Subtitle E—Cosmetics

SEC. 3501. SHORT TITLE.

This subtitle may be cited as the "Modernization of Cosmetics Regulation Act of 2022".

SEC. 3502. AMENDMENTS TO COSMETIC REQUIREMENTS.

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) ADVERSE EVENT.—The term 'adverse event' means any health-related event associated with the use of a cosmetic product that is adverse.

"(2) COSMETIC PRODUCT.—The term 'cosmetic product' means a preparation of cosmetic ingredients with a qualitatively and quantitatively set composition for use in a finished product.

"(3) FACILITY.—

"(A) IN GENERAL.—The term 'facility' includes any establishment (including an establishment of an importer) that manufactures or processes cosmetic products distributed in the United States.

"(B) Such term does not include any of the following:

"(i) Beauty shops and salons, unless such establishment manufactures or processes cosmetic products at that location.

"(ii) Cosmetic product retailers, including individual sales representatives, direct sellers (as defined in section 3508(b)(2) of the Internal Revenue Code of 1986), retail distribution facilities, and pharmacies, unless such establishment manufactures or processes cosmetic products that are not sold directly to consumers at that location.

"(iii) Hospitals, physicians' offices, and health care clinics.

"(iv) Public health agencies and other nonprofit entities that provide cosmetic products directly to the consumer.

"(v) Entities (such as hotels and airlines) that provide complimentary cosmetic products to customers incidental to other services.

"(vi) Trade shows and other venues where cosmetic product samples are provided free of charge.

"(vii) An establishment that manufactures or processes cosmetic products that are solely for use in research or evaluation, including for production testing and not offered for retail sale.

"(viii) An establishment that solely performs one or more of the following with respect to cosmetic products:

"(I) Labeling.
"(II) Relabeling.
"(III) Packaging.
"(IV) Repackaging.
"(V) Holding.
"(VI) Distributing.

"(C) CLARIFICATION.—For the purposes of subparagraph (B)(viii), the terms 'packaging' and 'repackaging' do not include filling a product container with a cosmetic product.

"(4) RESPONSIBLE PERSON.—The term 'responsible person' means the manufacturer, packer, or distributor of a cosmetic product whose name appears on the label of such cosmetic product in accordance with section 609(a) of this Act or section 4(a) of the Fair Packaging and Labeling Act.

"(5) SERIOUS ADVERSE EVENT.—The term 'serious adverse event' means an adverse event that—

"(A) results in—

"(i) death;

"(ii) a life-threatening experience;

"(iii) inpatient hospitalization;

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

"(v) a congenital anomaly or birth defect;

"(vi) an infection; or

"(vii) significant disfigurement (including serious and persistent rashes, second- or third-degree burns, significant hair loss, or persistent or significant alteration of appearance), other than as intended, under conditions of use that are customary or usual; or

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

"SEC. 605. ADVERSE EVENTS.

"(a) SERIOUS ADVERSE EVENT REPORTING REQUIREMENTS.—The responsible person shall submit to the Secretary any report received of a serious adverse event associated with the use, in the United States, of a cosmetic product manufactured, packed, or distributed by such person.

"(b) SUBMISSION OF REPORTS.—

"(1) SERIOUS ADVERSE EVENT REPORT.—The responsible person shall submit to the Secretary a serious adverse event report accompanied by a copy of the label on or within the retail packaging of such cosmetic product no later than 15 business days after the report is received by the responsible person.

"(2) NEW MEDICAL INFORMATION.—The responsible person shall submit to the Secretary any new and material medical information, related to a serious adverse event report submitted to the Secretary in accordance with paragraph (1), that is received by the responsible person within 1 year of the initial report to the Secretary, no later than 15 business days after such information is received by such responsible person.

"(3) CONSOLIDATION OF REPORTS.—The Secretary shall develop systems to enable responsible persons to submit a single report that includes duplicate reports of, or new medical information related to, a serious adverse event.

"(c) EXEMPTIONS.—The Secretary may establish by regulation an exemption to any of the requirements of this section if the Secretary determines that such exemption would have no significant adverse effect on public health.

"(d) CONTACT INFORMATION.—The responsible person shall receive reports of adverse events through the domestic address,

domestic telephone number, or electronic contact information included on the label in accordance with section 609(a).

"(e) MAINTENANCE AND INSPECTION OF ADVERSE EVENT RECORDS.—

"(1) MAINTENANCE.—The responsible person shall maintain records related to each report of an adverse event associated with the use, in the United States, of a cosmetic product manufactured or distributed by such person received by such person, for a period of 6 years, except that a responsible person that is considered a small business for the purposes of section 612, who does not engage in the manufacturing or processing of the cosmetic products described in subsection 612(b), shall maintain such records for a period of 3 years.

"(2) INSPECTION.—

"(A) IN GENERAL.— The responsible person shall permit an authorized person to have access to records required to be maintained under this section during an inspection pursuant to section 704.

"(B) AUTHORIZED PERSON.—For purposes of this paragraph, the term 'authorized person' means an officer or employee of the Department of Health and Human Services who has—

"(i) appropriate credentials, as determined by the Secretary; and

"(ii) been duly designated by the Secretary to have access to the records required under this section.

"(f) FRAGRANCE AND FLAVOR INGREDIENTS.—If the Secretary has reasonable grounds to believe that an ingredient or combination of ingredients in a fragrance or flavor has caused or contributed to a serious adverse event required to be reported under this section, the Secretary may request in writing a list of such ingredients or categories of ingredients in the specific fragrances or flavors in the cosmetic product, from the responsible person. The responsible person shall ensure that the requested information is submitted to the Secretary within 30 days of such request. In response to a request under section 552 of title 5, United States Code, information submitted to the Secretary under this subsection shall be withheld under section 552(b)(3) of title 5, United States Code.

"(g) PROTECTED INFORMATION.—A serious adverse event report submitted to the Secretary under this section, including any new medical information submitted under subsection (b)(2), or an adverse event report, or any new information, voluntarily submitted to the Secretary shall be considered to be—

"(1) 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 record about an individual under section 552a of title 5, United States Code (commonly referred to as the 'Privacy Act of 1974') and 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 shall not be publicly disclosed unless all personally identifiable information is redacted.

"(h) EFFECT OF SECTION.—

"(1) IN GENERAL.—Nothing in this section shall affect the authority of the Secretary to provide adverse event reports and information to any health, food, or drug officer or employee of any State, territory, or political subdivision of a State or territory, under a memorandum of understanding between the Secretary and such State, territory, or political subdivision.

"(2) PERSONALLY IDENTIFIABLE INFORMATION.—Notwithstanding any other provision of law, personally-identifiable information in adverse event reports provided by the Secretary to any health, food, or drug officer or employee of any State, territory, or political subdivision of a State or territory, shall not—

"(A) be made publicly available pursuant to any State or other law requiring disclosure of information or records; or

"(B) otherwise be disclosed or distributed to any party without the written consent of the Secretary and the person submitting such information to the Secretary.

"(3) USE OF REPORTS.—Nothing in this section shall permit a State, territory, or political subdivision of a State or territory, to use any safety report received from the Secretary in a manner inconsistent with this section.

"(4) RULE OF CONSTRUCTION.—The submission of any report in compliance with this section shall not be construed as an admission that the cosmetic product involved caused or contributed to the relevant adverse event.

"SEC. 606. GOOD MANUFACTURING PRACTICE.

"(a) IN GENERAL.—The Secretary shall by regulation establish good manufacturing practices for facilities that are consistent, to the extent practicable, and appropriate, with national and international standards, in accordance with section 601. Any such regulations shall be intended to protect the public health and ensure that cosmetic products are not adulterated. Such regulations may allow for the Secretary to inspect records necessary to demonstrate compliance with good manufacturing practices prescribed by the Secretary under this paragraph during an inspection conducted under section 704.

"(b) CONSIDERATIONS.—In establishing regulations for good manufacturing practices under this section, the Secretary shall take into account the size and scope of the businesses engaged in the manufacture of cosmetics, and the risks to public health posed by such cosmetics, and provide sufficient flexibility to be practicable for all sizes and types of facilities to which such regulations will apply. Such regulations shall include simplified good manufacturing practice requirements for smaller businesses, as appropriate, to ensure that such regulations do not impose undue economic hardship for smaller businesses, and may include longer compliance times for smaller businesses. Before issuing regulations to implement subsection (a), the Secretary shall consult with cosmetics manufacturers, including smaller businesses, consumer organizations, and other experts selected by the Secretary.

"(c) TIMEFRAME.—The Secretary shall publish a notice of proposed rulemaking not later than 2 years after the date of enactment of the Modernization of Cosmetics Regulation Act of 2022 and shall publish a final such rule not later than 3 years after such date of enactment.

"SEC. 607. REGISTRATION AND PRODUCT LISTING.

"(a) SUBMISSION OF REGISTRATION.—

"(1) INITIAL REGISTRATION.—

"(A) EXISTING FACILITIES.—Every person that, on the date of enactment of the Modernization of Cosmetics Regulation Act of 2022, owns or operates a facility that engages in the manufacturing or processing of a cosmetic product for distribution in the United States shall register each facility with the Secretary not later than 1 year after date of enactment of such Act.

"(B) NEW FACILITIES.—Every person that owns or operates a facility that first engages, after the date of enactment of the Modernization of Cosmetics Regulation Act of 2022, in manufacturing or processing of a cosmetic product for distribution in the United States, shall register with the Secretary such facility within 60 days of first engaging in such activity or 60 days after the deadline for registration under subparagraph (A), whichever is later.

"(2) BIENNIAL RENEWAL OF REGISTRATION.—A person required to register a facility under paragraph (1) shall renew such registrations with the Secretary biennially.

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

"(4) UPDATES TO CONTENT.—A person that is required to register under subsection (a)(1) shall notify the Secretary within 60 days of any changes to information required under subsection (b)(2).

"(5) ABBREVIATED RENEWAL REGISTRATIONS.—The Secretary shall provide for an abbreviated registration renewal process for any person that owns or operates a facility that has not been required to submit updates under paragraph (4) for a registered facility since submission of the most recent registration of such facility under paragraph (1) or (2).

"(b) FORMAT; CONTENTS OF REGISTRATION.—

"(1) IN GENERAL.—Registration information under this section may be submitted at such time and in such manner as the Secretary may prescribe.

"(2) CONTENTS.—The registration under subsection (a) shall contain—

"(A) the facility's name, physical address, email address, and telephone number;

"(B) with respect to any foreign facility, the contact for the United States agent of the facility, and, if available, the electronic contact information;

"(C) the facility registration number, if any, previously assigned by the Secretary under subsection (d);

"(D) all brand names under which cosmetic products manufactured or processed in the facility are sold; and

"(E) the product category or categories and responsible person for each cosmetic product manufactured or processed at the facility.

"(c) COSMETIC PRODUCT LISTING.—

"(1) IN GENERAL.—For each cosmetic product, the responsible person shall submit to the Secretary a cosmetic product listing, or ensure that such submission is made, at such time and in such manner as the Secretary may prescribe.

"(2) COSMETIC PRODUCT LISTING.—The responsible person of a cosmetic product that is marketed on the date of enactment of the Modernization of Cosmetics Regulation Act of 2022 shall submit to the Secretary a cosmetic product listing not later than 1 year after the date of enactment of the Modernization of Cosmetics Regulation Act of 2022, or for a cosmetic product that is first marketed after the date of enactment of such Act, within 120 days of marketing such product in interstate commerce. Thereafter, any updates to such listing shall be made annually, consistent with paragraphs (4) and (5).

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

"(4) CONTENTS OF LISTING.—

"(A) IN GENERAL.—Each such cosmetic product listing shall include—

"(i) the facility registration number of each facility where the cosmetic product is manufactured or processed;

"(ii) the name and contact number of the responsible person and the name for the cosmetic product, as such name appears on the label;

"(iii) the applicable cosmetic category or categories for the cosmetic product;

"(iv) a list of ingredients in the cosmetic product, including any fragrances, flavors, or colors, with each ingredient identified by the name, as required under section 701.3 of title 21, Code of Federal Regulations (or any successor regulations), or by the common or usual name of the ingredient; and

"(v) the product listing number, if any previously assigned by the Secretary under subsection (d).

"(B) FLEXIBLE LISTINGS.—A single listing submission for a cosmetic product may include multiple cosmetic products with identical formulations, or formulations that differ only with respect to colors, fragrances or flavors, or quantity of contents.

"(5) UPDATES TO CONTENT.—A responsible person that is required to submit a cosmetic product listing shall submit any updates to such cosmetic product listing annually.

"(6) SUBMISSION.—A responsible person may submit product listing information as part of a facility registration or separately.

"(d) FACILITY REGISTRATION AND PRODUCT LISTING NUMBERS.—At the time of the initial registration of any facility under subsection (a)(1) or initial listing of any cosmetic product under (c)(1), the Secretary shall assign a facility registration number to the facility

and a product listing number to each cosmetic product. The Secretary shall not make such product listing number publicly available.

"(e) CONFIDENTIALITY.—In response to a request under section 552 of title 5, United States Code, information described in subsection (b)(2)(D) or (c)(4)(A)(i) that is derived from a registration or listing under this section shall be withheld under section 552(b)(3) of title 5, United States Code.

"(f) SUSPENSIONS.—

"(1) SUSPENSION OF REGISTRATION OF A FACILITY.—The Secretary may suspend the registration of a facility if the Secretary determines that a cosmetic product manufactured or processed by a registered facility and distributed in the United States has a reasonable probability of causing serious adverse health consequences or death to humans and the Secretary has a reasonable belief that other products manufactured or processed by the facility may be similarly affected because of a failure that cannot be isolated to a product or products, or is sufficiently pervasive to raise concerns about other products manufactured in the facility.

"(2) NOTICE OF SUSPENSION.—Before suspending a facility registration under this section, the Secretary shall provide—

"(A) notice to the facility registrant of the cosmetic product or other responsible person, as appropriate, of the intent to suspend the facility registration, which shall specify the basis of the determination by the Secretary that the facility registration should be suspended; and

"(B) an opportunity, within 5 business days of the notice provided under subparagraph (A), for the responsible person to provide a plan for addressing the reasons for possible suspension of the facility registration.

"(3) HEARING ON SUSPENSION.—The Secretary shall provide the registrant subject to an order under paragraph (1) or (2) with an opportunity for an informal hearing, to be held as soon as possible but not later than 5 business days after the issuance of the order, or such other time period agreed upon by the Secretary and the registrant, on the actions required for reinstatement of registration and why the registration that is subject to the suspension should be reinstated. The Secretary shall reinstate a registration if the Secretary determines, based on evidence presented, that adequate grounds do not exist to continue the suspension of the registration.

"(4) POST-HEARING CORRECTIVE ACTION PLAN.—If, after providing opportunity for an informal hearing under paragraph (3), the Secretary determines that the suspension of registration remains necessary, the Secretary shall require the registrant to submit a corrective action plan to demonstrate how the registrant plans to correct the conditions found by the Secretary. The Secretary shall review such plan not later than 14 business days after the submission of the corrective action plan or such other time period as determined by the Secretary, in consultation with the registrant.

"(5) VACATING OF ORDER; REINSTATEMENT.—Upon a determination by the Secretary that adequate grounds do not exist to continue the suspension actions, the Secretary shall promptly vacate the suspension and reinstate the registration of the facility.

"(6) EFFECT OF SUSPENSION.—If the registration of the facility is suspended under this section, no person shall introduce or deliver for introduction into commerce in the United States cosmetic products from such facility.

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

"SEC. 608. SAFETY SUBSTANTIATION.

"(a) SUBSTANTIATION OF SAFETY.—A responsible person for a cosmetic product shall ensure, and maintain records supporting, that there is adequate substantiation of safety of such cosmetic product.

"(b) COAL-TAR HAIR DYE.—Subsection (a) shall not apply to coal-tar hair dye that otherwise complies with the requirements of section 601(a). A responsible person for a coal-tar hair dye shall maintain records related to the safety of such product.

"(c) DEFINITIONS.—For purposes of this section:

"(1) ADEQUATE SUBSTANTIATION OF SAFETY.—The term 'adequate substantiation of safety' means tests or studies, research, analyses, or other evidence or information that is considered, among experts qualified by scientific training and experience to evaluate the safety of cosmetic products and their ingredients, sufficient to support a reasonable certainty that a cosmetic product is safe.

"(2) SAFE.—The term 'safe' means that the cosmetic product, including any ingredient thereof, is not injurious to users under the conditions of use prescribed in the labeling thereof, or under such conditions of use as are customary or usual. The Secretary shall not consider a cosmetic ingredient or cosmetic product injurious to users solely because it can cause minor and transient reactions or minor and transient skin irritations in some users. In determining for purposes of this section whether a cosmetic product is safe, the Secretary may consider, as appropriate and available, the cumulative or other relevant exposure to the cosmetic product, including any ingredient thereof.

"SEC. 609. LABELING.

"(a) GENERAL REQUIREMENT.—Each cosmetic product shall bear a label that includes a domestic address, domestic phone number, or electronic contact information, which may include a website, through which the responsible person can receive adverse event reports with respect to such cosmetic product.

"(b) FRAGRANCE ALLERGENS.—The responsible person shall identify on the label of a cosmetic product each fragrance allergen included in such cosmetic product. Substances that are fragrance allergens for purposes of this subsection shall be determined by the Secretary by regulation. The Secretary shall issue a notice of proposed rulemaking promulgating the regulation implementing this requirement not later than 18 months after the date of enactment of the Modernization of Cosmetics Regulation Act of 2022, and not later than 180 days after the date on which the public comment period on the proposed rulemaking closes, shall issue a final rulemaking. In promulgating regulations implementing this subsection, the Secretary shall consider international, State, and local requirements for allergen disclosure, including the substance

and format of requirements in the European Union, and may establish threshold levels of amounts of substances subject to disclosure pursuant to such regulations.

"(c) COSMETIC PRODUCTS FOR PROFESSIONAL USE.—

"(1) DEFINITION OF PROFESSIONAL.—For purposes of this subsection, the term 'professional' means an individual who is licensed by an official State authority to practice in the field of cosmetology, nail care, barbering, or esthetics.

"(2) PROFESSIONAL USE LABELING.—A cosmetic product introduced into interstate commerce and intended to be used only by a professional shall bear a label that—

"(A) contains a clear and prominent statement that the product shall be administered or used only by licensed professionals; and

"(B) is in conformity with the requirements of the Secretary for cosmetics labeling under this Act and section 4(a) of the Fair Packaging and Labeling Act.

"SEC. 610. RECORDS.

"(a) IN GENERAL.—If the Secretary has a reasonable belief that a cosmetic product, including an ingredient in such cosmetic product, and any other cosmetic product that the Secretary reasonably believes is likely to be affected in a similar manner, is likely to be adulterated such that the use or exposure to such product presents a threat of serious adverse health consequences or death to humans, each responsible person and facility 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 a written notice to such person, at reasonable times and within reasonable limits and in a reasonable manner, to have access to and copy all records relating to such cosmetic product, and to any other cosmetic product that the Secretary reasonably believes is likely to be affected in a similar manner, that are needed to assist the Secretary in determining whether the cosmetic product is adulterated and presents a threat of serious adverse health consequences or death to humans. This subsection shall not be construed to extend to recipes or formulas for cosmetics, 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 substantiation data for cosmetic products and their ingredients), or sales data (other than shipment data regarding sales).

"(b) RULE OF CONSTRUCTION.—Nothing in this section shall be construed to limit the authority of the Secretary to inspect records or require establishment and maintenance of records under any other provision of this Act, including section 605 or 606.

"SEC. 611. MANDATORY RECALL AUTHORITY.

"(a) IN GENERAL.—If the Secretary determines that there is a reasonable probability that a cosmetic is adulterated under section 601 or misbranded under section 602 and the use of or exposure to such cosmetic will cause serious adverse health consequences or death, the Secretary shall provide the responsible person with an opportunity to voluntarily cease distribution and recall such article. If the responsible person refuses to or does not voluntarily cease distribution or recall such cosmetic within the time and manner prescribed by the Secretary (if so prescribed), the Secretary

may, by order, require, as the Secretary determines necessary, such person to immediately cease distribution of such article.

"(b) HEARING.—The Secretary shall provide the responsible person who is subject to an order under subsection (a) with an opportunity for an informal hearing, to be held not later than 10 days after the date of issuance of the order, on whether adequate evidence exists to justify the order.

"(c) ORDER RESOLUTION.—After an order is issued according to the process under subsections (a) and (b), the Secretary shall, except as provided in subsection (d)—

"(1) vacate the order, if the Secretary determines that inadequate grounds exist to support the actions required by the order;

"(2) continue the order ceasing distribution of the cosmetic until a date specified in such order; or

"(3) amend the order to require a recall of the cosmetic, including any requirements to notify appropriate persons, a timetable for the recall to occur, and a schedule for updates to be provided to the Secretary regarding such recall.

"(d) ACTION FOLLOWING ORDER.—Any person who is subject to an order pursuant to paragraph (2) or (3) of subsection (c) shall immediately cease distribution of or recall, as applicable, the cosmetic and provide notification as required by such order.

"(e) NOTICE TO PERSONS AFFECTED.—If the Secretary determines necessary, the Secretary may require the person subject to an order pursuant to subsection (a) or an amended order pursuant to paragraph (2) or (3) of subsection (c) to provide either a notice of a recall order for, or an order to cease distribution of, such cosmetic, as applicable, under this section to appropriate persons, including persons who manufacture, distribute, import, or offer for sale such product that is the subject of an order and to the public.

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

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

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

"(B) that includes, at a minimum—

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

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

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

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

"(g) NO DELEGATION.—The authority conferred by this section to order a recall or vacate a recall order shall not be delegated to any officer or employee other than the Commissioner.

"(h) EFFECT.—Nothing in this section shall affect the authority of the Secretary to request or participate in a voluntary recall, or to issue an order to cease distribution or to recall under any other provision of this chapter.

"SEC. 612. SMALL BUSINESSES.

"(a) IN GENERAL.—Responsible persons, and owners and operators of facilities, whose average gross annual sales in the United States of cosmetic products for the previous 3-year period is less than $1,000,000, adjusted for inflation, and who do not engage in the manufacturing or processing of the cosmetic products described in subsection (b), shall be considered small businesses and not subject to the requirements of section 606 or 607.

"(b) REQUIREMENTS APPLICABLE TO ALL MANUFACTURERS AND PROCESSORS OF COSMETICS.—The exemptions under subsection (a) shall not apply to any responsible person or facility engaged in the manufacturing or processing of any of the following products:

"(1) Cosmetic products that regularly come into contact with mucus membrane of the eye under conditions of use that are customary or usual.

"(2) Cosmetic products that are injected.

"(3) Cosmetic products that are intended for internal use.

"(4) Cosmetic products that are intended to alter appearance for more than 24 hours under conditions of use that are customary or usual and removal by the consumer is not part of such conditions of use that are customary or usual.

"SEC. 613. EXEMPTION FOR CERTAIN PRODUCTS AND FACILITIES.

"(a) IN GENERAL.—Notwithstanding any other provision of law, except as provided in subsection (b), a cosmetic product or facility that is also subject to the requirements of chapter V shall be exempt from the requirements of sections 605, 606, 607, 608, 609(a), 610, and 611.

"(b) EXCEPTION.—A facility described in subsection (a) that also manufactures or processes cosmetic products that are not subject to the requirements of chapter V shall not be exempt from the requirements of sections 605, 606, 607, 608, 609(a), 610, and 611, with respect to such cosmetic products.

"SEC. 614. PREEMPTION.

"(a) IN GENERAL.—No State or political subdivision of a State may establish or continue in effect any law, regulation, order, or other requirement for cosmetics that is different from or in addition to, or otherwise not identical with, any requirement applicable under this chapter with respect to registration and product listing, good manufacturing practice, records, recalls, adverse event reporting, or safety substantiation.

"(b) LIMITATION.—Nothing in the amendments to this Act made by the Modernization of Cosmetics Regulation Act of 2022 shall be construed to preempt any State statute, public initiative, referendum, regulation, or other State action, except as expressly provided in subsection (a). Notwithstanding subsection (a), nothing in this section shall be construed to prevent any State from prohibiting the use or limiting the amount of an ingredient in a cosmetic product, or from continuing in effect a requirement of any State that is in effect at the time of enactment of the Modernization of Cosmetics Regulation Act of 2022 for the reporting to the State of an ingredient in a cosmetic product.

"(c) SAVINGS.—Nothing in the amendments to this Act made by the Modernization of Cosmetics Regulation Act of 2022, nor any standard, rule, requirement, regulation, or adverse event report shall be construed to modify, preempt, or displace any action for

damages or the liability of any person under the law of any State, whether statutory or based in common law.

"(d) RULE OF CONSTRUCTION.—Nothing in this section shall be construed to amend, expand, or limit the provisions under section 752.".

SEC. 3503. ENFORCEMENT AND CONFORMING AMENDMENTS.

(a) IN GENERAL.—

(1) PROHIBITED ACTS.—Section 301 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 331), as amended by section 3210, is further amended—

(A) by adding at the end the following:

"(hhh) The failure to register or submit listing information in accordance with section 607.

"(iii) The refusal or failure to follow an order under section 611."; and

(B) in paragraph (d), by striking "or 564" and inserting ", 564, or 607".

(2) ADULTERATED PRODUCTS.—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 has been manufactured or processed under conditions that do not meet the good manufacturing practice requirements of section 606.

"(g) If it is a cosmetic product, and the cosmetic product, including each ingredient in the cosmetic product, does not have adequate substantiation for safety, as defined in section 608(c).".

(3) MISBRANDED COSMETICS.—Section 602(b) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 362(b)) is amended—

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

(B) by inserting after "numerical count" the following: "; and (3) the information required under section 609".

(4) ADVERSE EVENT REPORTING.—The Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.) is amended—

(A) in section 301(e) (21 U.S.C. 331(e))—

(i) by striking "564, 703" and inserting "564, 605, 703"; and

(ii) by striking "564, 760" and inserting "564, 605, 611, 760";

(B) in section 301(ii) (21 U.S.C. 331(ii))—

(i) by striking "760 or 761) or" and inserting "604, 760, or 761) or"; and

(ii) by inserting "or required under section 605(a)" after "report (as defined under section 760 or 761";

(C) in section 801(a) (21 U.S.C. 381(a))—

(i) by striking "under section 760 or 761" and inserting "under section 605, 760, or 761";

(ii) by striking "defined in such section 760 or 761" and inserting "defined in section 604, 760, or 761";

(iii) by striking "of such section 760 or 761" and inserting "of such section 605, 760, or 761"; and

(iv) by striking "described in such section 760 or 761" and inserting "described in such section 605, 760, or 761"; and

(D) in section 801(b) (21 U.S.C. 381(b))—

(i) by striking "requirements of sections 760 or 761," and inserting "requirements of section 605, 760, or 761";

(ii) by striking "as defined in section 760 or 761" and inserting "as defined in section 604, 760, or 761"; and

(iii) by striking "with section 760 or 761" and inserting "with section 605, 760, or 761".

(b) EFFECTIVE DATES.—

(1) IN GENERAL.—The amendments made by subsection (a) shall take effect on the date that is 1 year after the date of enactment of this Act.

(2) LABELING REQUIREMENT.—Section 609(a) of the Federal Food, Drug, and Cosmetic Act, as added by section 802, shall take effect on the date that is 2 years after the date of enactment of this Act.

(c) CONFIDENTIALITY.—

(1) IN GENERAL.—The Secretary shall take appropriate measures to ensure that there are in effect effective procedures to prevent the unauthorized disclosure of any trade secret or confidential commercial information that is obtained by the Secretary of Health and Human Services pursuant to this subtitle, including the amendments made by this subtitle.

(2) CLARIFICATION.—Nothing in this subtitle, including the amendments made by this subtitle, shall be construed to authorize the disclosure of information that is prohibited from disclosure under section 301(j) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 331(j)) or section 1905 of title 18, United States Code, or that is subject to withholding under section 552(b)(4) of title 5, United States Code.

SEC. 3504. RECORDS 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 second sentence the following: "In the case of a facility (as defined in section 604) that manufactures or processes cosmetic products, the inspection shall extend to all records and other information described in sections 605, 606, and 610, when the standard for records inspection under such section applies.".

SEC. 3505. TALC-CONTAINING COSMETICS.

The Secretary of Health and Human Services—

(1) not later than one year after the date of enactment of this Act, shall promulgate proposed regulations to establish and require standardized testing methods for detecting and identifying asbestos in talc-containing cosmetic products; and

(2) not later than 180 days after the date on which the public comment period on the proposed regulations closes, shall issue such final regulations.

SEC. 3506. PFAS IN COSMETICS.

(a) IN GENERAL.—The Secretary of Health and Human Services (referred to in this section as the "Secretary") shall assess the use of perfluoroalkyl and polyfluoroalkyl substances in cosmetic products and the scientific evidence regarding the safety of such use in cosmetic products, including any risks associated with such use. In conducting such assessment, the Secretary may, as appropriate, consult with the National Center for Toxicological Research.

(b) REPORT.—Not later than 3 years after enactment of this Act, the Secretary shall publish on the website of the Food and Drug Administration a report summarizing the results of the assessment conducted under subsection (a).

SEC. 3507. SENSE OF THE CONGRESS ON ANIMAL TESTING.

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

SEC. 3508. FUNDING.

There is authorized to be appropriated $14,200,000 for fiscal year 2023, $25,960,000 for fiscal year 2024, and $41,890,000 for each of fiscal years 2025 through 2027, for purposes of conducting the activities under this subtitle (including the amendments made by this subtitle) and hiring personnel required to carry out this subtitle (including the amendments made by this subtitle).

Subtitle F—Cross-Cutting Provisions

CHAPTER 1—CLINICAL TRIAL DIVERSITY AND MODERNIZATION

SEC. 3601. DIVERSITY ACTION PLANS FOR CLINICAL STUDIES.

(a) DRUGS.—Section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355) is amended by adding at the end the following:

"(z)(1) With respect to a clinical investigation of a new drug that is a phase 3 study, as defined in section 312.21(c) of title 21, Code of Federal Regulations (or successor regulations), or, as appropriate, another pivotal study of a new drug (other than bioavailability or bioequivalence studies), the sponsor of such drug shall submit to the Secretary a diversity action plan.

"(2) Such diversity action plan shall include—

"(A) the sponsor's goals for enrollment in such clinical study;

"(B) the sponsor's rationale for such goals; and

"(C) an explanation of how the sponsor intends to meet such goals.

"(3) The sponsor shall submit to the Secretary such diversity action plan, in the form and manner specified by the Secretary in guidance, as soon as practicable but not later than the date on which the sponsor submits the protocol to the Secretary for such a phase 3 study or other pivotal study of the drug. The sponsor may submit modifications to the diversity action plan. Any such modifications shall be in the form and manner specified by the Secretary in guidance.

"(4)(A) On the initiative of the Secretary or at the request of a sponsor, the Secretary may waive any requirement in paragraph (1), (2), or (3) if the Secretary determines that a waiver is necessary based on what is known or what can be determined about the prevalence or incidence of the disease or condition for which the new drug is under investigation (including in terms of the patient population that may use the drug), if conducting a clinical investigation in accordance with a diversity action plan