AMENDMENT IN THE NATURE OF A SUBSTITUTE TO H.R. 5279 OFFERED BY MR. PALLONE OF NEW JERSEY

Strike all after the enacting clause and insert the following:

SECTION 1. SHORT TITLE; TABLE OF CONTENTS.

(a) SHORT TITLE.—This Act may be cited as the ''Cosmetic Safety Enhancement Act of 2020''.

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

TITLE I—COSMETIC SAFETY

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

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) CATEGORY OF INGREDIENTS OR NONFUNCTIONAL CONSTITUENTS.—The term 'category of ingredients or nonfunctional constituents' means a group of ingredients or nonfunctional constituents, the members of which are similar in molecular structure, in physical, chemical, or biological properties, in use, or in mode of entrance into the human body or the members of which are in some other way suitable for classification as such for purposes of this chapter.

''(3) 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.

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

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

''(6) 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.

''(7) 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, beauty stores, retail counters, and salons that do not otherwise manufacture, process, or package cosmetic products or cosmetic formulations at that location, including those 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.

''(8) 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 fur-

ther 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.

''(9) 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.

''(10) 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.

''(11) 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 cos-

metology, nail care, barbering, esthetics, health care, and other professions as determined by the Secretary through regulation.

''(12) 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.

''(13) SOAP.—The term 'soap' means articles—

''(A) in which—

''(i) the bulk of the nonvolatile matter in the product consists of an alkali salt of fatty acids; and

''(ii) the detergent properties of the article are due to the alkali-fatty acid compounds; and

''(B) that are labeled, marketed, sold, and represented only for use as soap.

''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 cos-

metic product or a cosmetic formulation distributed in the United States shall register with the Secretary.

''(2) ELECTRONIC REGISTRATION SYSTEM.—

''(A) REQUIRED MAINTENANCE.—The Secretary shall—

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

''(ii) not later than one year after the date of enactment of the Cosmetic Safety Enhancement Act of 2020, announce that such system is operational.

''(B) TRANSFER FROM VOLUNTARY REGISTRATION PROGRAM ALLOWED.—The Secretary may transfer registrations of facilities engaged in an activity described in paragraph (1) and registered under the Food and Drug Administration Voluntary Cosmetic Registration Program to the electronic registration system referred to in subparagraph (A).

''(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 activ-

ity 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 or resumes engaging 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 2020, such facility shall register with the Secretary immediately upon engaging or reengaging in such activity, as applicable.

''(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) ANNUAL REGISTRATION RENEWAL.—A facility that continues to engage in any activity that would require registration under subsection (a) shall submit to the Secretary an annual registration during the first quarter of

the fiscal year for which such renewed registration shall be effective.

''(c) FEES.—

''(1) IN GENERAL.—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.

''(2) USER FEE TIER IDENTIFICATION.—A responsible person required to register under this subsection shall identify annually the applicable cosmetic product user fee tier based on the average gross annual sales of cosmetic products in the United States of all facilities of the responsible person registered under subsection (a)(1) for the previous 3-fiscal-year period.

''(d) 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) not later than 30 days after the date of such change, unless otherwise specified by the Secretary.

''(e) FORMAT; CONTENTS.—

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

''(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 or processed 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 or processing).

''(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) The name, street address, telephone number, and electronic contact information for each facility that packs or holds cosmetic products or cosmetic formulations distributed by the owner, operator, or agent in charge of a facility required to register under this section.

''(J) An assurance that the Secretary will be permitted to inspect such facility at the times and in the manner permitted by this Act.

''(K) A written assurance that each cosmetic product or cosmetic formulation manufactured or processed in a facility required to register under this section has been substantiated for safety prior to marketing or carries the warning required under section 740.10 of title 21, Code of Federal Regulations (or any successor regulations). The responsible person shall maintain records documenting such substantiation and the data or information on which such substantiation is based until 5 years after the cosmetic product or cosmetic formulation is no longer marketed.

''(L) Additional information pertaining to the facility or to the cosmetic products or cosmetic formulations manufactured or processed at the facility, or on whose label the facility's name and address appear, including all brand names known to consumers, as the 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.

''(f) 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 fee under section 744M 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 written notice to the facility of the intent of the Secretary to cancel such registration 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 fee under section 744M, if any, is paid, the Secretary shall not cancel such registration.

''(g) 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.

''(h) 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 or processing 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 cos-

metic ingredient statement, at such time and in such manner as described under this section. A cosmetic ingredient statement shall not be considered to be complete under this section until the responsible person pays any applicable fee required under section 744M.

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

''(1) EXISTING COSMETIC PRODUCTS.—

''(A) IN GENERAL.—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 2020, the responsible person shall—

''(i) 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

''(ii) beginning one year after the ingredient statement is submitted under clause (i) 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.

''(B) TRANSFER TO ELECTRONIC REGISTRATION SYSTEM ALLOWED.—The Secretary may transfer to the electronic registration system required by section 605 a cosmetic ingredient statement with respect to a cosmetic product or cosmetic formulation—

''(i) described in subparagraph (A); and

''(ii) registered under the Food and Drug Administration Voluntary Cosmetic Registration Program.

''(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 2020 or a cosmetic product or cosmetic formulation that is reformulated (or reintroduced to the market) 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 (or reintroduced) cosmetic product or reformulated (or reintroduced) 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 as determined by the Secretary, 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 state-

ment annually thereafter during the first quarter of the applicable fiscal year.

''(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 cosmetic ingredient 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, 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(g), 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.

''(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 including—

''(i) the name adopted in regulations promulgated by the Secretary, if any, or by the common or usual name of the ingredient;

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

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

''(iv) 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 613.

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

''(3) FRAGRANCE ALLERGENS, FRAGRANCES, FLAVORS.—

''(A) IN GENERAL.—Any fragrance allergen, fragrance, or flavor included in a cosmetic product or cosmetic formulation shall be listed in a cosmetic ingredient statement submitted under this section.

''(B) FRAGRANCE ALLERGEN.—Any fragrance allergen identified under section 614

and included in a cosmetic product or cosmetic formulation shall be listed in a cosmetic ingredient statement.

''(C) FLAVORS.—With respect to a flavor required to be included in a cosmetic ingredient statement under subparagraph (A)—

''(i) in the case of a flavor purchased from a flavor supplier, the cosmetic ingredient statement shall include, with respect to that flavor, the name or code provided by the supplier; and

''(ii) in the case of any other flavor, the cosmetic ingredient statement shall include, with respect to that flavor, the name and contact information for the flavor manufacturer or supplier.

''(D) FRAGRANCES.—With respect to a fragrance required to be included in a cosmetic ingredient statement under subparagraph (A)—

''(i) in the case of a fragrance purchased from a fragrance supplier, the cosmetic ingredient statement shall include, with respect to that fragrance, the name or code provided by the supplier; and

''(ii) in the case of any other fragrance, the cosmetic ingredient statement shall include, with respect to that fragrance, the name and contact information for the fragrance manufacturer or supplier.

''(4) CONFIDENTIALITY.—Fragrance ingredients included in a cosmetic ingredient statement under paragraph (2)(E), other than fragrance allergens identified pursuant to section 614, shall be treated as trade secret or confidential commercial information.

''(5) CONTRACT MANUFACTURING ORGANIZATION FACILITIES.—If a facility manufactures or processes 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.

''(6) 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 average gross annual sales of cosmetic products in the United States for the previous 3-fiscal-year period, 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;

''(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 address, telephone number, and electronic contact information.

''(d) 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 605(e)(2)(K).

''(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 product.

''(e) 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 commercial information by the State. Such State and its employees in possession of such information shall be subject to the same laws governing information dis-

closure as employees of the Food and Drug Administration.

''(f) 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 average gross annual sales of cosmetic products in the United States for the previous 3-fiscal-year period. 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 or processed 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 for an informal hearing, within 4 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 and the actions required for reinstatement of the registration 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. If the cosmetic ingredient statement is suspended under this section, no person shall import, export, or otherwise distribute any cosmetic product or cosmetic formulation that is the subject of such cosmetic ingredient statement.

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

''(g) GUIDANCE.—Not later than 180 days after enactment of the Cosmetic Safety Enhancement Act of 2020, the Secretary shall issue guidance identifying the procedures and criteria for a determination by the Secretary that a cosmetic product or cosmetic formulation manufactured, processed, packed, or held has a reasonable probability of causing serious adverse health consequences or death to humans that would result in a suspension.''.

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 2020, the Secretary shall initiate reviews of the safety of no fewer than three cosmetic ingredients or nonfunctional constituents (or categories thereof). Upon the completion of each 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 CONSTITUENTS 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 categories of ingredients or nonfunctional constituents, should be selected after consultation with stakeholders, including industry and consumer groups.

''(3) INGREDIENTS NOT SUBJECT TO REVIEW.—Ingredients imparting pigment to cosmetic products that are already subject to review and approval by the Secretary pursuant to section 721(b) shall not be subject to review under this section.

''(4) PROCESS FOR REVIEW.—

''(A) IN GENERAL.—The Secretary shall—

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

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

''(B) SELECTION OF NEXT INGREDIENT OR NONFUNCTIONAL CONSTITUENT.—Upon issuance of a final administrative order under subsection (d)(3), the Secretary shall—

''(i) select a new cosmetic ingredient or nonfunctional constituent, which may include any category of ingredients or nonfunctional constituents under subparagraph (A)(i); and

''(ii) open a docket under subparagraph (A)(ii).

''(5) CONTRACT AUTHORITY.—The Secretary may contract with one or more qualified entities to classify, compile, analyze, or aggregate data and information that is publicly available, provided by the Secretary, or collected through the public docket pursuant to paragraph (4) for purposes of review.

''(6) 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) or modified by any order under subsection (e); and

''(2) 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)(4) and any other information before the Secretary with respect to the safety of a cosmetic ingredient or non-

functional constituent (or category thereof), the Secretary shall—

''(A) not later than 180 days following the close of the docket under subsection (a)(4), 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 publish such order in the Federal Register not later than 2 years after the close of the docket under subsection (a)(4), 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 a determination described in subparagraph (B) or (C) of paragraph (4), include in such order a compliance date.

''(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) for a period of not less than 60 days, beginning on the date of the issuance 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 a final determination described in paragraph (4);

''(B) if the Secretary determines that there is adequate evidence to make such a final finding, issue a final administrative order not later than 90 days following the close of the comment period under paragraph (2), publish such order in the Federal Register, and 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 (B) or (C)

of paragraph (4), include in such order a compliance date.

''(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 613, 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.

''(7) COMPLIANCE DATES.—A final order issued under this subsection shall include a compliance date by which use of the ingredient or nonfunctional constituent in cosmetic products may no longer be marketed. Such date shall be no later than 2 years after publication of the final order.

''(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) convene a meeting with manufacturers of the relevant cosmetic ingredient or nonfunctional constituent (or a category thereof) or

their representatives and provide such manufacturers the opportunity to provide additional data and information;

''(B) publish such determination in the Federal Register not later than 180 days after the close of the comment period for the ingredient or nonfunctional constituent (or category thereof) under subsection (a)(6) or under subsection (d)(1), as applicable; and

''(C) 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 confidential 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) INADEQUATE DATA AND INFORMATION.—If the Secretary determines, after providing an opportunity for a meeting pursuant to paragraphs (1) or (2) and considering any additional data and information pursuant to paragraph (1) that the available data and information are still 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—

''(A) publish such finding in the Federal Register not later than 180 days after the close of the comment period for the ingredient or nonfunctional constituent (or category thereof) under paragraph (1)(B); and

''(B) include in such publication—

''(i) a summary of the data and information needed to make a proposed or final determination;

''(ii) a proposed timeframe for the generation and submission of such data and information, which timeframe shall be

as soon as practicable and not exceed two years; and

''(iii) an opportunity for a confidential meeting pursuant to paragraph (2) regarding the development of such data and information.

''(4) DETERMINATION; ORDER.—

''(A) DETERMINATION.—Not later than 180 days after the close of the docket under paragraph (1)(B) or the receipt of data and information generated and submitted pursuant to paragraph (3)(B), the Secretary shall make a determination whether there is adequate data and information to make a proposed or final determination under subsection (d).

''(B) INADEQUATE DATA AND INFORMATION.—If the Secretary determines after considering any additional data and information generated and submitted pursuant to paragraph (3)(B), or if the needed data and information identified pursuant to paragraph (3)(B) is not generated and submitted to the Secretary, the Secretary shall—

''(i) within 90 days of the close of the additional time period provided under

paragraph (3)(B) issue a proposed administrative order making a determination that the ingredient or nonfunctional constituent has not been shown to be safe in cosmetic products;

''(ii) identify in such proposed order the reasons why the available data and information are not adequate to assess the safety of the ingredient or nonfunctional constituent;

''(iii) include in such proposed order a timeline identifying the date by which the cosmetic ingredient or nonfunctional constituent (or category thereof) may no longer be marketed;

''(iv) provide for a period of not less than 60 days for public comment on the proposed administrative order; and

''(v) issue a final administrative order not later than 60 days following the close of the public comment period under clause (iv).

''(C) ADEQUATE DATA AND INFORMATION.—If the Secretary determines, after considering any additional data and information

submitted pursuant to paragraph (1)(B) or generated and submitted pursuant to paragraph (3)(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 paragraph (1)(B) or the end of the timeframe identified under paragraph (3)(B), 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 paragraph (1)(B) or the end of the timeframe identified under paragraph (3)(B), issue a proposed administrative order, allow for a period of not less than 60 days

for public comment, and issue 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 paragraph (1)(B) or the end of the timeframe identified under paragraph (3)(B), issue a final administrative order, with respect to such cosmetic ingredient or nonfunctional constituent (or category thereof), in accordance with subsection (d)(3) specifying the date by which sale of such ingredient or nonfunctional constituent must cease.

''(D) INFORMAL HEARING.—Following issuance of a final administrative order under this section, the manufacturer or manufacturers of a cosmetic product or cosmetic formulation utilizing an ingredient or nonfunctional constituent (or category thereof) may request an informal hearing with the Chief Scientist of the

Food and Drug Administration. Such hearing shall be held within 60 calendar days of such request and provide an opportunity for such manufacturer or manufacturers to seek changes to the findings of the Food and Drug Administration included in such order. The Chief Scientist may not delegate such hearing to employees other than those in the Office of the Commissioner of the Food and Drug Administration and shall issue a revised order, if applicable, within 60 calendar days of such hearing. Such revised order shall be considered final agency action subject to judicial review.

''(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 (or category thereof), the ingredient (or category thereof) 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 (or category thereof), that the nonfunctional constituent (or category thereof) 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 cosmetic 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 cosmetic ingredient or nonfunctional constituent (or category thereof) or to any chemically or pharmacologically related substances from use in cosmetic products or cosmetic formulations or other products with similar routes of exposure under recommended or suggested conditions of use or their customary use, to the extent adequate data are available for analysis, and if appropriate, available information on the total exposure to a cosmetic ingredient or non-

functional constituent (or category thereof) 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 under subsection (d)(4) 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 con-

stituent (or category thereof) 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 cosmetic 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 cosmetic 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 cosmetic 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.

''(i) RULE OF CONSTRUCTION.—Nothing in this section shall be construed to affect the ability of a responsible person to introduce into commerce a cosmetic product that contains a cosmetic ingredient or nonfunctional constituent (or category thereof) while such ingredient or nonfunctional constituent (or category thereof) is under review, being considered for review for safety, or subject of a public docket seeking additional information.''.

(b) 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.

(c) 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. 609. 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 2020; and

''(2) issue a rule establishing requirements for current good manufacturing practices 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) shall require facilities subject to requirements of this chapter to have adequate procedures in place to ensure the integrity of cosmetic ingredients and other raw materials used in the manufacture of cosmetic products or cosmetic formulations;

''(2) 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

''(3) 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 excluded from the definition of a facility under section 604, including those 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.—

''(1) PROPOSED RULE.—Not later than 24 months after the date of enactment of the Cosmetic Safety Enhancement Act of 2020, the Secretary

shall publish a proposed rule described in subsection (a).

''(2) PUBLIC COMMENT PERIOD.—Before promulgating a final rule under paragraph (3), the Secretary shall provide for a public comment period on the proposed rule issued under paragraph (1) for a period of not less than 60 days.

''(3) FINAL RULES.—

''(A) PUBLICATION.—Not later than 36 months after the date of enactment of the Cosmetic Safety Enhancement Act of 2020, the Secretary shall publish a final rule described in subsection (a).

''(B) EFFECTIVE DATE.—Such final rule shall be published not less than 30 days before the effective date of the final rule.''.

(b) EFFECTIVE DATE FOR COSMETIC MANUFACTURERS.—Regulations issued pursuant to section 609 of the Federal Food, Drug, and Cosmetic Act (as added by subsection (a)) shall apply with respect to—

(1) large manufacturers (as determined by the Secretary) beginning 180 days after the date on which the final rule described in subsection (a) is effective;

(2) midsize manufacturers (as determined by the Secretary), beginning 210 days after such date; and

(3) small manufacturers (as determined by the Secretary), 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 it is a cosmetic product or cosmetic formulation and it has been manufactured, processed, packed, or held under conditions that do not meet current good manufacturing practice regulations issued by the Secretary.''.

SEC. 104. ADVERSE EVENTS.

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. 610. 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 sub-

section (b), to the Secretary any report of a serious adverse event associated with the use of such 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 2020, 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. 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 EVENTS.—

''(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 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 or record 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 reports and 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 commercial information by the State. Such State and its employees in possession of such information shall be subject to the same laws governing infor-

mation disclosure as employees of the Food and Drug Administration.

''(g) PROTECTION OF INFORMATION.—A serious adverse event report submitted to the Secretary under this section, including any new medical information submitted under subsection (a)(2), or an adverse event report voluntarily submitted to the Secretary—

''(1) 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; and

''(2)(A) shall be considered to be—

''(i) a record about an individual under section 552a of title 5, United States Code (commonly referred to as the 'Privacy Act of 1974'); and

''(ii) a medical or similar file the disclosure of which would constitute a violation of section 552 of such title 5 (commonly referred to as the 'Freedom of Information Act'); and

''(B) shall not be publicly disclosed unless all personally identifiable information is redacted.

''(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 2020.

''(i) DEFINITIONS.—In this section:

''(1) ADVERSE EVENT.—The term 'adverse event' means, with respect to a cosmetic product, a health-related event associated with the use of such product that is adverse, including a risk of illness or injury. Such term does not include any instance of a consumer complaint related to efficacy, such as the cosmetic 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. 611. INSPECTION OF COSMETIC RECORDS.

"(a) INSPECTION OF RECORDS.—For purposes of section 704, each 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 related to such cosmetic product, including—

''(1) all records required to be maintained under section 610 and in accordance with the rules promulgated by the Secretary under section 609, as applicable;

''(2) all records maintained under section 605(e)(2)(K);

''(3) any records relating to an ingredient or ingredients in specific fragrances or flavors of a cosmetic product or cosmetic formulation, if requested by the Secretary by means of a written notification issued pursuant to this subsection; 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 performing 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 ingredients in fragrances

or flavors of a cosmetic product or cosmetic formulation.

''(2) EXCEPTION.—The Secretary may obtain information related to an ingredient or ingredients in fragrances or flavors in an identified cosmetic product or cosmetic formulation 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 an ingredient or 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 Office of Cosmetics and Colors within

the Center for Food Safety and Applied Nutrition, or any successor 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 commercial 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 commercial 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 commercial 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.

''(e) SUBMISSION OF RECORDS.—

''(1) IN GENERAL.—Any records required to be maintained by a facility registered under section 605(a) shall, upon the written request by the Secretary to the owner, operator, or agent in charge (or an affiliate thereof) of such facility, provide such records to the Secretary within a reasonable timeframe not to exceed 60 days, in either electronic or paper 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 cosmetic product or cosmetic formulation may be harmful based on adverse event reports or other scientific information; or

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

''(B) the Secretary, an expert regulatory body, or an expert body composed of scientific

and medical experts finds an ingredient in the cosmetic product to be unsafe under the conditions of use of the product; or

''(C) the Secretary concludes that submission of the records are necessary for purposes of protecting the public health.

''(f) DEFINITIONS.—For purposes of this section, the term 'for-cause inspection' means an inspection that is carried out in response to specific information that—

''(1) raises questions, concerns, or problems associated with a facility regulated under this chapter, or a cosmetic product, cosmetic formulation, or cosmetic ingredient, regulated firm, or commodity; and

''(2) may include the results of a sample analysis, observations made during prior inspections, recall or market withdrawal, consumer or employee complaint, adverse event report, or suspicion of fraud.

''SEC. 612. 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 there is a reasonable probability that the use of, and exposure to, such cosmetic product is likely to cause serious adverse health con-

sequences or death, the Secretary shall provide the responsible person with an opportunity to voluntarily cease distribution and recall such article. The Secretary shall provide such responsible person with an opportunity in writing to voluntarily provide to the Secretary a list of any known distributors, packers, or holders in the United States that received such cosmetic product directly from such responsible person.

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

''(1) IN GENERAL.—If the responsible person refuses to or does not voluntarily cease distribution or recall such cosmetic 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, distributing, 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 611; or

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

''(3) DETERMINATION TO LIMIT AREAS AFFECTED.—If the Secretary requires a 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 person 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 removal 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, and shall ensure trade secret and confidential commercial information remain subject to the applicable laws governing disclosure of information, unless disclosure is necessary to protect public health.

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

''(1) ensure that a press release or other means for public notification is published regarding the recall 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 and the Secretary determines such publication is necessary.

''(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.''.

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. 613. LABELING AND INTERNET SALES.

''(a) SAFETY REVIEW AND LABELING.—If a warning or condition of use is required pursuant to section 608(d)(5) to ensure the safe use of a cosmetic ingredient, the Secretary shall require appropriate labeling of any cosmetic product that contains such ingredient. Such labeling shall also indicate whether 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. 107. FRAGRANCE ALLERGEN DISCLOSURE.

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

''SEC. 614. FRAGRANCE ALLERGENS.

''(a) FRAGRANCE ALLERGENS.—Not later than 2 years after the date of enactment of the Cosmetic Safety Enhancement Act of 2020, the responsible person shall include on the label of any cosmetic product containing one or more fragrance allergens, a list of each such fragrance allergen included in such cosmetic product in a form and manner as specified by the Secretary.

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

''(1) Alpha-Isomethyl ionone;

''(2) Amyl cinnamal;

''(3) Amylcinnamyl alcohol;

''(4) Anise alcohol;

''(5) Benzyl alcohol;

''(6) Benzyl benzoate;

''(7) Benzyl cinnamate;

''(8) Benzyl salicylate;

''(9) Butylphenyl methylpropional;

''(10) Cinnamal;

''(11) Cinnamyl alcohol;

''(12) Citral;

''(13) Citronellol;

''(14) Coumarin;

''(15) Eugenol;

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

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

''(18) Farnesol;

''(19) Geraniol;

''(20) Hexyl cinnamal;

''(21) Hydroxycitronellal;

''(22) Hydroxyisohexyl 3-cyclohexene carboxaldehyde;

''(23) Isoeugenol;

''(24) Limonene;

''(25) Linalool;

''(26) Methyl 2-octynoate; and

''(27) other substances as identified by the Secretary in guidance issued pursuant to this section.

''(c) GUIDANCE.—

''(1) ISSUANCE.—Not later than one year after the date of enactment of the Cosmetic Safety Enhancement Act of 2020, the Secretary shall issue one or more guidances specifying the form and manner of fragrance allergen listing on the label of cosmetic products.

''(2) CONTENTS.—Such guidance shall—

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

''(B) specify thresholds for rinse-off and leave-on cosmetic formulations; and

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

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

''(d) CONTACT INFORMATION.—

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

''(2) RESPONSE.—

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

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

''(ii) in the case of information in the possession of a supplier, promptly obtain

such information from such supplier, if reasonably available.

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

(b) INGREDIENT STATEMENT.—Section 602 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 362) 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 2020) (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. 108. 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. 109. 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. 615. SMALL BUSINESSES.

''(a) IN GENERAL.—The Secretary, in coordination with the Administrator of the Small Business Administration, shall provide technical assistance, such as guidance and expertise, to small businesses regarding compliance with the Cosmetic Safety Enhancement Act of 2020, 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 2020, the Secretary shall issue a small business guide setting forth in plain language the requirements of sections 605, 606, 609, and 810, as added by the Cosmetic Safety Enhancement Act of 2020, in order to assist small businesses in complying with such requirements.''.

SEC. 110. ANIMAL TESTING RESTRICTIONS.

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

''(g) If 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 introduction 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 Secretary 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. 111. 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, pack-

er, 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 or technology,'' 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 or technology'' after ''stone,'';

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

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

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

(1) by striking ''(B) Any container'' and all that follows through ''(D) Any adulterated'' and inserting ''(B) Any cosmetic that is a counterfeit cosmetic, (C) Any container of a counterfeit drug or counterfeit cosmetic, (D) Any punch, die, plate, stone, labeling, container, digital printer or technology, 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 or technologies,'' after ''labeling,''.

SEC. 112. COSMETIC 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. COSMETIC 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 609; and

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

''(2) APPLICABILITY.—The requirements of this subsection apply only to cosmetic products or cosmetic ingredients that do not undergo furthering manufacturing or processing according to cosmetic product good manufacturing processes established under section 609 following import into the United States.

''(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 into the United States.

''(b) GUIDANCE.—Not later than 1 year after the date of enactment of the Cosmetic Safety Enhancement Act of 2020, the Secretary shall issue guidance to assist importers in developing cosmetic foreign supplier verification programs, including to assist importers—

''(1) in identifying the cosmetic products and cosmetic ingredients subject to the requirements of subsection (a); and

''(2) in complying with the streamlined mechanisms for compliance.

''(c) REGULATIONS.—

''(1) IN GENERAL.—Not later than 1 year after the date of enactment of Cosmetic Safety Enhancement Act of 2020, 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) shall require that the for-

eign 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—

''(A) cosmetic good manufacturing practices established under section 609; and

''(B) sections 601 and 602.

''(3) CONSIDERATIONS; STREAMLINED MECHANISMS.—

''(A) IN GENERAL.—In promulgating regulations under this subsection, the Secretary shall, as appropriate—

''(i) 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;

''(ii) include streamlined mechanisms for compliance for manufacturers and processors whose name appears on the label of a cosmetic product pursuant to section 602 and that act as an importer of their own products.

''(B) STREAMLINED MECHANISMS.—The streamlined mechanisms of compliance referred to in subparagraph (A)(ii) shall apply to cosmetic products that are manufactured pursuant to the requirements of section 609 and—

''(i) whose importer has retained an export certificate from a country with a regulatory system that the Secretary has determined to be equivalent to that of the United States pursuant to the Federal Register notice described in subsection (e);

''(ii) whose importer has retained a record of inspection of the facility where the cosmetic products were manufactured by a foreign regulatory authority of a country with a regulatory system that the Secretary has determined to be equivalent to that of the United States in such a notice,

''(iii) whose importer retains records in compliance with section 609 and makes such records available upon request by the Secretary; or

''(iv) that satisfies such other criteria as the Secretary determines appropriate to document compliance with section 609.

''(4) ACTIVITIES.—Verification activities under a cosmetic foreign supplier verification program under this section may include review of third-party facility audits or regulatory inspection history, monitoring records for shipments, lot-by-lot certification of compliance, annual onsite inspections, review of records demonstrating 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 cosmetic 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—

''(1) 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; and

''(2) may exempt other cosmetic products or cosmetic ingredients from the requirements of this section if such products or ingredients are imported from a country determined by the Secretary to have a cosmetic regulatory system equivalent to that of the United States.

''(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. 113. APPLICABILITY WITH RESPECT TO CERTAIN COSMETICS.

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

''SEC. 616. APPLICABILITY WITH RESPECT TO CERTAIN PRODUCTS.

''(a) DRUGS.—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.

''(b) SOAP.—In the case of a product that meets the definition of a soap under section 604, the requirements of this chapter shall not apply with respect to that product so long as the product continues to meet that definition.''.

SEC. 114. SAVING CLAUSE.

Chapter VI of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 361 et seq.), as amended by section 113, is further amended by adding the following:

''SEC. 617. SAVINGS CLAUSE.

''Nothing in the amendments to this Act made by the Cosmetic Safety Enhancement Act of 2020, 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. 115. 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, 610, 611''; and

(B) by striking ''519, 564,'' and inserting ''519, 564, 609, 610,'';

(2) in paragraph (j) by inserting ''607, 608, 609, 610'' 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 ''610, 760, or 761) submitted'';

(4) in paragraph (xx), by inserting ''or 612'' 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 110, is further amended by adding at the end the following:

''(h) 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).

''(i) If it is a cosmetic product or cosmetic formulation for which assurances regarding safety substantiation have not been submitted under section 605(e)(2)(K).''.

(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 or cosmetic formulation for which assurances regarding safety substantiation have not been submitted under section 605(e)(2)(K) .

''(i) If a fragrance ingredient described in section 614 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 613.''.

(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 610, 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 611 (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 authorized by the reauthorization of part 10 of subchapter C of chapter VII of the Federal Food, Drug, and Cosmetic Act 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 such

part 10, in the letters from the Secretary of Health and Human Services to the Chairman of the Committee on Energy and Commerce of the House of Representatives and the Chairman of the Committee on Health, Education, Labor, and Pensions of the Senate, 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) COSMETIC FORMULATION.—The term 'cosmetic formulation' has the meaning given to such term in section 604.

''(3) 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.

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

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

''(A) means activities of the Secretary related to compliance by responsible persons 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 under section 605 and the cos-

metic 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 and related meetings with regulated industry regarding determination made under such section;

''(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 other issues related to implementation of the Cosmetic Safety Enhancement Act of 2020.

''(6) 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 manufacturer, including the sales of cosmetic products of all of its affiliates, as reported in the registration under section 605.

''(7) MANUFACTURER.—The term 'manufacturer' means the manufacturer, packer, or distributor whose name appears on the label of a cosmetic product marketed in the United States pursuant to section 602. If more than one name of a manufacturer, packer, or distributor appears on the label of such cosmetic product, the 'manufacturer' shall be the brand owner. All affiliates shall be considered one manufacturer for the purpose of this term. Subject to the exemption in the subsequent sentence, each cosmetic product marketed in the United States shall have a 'manufacturer' for the purposes of this section. Such term does not include—

''(A) beauty shops, beauty stores, retail counters, and salons that do not otherwise manufacture or process cosmetic products or cos-

metic formulations at that location, including those 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 or process 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; and

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

''(8) TIER 6 MANUFACTURER.—The term 'Tier 6 manufacturer'means any entity that manufactures cosmetic products for sale or distribution in the United States and has gross annual sales of over $4,000,000,000.

''(9) TIER 5 MANUFACTURER.—The term 'Tier 5 manufacturer' means any entity that manufactures cosmetic products for sale or distribution in the United States and has gross annual sales that are not more than $4,000,000,000 and over $1,000,000,000.

''(10) TIER 4 MANUFACTURER.—The term 'Tier 4 manufacturer' means any entity that manufactures cosmetic products for sale or distribution in the United States and has gross annual sales that are not more than $1,000,000,000 and over $500,000,000.

''(11) TIER 3 MANUFACTURER.—The term 'Tier 3 manufacturer' means any entity that manufactures cosmetic products for sale or distribution in

the United States and has gross annual sales that are not more than $500,000,000 and over $100,000,000.

''(12) TIER 2 MANUFACTURER.—The term 'Tier 2 manufacturer' means any entity that manufactures cosmetic products for sale or distribution in the United States and has gross annual sales that are not more than $100,000,000 and over $30,000,000.

''(13) TIER 1 MANUFACTURER.—The term 'Tier 1 manufacturer' means any entity that manufactures cosmetic products for sale or distribution in the United States and has gross annual sales that are not more than $30,000,000 and over $1,000,000.

''SEC. 744M. COSMETIC PRODUCT FEE.

''(a) ASSESSMENT AND COLLECTION.—

''(1) IN GENERAL.—Beginning in fiscal year 2020 and ending in fiscal year 2027, the Secretary shall in accordance with this section assess and collect an annual fee from every manufacturer that markets cosmetic products in the United States during the relevant fiscal year.

''(2) PAYABLE DATE.—An annual fee under this section shall be paid only once for each manu-

facturer, including all affiliates of such manufacturer, for a fiscal year in which the fee is payable. Fees under this section shall be due and payable—

"(A) for fiscal year 2020, with respect to manufacturers as described in paragraph (1) for such first program year, on the date during such fiscal year as set forth by the Secretary in the Federal Register; and

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

"(i) the first business day on or after October 1 of such fiscal year; or

"(ii) the first business day after the enactment of an appropriations Act providing for the collection and obligation of fees for such fiscal year under this section.

"(b) ONE-TIME IDENTIFICATION OF MANUFACTURERS FOR PURPOSES OF APPORTIONING FEES.—

"(1) REQUIRED IDENTIFICATION OF MANUFACTURERS.—Not later than the date that is 120 days after enactment of the Cosmetic Safety Enhancement Act of 2020, each manufacturer that markets a cosmetic product in the United States on such date shall submit to the Secretary the information required under this notification.

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

''(A) the gross annual sales of such manufacturer. of cosmetic products or cosmetic formulations for the previous 3 fiscal years as will be reported in the first registration under section 605 for such responsible person, and an assessment of which tier as defined in subsection (a) such manufacturer qualifies for the purposes of subsection (c)(3)(A);

''(B) identification of facilities where such responsible person'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.

''(2) NOTICE.—The Secretary may, by notice published in the Federal Register, specify the means

and format for submission of the information under paragraph (1) 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 of fiscal years 2020 to 2027, based on the methodology described in paragraph (3), 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 Secretary shall publish the fees 150 days after the date of enactment of the Cosmetic Safety Enhancement Act of 2020.

''(2) FEE EXEMPTION.—Any manufacturer 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 fees under this section for that fiscal year.

''(3) ANNUAL FEE SETTING.—

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

''(i) Thirty-five percent shall be derived from fees from Tier 6 and Tier 5 manufacturers.

''(ii) Fifty percent shall be derived from fees from Tier 3 and 4 manufacturers.

''(iii) Fifteen percent shall be derived from fees from Tier 1 and 2 manufacturers.

''(B) TOTAL REVENUE.—The Secretary shall establish the fee amounts for 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 years 2022 to 2023; and

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

''(d) ADJUSTMENTS.—

''(1) INFLATION ADJUSTMENTS.—

''(A) ADJUSTMENT TO TOTAL REVENUE AMOUNTS.—For fiscal year 2022 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 2022 and each subsequent fiscal year through fiscal year 2027 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 fiscal years of the preceding 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 1.04, such adjustment shall be considered to be equal to 1.04.

''(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 establishing fees 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 is appropriated for a fiscal year for the cosmetics program of the Center for Food Safety and Applied Nutrition of the Food and Drug Administration and related field activities, fees may not be assessed under subsection (a) for the fiscal year unless

the amount so appropriated (excluding the amount of fees appropriated for the fiscal year), is equal to or greater than the amount that is appropriated for such program 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 until such time the Secretary again assesses fees in a fiscal year under subsection (a).

''(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, at any time in such fiscal year by providing notice of no less than 60 days in the Federal Register.

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

''(1) IN GENERAL.—Fees authorized under subsection (a) shall be collected and available for obligation only to the extent and in the amount provided in advance in appropriations Acts. Such fees are authorized to remain available until expended. Such

sums as may be necessary may be transferred from the Food and Drug Administration salaries and expenses appropriation account without fiscal year limitation to such appropriation account for salaries and expenses with such fiscal year limitation. The sums transferred shall be available solely for cosmetic safety activities.

''(2) COLLECTIONS AND APPROPRIATIONS ACTS.—

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

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

''(C) FEE COLLECTIONS DURING FIRST PROGRAM YEAR.—Until the date of enactment of appropriations through September 30, 2020, for the 'Food and Drug Administration—Salaries and Expenses' account, fees authorized by

this section for fiscal year 2020 may be collected, and any fees so collected shall be credited to such account, to remain available until expended.

''(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 2020.

''(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 and related field activities funded through such allocation) for such period. This paragraph shall not be construed to authorize the Secretary to assess any fees in any amounts greater than otherwise authorized under subsection (c)(3).

''(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 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 years 2022 through 2023; and

''(D) $46,000,000 for each of fiscal years 2024 through 2027.

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

''(h) 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.

''(i) 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 safety activities, be reduced to offset the number of officers, employees, and advisory committees so engaged.

''(j) RECORDS.—Each responsible person 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 Secretary for review and duplication upon request of the Secretary.

''(k) LIMITATION.—This part does not authorize the assessment or collection of a fee for registration under section 605 occurring after fiscal year 2025.''.

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.

''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 Cosmetic Safety Enhancement Act of 2020 and the amendments made thereby.

"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 during such fiscal year, including 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 reauthorization 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, 744M, and 744N 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.

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