I

111TH CONGRESS
2D SESSION

H. R. 5786

To amend title VI of the Federal Food, Drug, and Cosmetic Act to ensure the safe use of cosmetics, and for other purposes.

IN THE HOUSE OF REPRESENTATIVES

JULY 20, 2010

Ms. SCHAKOWSKY (for herself, Mr. MARKEY of Massachusetts, and Ms. BALDWIN) introduced the following bill; which was referred to the Committee on Energy and Commerce, and in addition to the Committee on Education and Labor, for a period to be subsequently determined by the Speaker, in each case for consideration of such provisions as fall within the jurisdiction of the committee concerned

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A BILL

To amend title VI of the Federal Food, Drug, and Cosmetic Act to ensure the safe use of cosmetics, and for other purposes.

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

SECTION 1. SHORT TITLE.

This Act may be cited as the ''Safe Cosmetics Act of 2010''.

SEC. 2. COSMETIC REGULATION.

(a) IN GENERAL.—Chapter VI of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 361 et seq.) is amended—

(1) by inserting before section 601 the following:

"Subchapter A—Adulterated and Misbranded Cosmetics";

and

(2) by adding at the end the following:

"Subchapter B—Regulation of Cosmetics

"SEC. 611. DEFINITIONS.

''In this subchapter:

''(1) INGREDIENT.—The term 'ingredient' means a chemical in a cosmetic, including—

''(A) chemicals that provide a technical or functional effect;

''(B) chemicals that have no technical or functional effect in the cosmetic but are present by reason of having been incorporated into the cosmetic as an ingredient of another cosmetic ingredient;

''(C) processing aids that are present by reason of having been added to a cosmetic during the processing of such cosmetic;

"(D) substances that are present by reason of having been added to a cosmetic during processing for their technical or functional effect;

"(E) contaminants present at levels above technically feasible detection limits;

"(F) contaminants that may leach from container materials or form via reactions over the shelf life of a cosmetic and that may be present at levels above technically feasible detection limits;

"(G) the components of a fragrance, flavor, or preservative declared individually by their appropriate label names; and

"(H) any individual component of a botanical, petroleum-derived, animal-derived, or other ingredient that the Secretary determines be considered an ingredient.

"(2) PROFESSIONAL USE.—The term 'professional use' means the use of any cosmetic—

"(A) by an employee (within the scope of the employment of such employee) of; or

"(B) purchased by a consumer in,

a hair salon, nail salon, beauty salon, spa, or other establishment that provides cosmetic treatment services for humans.

''(3) REASONABLE CERTAINTY.—The term 'reasonable certainty', when used in establishing a safety standard (as defined in paragraph (5)) for an ingredient or cosmetic—

''(A) means that no harm will be caused by aggregate exposure for a member of a vulnerable population to that ingredient or cosmetic; and

''(B) corresponds to the lower dose derived from—

''(i) data demonstrating that exposure to all sources of the ingredient or cosmetic present not more than a 1 in a million risk for any adverse effect in the population of concern, at the lower 95th percentile confidence bound; or

''(ii) the amount of an ingredient or cosmetic shown to produce no adverse effects, incorporating an uncertainty factor of at least 1,000 and considering all sources of exposure.

''(4) REPRODUCTIVE AND DEVELOPMENTAL TOXICITY.—With respect to an ingredient or cosmetic, the term 'reproductive and developmental toxicity' means that the ingredient or cosmetic causes

biologically adverse effects on the reproductive systems of female or male humans or animals, including alterations to the female or male reproductive system development, the related endocrine system, fertility, pregnancy, pregnancy outcomes, or modifications in other functions that are dependent on the integrity of the reproductive system.

''(5) SAFETY STANDARD.—

''(A) IN GENERAL.—The term 'safety standard' means—

''(i) with respect to an ingredient, when the route of exposure is directly relevant to a particular cosmetic use, a standard that—

''(I) provides a reasonable certainty that no harm will result from aggregate exposure to the cosmetic or ingredient, including impacts on vulnerable populations, taking into account possible harmful effects from low dose exposures to the cosmetic or ingredient or from additive effects, where such evidence exists; and

''(II) is requisite to protect the public welfare from any known or an-

ticipated adverse effects associated with the cosmetic or ingredient; and

''(ii) with respect to a cosmetic, when the route of exposure is directly relevant to the use of the cosmetic, a standard that a cosmetic fails to meet if—

''(I) the cosmetic would fail to meet the standard under clause (i) if the cosmetic was treated in the same manner as an ingredient under such clause; or

''(II) one or more ingredients in the cosmetic fail to meet such standard.

''(B) DETERMINATION OF SAFETY.—A cosmetic or ingredient shall fail to meet the safety standard under subparagraph (A)—

''(i) unless the Secretary determines that there is a reasonable certainty that no harm will result from aggregate exposure to the ingredient or cosmetic, including impacts on highly exposed or vulnerable populations, taking into account, where evidence exists, possible harmful effects from—

''(I) low dose exposures to the cosmetic or ingredient; or

''(II) additive effects; or

''(ii) if the Secretary determines necessary to protect the public welfare from any known or anticipated adverse effects associated with the cosmetic or ingredient.

''(6) VULNERABLE POPULATIONS.—The term 'vulnerable populations' includes pregnant women, infants, children, the elderly, people with compromised immune systems, and highly exposed populations, including workers employed by establishments listed under paragraph (2) and cosmetic manufacturing plants.

''SEC. 612. REGISTRATION OF ESTABLISHMENTS AND REGISTRATION FEES.

''(a) DEFINITIONS.—In this section:

''(1) DOMESTIC ESTABLISHMENT.—The term 'domestic establishment' means an establishment located in any State that manufactures, packages, or distributes cosmetics.

''(2) FOREIGN ESTABLISHMENT.—

''(A) IN GENERAL.—The term 'foreign establishment' means an establishment that manufactures, packages, or distributes cosmetics

that are exported to the United States without further processing or packaging outside the United States.

''(B) NOT CONSIDERED TO HAVE UNDERGONE FURTHER PROCESSING OR PACKAGING.—A cosmetic may not be considered to have undergone further processing or packaging for purposes of subparagraph (A) 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.

''(b) REGISTRATION.—The Secretary shall require that any establishment engaged in manufacturing, packaging, or distributing cosmetics for use in the United States register annually with the Secretary. To be registered—

''(1) as a domestic establishment, the owner, operator, or agent in charge of the domestic establishment shall submit a registration to the Secretary; or

''(2) as a foreign establishment, the owner, operator, or agent in charge of the foreign establishment—

''(A) shall submit a registration to the Secretary; and

''(B) shall include with the registration the name of the United States agent for the foreign establishment.

''(c) SUBMISSION OF REGISTRATION.—

''(1) IN GENERAL.—An establishment (referred to in this section as the 'registrant') shall submit a registration under subsection (b) to the Secretary containing, with respect to any cosmetics that the establishment manufactures, packages, or distributes—

''(A) any information necessary to notify the Secretary of the name and address of each establishment at which, and all trade names under which, the registrant manufactures, packages, or distributes cosmetics;

''(B) a description of the establishment's activities with respect to cosmetics;

''(C) the number of workers employed at the establishment;

''(D) the gross receipts of sales; and

''(E) the name and address of any company that supplies the establishment, if the establishment manufactures cosmetics, with any ingredient (including preservatives, fragrances, or any other chemical component of a finished

cosmetic product) and the name of the ingredient supplied to such establishment by such supplier.

''(2) NOTIFICATION OF CHANGES.—

''(A) IN GENERAL.—The registrant shall notify the Secretary in a timely manner of changes to the information described in paragraph (1).

''(B) DEADLINE FOR CERTAIN CHANGES.—The registrant shall notify the Secretary of any change in the products, function, or legal status of each establishment at which the registrant manufactures, packages, or distributes cosmetics (including cessation of business activities) not later than 60 days after the date of such change.

''(d) PROCEDURE.—Upon receipt of a completed registration submitted under subsection (b), the Secretary shall notify the registrant of the receipt of such registration and assign a registration number to each registered establishment.

''(e) LIST OF REGISTERED ESTABLISHMENTS.—

''(1) MAINTENANCE OF LIST.—The Secretary shall compile and maintain an up-to-date list of establishments that are registered under this section.

''(2) REMOVAL AND SUSPENSION.—The Secretary shall remove from the list under paragraph (1) the name of any establishment that fails to re-register in accordance with this section and shall treat such removal as a suspension of the establishment's registration.

''(3) APPLICATION OF FOIA.—

''(A) LIST.—The list under paragraph (1) shall be subject to disclosure under section 552 of title 5, United States Code.

''(B) REGISTRATION DOCUMENTS.—Any registration documents submitted pursuant to this section shall not be subject to disclosure under section 552 of title 5, United States Code.

''(C) OTHER INFORMATION.—Information derived from—

''(i) the list under paragraph (1); or

''(ii) registration documents submitted pursuant to this section,

shall not be subject to disclosure under section 552 of title 5, United States Code, except to the extent that such information discloses the identity or location of a specific registrant.

''(f) FEE SCHEDULE.—A schedule of fees shall be developed by the Secretary to provide for oversight and enforcement of this subchapter. The fee structure shall—

''(1) be prorated based on the establishment's gross receipts or sales; and

''(2) only be assessed on companies with annual gross receipts or sales of more than $1,000,000.

''(g) REGISTRATION CANCELLATION.—The Secretary may cancel the registration of any establishment under this section—

''(1) if the information submitted by the establishment for such registration is incomplete, inaccurate, or out-of-date; or

''(2) if a registered establishment fails to update such information promptly when there is a change in such information.

"SEC. 613. INGREDIENTS LABELS ON COSMETICS.

''(a) IN GENERAL.—The Secretary shall require the label on each package of cosmetics, including cosmetics distributed for retail sale and professional use, to bear a declaration of the name of each ingredient in such cosmetic in descending order of predominance. The Secretary may allow that the declaration of an ingredient present as a contaminant is not required if the contaminant is present at levels below technically feasible detection limits.

''(b) LABELING OF INGREDIENTS IN COSMETICS SOLD THROUGH INTERNET COMMERCE.—Subject to subsection (d), the Secretary shall require—

''(1) in the case of a cosmetic sold on the Web site of an Internet vendor, that the manufacturers and distributors of such cosmetic provide to such Internet vendor a list of the ingredients of the cosmetic; and

''(2) each Internet vendor to display the list of ingredients of each cosmetic sold by such vendor on the Web site of the vendor.

''(c) TRADE SECRETS.—Notwithstanding any other provision of law, an ingredient required to be listed or labeled under this section shall not have protection as a trade secret.

''(d) DEADLINE.—Not later than one year after the date of the enactment of the Safe Cosmetics Act of 2010—

''(1) all cosmetics that are available for retail sale shall be labeled in a manner that complies with the requirements under subsection (a); and

''(2) manufacturers, distributors, and Internet venders shall comply with the applicable requirements of subsection (b).

"SEC. 614. COSMETIC AND INGREDIENT TESTING AND SAFETY.

"(a) PUBLICLY AVAILABLE COSMETIC AND INGREDIENT TEST DATA.—

"(1) SUBMISSION OF INFORMATION.—

"(A) INITIAL SUBMISSION.—Not later than 1 year after the date of the enactment of the Safe Cosmetics Act of 2010, manufacturers and distributors of cosmetics and ingredients shall submit to the Secretary (in an electronic format that the Secretary shall determine) all reasonably available information in the possession or control of the manufacturer or distributor that has not previously been submitted to the Secretary regarding the physical, chemical, and toxicological properties of single or multiple chemicals listed on the cosmetic labels under section 613, including—

"(i) functions and uses;

"(ii) exposure and fate information;

"(iii) tests of finished cosmetics; and

"(iv) any other information used to substantiate the safety of such cosmetics or ingredients.

"(B) NEW OR UPDATED INFORMATION.—Not later than 60 days after the date on which

new or updated information that is required under subparagraph (A) becomes available to a manufacturer or distributer, such manufacturer or distributor shall submit such information to the Secretary in the same form and manner as information submitted under subparagraph (A).

''(2) AVAILABILITY OF INFORMATION.—The Secretary shall require that any manufacturer, distributor, or marketer of a cosmetic or ingredient (including a fragrance or preservative) make available to any entity purchasing the cosmetic or ingredient (excluding an individual who is a consumer and who is purchasing the cosmetic or ingredient for personal use) all available information in the possession or control of the manufacturer, distributor, or marketer described in paragraph (1), within 90 days of receipt of the request from such entity.

''(3) DATABASE.—

''(A) INITIAL PUBLICATION.—Not later than 12 months after the date of the enactment of the Safe Cosmetics Act of 2010, the Secretary shall publish a comprehensive, publicly accessible database containing all non-confidential information submitted under paragraph (1).

"(B) UPDATES.—Not later than 90 days after the Secretary receives new or updated information under paragraph (1)(B), the Secretary shall update the database described in subparagraph (A) with such information.

"(b) LISTS OF INGREDIENTS.—

"(1) PROHIBITED AND RESTRICTED INGREDIENTS.—

"(A) LIST OF INGREDIENTS THAT ARE PROHIBITED OR RESTRICTED.—Not later than 2 years after the date of the enactment of the Safe Cosmetics Act of 2010, the Secretary shall issue, by regulation, a list of ingredients that are identified by the Secretary as—

"(i) prohibited ingredients; or

"(ii) restricted ingredients.

"(B) UPDATES.—The Secretary shall continually update the list under subparagraph (A), including when—

"(i) determinations under paragraph (3)(D) are made; or

"(ii) new information becomes available demonstrating that an ingredient fails to meet the safety standard.

"(C) INFORMATION SOURCES.—

"(i) USE OF AUTHORITATIVE INFORMATION.—The list under subparagraph (A) shall contain ingredients that are known to be carcinogenic, mutagenic, or have reproductive and developmental toxicity, based on information from the Environmental Protection Agency, the International Agency for Research on Cancer, the National Toxicity Program through the National Institutes of Health, the California Environmental Protection Agency, and other authoritative international, Federal, and State entities (as determined by the Secretary).

"(ii) USE OF OTHER INFORMATION SOURCES.—In identifying ingredients for purposes of the list under subparagraph (A), the Secretary shall use all reasonably available information, including new scientific information and submissions from manufacturers and distributors of cosmetics.

"(D) PROHIBITED INGREDIENTS.—Ingredients that are listed as prohibited under subparagraph (A) shall include all ingredients that

the Secretary determines are unsafe for use in cosmetics in any amount because such ingredients fail to meet the safety standard defined in section 611(5).

''(E) RESTRICTED INGREDIENTS.—Ingredients that are listed as restricted under subparagraph (A) shall include all ingredients for which the Secretary determines that limits on use or concentration are necessary to satisfy the safety standard defined in section 611(5).

''(F) INGREDIENTS AND COSMETICS FOUND TO INDUCE CANCER OR BIRTH DEFECTS OR HAVE REPRODUCTIVE OR DEVELOPMENTAL TOXICITY.—

''(i) PRESUMPTION.—The Secretary shall presume that any ingredient or cosmetic that induces cancer or birth defects or has reproductive or developmental toxicity when ingested by, inhaled by, or dermally applied to a human or an animal has failed to meet the safety standard (as defined in section 611(5)).

''(ii) REBUTTAL.—The presumption under clause (i) may be rebutted only if the Secretary determines that the ingre-

dient or cosmetic meets such safety standard.

''(iii) PUBLIC COMMENT.—The Secretary shall solicit public comment before making a determination under clause (ii).

''(2) SAFE WITHOUT LIMITS.—

''(A) IN GENERAL.—Not later than 2 years after the date of the enactment of the Safe Cosmetics Act of 2010, the Secretary shall issue, by regulation, a list of ingredients that the Secretary has determined are safe without limits for use in cosmetics.

''(B) STANDARD FOR INCLUSION IN LIST.—The Secretary may only include an ingredient on the list under subparagraph (A) if the Secretary determines that such ingredient meets the safety standard (as defined in section 611(5)) regardless of—

''(i) the type and form of cosmetic the ingredient is used in; or

''(ii) the concentration of the ingredient that is used in a cosmetic.

''(C) UPDATE.—The Secretary shall update the list under subparagraph (A) when new information becomes available.

''(D) CONSULTATIONS.—In determining whether a cosmetic or ingredient is safe, the Secretary shall consult hazard listings and assessments from authoritative international, Federal, and State entities, including the entities listed in paragraph (1)(C)(i).

''(E) REDETERMINATIONS.—The Secretary may redetermine whether a cosmetic or ingredient distributed in commerce meets the safety standard if, in the judgment of the Secretary, new information raises a credible question as to whether the cosmetic or ingredient continues to meet the safety standard.

''(3) PRIORITY ASSESSMENT LIST.—

''(A) IN GENERAL.—Not later than 18 months after the date of the enactment of the Safe Cosmetics Act of 2010, the Secretary shall develop a priority assessment list of not less than 300 ingredients—

''(i) which cannot be included on the restricted and prohibited list under paragraph (1) or the safe without limits list under paragraph (2) because of a lack of authoritative information on the safety of the ingredient; and

"(ii) for which safety determinations under subparagraph (D) shall be made.

"(B) ADDITIONAL INGREDIENTS.—The Secretary shall add not less than 100 ingredients to the priority assessment list under subparagraph (A) annually until all ingredients that are used in the formulation or manufacture of cosmetics have been added to the priority assessment list, the safe without limits list, or the prohibited and restricted list.

"(C) CONSIDERATIONS.—In developing or updating the priority assessment list under this paragraph, the Secretary shall take into account all relevant data with respect to ingredients including whether the ingredients—

"(i) react to form harmful byproducts;

"(ii) are found to be present in the body through biomonitoring;

"(iii) are found in drinking water or indoor or outdoor air;

"(iv) are a known or suspected neurological or immunological toxicant, respiratory asthmagens, or endocrine disruptor, or have other toxicological concerns; or

"(v) persist in the environment or bioaccumulate.

"(D) DETERMINATION OF WHETHER INGREDIENT MEETS SAFETY STANDARD.—

"(i) IN GENERAL.—Not later than 24 months after the date on which an ingredient is placed on the priority assessment list under subparagraph (A), the Secretary shall issue, by rule, a determination of—

"(I) whether the ingredient meets the safety standard (as defined in section 611(5)) and can be placed on the safe without limits list under paragraph (2); or

"(II) whether to include the ingredient in the prohibited and restricted ingredients list under paragraph (1), to ensure that the safety standard is not violated.

"(ii) RULEMAKING.—Before issuing final regulations under clause (ii), the Secretary shall issue a notice of proposed rulemaking and provide a period of not less than 60 days for public comment on the proposed regulation, except that a shorter

period for comment may be provided if the Secretary—

"(I) finds that it would be in the public interest to have a shorter period; and

"(II) states the reasons for such finding in the notice of proposed rulemaking.

"(c) MANUFACTURER INFORMATION AND SAFETY TESTING.—

"(1) PROVISION OF INFORMATION.—A manufacturer of an ingredient or cosmetic shall provide to the Secretary, through a statement under paragraph (3), all information required to determine if an ingredient or cosmetic meets the safety standard.

"(2) MINIMUM DATA REQUIREMENTS AND TEST PROTOCOLS.—Not later than 1 year after the date of the enactment of the Safe Cosmetics Act of 2010, the Secretary shall establish minimum data requirements and test protocols to be used by manufacturers to assess the safety of cosmetic ingredients that would ensure that statements under paragraph (3)(A) regarding compliance with the safety standard are based on sufficient and reliable data.

"(3) STATEMENTS.—

''(A) IN GENERAL.—Not later than 18 months after the date of the enactment of the Safe Cosmetics Act of 2010, each manufacturer or marketer of a cosmetic shall submit to the Secretary a statement signed by the chief executive officer of such manufacturer or marketer, based on available information after a good faith inquiry, that—

''(i) the cosmetic and its ingredients meet the safety standard; or

''(ii) there is insufficient data to determine whether the cosmetic and its ingredients meet the safety standard.

''(B) UPDATES.—Each manufacturer or marketer of a cosmetic shall update the statement under subparagraph (A) when there becomes available significant new information regarding the safety, or lack thereof, of a cosmetic or its ingredients.

''(4) AUDIT.—The Secretary shall perform an annual comprehensive data audit on a statistically significant number of the statements submitted by manufacturers or marketers under paragraph (3).

''(d) NANOMATERIALS IN COSMETICS.—The Secretary shall—

''(1) monitor developments in the scientific understanding of any adverse health effects related to the use of nanotechnology in the formulation of cosmetics; and

''(2) consider scale specific hazard properties of ingredients when conducting or reviewing safety substantiation of cosmetic ingredients.

''(e) PRODUCT TESTING AND REVIEW AUDIT.—The Secretary shall conduct annual audits of random samples of cosmetic products to assess or test for acute negative reactions, pathogen hazards, contaminants, or leaching of packaging additives, mislabeling, or other relevant issues of concern (as determined by the Secretary).

''SEC. 615. MARKET RESTRICTIONS.

''(a) FAILURE TO PROVIDE DATA OR MEET SAFETY STANDARD.—No person shall manufacture, import, distribute, or market in commerce a cosmetic or an ingredient for use in a cosmetic if the Secretary determines that—

''(1) the person failed to provide information to the Secretary as required under this subchapter; or

''(2) beginning 180 days after the date on which the Secretary places an ingredient on a list under section 614(b)(1)—

''(A) the ingredient—

"(i) is on the list under section 614(b)(1)(A)(i); or

"(ii) is a cosmetic containing an ingredient on such list;

"(B) the ingredient is on the list under section 614(b)(1)(A)(ii) and is being used in a cosmetic in a manner that violates the limit on use or concentration of such ingredient under section 614(b)(1)(E).

"(b) FAILURE OF SECRETARY TO ACT.—

"(1) ISSUANCE OF PENDING NOTIFICATION.—If the Secretary fails to act by an applicable deadline under section 614, a manufacturer or marketer of an ingredient affected by the failure to act shall issue to the Secretary, the public, and each known customer of the ingredient a written notice that a determination by the Secretary of the safety of the ingredient for use in cosmetics is pending.

"(2) PROHIBITED USE.—If, by the last day of the 5 year period beginning on the date on which an ingredient is placed on the priority assessment list under section 614(b)(3), the Secretary has not made a determination under such section concerning whether such ingredient meets the safety standard, the ingredient may not be—

"(A) used in cosmetics; or

"(B) manufactured, imported, distributed, or marketed for use in cosmetics.

"SEC. 616. NOTIFICATION, NONDISTRIBUTION, AND RECALL OF ADULTERATED OR MISBRANDED COSMETICS.

"(a) NOTIFICATION, NONDISTRIBUTION, AND RECALL OF ADULTERATED OR MISBRANDED COSMETICS.—

"(1) IN GENERAL.—A responsible party that has reason to believe that a cosmetic, when introduced into or while in interstate commerce, or while held for sale (regardless of whether such sale is the first sale of such cosmetic) after shipment in interstate commerce, is adulterated or misbranded in a manner that presents a reasonable probability that the use or exposure to the cosmetic (or an ingredient or component used in any such cosmetic) will cause a threat of serious adverse health consequences or death to humans shall, as soon as practicable, notify the Secretary of the identity and location of the cosmetic.

"(2) MANNER OF NOTIFICATION.—Notification under paragraph (1) shall be made in such manner and by such means as the Secretary may require by regulation or guidance.

''(3) RESPONSIBLE PARTY DEFINED.—For purposes of this subsection, the term 'responsible party' means a manufacturer, packager, retailer, or distributor of the cosmetic.

''(b) VOLUNTARY RECALL.—The Secretary may request that any person who distributes a cosmetic that the Secretary has reason to believe is adulterated, misbranded, or otherwise in violation of this Act voluntarily—

''(1) recall such cosmetic; and

''(2) provide for notice, including to individuals as appropriate, to persons who may be affected by the recall.

''(c) ORDER TO CEASE DISTRIBUTION.—

''(1) IN GENERAL.—If the Secretary has reason to believe that—

''(A) the use of, or exposure to, a cosmetic may cause serious adverse health consequences or death to humans;

''(B) the cosmetic is misbranded; or

''(C) the cosmetic is manufactured, packaged, or distributed by an unregistered facility;

the Secretary shall have the authority to issue an order requiring any person who distributes such cosmetic to immediately cease distribution of such cosmetic.

''(2) ACTION FOLLOWING ORDER.—Any person who is subject to an order under paragraph (1) shall immediately cease distribution of such cosmetic and provide notification as required by such order, and may appeal such order to the Secretary within 24 hours of the issuance of such order. Such appeal may include a request for an informal hearing and a description of any efforts to recall such cosmetic undertaken voluntarily by the person, including after a request under subsection (b). Except as provided in subsection (e), an informal hearing shall be held as soon as practicable, but not later than 5 calendar days, or less as determined by the Secretary, after such an appeal is filed, unless the parties jointly agree to an extension. After affording an opportunity for an informal hearing, the Secretary shall determine whether the order should be amended to require a recall of such cosmetic. If, after providing an opportunity for such a hearing, the Secretary determines that inadequate grounds exist to support the actions required by the order, the Secretary shall vacate the order.

''(d) ORDER TO RECALL.—

''(1) AMENDMENT.—Except as provided under subsection (e), if after providing an opportunity for

an informal hearing under subsection (c)(2), the Secretary determines that the order should be amended to include a recall of the cosmetic with respect to which the order was issued, the Secretary shall amend the order to require a recall.

''(2) CONTENTS.—An amended order under paragraph (1) shall—

''(A) specify a timetable in which the recall will occur;

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

''(C) provide for notice, including to individuals as appropriate, to persons who may be affected by the recall.

In providing for such notice, the Secretary may allow for the assistance of health professionals, State or local officials, or other individuals designated by the Secretary.

''(3) NONDELEGATION.—An amended order under this subsection shall be ordered by the Secretary or an official designated by the Secretary. An official may not be so designated unless the official is the director of the district under this Act in which the cosmetic involved is located, or is an official senior to such director.

''(e) EMERGENCY RECALL ORDER.—

''(1) IN GENERAL.—If the Secretary has credible evidence or information that a cosmetic subject to an order under subsection (c) presents an imminent threat of serious adverse health consequences or death to humans, the Secretary may issue an order requiring any person who distributes such cosmetic—

''(A) to immediately recall such cosmetic; and

''(B) to provide for notice, including to individuals as appropriate, to persons who may be affected by the recall.

''(2) ACTION FOLLOWING ORDER.—Any person who is subject to an emergency recall order under this subsection shall immediately recall such cosmetic and provide notification as required by such order, and may appeal within 24 hours after issuance such order to the Secretary. An informal hearing shall be held as soon as practicable but not later than 5 calendar days, or less as determined by the Secretary, after such an appeal is filed, unless the parties jointly agree to an extension. After affording an opportunity for an informal hearing, the Secretary shall determine whether the order should

be amended pursuant to subsection (d)(1). If, after providing an opportunity for such a hearing, the Secretary determines that inadequate grounds exist to support the actions required by the order, the Secretary shall vacate the order.

''(3) NONDELEGATION.—An order under this subsection shall be issued by the Commissioner of Food and Drugs, the Principal Deputy Commissioner, or the Associate Commissioner for Regulatory Affairs of the Food and Drug Administration.

''(f) NOTICE TO CONSUMERS AND HEALTH OFFICIALS.—The Secretary shall, as the Secretary determines to be necessary, provide notice of a recall order under this section to consumers to whom the cosmetic was, or may have been, distributed and to appropriate State and local health officials.

''(g) SAVINGS CLAUSE.—Nothing contained in this section shall be construed as limiting the authority of the Secretary to issue an order to cease distribution of, or to recall, a cosmetic under any other provision of this Act.

''SEC. 617. PETITIONS.

''(a) IN GENERAL.—The Secretary shall complete and publish a review, and, if appropriate, immediately revise related, relevant information, including ingredient lists, ingredient restrictions or prohibitions, or ingredient

or cosmetic safety determinations, not later than 180 days after the date on which the Secretary receives from any individual or entity a reasonable petition—

''(1) to prohibit or restrict an ingredient for use in cosmetics and list such ingredient on the list under section 614(b)(1);

''(2) to remove an ingredient from the list of ingredients that are safe without limits under section 614(b)(2); or

''(3) to add an ingredient to the priority assessment list under section 614(b)(3).

''(b) REASONABLE PETITION.—Not later than one year after the date of the enactment of this Act, the Secretary shall issue rules specifying the criteria which the Secretary will use to determine if a petition submitted under this section is a reasonable petition.

''SEC. 618. COSMETIC AND INGREDIENT STATEMENTS.

''(a) IN GENERAL.—Each establishment engaged in the manufacture of a cosmetic intended to be marketed in the United States shall submit electronically to the Secretary for each cosmetic manufactured in the establishment that is intended to be marketed in the United States a statement containing—

''(1) the registration number of the manufacturing establishment where the cosmetic is manufac-

tured or, if the same cosmetic is manufactured in more than 1 establishment, the registration number of each establishment where it is manufactured;

''(2) the registration number of the establishment responsible for distributing the cosmetic;

''(3) the brand name and the product name for the cosmetic;

''(4) the applicable use for the cosmetic;

''(5) the ingredient list as it appears on the cosmetic label or insert, including the particle size of any nanoscale cosmetic ingredients;

''(6) any warnings and directions for use from the cosmetic label or insert; and

''(7) the title and full contact information for the individual responsible for submitting and maintaining such statement.

''(b) NOTIFICATION OF CHANGES.—The establishment shall notify the Secretary in a timely manner of any change to the information required under subsection (a).

''(c) PROCEDURE.—Upon receipt of a completed statement described under subsection (a), the Secretary shall notify the establishment of the receipt of such statement and assign a cosmetic statement number.

''(d) LIST.—The Secretary shall compile and maintain an up-to-date list of cosmetics for which statements are submitted under this section.

''(e) LABELING OF NANOMATERIALS IN COSMETICS.—The Secretary may require that—

''(1) minerals and other particulate ingredients be labeled as 'nano-scale' on a cosmetic ingredient label or list if not less than 1 dimension is 100 nanometers or smaller for not less than 1 percent of the ingredient particles in the cosmetic; and

''(2) other ingredients in a cosmetic be designated with scale-specific information on a cosmetic ingredient label or list if such ingredients possess scale-specific hazard properties.

''(f) ACCESS TO SAFETY INFORMATION.—The cosmetic and ingredient statements collected under this section shall be added to the publicly accessible database created by the Secretary under section 614(a)(3).

''(g) EFFECTIVE DATES.—

''(1) IN GENERAL.—The provisions of this section shall take effect 1 year after the date of the enactment of the Safe Cosmetics Act of 2010.

''(2) APPLICATION TO NEW COSMETICS.—An establishment that begins to manufacture a cosmetic after the date of the enactment of the Safe Cos-

metics Act of 2010 shall comply with the requirements of subsections (a) and (b) not later than 6 months after beginning to manufacture such cosmetic.

"SEC. 619. MANDATORY REPORTING OF ADVERSE HEALTH EFFECTS.

''(a) SUBMISSION OF REPORT ON ADVERSE HEALTH EFFECTS.—The Secretary shall require that the manufacturer, packager, or distributer of a cosmetic whose name appears on the label of a cosmetic marketed in the United States submit to the Secretary a report containing information received concerning any serious adverse event associated with the use of the cosmetic.

''(b) TIMING OF REPORT.—A report under subsection (a) shall be submitted to the Secretary not later than 15 business days after information concerning the adverse event is received at the place of business of the manufacturer, packager, or distributer.

''(c) CONTENT OF REPORT.—A report under subsection (a) shall include the following information to the extent to which the manufacturer, packager, or distributer submitting the report has been able to verify the information:

''(1) An identifiable patient.

''(2) An identifiable report.

''(3) A suspect cosmetic.

''(4) A serious and unexpected adverse event.

''(d) PUBLIC AVAILABILITY AND PRIVACY.—

''(1) PUBLIC AVAILABILITY.—Subject to paragraph (2), the adverse health effects reports collected by the Secretary under this section shall be submitted electronically and shall be made accessible to the public.

''(2) PRIVACY.—

''(A) PERSONALLY IDENTIFIABLE INFORMATION.—Notwithstanding any other provision of law, personally identifiable information in adverse event reports provided to the Secretary under this section, shall not—

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

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

''(B) TREATMENT OF INFORMATION UNDER PRIVACY ACT AND FOIA.—An adverse event report submitted to the Secretary under this section, shall be considered to be 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.

''SEC. 620. NONCONFIDENTIAL INFORMATION.

''(a) IN GENERAL.—Subject to subsection (b) and section 619(d)(2), all nonconfidential information submitted pursuant to this subchapter shall be made available to the public. The name, identity, and structure of a chemical substance, contaminant, or impurity that is an ingredient and all information concerning function, exposure, health hazards, and environmental hazards, and the functions of ingredients in cosmetics shall not be considered to be confidential business information under this subchapter. Fragrance, flavor, and colorants shall not be considered confidential business information under this subchapter. The concentration of cosmetic ingredients used in a finished cosmetic shall be considered confidential business information except as otherwise required in section 613.

''(b) PETITION FOR INFORMATION TO REMAIN CONFIDENTIAL.—

''(1) IN GENERAL.—The Secretary shall create a process for an entity to petition for nonconfidential information described in subsection (a) to remain confidential if the entity shows that there would be serious commercial harm to such entity if such information were disclosed publicly.

''(2) LIMITATION.—The Secretary may not approve a petition under paragraph (1) to the extent that such petition would prevent the public disclosure of—

''(A) the name, identity, and structure of any substance referred to in subsection (a);

''(B) all health and safety data related to that substance; or

''(C) any data used to substantiate the safety of that substance.

''SEC. 621. SAVINGS CLAUSE.

''Nothing in this subchapter shall affect the right of a State, political subdivision of a State, or tribe to adopt or enforce any regulation, requirement, liability, or standard of performance that is more stringent than a regulation, requirement, liability, or standard of performance es-

tablished by this subchapter, including requiring the provision of a warning of risk, illness, or injury.

"SEC. 622. ANIMAL TESTING ALTERNATIVES.

"(a) IN GENERAL.—To minimize the use of animal testing of ingredients, the Secretary shall—

"(1) require, where practicable, alternative testing methods that—

"(A) do not involve the use of an animal to test the chemical substance;

"(B) provide information that is equivalent or superior in scientific quality to the animal testing method; and

"(C) use fewer animals than conventional animal-based tests when non-animal methods are impracticable, including the use of tests that combine multiple endpoints; and

"(2) encourage, where practicable—

"(A) estimation of toxicological properties of a chemical through the use of testing information for 1 or more structurally similar chemicals where such estimates provide information of sufficient scientific quality;

"(B) the formation of industry consortia to conduct testing to avoid duplication of tests; and

''(C) funding for research and validation of alternative test methods, in accordance with this subsection.

''(b) LIST OF ALTERNATIVE TESTING METHODS.—Not later than 1 year after the date of the enactment of the Safe Cosmetics Act of 2010, and triennially thereafter, the Secretary shall publish a list of the alternative testing methods described in subsection (a).

''SEC. 623. INTERAGENCY COOPERATION AND FUNDING.

''There is established an Interagency Council on Cosmetic Safety for the purpose of sharing data and promoting collaboration on cosmetic safety among and between the Food and Drug Administration, the National Institute of Environmental Health Sciences, the Centers for Disease Control and Prevention, the Occupational Safety and Health Administration, and the Environmental Protection Agency.

''SEC. 624. AUTHORIZATION OF APPROPRIATIONS.

''There are authorized to be appropriated such sums as may be necessary to carry out this subchapter for each of the fiscal years 2011 through 2015.''.

(b) ADULTERATED AND MISBRANDED COSMETICS.—

(1) ADULTERATED COSMETICS.—Section 601 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 361) is amended—

(A) in subsection (a), by striking ", except that this provision shall not apply to coal-tar hair dye" and all that follows through "or eyebrow dyes"; and

(B) by adding at the end the following:

"(f) If it—

"(1) was manufactured, packaged, or distributed by an entity that failed to register as required under section 612;

"(2) was sold by an Internet vendor that failed to comply with the requirements of section 613(b);

"(3) the person who manufactures, imports, distributes, or markets the cosmetic, or an ingredient in the cosmetic, fails to comply with the applicable requirements of section 615 (including failure to issue a notice required under section 615(b)(1));

"(4) is manufactured, packaged, distributed, or sold in retail by a manufacturer, packager, distributor, or retailer, respectively, who fails to notify the Secretary as required under section 616(a);

"(5) is distributed in violation of an order under section 616(c);

"(6) is not recalled as required by an order under subsection (d) or (e) of section 616;

''(7) is manufactured in a manner that fails to comply with good manufacturing practices for cosmetics, as determined (and periodically updated), by the Secretary; or

''(8) is manufactured by a manufacturer who fails to submit the statement required under section 618 or notify the Secretary of changes to information contained in such statement as required by such section.''.

(2) MISBRANDED COSMETICS.—Section 602 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 362) is amended in subsection (a), by inserting '', fails to meet the requirements of section 613(a), or fails to meet any requirements under section 618(e)'' before the period.

SEC. 3. WORKER ISSUES.

(a) IN GENERAL.—The Secretary of Labor shall promulgate an occupational safety and health standard under section 6 of the Occupational Safety and Health Act of 1970 (29 U.S.C. 655) that requires the following:

(1) MANUFACTURERS AND IMPORTERS.—

(A) IN GENERAL.—Each manufacturer or importer selling any cosmetic for professional use shall—

(i) obtain or develop an expanded material safety data sheet described in subsection (b) for each such cosmetic or personal care product that—

(I) the manufacturer or importer produces or imports; and

(II) includes a hazardous chemical, or product ingredient associated with any chemical hazard, that has been indicated by authoritative bodies or scientific studies to be linked to health hazards including mutation, reproductive or developmental toxicity, neurotoxicity, endocrine disruption, asthma, or other immunological toxicity; and

(ii) make the expanded material safety data sheet available to distributors and employers, including salon owners, in English and, upon request, in other languages, including Spanish and Vietnamese.

(B) PROFESSIONAL USE DEFINED.—In this paragraph, the term ''professional use'' has the meaning given such term in section 611 of the Federal Food, Drug, and Cosmetic Act.

(2) DISTRIBUTORS.—Each distributor of a cosmetic or personal care product for professional use shall distribute and provide expanded material safety data sheets described in subsection (b) in the same manner as a distributor of a chemical hazard is required to distribute and provide material safety data sheets under section 1910.1200(g) of title 29, Code of Federal Regulations, or any successor regulations.

(3) EMPLOYERS.—Each employer, including any operator of a salon, shall—

(A) have an expanded material safety data sheet in the workplace for each cosmetic or personal care product for professional use that is used in the course of the employer's business;

(B) make such expanded material safety data sheet available to all employees of the employer who are exposed or use the product to the same extent and in the same manner as material safety data sheets are required to be made available under section 1910.1200(g) of title 29, Code of Federal Regulations, or any successor regulations; and

(C) upon request, provide employees with translations of such expanded material safety

data sheet in other languages, including Spanish and Vietnamese.

(b) CONTENTS OF EXPANDED MATERIAL SAFETY DATA SHEET.—An expanded material safety data sheet for a cosmetic or personal care product for professional use described in this section shall—

(1) contain the information required in a material safety data sheet under section 1910.1200(g) of title 29, Code of Federal Regulations, or any successor regulations, for each hazardous chemical, or product ingredient associated with any chemical hazard, described in subsection (a)(1)(A)(i)(II); and

(2) include the following statement: ''This expanded material safety data sheet is also available in multiple languages by contacting the manufacturer, using the contact information provided on this sheet.''.

SEC. 4. FDA SAFETY STANDARD AS IT RELATES TO OTHER ADMINISTRATIVE AGENCIES.

(a) USE OF DATA FROM FEDERAL SOURCES.—The Secretary shall request and utilize ingredient toxicity, use, and exposure data from other Federal agencies as appropriate, to assist with developing the priority assessment list under section 614(b)(3) of the Federal Food, Drug,

and Cosmetic Act, and for reaching safety determinations under section 614(b)(3)(E) of such Act.

(b) USE OF OTHER FEDERAL STANDARDS.—If any Federal agency has promulgated a standard for an ingredient that satisfies the safety standard under section 611 of the Federal Food, Drug, and Cosmetic Act, the Secretary may adopt it for purposes of this Act or an amendment made by this Act.

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