, no State or political subdivision of a State may establish or continue in effect any requirement with respect to the safety of a cosmetic ingredient or non-functional constituent that is the subject of a final order under
section 608(d)(3) that is different from, or in addi-
tion to, a final order issued under section 608(d)(3).

“(2) Delayed effect of new state re-
quirements.—From the date that the Food and
Drug Administration has made public the final selec-
tion of a cosmetic ingredient or non-functional con-
stituent to be reviewed in the coming year under sec-
tion 608(a)(3)(B), and opened the public comment
period under section 608(a)(2), until the date that
is one year after the Food and Drug Administration
has made public such selection, no State or political
subdivision of a State may establish any new re-
quirement related to such cosmetic ingredient or
non-functional constituent.

“(3) Scope.—This subsection shall not be con-
strued to modify or affect the authority of a State
or political subdivision of a State with respect to
such safety requirements unrelated to the scope of
the safety assessment under section 608.

“(4) Sense of Congress.—It is the sense of
Congress that a State or political subdivision that
regulates the safety of cosmetics with respect to the
health of humans beyond the scope of section 608
should utilize the safety assessment criteria de-
scribed in section 608(h).
“(c) State Requirement That Is in Full Effect and Implemented.—For purposes of this section:

“(1) State Requirement.—A State requirement includes a State requirement that is adopted by a State public initiative or referendum.

“(2) Full Effect and Implemented.—The term ‘full effect and implemented’ includes requirements of States that are implemented after the date of enactment of the Personal Care Products Safety Act, if such requirements are under a law that was in effect, or a lawful program that was established and functioning, prior to the date of enactment of the Personal Care Products Safety Act.

“(d) Rule of Construction Regarding Product Liability.—Notwithstanding any other provision of this Act, no provision of this chapter relating to a cosmetic shall be construed to modify or otherwise affect any action or the liability of any person under State or Federal common law.

“(e) Limitation.—The Personal Care Products Safety Act, including the amendments made by such Act, shall not be construed to preempt any State statute, public initiative, referendum, or common law, except as expressly provided in this section.”.
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 2016, 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 Personal Care Products Safety Act during such fiscal year and the future plans of the Food and Drug Administration for meeting the objectives.

The annual report for a fiscal year shall include—

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

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

“(3) identification of at least 5 specific cosmetic ingredients and non-functional constituents that will
be reviewed by the Food and Drug Administration in the next fiscal year;

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

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

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

“(7) efforts of the Food and Drug Administration to reduce animal testing for safety of cosmetic ingredients, non-functional constituents, and cosmetic products.

“(b) Public Availability.—The Food and Drug Administration shall make the reports required under subsections (a) available to the public on the Internet website of the Food and Drug Administration on the date of submission of such reports to Congress.

“(c) Public Input on Safety Review.—Upon release of the report described in subsection (a), the Food and Drug Administration shall provide the public with an opportunity to provide feedback on subsection (a)(3) by—
“(1) providing an electronic portal, upon release of the report, enabling the public to—

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

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

“(2) announcing on the Internet website of the Food and Drug Administration, within the first 30 days of the new fiscal year, any amendments to subsection (a)(3) based on public input, pursuant to paragraph (1); and

“(3) together with the final announcement of 5 specific cosmetic ingredients and non-functional constituents that will be reviewed in the coming year under subsection (a)(3), providing a comment period for further public input, pursuant to section 608(a)(2).”.
SECA. 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.

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

SECA. 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 infor-
mation 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 Ad-
ministration has determined under section 608(d)(4) to be
not safe, or not safe under the conditions of use rec-
ommended or suggested in the label or a non-functional
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 require-
ment 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 ad-
dress or a domestic telephone number, and it is
encouraged that the label include both a domes-
tie 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 non-functional 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 of Health, Education, Labor, and Pensions of the Senate and the Chairman of the Committee of 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 2016, the Food and Drug Administration shall assess and collect an annual fee from every responsible
person (referred to in this section as a ‘registrant’) who owns or operates any cosmetic facility engaged in manufacturing or processing, or whose name and address appear on the label of a cosmetic product distributed in the United States, except that this subsection shall not apply to entities described in subparagraphs (A) through (H) of section 604(3).

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

“(b) DEFINITIONS.—In this section:

“(1) ADJUSTMENT FACTOR.—The term ‘adjustment factor’ applicable to a fiscal year means the Consumer Price Index for all urban consumers (all items; United States city average) for October of the preceding fiscal year divided by such index for October 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 registrants under section 605 with the requirements of this Act with respect to cosmetics, including—

“(i) administrative activities, such as information technology support, human resources, financial management, the administration and maintenance of the cosmetic registration system and the cosmetic ingredient statement system under sections 605 and 606, and fee assessment and collection under this section; and

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

“(B) includes activities related to implementation of section 608, regarding the review of cosmetic ingredients and non-functional constituents.
“(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 registrant, including the sales of all of its affiliates, as reported in the registration under section 605.

“(c) Fee Setting and Amounts.—

“(1) In general.—Subject to subsection (d), the Food and Drug Administration shall establish the fees to be collected under this section for each fiscal year after fiscal year 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 registrant 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 2016.—For fiscal year 2016, to generate a total estimated revenue amount of $20,600,000, the amount of the reg-
istration fee under subsection (a) shall be as follows:

“(i) TIER I-A.—For a registrant that has gross annual sales of $5,000,000,000 or more in 2015, $1,100,000.

“(ii) TIER I-B.—For a registrant that has gross annual sales of at least $4,000,000,000 per annum but less than $5,000,000,000 in 2015, $840,000.

“(iii) TIER II-A.—For a registrant that has gross annual sales of at least $3,000,000,000 per annum but less than $4,000,000,000 in 2015, $720,000.

“(iv) TIER II-B.—For a registrant that has gross annual sales of at least $2,000,000,000 per annum but less than $3,000,000,000 in 2015, $600,000.

“(v) TIER III-A.—For a registrant that has gross annual sales of at least $1,000,000,000 per annum but less than $2,000,000,000 in 2015, $500,000.

“(vi) TIER III-B.—For a registrant that has gross annual sales of at least $500,000,000 per annum but less than $1,000,000,000 in 2015, $395,000.
“(vii) TIER IV-A.—For a registrant that has gross annual sales of at least $200,000,000 per annum but less than $500,000,000 in 2015, $325,000.

“(viii) TIER IV-B.—For a registrant that has gross annual sales of at least $100,000,000 per annum but less than $200,000,000 in 2015, $275,000.

“(ix) TIER V-A.—For a registrant that has gross annual sales of at least $80,000,000 per annum but less than $100,000,000 in 2015, $185,000.

“(x) TIER V-B.—For a registrant that has gross annual sales of at least $60,000,000 per annum but less than $80,000,000 in 2015, $95,000.

“(xi) TIER VI-A.—For a registrant that has gross annual sales of at least $40,000,000 per annum but less than $60,000,000 in 2015, $15,000.

“(xii) TIER IV-B.—For a registrant that has gross annual sales of at least $20,000,000 per annum but less than $40,000,000 in 2015, $12,000.
“(xiii) TIER VII-A.—For a registrant 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 registrant 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.—Registrants 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.—Registrants 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 re-
ponsible, collectively, for 4.1 percent.

“(iii) Tier II-A.—Registrants 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 imme-
diately preceding the fiscal year in which the annual fee will be paid, shall be re-
sponsible, collectively, for 3.5 percent.

“(iv) Tier II-B.—Registrants 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 imme-
diately preceding the fiscal year in which the annual fee will be paid, shall be re-
sponsible, collectively, for 2.9 percent.

“(v) Tier III-A.—Registrants 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 imme-
diately preceding the fiscal year in which the annual fee will be paid, shall be re-
sponsible, collectively, for 7.3 percent.

“(vi) Tier III-B.—Registrants that have gross annual sales of at least
85

$500,000,000 per annum but less than $1,000,000,000 in the fiscal year imme-
diately preceding the fiscal year in which the annual fee will be paid, shall be re-
sponsible, collectively, for 13.4 percent.

“(vii) Tier IV-A.—Registrants that have gross annual sales of at least $200,000,000 per annum but less than $500,000,000 in the fiscal year imme-
diately preceding the fiscal year in which the annual fee will be paid, shall be re-
sponsible, collectively, for 15.8 percent.

“(viii) Tier IV-B.—Registrants that have gross annual sales of at least $100,000,000 per annum but less than $200,000,000 in the fiscal year imme-
diately preceding the fiscal year in which the annual fee will be paid, shall be re-
sponsible, collectively, for 13.3 percent.

“(ix) Tier V-A.—Registrants that have gross annual sales of at least $80,000,000 per annum but less than $100,000,000 in the fiscal year imme-
diately preceding the fiscal year in which
the annual fee will be paid, shall be re-
sponsible, collectively, for 9 percent.

“(x) Tier V-B.—Registrants 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.—Registrants 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 annual fee will be paid, shall be responsible, collectively, for 5.1 percent.

“(xii) Tier VI-B.—Registrants 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.—Registrants 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.—Registrants 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 registrant shall be responsible for more than $250 per fiscal year.

“(d) ADJUSTMENTS.—

“(1) INFLATION ADJUSTMENT.—

“(A) IN GENERAL.—For fiscal year 2017 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 2016 under this subsection.

“(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 subparagraph shall not be made.

“(3) Workload Adjustment.—

“(A) In General.—For fiscal year 2017 and each subsequent fiscal year, after fee reve-
nues 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 non-functional 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 is available. The Food and Drug Administration shall publish in the Federal Register the fee revenues and fees resulting from the adjustment and the supporting methodologies.

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

“(e) LIMITATIONS.—
“(1) IN GENERAL.—With respect to the amount
that, under the salaries and expenses account of the
Food and Drug Administration, is appropriated for
a fiscal year for the cosmetics program in the Center
for Food Safety and Applied Nutrition and related
field activities, fees may not be assessed under sub-
section (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
2015, multiplied by the adjustment factor applicable
to the fiscal year involved.

“(2) AUTHORITY.—If the Food and Drug Ad-
ministration 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 modifica-
tion 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 sub-
section (a) shall be collected and available for obliga-
tion only to the extent and in the amount provided
in advance in appropriations Acts. Such fees are au-
thorized to remain available until expended. Such
sums as may be necessary may be transferred from
the Food and Drug Administration salaries and ex-
penses appropriation account without fiscal year lim-
itation to such appropriation account for salaries
and expenses with such fiscal year limitation. The
sums transferred shall be available solely for cos-
metic safety activities.

“(2) COLLECTIONS AND APPROPRIATIONS
ACTS.—The fees authorized by this section—

“(A) IN GENERAL.—Subject to subpara-
graphs (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 oth-
otherwise made available for obligation for such
fiscal year.

“(B) USE OF FEES AND LIMITATION.—
The fees authorized by this section shall be col-
lected 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, 2015, for the salaries and expenses
account of the Food and Drug Administration,
fees authorized by this section for fiscal year
2016 may be collected and shall be credited to
such account to remain available until ex-
pended. Fees collected under this subparagraph
shall be considered discretionary for purposes of
the Balanced Budget and Emergency Deficit

“(D) Reimbursement of start-up
amounts.—Any amounts allocated to establish
programs under sections 605 and 606, prior to
collection of fees, may be reimbursed through
any appropriated fees collected under this sec-
tion, in such manner as the Food and Drug Ad-
ministration determines appropriate. Any
amounts reimbursed under this subparagraph
shall be available for the programs and activi-
ties for which funds allocated to establish the
programs were available, prior to such alloca-
tion, until the end of the fiscal year in which
the reimbursement occurs, notwithstanding any
otherwise applicable limits on amounts for such
program or activities for a fiscal year.
“(3) Authorization of Appropriations.—
For each of fiscal years 2016–2022, there are au-
thorized to be appropriated for fees under this sec-
tion $20,600,000, as adjusted by subsection (d).

“(4) Offset of overcollections; recovery
of collection shortfalls.—

“(A) Offset of overcollections.—If
the sum of the cumulative amount of fees col-
lected under this section for the fiscal years
2016 through 2020 exceeds the cumulative
amount appropriated pursuant to paragraph (3)
for fiscal years 2016–2021, the excess amount
shall be credited to the appropriation account of
the Food and Drug Administration as provided
in paragraph (1), and shall be subtracted from
the amount of fees that would otherwise be au-
thorized to be collected under this section pur-
suant to appropriation Acts for fiscal year
2022.

“(B) Recovery of collection short-
falls.—

“(i) 2018.—For fiscal year 2018, the
amount of fees otherwise authorized to be
collected under this section shall be in-
creased by the amount, if any, by which
the amount collected under this section
and appropriated for fiscal year 2016 falls
below the amount of fees authorized for
fiscal year 2016 under paragraph (3).

“(ii) 2019.—For fiscal year 2019, the
amount of fees otherwise authorized to be
collected under this section shall be in-
creased by the amount, if any, by which
the amount collected under this section
and appropriated for fiscal year 2017 falls
below the amount of fees authorized for
fiscal year 2017 under paragraph (3).

“(iii) 2020.—For fiscal year 2020,
the amount of fees otherwise authorized to
be collected under this section shall be in-
creased by the amount, if any, by which
the amount collected under this section
and appropriated for fiscal year 2018 falls
below the amount of fees authorized for
fiscal year 2018 under paragraph (3).

“(iv) 2021.—For fiscal year 2021, the
amount of fees otherwise authorized to be
collected under this section shall be in-
creased by the amount, if any, by which
the amount collected under this section
and appropriated for fiscal year 2019 falls below the amount of fees authorized for fiscal year 2019 under paragraph (3).

“(v) 2022.—For fiscal year 2022, the amount of fees otherwise authorized to be collected under this section shall be increased by the amount, if any, by which the amount collected under this section and appropriated for fiscal year 2020 falls below the amount of fees authorized for fiscal year 2020 under paragraph (3).

“(g) Effect of Failure to Pay Fees.—The Food and Drug Administration shall not consider a registration submitted to be complete until such fee under subparagraph (a) is paid. Until the fee is paid, the registration is incomplete and the registrant is deemed to have failed to register in accordance with section 605.

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

“(i) Collection of Unpaid Fees.—In any case where the Food and Drug Administration does not receive payment of a fee assessed under subsection (a), such fee shall be treated as a claim of the United States Govern-
ment subject to subchapter II of chapter 37 of title 31, United States Code.

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

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

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

Part 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 Personal Care Products Safety Act. 

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