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(Original Signature of Member)

116TH CONGRESS
1ST SESSION

H. R. _____

To amend the Federal Food, Drug, and Cosmetic Act to improve cosmetic safety, and for other purposes.

IN THE HOUSE OF REPRESENTATIVES

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

A BILL

To amend the Federal Food, Drug, and Cosmetic Act to improve cosmetic safety, and for other purposes.

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

SECTION 1. SHORT TITLE; TABLE OF CONTENTS.

(a) SHORT TITLE.—This Act may be cited as the ''Cosmetic Safety Enhancement Act of 2019''.

(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 statements.
Sec. 102. Review of ingredients and nonfunctional constituents; safety of finished products.
Sec. 103. Good manufacturing practices for cosmetics.
Sec. 104. Adverse event reports.
Sec. 105. Records inspection; mandatory recall authority.
Sec. 106. Labeling and internet sales.
Sec. 107. Consumer information.
Sec. 108. Small businesses.
Sec. 109. Animal testing restrictions.
Sec. 110. Counterfeit cosmetics.
Sec. 111. Foreign supplier verification.
Sec. 112. Applicability with respect to certain cosmetics.
Sec. 113. Saving clause.
Sec. 114. Enforcement.

TITLE II—FEES RELATED TO COSMETIC PRODUCTS

Sec. 201. Findings.
Sec. 202. Authority to assess and use cosmetic product fees.
Sec. 203. Direct hiring authority to support activities related to cosmetics.
Sec. 204. Sunset dates.

TITLE I—COSMETIC SAFETY

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

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) ANIMAL TEST.—The term 'animal test' means the internal or external application or exposure of a cosmetic product, cosmetic formulation, or cosmetic ingredient to the skin, eyes, or other body part of a live non-human vertebrate for the purpose of evaluating the safety of a cosmetic product, cosmetic formulation, or cosmetic ingredient.

''(2) CONTRACT MANUFACTURER.—The term 'contract manufacturer' means a manufacturer (including the owner, operator, or agent in charge (or any affiliate thereof)) of a cosmetic ingredient, cosmetic formulation, or cosmetic product that does not sell any such cosmetic ingredient, cosmetic formulation, or cosmetic product unless there is a specific contractual agreement in place with respect to that sale.

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

''(4) COSMETIC INGREDIENT.—The term 'cosmetic ingredient' means any single chemical entity or mixture used as a component in the manufacture of a finished cosmetic product or cosmetic formulation.

''(5) COSMETIC PRODUCT.—(A) The term 'cosmetic product' means a finished cosmetic comprised of a specified set of cosmetic ingredients, which may come in a range of possible amounts for each cosmetic ingredient and which may include a variety of fragrances and colors, and in some specific cosmetic applications, flavors.

''(B) Such term shall include tattoo ink whether or not labeled as a finished cosmetic.

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

''(A) beauty shops and salons that do not otherwise manufacture, process, or package cosmetic products or cosmetic formulations at that location, including beauty stores or counters that offer customized or personalized cosmetic products or cosmetic formulations tailored to individual consumers for sale solely in-person;

''(B) cosmetic product retailers, including individual sales representatives, direct sellers (as defined in section 3508 of the Internal Revenue Code of 1986), retail distribution facilities, retail franchises, retail warehouses, and pharmacies, that do not otherwise manufacture, process, or package cosmetic products or cosmetic formulations at that location;

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

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

''(E) hotels, airlines, and other entities that provide complimentary cosmetic products to guests;

''(F) public health agencies and other nonprofit entities that provide cosmetic products or cosmetic formulations directly to the consumer; or

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

''(7) FOREIGN FACILITY.—The term 'foreign facility' means a facility that manufactures, processes, packs, or holds, cosmetic products or cosmetic formulations that are exported to the United States without further processing or packaging inside the United States. A cosmetic product or cosmetic formulation 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 product or cosmetic formulation.

''(8) NONFUNCTIONAL CONSTITUENT.—The term 'nonfunctional constituent' means any substance that is an incidental component of an ingredient, a breakdown product of an ingredient, or a byproduct of the manufacturing process that has not been intentionally added as a separate substance and serves no technical function in the cosmetic product.

''(9) PROFESSIONAL.—With respect to a cosmetic product, the term 'professional' means—

''(A) a dermatologist or other health care professional that administers or provides cosmetic products to patients; or

''(B) a cosmetologist, nail technician, barber, or esthetician who administers or provides cosmetics within the scope of their business practices.

''(10) PROFESSIONAL USE.—With respect to a cosmetic product, the term 'professional use' means a preparation of a cosmetic formulation intended only for use by professionals in settings such as cosmetology, nail care, barbering, esthetics, health care,

and other professions as determined by the Secretary through regulation.

''(11) RESPONSIBLE PERSON.—The term 'responsible person' means the brand owner, operator, or agent in charge who is the domestic or foreign manufacturer, processor, or entity whose name appears on the label of a cosmetic product or a cosmetic formulation distributed in the United States.

''SEC. 605. REGISTRATION OF COSMETIC FACILITIES.

''(a) REGISTRATION FOR MANUFACTURING AND PROCESSING FACILITIES.—

''(1) IN GENERAL.—The owner, operator, or agent in charge of (or an affiliate thereof) a facility engaged in manufacturing, or processing, of a cosmetic product or a cosmetic formulation distributed in the United States shall register with the Secretary.

''(2) ELECTRONIC REGISTRATION SYSTEM.—The Secretary shall—

''(A) maintain an electronic registration system for purposes of this section; and

''(B) not later than one year after the date of enactment of the Cosmetic Safety Enhancement Act of 2019, announce that such system is operational.

''(3) INITIAL REGISTRATION OF EXISTING FACILITIES.—Not later than the date that is 6 months after the date of the announcement required by paragraph (2)(B), each facility engaged in an activity described in paragraph (1) shall be registered under such paragraph.

''(4) INITIAL REGISTRATION OF NEW FACILITIES.—In the case of a facility that first engages in an activity described in paragraph (1) on or after the date that is 18 months after the date of enactment of the Cosmetic Safety Enhancement Act of 2019, such a facility shall register with the Secretary immediately upon engaging in such activity.

''(5) SINGLE REGISTRATION.—The Secretary shall require only a single registration per registration period for a facility required to be registered under paragraph (1), regardless of whether such facility is manufacturing or processing—

''(A) its own cosmetic products or cosmetic formulations; or

''(B) cosmetic products or cosmetic formulations on behalf of more than one owner, operator, or agent in charge (or affiliate thereof).

''(b) REGISTRATION FOR PACKING OR HOLDING FACILITIES.—Each facility engaged in packing or holding a

cosmetic product or cosmetic formulation distributed in the United States shall register with the Food and Drug Administration. Each such facility shall, not later than 6 months after the Secretary announces the establishment of an electronic registration system for purposes of this section, submit a registration utilizing such system.

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

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

''(e) CHANGES TO INFORMATION.—A facility that submitted a registration under this section shall notify the Secretary of any change to the information required under subsection (a) or (b) not later than 30 days after the date of such change, unless otherwise specified by the Secretary.

''(f) FORMAT; CONTENTS.—

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

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

''(A) Each facility's name (including any parent company of the facility) 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 Secretary to the facility under subsection (i).

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

''(D) The product category(as identified under section 720.4(c) of title 21, Code of Federal Regulations (or any successor regulation), or other cosmetic categories as determined appropriate by the Secretary (including by guidance) of each cosmetic product or cosmetic formulation manufactured, processed, packed, or

held at the facility or on whose label the facility's name and address appear.

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

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

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

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

''(I) An assurance that the Secretary 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 Secretary may require by regulation.

''(3) ABBREVIATED REGISTRATION.—The Secretary shall provide for an abbreviated registration renewal process for any facility that has not had any changes to the information submitted by the facility for the preceding registration.

''(g) INCOMPLETE OR INACCURATE REGISTRATION.—

''(1) IN GENERAL.—Subject to paragraph (2), the Secretary may cancel a registration of a facility under this section if—

''(A) the Secretary has reasonable grounds to believe that the registration was not properly completed or updated in accordance with this section;

''(B) a required registration fee has not been paid within 30 days; or

''(C) the registration otherwise contains false, incomplete, or inaccurate information.

''(2) NOTIFICATION.—The Secretary shall, at least 10 days before canceling a registration pursuant to paragraph (1), provide notice to the facility of the intent of the Secretary to cancel such reg-

istration that contains the Secretary's basis for the determination to so cancel the registration.

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

''(h) UNIQUE IDENTIFIER.—At the time of the initial registration of any cosmetic facility under this section, the Secretary shall assign a unique identifier to the facility and provide such identifier to such facility in writing.

''(i) REGISTRY OF FACILITIES.—

''(1) IN GENERAL.—The Secretary 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 an owner, operator, or agent in charge of (or an affiliate thereof) a facility engaged in manufacturing,

processing, packing, or holding a cosmetic product or formulation, or a facility owned by such person, or that discloses specific facilities where specific brands of cosmetic products are manufactured or processed shall not be subject to disclosure under section 552 of title 5, United States Code.

"SEC. 606. COSMETIC INGREDIENT STATEMENTS.

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

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

''(1) EXISTING COSMETIC PRODUCTS.—In the case of a cosmetic product or cosmetic formulation that is marketed on the date of enactment of the Cosmetic Safety Enhancement Act of 2019, the responsible person shall—

''(A) not later than the date that is 6 months after the date of the announcement of an electronic registration system required by section 605, submit to the Secretary a cosmetic

ingredient statement in accordance with this section; and

"(B) beginning one year after the ingredient statement is submitted under subparagraph (A) and each year thereafter, submit to the Secretary a renewal of such statement, consistent with the requirements in subsection (e), during the first quarter of the fiscal year for which such renewed statement is applicable.

"(2) COSMETIC INGREDIENT STATEMENT FOR NEW COSMETIC PRODUCTS.—

"(A) IN GENERAL.—Except as provided under subparagraph (B), in the case of a cosmetic product or cosmetic formulation that is first marketed after the date of enactment of the Cosmetic Safety Enhancement Act of 2019 or a cosmetic product or cosmetic formulation that is reformulated after such date of enactment, the responsible person shall —

"(i) submit to the Secretary a cosmetic ingredient statement prior to first marketing the new cosmetic product, new cosmetic formulation, or the reformulated cosmetic product or reformulated cosmetic formulation; and

"(ii) beginning one year after the ingredient statement is submitted under clause (i), submit to the Secretary annually thereafter a renewal of such statement during the first quarter of the fiscal year for which the cosmetic ingredient statement is applicable, consistent with the requirements in subsection (e).

"(B) SMALL BUSINESSES.—In the case of a responsible person that is a small business, the Secretary shall allow such responsible person to have an additional time period, of a duration to be determined by the Secretary, in which to submit the first cosmetic ingredient statement under subparagraph (A). Such responsible person shall, consistent with the requirements in subsection (e), submit a cosmetic ingredient statement annually thereafter during the first quarter of the applicable fiscal year.

"(C) APPLICABILITY.—In applying subparagraph (A), a cosmetic product or cosmetic formulation shall not be considered to be first marketed or reformulated after the date of enactment of the Cosmetic Safety Enhancement

Act of 2019 if the only change in such product or formulation is—

''(i) a change in the amount of an existing ingredient that is 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 Secretary in regulations or guidance, previously reported as a potential ingredient under subsection (c)(2).

''(3) ABBREVIATED RENEWAL.—The Secretary shall provide for an abbreviated process for the renewal of any cosmetic ingredient statement under this subsection with respect to which there has been no change since the responsible person submitted the previous statement.

''(c) FORMAT; CONTENTS.—

''(1) FORM.—For each cosmetic ingredient statement submitted with respect to a cosmetic product or cosmetic formulation under this section, such statement shall be submitted using an electronic format, as specified in a form specified by the Secretary.

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

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

''(i) the facility or facilities where the cosmetic product or cosmetic formulation is manufactured, processed, packed, or held or, if the same cosmetic product or cosmetic formulation 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 or cosmetic formulation as it appears on the label.

''(C) The listing number, if any, previously assigned by the Secretary under subsection (f) to the cosmetic product or cosmetic formulation.

''(D) The applicable cosmetic category for the cosmetic product or cosmetic formulation.

''(E) A list of ingredients in the cosmetic product or cosmetic formulation that—

''(i) with respect to each such ingredient, the name adopted in regulations promulgated by the Secretary, if any, or by the common or usual name of the ingredient; and

''(ii) is consistent with the regulations promulgated by the Food and Drug Administration related to cosmetic labeling requirements; and

''(iii) contains a list of fragrances, flavors, and colors that may be included in the product, interchangeably, which shall include—

''(I) in the case of fragrances, each fragrance allergen contained in the cosmetic product as described in section 615, and for 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

''(iv) other appropriate interchangeable ingredients as the Secretary may specify in regulations or guidance that may be included in the product;

''(v) in the case of an ingredient (other than a fragrance, flavor, or color) that has been designated for review under section 608, includes potential ranges and amounts of such ingredient.

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

''(G) If applicable, information on labeling required under section 614.

''(H) Such additional information pertaining to the cosmetic product as the Secretary may require by regulation.

''(3) CONFIDENTIALITY.—Fragrance ingredients included in a cosmetic ingredient statement under paragraph (2)(E), other than fragrance allergens, shall be treated as confidential commercial or trade secret information.

''(4) CONTRACT MANUFACTURING ORGANIZATION FACILITIES.—If a facility manufactures or process cosmetic products or cosmetic formulations on behalf of an owner, operator, or agent in charge whose name appears on the label of such products or formulations, the Secretary shall require only a single cosmetic ingredient statement for such cosmetic product. Such single cosmetic ingredient statement shall be submitted to the Secretary by the responsible person.

''(5) COSMETIC INGREDIENT STATEMENT FOR CERTAIN SMALL BUSINESSES.—

''(A) IN GENERAL.—Notwithstanding any other provision of this subsection, in the case of a responsible person that has had an average of less than $1,000,000 in annual domestic cosmetic sales over the previous 3 years, the Secretary may allow such responsible person—

''(i) to submit a simplified cosmetic ingredient statement under this section; and

''(ii) an additional time period, of a duration to be determined by the Secretary, in which to submit such simplified cosmetic ingredient statement.

''(B) CONTENTS.—A responsible person described in subparagraph (A) shall include in each cosmetic ingredient statement submitted under this section, at a minimum—

''(i) a list of ingredients in the cosmetic product or cosmetic formulation, including any fragrance allergens as described in section 614(e);

''(ii) the applicable cosmetic category for the cosmetic product or cosmetic formulation; and

''(iii) in the case of a cosmetic product or cosmetic formulation that includes a fragrance or flavor purchased from a fragrance or flavor supplier, the contact information for the fragrance or flavor supplier, including the supplier's name, street ad-

dress, telephone number, and electronic contact information.

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

''(1) IN GENERAL.—Not earlier than 30 days after providing notice under paragraph (2) and subject to paragraph (3), the Secretary may nullify a cosmetic ingredient statement submitted under this section if the Secretary has reasonable grounds to believe that, except for minor or immaterial errors, 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.—If the Secretary nullifies a cosmetic ingredient statement under paragraph (1), the Secretary shall provide to the responsible person submitting such cosmetic ingredient statement under this section notice of any such nullification, including the basis for such nullification.

''(3) TIMELY UPDATE OR CORRECTION.—In the case of a cosmetic ingredient statement with respect to which the Secretary has provided notice under paragraph (2), the Secretary shall not nullify such

cosmetic ingredient statement if the cosmetic ingredient statement is appropriately updated or corrected not later than 10 days after the date on which such notice is provided.

''(4) EFFECT OF NULLIFICATION.—No person shall import, export, or otherwise distribute any cosmetic product or cosmetic formulation that is the subject of a cosmetic ingredient statement that is nullified under this subsection.

''(e) ADDITIONAL REQUIREMENTS.—

''(1) SAFETY REQUIREMENTS.—In submitting a cosmetic ingredient statement for each cosmetic product or cosmetic formulation under this section, a responsible person shall include an attestation that the safety of the product or formulation, including the individual ingredients of such product or formulation, has been substantiated in accordance with section 609.

''(2) CHANGES TO INFORMATION.—Not later than 90 days after any change to the information required to be in a cosmetic ingredient statement under this section, the responsible person shall notify the Secretary of such change, including the discontinuation of the manufacture of a cosmetic prod-

uct. Such notification is not required for a change described in subsection (b)(2)(C).

''(f) COSMETIC PRODUCTS LIST.—

''(1) LISTING NUMBER.—At the time of the initial submission of any cosmetic ingredient statement under this section, the Secretary shall—

''(A) assign a unique cosmetic product listing number to the cosmetic ingredient statement; and

''(B) provide such number to the responsible person who submitted such statement in writing.

''(2) COSMETIC PRODUCTS LIST.—Using cosmetic ingredient statements submitted under this section, the Secretary shall—

''(A) compile and maintain a list of cosmetic products or cosmetic formulations distributed in the United States, including the ingredients of each such product or formulation; and

''(B) upon request of any State, shall make such list available to such State .

''(3) CONFIDENTIALITY.—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 infor-

mation by the State. Such State and its employees in possession of such information shall be subject to the same laws governing information disclosure as employees of the Food and Drug Administration.

''(g) EXEMPTION.—A responsible person shall be exempt from the requirements of this section if such person has had an average of less than $500,000 in annual domestic cosmetic product sales over the previous three years. Such exemption shall not apply to cosmetic products that are intended to be injected under the skin or into the eye, including tattoo ink, or ingredients selected by the Food and Drug Administration for review under section 608 if such ingredient is included in a cosmetic product or cosmetic formulation distributed by such person described.

''SEC. 607. SUSPENSION OF REGISTRATION OR COSMETIC INGREDIENT STATEMENT.

''(a) SUSPENSION OF REGISTRATION OF A FACILITY.—If the Secretary determines that a cosmetic product or cosmetic formulation manufactured, processed, packed, or held by a facility registered under section 605 has a reasonable probability of causing serious adverse health consequences or death to humans, the Secretary may suspend the registration of such facility.

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

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

''(1) notice to the facility or responsible person, as appropriate, of the intent to suspend such registration or the cosmetic ingredient statement, which shall specify the basis of the determination by the Secretary for that suspension; and

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

''(d) REINSTATEMENT.—Upon a determination by the Secretary that adequate grounds do not exist to continue the suspension actions under subsection (a) or (b), the Secretary shall promptly vacate the suspension and re-

instate the registration of the facility or the cosmetic ingredient statement.

''(e) EFFECT OF SUSPENSION.—If the registration of a facility is suspended under this section, no person shall import or export cosmetics or otherwise distribute cosmetic products or cosmetic formulations from such facility.

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

SEC. 102. REVIEW OF INGREDIENTS AND NONFUNCTIONAL CONSTITUENTS; SAFETY OF FINISHED PRODUCTS.

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

''SEC. 608. REVIEW OF INGREDIENTS AND NONFUNCTIONAL CONSTITUENTS.

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

''(1) IN GENERAL.—Not later than 3 years after the date of the enactment of the Cosmetic Safety Enhancement Act of 2019, the Secretary

shall review the safety of cosmetic ingredients or nonfunctional constituents (or categories thereof). Upon the completion of such review, the Secretary shall issue an order under subsection (d) with respect to the use of each such ingredient (or a category thereof) and presence of each such nonfunctional constituent in cosmetic products or cosmetic formulations (or a category thereof).

''(2) INGREDIENTS AND NONFUNCTIONAL CONSTITUTENTS TO BE REVIEWED.—The Secretary shall select and complete a review, on an ongoing basis, of cosmetic ingredients or nonfunctional constituents that were not reviewed in the prior 3 years. Such ingredients or nonfunctional constituents, including any classes of ingredients or nonfunctional constituents, should be selected after consultation with stakeholders, including industry and consumer groups.

''(3) PROCESS FOR REVIEW.—The Secretary shall—

''(A) publish in the Federal Register a list of the ingredients, nonfunctional constituents (or categories thereof) identified for review under paragraph (2); and

''(B) open a public docket to solicit public input and data relevant to the safety of the ingredients, nonfunctional constituents (or classes or categories thereof) so listed for a period of not less than 60 days.

''(4) PUBLIC COMMENT.—Comments may be submitted to the Secretary at any time with respect to the safety of cosmetic ingredients or nonfunctional constituents (or categories thereof), regardless of whether such ingredients or constituents (or categories thereof) have been selected for review under this subsection.

''(b) REVIEWED INGREDIENTS AND NONFUNCTIONAL CONSTITUENTS.—The Secretary shall maintain a list, posted on the Internet website of the Food and Drug Administration, of each cosmetic ingredient, nonfunctional constituent, and category of ingredients or nonfunctional constituents for which final orders have been issued under subsection (d)(3), and with respect to each such ingredient or nonfunctional constituent—

''(1) the finding made for each such ingredient, nonfunctional constituent, or category under subsection (d)(4), as modified by any order under subsection (e); and

''(2) if applicable, compliance dates that are the subject of a final order under subsection (d)(3).

''(c) INITIATIVE OF THE FDA.—The Secretary may, at any time, propose the issuance of an order on the safety of a cosmetic ingredient or nonfunctional constituent (or category thereof) that was not previously listed pursuant to subsection (a).

''(d) DETERMINATION ON SAFETY.—

''(1) PROPOSED ADMINISTRATIVE ORDER.—Following consideration of data and comments to the public docket opened under subsection (a)(3) and any other information before the Secretary with respect to the safety of a cosmetic ingredient or nonfunctional constituent (or category thereof), the Secretary shall—

''(A) determine whether there is adequate evidence to make an initial finding for purposes of making a determination described in paragraph (4);

''(B) if the Secretary determines that there is adequate evidence to make such a finding, issue a proposed administrative order containing the Secretary's initial determination on the safety of such ingredient or nonfunctional constituent (or category thereof) as described in

paragraph (4) 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; and

''(C) in the case of a proposed administrative order in which the Secretary makes the determination described in subparagraph (C) of paragraph (4), include in such order a compliance date by which the sale of the ingredient, nonfunctional constituent (or category thereof) in cosmetic products or cosmetic formulations shall comply with the requirements specified in the final administrative order.

''(2) PUBLIC COMMENT.—The Secretary shall open a public docket for the submission of public comments (including comments on whether any proposed compliance date included in such order is feasible)—

''(A) in the case of a proposed administrative order under paragraph (1), for a period of not less than 60 days, beginning on the date of the issuance of the order; or

''(B) in the case of a final administrative order under paragraph (3), for a period of not less than 60 days, beginning on the date that

is at least 60 days before the effective date of the order.

''(3) FINAL ADMINISTRATIVE ORDER.—Following the public comment period under paragraph (2) and consideration of comments to the public docket under such paragraph and any other information before the Secretary, the Secretary shall—

''(A) determine whether there is adequate evidence to make an initial finding for purposes of making a determination described in paragraph (4);

''(B) if the Secretary determines that there is adequate evidence to make such a final finding, the Secretary 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; and

''(C) in the case of a final administrative order in which the Secretary makes the determination described in subparagraph (C) of paragraph (4), include in such order a compliance date by which the sale of the ingredient, nonfunctional constituent (or category thereof)

in cosmetic products or cosmetic formulations shall comply with the final administrative order.

''(4) DETERMINATIONS.—In a proposed administrative order issued under paragraph (1) or a final administrative order issued under paragraph (3), as applicable, the Secretary shall make a determination that the ingredient or nonfunctional constituent is—

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

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

''(C) not safe in cosmetic products.

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

''(A) limits on the amount or concentration of the ingredient or nonfunctional constituent (or category thereof) that may be present in a cosmetic product, including limits in products

intended for children, pregnant women, and other vulnerable populations, and limits on use near the eye or mucosal membranes;

''(B) warnings that are necessary or appropriate under section 614, including warnings related to use by children, pregnant women, populations with high exposure to the ingredient (such as workers who are exposed through production practices or handling of final products), or other vulnerable populations, to help ensure safe use of cosmetic products containing the ingredient or nonfunctional constituent (or a category thereof); and

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

''(6) CONTENTS OF ORDER.—A final administrative order under this subsection shall—

''(A) set forth the determination of the Secretary on safety;

''(B) include a summary of the valid scientific evidence supporting the determination;

''(C) include any conditions of use or tolerances under paragraph (4)(B); and

''(D) be effective upon its publication on the Internet website of the Food and Drug Administration and shall be considered final agency action unless a later compliance date is otherwise specified.

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

''(f) INADEQUATE EVIDENCE.—

''(1) NOTICE; EXTENSION.—If the Secretary determines that available data and information are not adequate to make a proposed or final determination under subsection (d), with respect to the safety of a cosmetic ingredient or nonfunctional constituent (or a category thereof), the Secretary shall—

''(A) publish such determination on the Internet website of the Food and Drug Administration not later than 180 days after the close of the relevant comment period for the ingredient or nonfunctional constituent (or category thereof) under paragraph (2) or (3) of subsection (d), as applicable; and

''(B) include in such publication a notice providing interested persons an additional 30

days from the date on which the notice is published to provide additional data and information and an opportunity for a meeting pursuant to paragraph (2).

''(2) MEETINGS.—The Secretary may offer a responsible person of such cosmetic ingredient or nonfunctional constituent (or category thereof) a confidential meeting with respect to a finding under paragraph (1), to discuss matters relating to the data and information requirements to support a determination of safety of such ingredient or nonfunctional constituent (or category thereof), which may involve confidential information. Such meeting should be convened in a reasonable time period agreed upon between the responsible person and the Secretary.

''(3) DETERMINATION; ORDER.—

''(A) INADEQUATE DATA AND INFORMATION.—If the Secretary determines that the available data and information are not adequate to make a proposed or final determination under subsection (d) with respect to the safety of a cosmetic ingredient or nonfunctional constituent (or category thereof), the Secretary shall—

''(i) publish such finding on the Internet website of the Food and Drug Administration not later than 180 days after the close of the relevant comment period for the ingredient or nonfunctional constituent (or category thereof) under paragraph (2) or (3) of subsection (d), as applicable; and

''(ii) include in such publication a notice providing interested persons an additional 30 days from the date on which the notice is published to provide additional data and information and an opportunity for a meeting pursuant to paragraph (2).

''(B) ADEQUATE DATA AND INFORMATION.—If the Secretary determines, after considering any additional data and information submitted pursuant to paragraph (1)(B), that the available data and information are adequate to make a determination with respect to the safety of a cosmetic ingredient or nonfunctional constituent (or category thereof), the Secretary shall—

''(i) in the case of a determination described in subparagraph (A) of subsection (d)(4), within 180 days of the close of the

applicable comment period under subsection (d)(2), issue a final administrative order, with respect to such cosmetic ingredient or nonfunctional constituent (or category thereof), in accordance with subsection (d)(3);

''(ii) in the case of a determination described in subparagraph (B) of subsection (d)(4), within 180 days of the close of the applicable comment period under subsection (d)(2), issue a proposed administrative order, followed by a final administrative order, with respect to such cosmetic ingredient or nonfunctional constituent (or category thereof), in accordance with subsection (d)(3); and

''(iii) in the case of a determination described in subparagraph (C) of subsection (d)(4), within 180 days of the close of the applicable comment period under subsection (d)(2), issue a final administrative order, with respect to such cosmetic ingredient or nonfunctional constituent (or category thereof), in accordance with (d)(3) specifying the date by which sale of

such ingredient or nonfunctional constituent must cease.

''(g) SAFETY ASSESSMENT STANDARDS.—

''(1) IN GENERAL.—In assessing the safety of an ingredient or nonfunctional constituent (or category thereof) under this section, the Secretary shall consider—

''(A) whether there is adequate evidence to support a reasonable certainty among competent scientists that—

''(i) in the case of a cosmetic ingredient, the ingredient is not harmful under the recommended or suggested conditions of use or customary or usual use; or

''(ii) in the case of a nonfunctional constituent, that the nonfunctional constituent is not harmful under the recommended or suggested tolerance levels or the level at which it is customarily or usually present;

''(B) the probable human exposure to the ingredient or nonfunctional constituent (or category thereof) from expected use in cosmetic products and cosmetic formulations;

''(C) the probable cumulative and aggregate effect in humans of relevant exposure to the ingredient or nonfunctional constituent (or category thereof) or to any chemically or pharmacologically related substances from use in cosmetics or other products with similar routes of exposure under recommended or suggested conditions of use or their customary use, to the extent adequate data is available for analysis, and if appropriate, available information on the total exposure to a cosmetic ingredient or nonfunctional constituent from all sources; and

''(D) whether warnings or recommendations in a cosmetic product label, as part of any conditions of use or tolerances imposed by the Secretary in a determination described in subparagraph (B) of subsection (d)(4), would be necessary and appropriate to help ensure the safety of the ingredient or nonfunctional constituent (or category thereof).

''(2) MINOR ADVERSE REACTIONS.—The Secretary may not consider a cosmetic ingredient or nonfunctional constituent (or category thereof) harmful under paragraph (1) solely because it can cause minor adverse health reactions, such as minor

transient allergic reactions or minor transient skin irritations, in some users.

''(3) DATA AND INFORMATION.—

''(A) REQUIRED INFORMATION.—A determination that a cosmetic ingredient or nonfunctional constituent (or category thereof) is safe in cosmetics under this section shall be based upon adequate evidence submitted or otherwise known to the Secretary, which shall include full reports of all available studies, published or unpublished, that are adequately designed to show whether the ingredient or nonfunctional constituent is safe. Such studies may include in vitro and in silico studies and epidemiological studies, biomonitoring studies, and studies focused on various points during the lifespan of the subject, that use scientifically valid methodology.

''(B) ADDITIONAL RELEVANT INFORMATION.—The Secretary shall consider any other relevant information related to the safety of a cosmetic ingredient or nonfunctional constituent (or category thereof), including—

''(i) adverse event reports;

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

''(iii) if the ingredient or nonfunctional constituent (or category thereof) is lawfully used or present in other products regulated by the Secretary, the scientific basis for such use; and

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

''(h) COAL TAR HAIR DYE.—In assessing for purposes of this section the safety of coal tar hair dye or any ingredient or nonfunctional constituent therein, the Secretary shall not make a determination that the dye, ingredient, or nonfunctional constituent is not safe for use in cosmetic products solely because the dye, ingredient, or nonfunctional constituent can cause allergic reactions.

"SEC. 609. SAFETY OF FINISHED COSMETIC PRODUCTS.

''(a) DETERMINATION.—

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

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

''(b) PRESUMPTION OF ADEQUATE EVIDENCE.—

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

''(A) with respect to each ingredient in the finished cosmetic 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 under such conditions of use as are customary or usual; or

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

''(B) appropriate safety substantiation of the finished cosmetic 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 applying paragraph (1)(A)(i), 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 Secretary; 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 Secretary issues an order under section 608 that an ingredient or nonfunctional constituent in the finished product is not safe under the product's conditions of use or customary or usual use; or

''(2) the Secretary has provided the manufacturer with notice that—

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

''(B) the Secretary 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 Secretary regarding the safety of an ingredient, nonfunctional constituent, or the entire cosmetic product, and the Secretary 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 Secretary to the responsible person, be provided to the Secretary within a reasonable timeframe not to exceed 30 days, in electronic form.

''(2) CRITERIA.—The Secretary may require records under paragraph (1) if—

''(A) the Secretary has a reasonable belief, described in written notice, that—

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

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

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

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

''(B) the Secretary, 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 Secretary concludes that submission of the records will serve the public health or otherwise enable the Secretary to fulfill the cosmetic safety purposes of this section.

''(g) GUIDANCE AND REGULATIONS.—

''(1) IN GENERAL.—The Secretary shall issue guidance describing the evidence necessary to support a determination under subsection (a), and may, by regulation, establish exemptions to the requirements of this section, if the Secretary determines that such exemptions are supported by adequate evidence and would have no adverse effect on public health.

''(2) SMALL BUSINESSES.—The Secretary shall, after consultation with the Small Business Administration and small businesses that manufacture cosmetics, provide additional guidance for small businesses on compliance with the requirements of this section. Such guidance shall include specific examples of options for compliance that do not place an undue burden on small businesses.''.

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

(c) PUBLIC MEETING AND GUIDANCE.—

(1) PUBLIC MEETING.—Not later than 12 months after the date of the enactment of this Act, the Secretary of Health and Human Services (in this subsection referred to as the ''Secretary'') shall convene a public meeting to describe and solicit public input regarding the ingredient review process under section 608 of the Federal Food, Drug, and Cosmetic Act (as added by subsection (a)). Such meeting shall include representatives from the cosmetics industry, medical practitioners and scientific experts with cosmetic expertise, and consumer and public health advocacy organizations.

(2) GUIDANCE.—Not less than one year after the public meeting conducted under paragraph (1), the Secretary shall issue one or more guidance documents to implement section 608 of the Federal Food, Drug, and Cosmetic Act (as added by subsection (a)). Such guidance documents shall include information regarding—

(A) the types of scientific evidence, clinical studies, data, or other information needed to support the review of cosmetic ingredients or nonfunctional constituents (or categories thereof) selected for review under such section;

(B) the recommended format in which to submit to the Secretary such data and information, including any applicable foreign data and information, related to a cosmetic ingredient or nonfunctional constituent (or category thereof) that has been selected for such review;

(C) the manner and the number of days by which the Secretary intends to review and respond to such data and information, including with respect to providing a scientific rationale for any additional data and information;

(D) the process for communication between the Secretary and industry related to an

ingredient or nonfunctional constituent (or a category thereof) that has been selected for review; and

(E) includes such other information as the Secretary determines appropriate.

(3) TIMING.—Not later than 24 months after the date of the enactment of this Act, the Secretary shall issue draft guidance under paragraph (1) on the implementation of section 608 of the Federal Food, Drug, and Cosmetic Act (as added by subsection (a)). The Secretary shall issue final guidance on the implementation of such section not later than 6 months after the date on which the comment period for the draft guidance closes.

(d) GAO STUDY.—Not later than 6 years after the date of the enactment of this Act, the Comptroller General of the United States shall submit to the Committee on Energy and Commerce of the House of Representatives and the Committee on Health, Education, Labor, and Pensions of the Senate a report addressing the effectiveness and overall impact of the ingredient review program established under section 608 of the Federal Food, Drug, and Cosmetic Act (as added by subsection (a)), including with respect to its impact on the safety of cosmetic ingredients—

(1) for each ingredient or nonfunctional constituent (or category thereof) selected for review—

(A) whether the ingredient or nonfunctional constituent (or category thereof) was determined—

(i) to be safe in cosmetic products without the need for specified conditions of use or tolerances;

(ii) to be safe in cosmetic products under specified conditions of use of tolerances; or

(iii) to be not safe in cosmetic products;

(B) the timeline for such review;

(C) the types of scientific evidence, clinical studies, data, or other information used to make such a determination;

(D) whether, and to what extent, the review of the ingredient or nonfunctional constituent (or category thereof) resulted in cosmetic products being reformulated or removed from the market; and

(E) the impact the review and determination had on consumer use and access to such product; and

(2) an analysis of the ingredient, nonfunctional constituent (or category thereof) review conducted under such section 608, including—

(A) the resources used by the Secretary in reviewing ingredients and nonfunctional constituents (or categories thereof), including the effects of the program on other cosmetic safety activities of the Secretary;

(B) the impact of such section on innovation and consumer access to cosmetic products; and

(C) whether any improvements to the program under such section 608 are necessary for increasing the efficiency and effectiveness of the review of cosmetic ingredients, nonfunctional constituents, or categories thereof.

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 Secretary shall—

''(1) review national and international standards for cosmetic good manufacturing practices that are in effect on the date of enactment of the Cosmetic Safety Enhancement Act of 2019; and

''(2) issue a rule establishing current good manufacturing standards consistent, to the extent the Secretary determines practicable and appropriate, with such national and international standards.

''(b) CONTENT OF REGULATIONS.—The regulations issued pursuant to subsection (a)(2)—

''(1) may specify requirements for the use of certain analytical or recordkeeping methods by a manufacturer as may be necessary to ensure that a cosmetic product or cosmetic formulation is not injurious to health under the recommended or suggested conditions of use, or customary or usual use of the product or formulation; and

''(2) shall not—

''(A) impose standards for which there is no current and generally available analytic method; or

''(B) apply to facilities meeting the criteria to be considered a facility under section 604(6), including retail stores or counters offering customized or personalized cosmetics to consumers,

or to entities that are in compliance with the good manufacturing practice regulations specified in parts 210 and 211 of title 21, Code of Federal Regulations (or any successor regulations).

''(c) TIMEFRAME.—The Secretary shall publish a proposed rule described in subsection (a) not later than 24 months after the date of enactment of the Cosmetic Safety Enhancement Act of 2019 and shall publish a final such rule not later than 36 months after such date of enactment.''.

(b) EFFECTIVE DATE FOR COSMETIC MANUFACTURERS.—Regulations issued pursuant to section 610 of the Federal Food, Drug, and Cosmetic Act (as added by subsection (a)) shall apply with respect to—

(1) large manufacturers (as defined in section 744L of such Act (as added by section 202 of this Act), beginning 180 days after the date on which the final rule described in subsection (a) is effective;

(2) mid-size manufacturers (as defined in section 744L of such Act (as added by section 202 of this Act), beginning 210 days after such date; and

(3) small manufacturers (as defined in section 744L of such Act (as added by section 202 of this Act), beginning 2 years after such date.

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

''(f) If the methods used in, or the facilities or controls used for, its manufacture, processing, packing, or holding do not conform to current good manufacturing practice, as prescribed by the Secretary.''.

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) SUBMISSION OF SERIOUS ADVERSE EVENT REPORTS.—

''(1) IN GENERAL.—With respect to any cosmetic product distributed in the United States, the responsible person shall submit, not later than 15 days after the receipt by the responsible person, using an electronic system developed under subsection (b), to the Secretary any report of a serious adverse event associated with the use of the cosmetic product, accompanied by a copy of the label on or with the retail packaging of the cosmetic product.

''(2) NEW MEDICAL INFORMATION.—During the 12-month period following the submission of a serious adverse event report under paragraph (1), with respect to any cosmetic product distributed in the United States, the responsible person shall submit, not later than 15 days after the receipt by the responsible person, using an electronic system developed under subsection (b), to the Secretary any new medical information related to such serious adverse event report that is received by the responsible person.

''(3) PUBLICATION.—The Secretary shall make publicly available on the Internet website of the Food and Drug Administration reports submitted under paragraph (1).

''(4) NO DUPLICATION.—In the case of cosmetic product that is also a drug for which a serious adverse event report 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 be required to submit a serious adverse event report under paragraph (1) with respect to that cosmetic product.

''(b) REQUIREMENTS FOR SERIOUS ADVERSE EVENT REPORTS.—

''(1) ELECTRONIC SYSTEM.—

''(A) IN GENERAL.—The Secretary shall, not later than 1 year after the date of enactment of the Cosmetic Safety Enhancement Act of 2019, develop and implement an electronic system for use for the submission of serious adverse event reports under this section.

''(B) MODIFICATION.—The format of the electronic system developed and implemented under paragraph (1) may be modified by the Secretary and the reports may include additional information. The Secretary may, in guidance, further specify the format and contents of required reports.

''(2) CONTENT OF REPORTS.—A serious adverse event report submitted under paragraph (1) of subsection (a) shall include all information submitted with the initial report and any information subsequently added to such report pursuant to paragraph (2) of such subsection and—

''(A) any report by the responsible person under section 756 with respect to the safety of

the cosmetic product that is the subject of the report;

''(B) information on the individual or individuals with respect to whom the adverse event report is submitted, in accordance with the disclosure requirements of section 552a of title 5, United States Code;

''(C) notwithstanding section 552(b)(6) of title 5, United States Code, medical (or similar) documentation of the serious adverse event that is the subject of the report, with all personally identifiable information redacted; and

''(D) contact information for the individual or individuals reporting the serious adverse event.

''(3) 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 reasonably available to such person to complete and file the report with the Secretary under subsection (a)(1).

''(4) NO ADVERSE EVENTS TO REPORT.—The Secretary 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.

''(5) EXEMPTION.—The Secretary may establish by regulation an exemption to any of the requirements under this section if the Secretary determines that such exemption is supported by adequate evidence and would have no adverse effect on public health.

''(c) REQUIREMENTS FOR OTHER ADVERSE EVENT REPORTS.—

''(1) IN GENERAL.—Each responsible person shall maintain records related to each report of an adverse event (including serious adverse events) associated with each cosmetic product marketed by such responsible person and received by such responsible person for a period of 6 years. Such records shall be made available to an officer or an employee duly designated by the Secretary upon request, at reasonable times and within reasonable limits and in a reasonable manner, including allowing electronic access and to copy such records.

''(2) CONTENT.—Records required to be maintained under this paragraph shall contain all information reasonably available, including—

''(A) a summary of all adverse events received during the calendar year for each cosmetic product marketed;

''(B) a complete list of individual reports of adverse events for each cosmetic product marketed and with respect to each such event, the same information required to be included in a report with respect to a serious adverse event under subsection (b)(2), subject to the same conditions with respect to the disclosure of such information;

''(C) an estimate of the total number of product units estimated to have been distributed to consumers during the period specified in paragraph (1); and

''(D) such other information as may be specified in regulation or guidance issued by the Secretary.

''(3) RULE OF CONSTRUCTION.—This section shall not be construed to require the inclusion in any report under this section any consumer complaint

that concerns solely efficacy and does not contain any information about an adverse event.

''(d) LIMITATION WITH RESPECT TO ADVERSE EVENT REPORTS.— Section 756 shall apply with respect to the submission of an adverse event report in compliance with subsection (a).

''(e) CONTACT INFORMATION.—The label of a cosmetic product shall bear the domestic address, and either the domestic telephone number or electronic contact information, through which the responsible person may receive a report of an adverse event.

''(f) AVAILABILITY TO STATES.—The Secretary shall make records submitted under this section available to any State, upon request, to the extent permissible under the laws governing disclosure of information by the Secretary. 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. Such State and its employees in possession of such information shall be subject to the same laws governing information disclosure as employees of the Food and Drug Administration.

''(g) PROTECTION OF INFORMATION.—A serious adverse event report submitted to the Secretary under subsection (a), including any new medical information sub-

mitted under paragraph (2) of such subsection, or an adverse event report voluntarily submitted to the Secretary, shall be considered to be a safety report under section 756 and may be accompanied by a statement, which shall be a part of any report that is released for public disclosure, that denies that the report or the records constitute an admission that the product involved caused or contributed to the adverse event.

''(h) EFFECTIVE DATES.—

''(1) SERIOUS ADVERSE EVENTS.—The requirement under this section to report serious adverse events shall become effective on the date that the Secretary publicizes the availability of the electronic system described in subsection (b)(1).

''(2) OTHER ADVERSE EVENTS.—The requirement under this section to maintain records relating to adverse events which are not serious adverse events shall become effective 18 months after the date of the enactment of the Cosmetic Safety Enhancement Act of 2019.

''(i) DEFINITIONS.—In this section:

''(1) ADVERSE EVENT.—The term 'adverse event' means, with respect to a cosmetic product, a health-related or medical event associated with the use of such product, including a risk of illness or in-

jury. Such term does not include any instance of a consumer complaint that such product did not work as advertised or marketed.

''(2) SERIOUS ADVERSE EVENT.—The term 'serious adverse event' means, with respect to a cosmetic product, an adverse event that—

''(A) results in—

''(i) death;

''(ii) a life-threatening experience;

''(iii) inpatient hospitalization;

''(iv) a persistent or significant adverse health condition, disability or incapacity;

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

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

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

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 facility, including a facility owned or operated by a responsible person for a cosmetic product shall, at the request of an officer or employee duly designated by the Secretary, 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, or receive electronically records maintained by or on behalf of such person in any format (including paper and electronic formats) and at any location, including—

"(1) all records maintained under section 611 and in accordance with the rules promulgated by the Secretary under section 610, as applicable;

"(2) all records maintained under section 609;

"(3) any records relating to the list of ingredients in specific fragrances or flavors of a cosmetic product or cosmetic formulation, if requested by the Secretary by means of a written notification; and

''(4) except as provided in subsection (b), all other records relating to the cosmetic product or cosmetic formulation and to any other cosmetic product or cosmetic formulation the Secretary reasonably believes is likely to be affected in a similar manner, if the Secretary—

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

''(i) is adulterated;

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

''(iii) contains an ingredient for which new scientific information shows may be unsafe when present in a cosmetic product or cosmetic formulation; and

''(B) provides written notice to the responsible person of the basis for the Secretary's reasonable belief described in subparagraph (A), as applicable.

''(b) EXCLUSIONS.—

''(1) IN GENERAL.—No inspection authorized by this section shall extend to—

''(A) recipes, financial data, pricing data, personnel data (other than data as to qualification of technical and professional personnel per-

forming functions subject to this Act), research data (other than safety data) or sales data other than shipment and distribution data; or

''(B) except as provided in paragraph (2), information related to ingredient in fragrances or flavors of a cosmetic product or cosmetic formulation.

''(2) EXCEPTION.—The Secretary may obtain information related to the ingredients in fragrances or flavors in an identified product only by a request in a written notification provided to the manufacturer pursuant to a for-cause inspection. In response to such written notification, the manufacturer of such fragrance or flavor shall provide information about the ingredients in the specified fragrance or flavor that the Secretary determines is necessary to assist its investigation, in the manufacturer's preferred electronic or written format, to the Secretary upon receipt of such notification. Any information provided in response to such written notification shall be considered a trade secret under section 301(j) and, notwithstanding such section, shall only be disclosed if the Secretary determines such disclosure is necessary to protect the public health. The authority to determine such disclosure is necessary

to protect the public health shall not be delegated to any officer or employee other than the director of the applicable office.

''(c) PROTECTION OF SENSITIVE INFORMATION.—The Secretary 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 Secretary pursuant to this section. Information disclosed to a State shall be pursuant to the laws governing disclosure of information. Confidential information disclosed to the State that is exempt from disclosure under section 552(b)(4) of title 5, United States Code, shall be treated as confidential information by the State. Such State and its employees in possession of such information under this section shall be subject to the same laws governing information disclosure as employees of the Food and Drug Administration.

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

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

''(2) to require the Secretary to publicly disclose any information that is exempt from disclosure

under section 522 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 Secretary determines that there is a reasonable probability that a cosmetic product is adulterated under section 601 or misbranded under section 602 and the use of, and exposure to, such cosmetic product is likely to cause serious adverse health consequences or death, the Secretary 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 domestic responsible person refuses to or does not voluntarily cease distribution or recall such cosmetic product within the time and in the manner prescribed by the Secretary, the Secretary may order such person to—

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

"(B) as applicable, immediately order all facilities—

"(i) manufacturing, processing, packing, transporting, holding, receiving, dis-

tributing, or importing and selling such cosmetic product; and

''(ii) to which such cosmetic product has been distributed, transported, or sold, to immediately cease distribution of such cosmetic product.

''(2) REQUIRED ADDITIONAL INFORMATION.—

''(A) IN GENERAL.—In the case of a cosmetic product that is subject to a recall order issued under paragraph (1)(B) with respect to which the responsible person, before the issuance of such order, distributed to a warehouse-based third party logistics provider without providing such logistics provider with sufficient information to know or reasonably determine the precise identity of such cosmetic product, the notice provided by the domestic responsible person pursuant to such order shall include such information as is necessary for the logistics provider to identify the cosmetic product.

''(B) RULES OF CONSTRUCTION.—Nothing in this paragraph shall be construed to exempt a warehouse-based, third-party logistics provider from—

''(i) the requirements of this chapter, including the requirements of this section and section 612; or

''(ii) being the subject of a mandatory recall order under this section.

''(3) DETERMINATION TO LIMIT AREAS AFFECTED.—If the Secretary requires a domestic responsible person to cease distribution under paragraph (1)(A) of a cosmetic product, the Secretary 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 Secretary 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 product that is the subject of the order should not be recalled.

''(d) POSTHEARING RECALL ORDER AND MODIFICATION OF ORDER.—

''(1) AMENDMENT OF ORDER.—If, after providing opportunity for an informal hearing under subsection (c), the Secretary determines that re-

moval of the cosmetic product from commerce is necessary, the Secretary shall, as appropriate—

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

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

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

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

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

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

''(f) PUBLIC NOTIFICATION.—In conducting a recall under this section, the Secretary shall—

''(1) ensure that a press release is published regarding the recall, and that alerts and public notices

are issued, as appropriate, in order to provide notification—

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

"(B) that includes, at a minimum—

"(i) the name of the cosmetic product subject to the recall;

"(ii) a description of the risk associated with the use of such cosmetic product; and

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

"(2) ensure publication on the Internet website of the Food and Drug Administration of an image of the cosmetic product 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 of Food and Drugs.

"(h) RULE OF CONSTRUCTION.—Nothing in this section shall affect the authority of the Secretary to request

or participate in a voluntary recall, or to issue an order to cease distribution or to recall any article under any other provision of this Act or under the Public Health Service Act.

''(i) DEFINITION.—In this section, the term 'domestic responsible person' means a person who is the domestic contact for a responsible person.''.

SEC. 106. LABELING AND INTERNET SALES.

(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 AND INTERNET SALES.

''(a) SAFETY REVIEW AND LABELING.—If a warning or condition of use is required pursuant to section 608(d)(4) to ensure the safe use of a cosmetic ingredient, the Secretary shall require appropriate labeling of any cosmetic product that contains such ingredient, including if such ingredient—

''(1) is not appropriate for use in the entire population; or

''(2) requires warnings that children, pregnant women, and other vulnerable populations should limit or avoid using the product.

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

''(1) LISTING OF INGREDIENTS.—The labeling of cosmetic products used and sold by professionals shall list all ingredients, as required for other cosmetic products pursuant to section 602(g).

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

''(c) DISPLAY.—A warning required under subsection (a) and any statement required under subsection (b)(2) shall be prominently displayed—

''(1) in the primary language used on the label or on packaging; 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.—

''(1) IN GENERAL.—In the case of Internet sales of cosmetic products, each primary seller offering a cosmetic product for sale to consumers on an

Internet website shall prominently and conspicuously display on such Internet website—

''(A) the same information that is included on the packaging of the cosmetic product as regularly available, such as any warnings, ingredient list, and contact information; and

''(B) the warnings and statements described in subsection (c).

''(2) DEFINITION.—For purposes of this subsection, the term 'primary seller' refers to the entity who offers a cosmetic product for sale on an Internet website, including the responsible person.

''SEC. 615. FRAGRANCE INGREDIENTS.

''(a) FRAGRANCE INGREDIENTS.—Not later than two years after the date of enactment of the Cosmetic Safety Enhancement Act of 2019, the responsible person shall include on the label of any cosmetic products containing one or more fragrance allergens, a list of each such fragrance allergen included in such cosmetic product that is consistent with national and international regulations for fragrance allergens labeling.

''(b) CONTACT INFORMATION.—

''(1) IN GENERAL.—The contact information on the label on a cosmetic product for consumers to report adverse events shall also provide a means for

consumers to obtain additional information about the inclusion of any recognized fragrance allergen required to be included on such label under subsection (e).

''(2) RESPONSE.—

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

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

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

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

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

''(g) If its labeling or packaging does not contain a listing of ingredients that meets the requirements of part 701 of title 21, Code of Federal Regulations (as in effect

on date of enactment of the Cosmetic Safety Enhancement Act of 2019) (or any successor regulations).''.

(c) EFFECTIVE DATE.—The amendments made by this section shall apply with respect to products introduced or delivered for introduction into interstate commerce on or after the date that is 2 years after the date of enactment of this Act.

SEC. 107. CONSUMER INFORMATION.

The Secretary of Health and Human Services, acting through the Commissioner of Food and Drugs, shall post on its Internet website information for consumers regarding—

(1) final orders regarding the safety of a cosmetic ingredient or nonfunctional constituent under section 608(d)(3);

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

(3) identified counterfeit cosmetic products.

SEC. 108. SMALL BUSINESSES.

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. 616. SMALL BUSINESSES.

''(a) IN GENERAL.—The Commissioner, in coordination with the Administrator of the Small Business Admin-

istration, shall provide technical assistance, such as guidance and expertise, to small businesses regarding compliance with the Cosmetic Safety Enhancement Act of 2019, including the amendments made by such Act.

''(b) COMPLIANCE GUIDE.—Not later than 180 days after the date of the enactment of Cosmetic Safety Enhancement Act of 2019, the Secretary shall issue a small business guide setting forth in plain language the requirements of sections 605 and 606 in order to assist small businesses in complying with such requirements.''.

SEC. 109. ANIMAL TESTING RESTRICTIONS.

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

''(f) If the cosmetic product, cosmetic formulation, or cosmetic ingredient was developed or manufactured using an animal test that was conducted or contracted by the manufacturer, or any affiliate or supplier of the manufacturer, unless one of the following applies:

''(1) With respect to a cosmetic ingredient of the cosmetic product or cosmetic formulation, an animal test is required by the Secretary to evaluate the safety of such ingredient or formulation.

''(2) With respect to a cosmetic ingredient of the cosmetic product or cosmetic formulation, the

cosmetic ingredient or cosmetic formulation is in wide use and cannot be replaced by another ingredient that is capable of performing a similar function without posing a potentially greater risk to human health and there is not an alternative method for testing the cosmetic ingredient that is accepted by the Secretary and the Interagency Coordinating Committee on Validation of Alternative Methods.

''(3) The animal test was conducted to comply with a requirement of another Federal agency or a State or foreign regulatory authority.

''(4) In the case of a cosmetic product, cosmetic formulation, or cosmetic ingredient that is also a drug, the animal test was conducted with respect to the approval under chapter V of the application submitted with respect to such product, formulation, or ingredient.

''(5) The animal test was conducted for purposes not related to developing or manufacturing the cosmetic product, cosmetic formulation, or cosmetic ingredient, and in response to a requirement of a Federal, State, or foreign regulatory authority.' ''.

(b) APPLICABILITY.—The amendment made by subsection (a) shall apply with respect to cosmetic products or cosmetic formulations introduced or delivered for intro-

duction into interstate commerce on or after the date that is two years after the date of enactment of this Act.

(c) GUIDANCE.—Not later than 1 year after the date of enactment of this Act, the Secretary shall issue guidance on the acceptability of scientifically reliable and relevant alternatives to animal testing for the safety of cosmetic products, cosmetic formulations, and cosmetic ingredients, and encouraging the use of such methods.

(d) RESOURCES REGARDING ANIMAL TESTING ALTERNATIVES.—Not later than 180 days after the date of enactment of this Act, the Secretary shall publish information on the Internet website of the Food and Drug Administration regarding resources available for information about non-animal methods, and methods that reduce animal usage, in testing for the safety of cosmetic products, cosmetic formulations, and cosmetic ingredients.

(e) RULES OF CONSTRUCTION.—

(1) USE OF EVIDENCE.—Nothing in this section, or the amendment made by this section, shall be construed to prohibit any entity from reviewing, assessing, or retaining evidence generated from animal testing.

(2) ACCEPTANCE OF DATA BY SECRETARY.—Nothing in this section, or the amendment made by this section, shall be construed to prohibit the Sec-

retary from accepting data from animal testing conducted—

(A) prior to the date specified in subsection (b); or

(B) on or after such date—

(i) in the case of a cosmetic product, cosmetic formulation, or cosmetic ingredient that is also a drug, with respect to the approval under chapter V of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 351 et seq.) of the application submitted with respect to such product, formulation, or ingredient; or

(ii) pursuant to requirements of a Federal, State, or foreign regulatory authority.

SEC. 110. COUNTERFEIT COSMETICS.

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

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

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

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

(4) by adding at the end the following:

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

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

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

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

(1) in subparagraph (2)—

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

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

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

(2) in subparagraph (3)—

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

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

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

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

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

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

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

(1) by striking ''(B) Any container'' and all that follows through ''(D) Any adulterated'' and inserting ''(B) Any cosmetic that is a counterfeit cos-

metic, (C) Any container of a counterfeit drug or counterfeit cosmetic, (D) Any punch, die, plate, stone, labeling, container, digital printer, or other thing used or designed for use in making a counterfeit drug or drugs or a counterfeit cosmetic or cosmetics, (E) Any adulterated''; and

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

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

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

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

(3) in paragraph (5)—

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

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

SEC. 111. FOREIGN SUPPLIER VERIFICATION.

(a) IN GENERAL.—Chapter VIII of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 381 et seq.) is amended by adding at the end the following:

"SEC. 810. COSMETICS FOREIGN SUPPLIER VERIFICATION PROGRAM.

''(a) IN GENERAL.—

''(1) VERIFICATION REQUIREMENT.—Except as provided under subsection (e), each importer shall perform risk-based foreign supplier verification activities for the purpose of verifying that the cosmetic product or cosmetic ingredient imported by the importer (or agent thereof)—

''(A) has been manufactured according to the cosmetic product good manufacturing practices established under section 610; and

''(B) is not adulterated under section 601 or misbranded under section 602.

''(2) IMPORTER DEFINED.—For purposes of this section, the term 'importer' means, with respect to a cosmetic product or cosmetic ingredient—

''(A) the United States owner or consignee of the cosmetic product or cosmetic ingredient at the time of entry of such cosmetic product or cosmetic ingredient into the United States; or

''(B) in the case when there is no United States owner or consignee as described in subparagraph (A), the United States agent or representative of a foreign owner or consignee of the cosmetic product or cosmetic ingredient at the time of entry of such article into the United States.

''(b) GUIDANCE.—Not later than 1 year after the date of enactment of the Cosmetic Safety Enhancement Act of 2019, the Secretary shall issue guidance to assist importers in developing foreign supplier verification programs.

''(c) REGULATIONS.—

''(1) IN GENERAL.—Not later than 1 year after the date of enactment of Cosmetic Safety Enhancement Act of 2019, the Secretary shall promulgate regulations to provide for the content of the foreign supplier verification program established under subsection (a).

''(2) REQUIREMENTS.—The regulations promulgated under paragraph (1)—

''(A) shall require that the foreign supplier verification program of each importer be adequate to provide assurances that each foreign supplier to the importer produces the imported

cosmetic product or cosmetic ingredient in compliance with—

''(i) with cosmetic good manufacturing practices established under section 610; and

''(ii) sections 601 and 602; and

''(B) shall include such other requirements as the Secretary deems necessary and appropriate to verify that cosmetic products and cosmetic ingredients imported into the United States are as safe as cosmetic products and cosmetic ingredients produced and sold within the United States.

''(3) CONSIDERATIONS.—In promulgating regulations under this subsection, the Secretary shall, as appropriate, take into account differences among importers and types of imported cosmetic products and cosmetic ingredients, including based on the level of risk posed by the imported cosmetic product or cosmetic ingredient.

''(4) ACTIVITIES.—Verification activities under a foreign supplier verification program under this section may include monitoring records for shipments, lot-by-lot certification of compliance, annual on-site inspections, compliance with cosmetic good

manufacturing practices and other safety processes, and periodically testing and sampling shipments.

''(d) RECORD MAINTENANCE AND ACCESS.—Records of an importer related to a foreign supplier verification program shall—

''(1) be maintained for a period of not less than 2 years; and

''(2) be made available promptly to a duly authorized representative of the Secretary upon request.

''(e) EXEMPTIONS.—The Secretary, by notice published in the Federal Register, shall establish an exemption from the requirements of this section for cosmetic products or cosmetic ingredients imported in small quantities for research and evaluation purposes or for personal consumption, provided that such cosmetic products or cosmetic ingredients are not intended for retail sale and are not sold or distributed to the public.

''(f) PUBLICATION OF LIST OF PARTICIPANTS.—The Secretary shall publish and maintain on the Internet website of the Food and Drug Administration a current list that includes the name of, location of, and other information deemed necessary by the Secretary about, importers participating under this section.''.

(b) PROHIBITED ACT.—Section 301 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 331), as amended by section 113, is further amended by adding at the end the following:

''(ggg) The importation or offering for importation of a cosmetic product or cosmetic ingredient if the importer (as defined in section 810) does not have in place a foreign supplier verification program in compliance with such section 810.''.

(c) IMPORTS.—Section 801(a) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 381(a)) is amended by striking ''or the importer (as defined in section 805) is in violation of such section 805'' and inserting '', or being imported or offered for import into the United States by an importer (as defined in section 805 or 810, as applicable) that is in violation of section 805 or 810, respectively''.

(d) EFFECTIVE DATE.—The amendments made by this section shall take effect 2 years after the date of enactment of this Act.

SEC. 112. APPLICABILITY WITH RESPECT TO CERTAIN COSMETICS.

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

''SEC. 617. 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. SAVING CLAUSE.

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

''SEC. 616. SAVINGS CLAUSE.

''Nothing in the amendments to this Act made by the Cosmetic Safety Enhancement Act of 2019, nor any standard, rule, requirement, regulation, adverse event report, safety assessment, safety determination, scientific assessment, or order issued or implemented pursuant to such amendments, shall be construed to modify or otherwise affect, preempt, or displace any cause of action or State or Federal law creating a remedy for civil relief or

criminal cause of action, whether statutory or based in common law.''.

SEC. 114. ENFORCEMENT.

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

(1) in paragraph (e)—

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

(B) by striking ''519, 564,'' and inserting ''519, 564, 609, 611,'';

(2) in paragraph (j) by inserting ''607, 608, 610, 611'' before ''704'';

(3) in paragraph (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 paragraph (xx), by inserting ''or 613'' after ''423''; and

(5) by adding at the end the following:

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

the information required by section 605 or 606, as required.''.

(b) ADULTERATION.—Section 601 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 361), as amended by section 603, is further amended by adding at the end the following:

''(g) If it contains, after the date prescribed under section 608(d)(3), an ingredient that the Secretary has determined under section 608(d)(4) to be not safe, or not safe under the conditions of use recommended or suggested in the label based on an order issued by the Secretary under section 608(d)(4).

''(h) If it is a cosmetic product for which any requirement of section 609 is not met.''.

(c) MISBRANDING.—Section 602 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 362), as amended by section 106, is further amended—

(1) in paragraph (b)—

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

(B) by inserting ''; and (3) a domestic address or a domestic telephone number, or electronic contact information, 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:

''(h) If it is a cosmetic product and it has been manufactured, processed, packed, or held in any factory, warehouse, or establishment and the responsible person delays, denies, or limits an inspection, or refuses to permit entry or inspection.

''(i) If a fragrance ingredient described in section 615 is not disclosed to consumers through a method identified by the Food and Drug Administration in the guidance document issued under such section.

''(j) 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 Secretary of Health and Human Services, acting through the Commissioner of Food and Drugs, shall issue guidance that defines the circumstances that would constitute delaying, denying, or limiting inspection, or refusing to permit entry or inspection, for purposes of section 602(g) of the Federal Food, Drug, and Cosmetic Act, as added by subsection (c)(2).

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

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

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

(f) FACILITY INSPECTION.—Section 704(a)(1) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 374(a)(1)) is amended by inserting after the third sentence the following: ''In the case of any person who manufactures, processes, 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), subject to the limitations under of such section.''.

TITLE II—FEES RELATED TO COSMETIC PRODUCTS

SEC. 201. FINDINGS.

The Congress finds that the fees authorized by the amendment made by section 202 of this Act will be dedicated to cosmetic safety activities, as defined in section 744L of the Federal Food, Drug, and Cosmetic Act, as added by such section 202. Such fees should supplement, not supplant, funding dedicated to cosmetic safety activities of the Food and Drug Administration. Future fees

to be collected by the Secretary of Health and Human Services should be dedicated to cosmetic safety activities as set forth in the goals identified for purposes of part 10 of subchapter C of chapter VII of the Federal Food, Drug, and Cosmetic Act, in the letters from the Secretary of Health and Human Services to the Chairman of the Committee on Health, Education, Labor, and Pensions of the Senate and the Chairman of the Committee on Energy and Commerce of the House of Representatives, as set forth in the Congressional Record.

SEC. 202. AUTHORITY TO ASSESS AND USE COSMETIC PRODUCT 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 COSMETIC PRODUCTS

"SEC. 744L. DEFINITIONS.

''For the purposes of this part:

''(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 2018.

''(2) CONTRACT MANUFACTURER.—The term 'contract manufacturer' means a cosmetic manufacturer where neither the owner, operator, or agent in charge of such entity nor any affiliate of such owner, operator, or agent in charge sells the cosmetic ingredient, cosmetic formulation, or cosmetic product unless there is a specific contractual agreement in place.

''(3) COSMETIC PRODUCT.—The term 'cosmetic product' means a finished 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 and colors, and in some specific cosmetic applications, flavors. Such term shall include tattoo ink whether or not labeled as a finished cosmetic.

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

''(A) means activities of the Secretary related to compliance by responsible parties required to register under section 605 with respect to cosmetics, including administrative activities, such as—

''(i) information technology acquisition, management, maintenance, and support;

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

''(iii) fee assessment and collection under this part; and

''(iv) the acquisition, leasing, maintenance, renovation and repair of facilities, fixtures, furniture, scientific equipment, and other necessary materials and supplies for purposes of clauses (i) through (iii);

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

''(C) includes activities of the Secretary related to implementation of section 606;

''(D) includes activities of the Secretary related to implementation and enforcement, such as the establishment of good manufacturing practices, the review of adverse event reports,

inspection planning and inspections, and use of enforcement tools; and

''(E) includes activities of the Secretary related to meetings with regulated industry regarding determinations under section 608.

''(5) GROSS ANNUAL SALES.—The term 'gross annual sales' means the average United States gross annual sales for the previous 3 fiscal years of cosmetic products for a responsible party as described in paragraph (2), including the sales of cosmetic products of all of its affiliates, as reported in the registration under section 605.

''(6) LARGE MANUFACTURER.—The term 'large manufacturer' means any entity that manufactures cosmetic products or cosmetic formulations for sale or distribution in the United States and has gross annual sales of over $500,000,000.

''(7) MID-SIZE MANUFACTURER .—The term 'mid-size manufacturer' means any entity that manufactures cosmetic products or cosmetic formulations for sale or distribution in the United States and has gross annual sales between $499,000,000 and $31,000,000.

''(8) SMALL MANUFACTURER.—The term 'small manufacturer' means any entity that manufactures

cosmetic products or cosmetic formulations for sale or distribution in the United States and has gross annual sales between $30,000,000 and $1,000,000.

''(9) RESPONSIBLE PARTY.—The term 'responsible party' means the owner, operator, agent in charge, or affiliate that owns the brand under which a cosmetic product is sold.

"SEC. 744M. REGISTRATION FEE.

''(a) ASSESSMENT AND COLLECTION.—

''(1) IN GENERAL.—Beginning in fiscal year 2020, the Secretary shall in accordance with this section assess and collect an annual fee from every responsible party that manufactures or distributes cosmetic products or cosmetic formulations in the United States.

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

''(A) for fiscal year 2020, with respect to responsible parties as described in paragraph (1) for such first program year, on the date that is 180 days after the identification in subsection (b); and

''(B) for fiscal year 2021 and each subsequent fiscal year, on the later of—

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

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

''(b) ONE-TIME IDENTIFICATION OF RESPONSIBLE PARTIES FOR PURPOSES OF APPORTIONING FEES.—

''(1) REQUIRED IDENTIFICATION OF RESPONSIBLE PARTIES.—Not later than 120 days after enactment of the Cosmetic Safety Enhancement Act of 2019, each responsible party that markets or sells a cosmetic product as defined in section 744L(4) shall submit to the Secretary the information required under this subsection.

''(2) INFORMATION REQUIRED TO BE SUBMITTED.—At a minimum, the submission required by paragraph (1) shall include for each such responsible party—

''(A) the gross annual sales of cosmetic products or formulations as defined in section 744L for the previous 3 fiscal years and as will be reported in the first registration under section 605, and an assessment of whether such

responsible party qualifies as a small, mid-size, or large manufacturer for the purposes of subsection (c)(3)(A);

''(B) identification of facilities where such responsible party's cosmetic products or cosmetic formulations are manufactured, which cosmetic products or cosmetic formulations are manufactured there, and any other products regulated under this Act that the facility manufactures;

''(C) the location of all such facilities identified in subparagraph (B); and

''(D) whether the facility is owned and operated by a contract manufacturer.

''(3) NOTICE.—The Secretary may, by notice published in the Federal Register, specify the means and format for submission of the information under paragraph (2) and may specify, as necessary for purposes of this section, any additional information relevant to setting the annual fee under this section to be submitted.

''(c) FEE SETTING AND AMOUNTS.—

''(1) IN GENERAL.—Subject to subsection (d), the Secretary shall establish the fees to be collected under this section for each fiscal year beginning in

fiscal year 2020, based on the methodology described in paragraph (3)(A), and shall publish such fees in each fiscal year after fiscal year 2020 in a Federal Register notice not later than 60 days before the beginning of each such fiscal year. For fiscal year 2020, the Food and Drug Administration shall publish the fees 150 days after enactment of the Cosmetic Safety Enhancement Act of 2019.

''(2) FEE EXEMPTION.—Any facility required to register under section 605 whose average gross annual sales of cosmetic products in the 3 fiscal years immediately preceding the fiscal year for which the annual fee will be paid was not more than $1,000,000, shall be exempt from registration fees under this section for that fiscal year.

''(3) ANNUAL FEE SETTING.—

''(A) FEE SETTING.—For fiscal years 2020 to 2027 as described in subparagraph (B), the amount of the registration fee under subsection (a) shall be as follows:

''(i) Seventy percent shall be derived from fees from large manufacturers.

''(ii) Twenty percent shall be derived from fees from mid-size manufacturers.

''(iii) Ten percent shall be derived from fees from small manufacturers.

''(B) TOTAL REVENUE.—The Food and Drug Administration shall apportion the fees in each fiscal year in accordance with subparagraph (A), in order to generate a total estimated revenue of—

''(i) $10,000,000 for fiscal year 2020;

''(ii) $20,000,000 for fiscal year 2021;

''(iii) $35,000,000 for fiscal year 2022; and

''(iv) $46,000,000 for each of fiscal years 2023 through 2027.

''(d) ADJUSTMENTS.—

''(1) INFLATION ADJUSTMENTS.—

''(A) ADJUSTMENT TO TOTAL REVENUE AMOUNTS.—For fiscal year 2020 and each subsequent fiscal year, the Secretary shall adjust the total revenue amount specified in subsection (c)(3) for such fiscal year by multiplying such amount by the applicable inflation adjustment under subparagraph (B) for such year.

''(B) APPLICABLE INFLATION ADJUSTMENT.—The applicable inflation adjustment for

fiscal year 2020 and each subsequent fiscal year is the product of—

"(i) the base inflation adjustment under subparagraph (C) for such fiscal year; and

"(ii) the product of the base inflation adjustment under subparagraph (C) for each of the fiscal years preceding such fiscal year, beginning with fiscal year 2020.

"(C) BASE INFLATION ADJUSTMENT.—

"(i) IN GENERAL.—Subject to further adjustment under clause (ii), the base inflation adjustment for a fiscal year is the sum of one plus—

"(I) 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 fiscal years of the preceding 4 fiscal years, multiplied by 0.60; and

"(II) the average annual percent change that occurred in the Consumer Price Index for urban consumers

(Washington-Arlington-Alexandria; Not Seasonally Adjusted; All items; Annual Index) for the first 3 fiscal years of the preceding 4 years of available data multiplied by 0.40.

''(ii) LIMITATIONS.—For purposes of subparagraph (B), if the base inflation adjustment for a fiscal year under clause (i)—

''(I) is less than 1, such adjustment shall be considered to be equal to 1; or

''(II) is greater than 1, such adjustment shall be considered to be equal to 1.

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

tablishing fees, in subsection (c)(1), for fiscal year 2027. If the Food and Drug Administration has carryover balances for such activities in excess of 3 months of such operating reserves, the adjustment under this paragraph shall not be made.

''(e) LIMITATIONS.—

''(1) IN GENERAL.—With respect to the amount that, under the salaries and expenses account of the Food and Drug Administration, is appropriated for a fiscal year for the cosmetics program in the Center for Food Safety and Applied Nutrition and related field activities, fees may not be assessed under subsection (a) for the fiscal year unless the amount so appropriated for the fiscal year (excluding the amount of fees appropriated for the fiscal year), is equal to or greater than that assessed for fiscal year 2019, multiplied by the adjustment factor applicable to the fiscal year involved. If the amount so appropriated prevents the Secretary from assessing fees under subsection (a), the Secretary is not required to carry out any activities described in section 608 during that fiscal year.

''(2) AUTHORITY.—If the Secretary 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 Secretary may assess such fees, the Secretary may assess and collect such fees, without any modification in the rate, for registration under section 605 at any time in such fiscal year.

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

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

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

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

erwise made available for obligation for such fiscal year.

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

''(C) FEE COLLECTIONS DURING FIRST PROGRAM YEAR.—Until the date of enactment of an Act making appropriations through September 30, 2020, for the salaries and expenses account of the Food and Drug Administration, fees authorized by this section for fiscal year 2020 may be collected and shall be credited to such account to remain available until expended. Fees collected under this subparagraph shall be considered discretionary for purposes of the Balanced Budget and Emergency Deficit Control Act of 1985.

''(D) STARTUP COSTS.—Until one year after the Secretary begins collecting user fees under subsection (a), any amounts available for the Center for Food Safety and Applied Nutrition and related field activities (excluding user fees) shall be available and allocated as needed to pay the costs of any cosmetic safety activities

not authorized before enactment of the Cosmetic Safety Enhancement Act of 2019.

''(E) REIMBURSEMENT OF STARTUP AMOUNTS.—

''(i) IN GENERAL.—Any amounts allocated for the startup period pursuant to subparagraph (D) shall be reimbursed through any appropriated fees collected under subsection (a), in such manner as the Secretary determines appropriate to ensure that such allocation results in no net change in the total amount of funds otherwise available, for a period not to exceed two years after the Secretary begins collecting user fees under subsection (a), for the Center for Food Safety and Applied Nutrition and related field activities (other than cosmetic safety activities funded through such allocation) for such period.

''(ii) TREATMENT OF REIMBURSED AMOUNTS.—Amounts reimbursed under clause (i) shall be available for the programs and activities for which funds allocated for the startup period were available, prior to such allocation, until 1 year after

the Secretary begins collecting user fees under subsection (a), notwithstanding any otherwise applicable limits on amounts for such programs or activities for a fiscal year.

''(3) AUTHORIZATION OF APPROPRIATIONS.—There are authorized to be appropriated for fees under this section the following:

''(A) $10,000,000 for fiscal year 2020;

''(B) $20,000,000 for fiscal year 2021;

''(C) $35,000,000 for fiscal year 2022; and

''(D) $46,000,000 for each of fiscal years 2023 through 2027.

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

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

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

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

''(k) RECORDS.—Each responsible party that is required to register under section 605 shall retain all records necessary to demonstrate gross annual sales for at least 2 fiscal years after such information is reported in its registration. Such records shall be made available to the Food and Drug Administration for review and duplication upon request of the Food and Drug Administration.

''(l) LIMITATION.—This part does not authorize the assessment or collection of a fee for registration under section 605 occurring after fiscal year 2027.''.

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 744M the following:

"SEC. 744N. DIRECT HIRING AUTHORITY TO SUPPORT ACTIVITIES RELATED TO COSMETICS.

''(a) IN GENERAL.—The Secretary 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 Cosmetic Safety Enhancement Act of 2019.

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

"SEC. 744O. REPORTING REQUIREMENTS; REAUTHORIZATION.

''(a) PERFORMANCE REPORT.—Beginning with fiscal year 2021, and not later than 120 calendar days after the end of each fiscal year thereafter for which fees are collected under this part, the Secretary shall prepare and submit to the Committee on Energy and Commerce of the House of Representatives and the Committee on Health, Education, Labor, and Pensions of the Senate a report concerning the progress of the Food and Drug Administration on cosmetic safety activities, including implemen-

tation and enforcement activities as described in the Cosmetic Safety Enhancement Act of 2019 during such fiscal year and the future plans of the Food and Drug Administration for such activities.

''(b) FISCAL REPORT.—Not later than 120 calendar days after the end of fiscal year 2021 and each subsequent fiscal year for which fees are collected under this part, the Secretary shall prepare and submit to the Committee on Energy and Commerce of the House of Representatives and the Committee on Health, Education, Labor, and Pensions of the Senate a report on the implementation of the authority for such fees during such fiscal year and the use, by the Food and Drug Administration, of the fees collected for such fiscal year.

''(c) PUBLIC AVAILABILITY.—The Secretary shall make the reports required under subsections (a) and (b) available to the public on the internet website of the Food and Drug Administration.

''(d) REAUTHORIZATION.—

''(1) CONSULTATION.—In developing recommendations to present to the Congress with respect to performance goals developed by the Food and Drug Administration, and plans for meeting the goals, for cosmetic safety activities for the first 5 fiscal years after fiscal year 2027, and for the reau-

thorization of this part for such fiscal years, the Secretary shall consult with—

''(A) the Committee on Energy and Commerce of the House of Representatives;

''(B) the Committee on Health, Education, Labor, and Pensions of the Senate;

''(C) scientific and academic experts;

''(D) health care professionals;

''(E) representatives of public health and consumer advocacy groups; and

''(F) the regulated industry.

''(2) PUBLIC REVIEW OF RECOMMENDATIONS.—After negotiations with the regulated industry, the Secretary shall—

''(A) present the recommendations developed under paragraph (1) to the congressional committees specified in such paragraph;

''(B) publish such recommendations in the Federal Register;

''(C) provide for a period of 30 calendar days for the public to provide written comments on such recommendations;

''(D) hold a meeting at which the public may present its views on such recommendations; and

''(E) after consideration of such public views and comments, revise such recommendations as necessary.

''(3) TRANSMITTAL OF RECOMMENDATIONS.—Not later than January 15, 2026, the Secretary shall transmit to the Congress the revised recommendations under paragraph (2), a summary of the views and comments received under such paragraph, and any changes made to the recommendations in response to such views and comments.''.

SEC. 204. SUNSET DATES.

(a) AUTHORIZATION.—Sections 744L and 744M of the Federal Food, Drug, and Cosmetic Act, as added by section 202, shall cease to be effective October 1, 2027.

(b) REPORTING REQUIREMENTS.—Section 744O of the Federal Food, Drug, and Cosmetic Act, as added by section 203, shall cease to be effective January 31, 2028.