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112TH CONGRESS
2D SESSION

H. R. 4395

To amend the Federal Food, Drug, and Cosmetic Act to establish new procedures and requirements for the registration of cosmetic product manufacturing establishments, the submission of cosmetic product and ingredient statements, and the reporting of serious and unexpected cosmetic product adverse events, and for other purposes.

IN THE HOUSE OF REPRESENTATIVES

APRIL 18, 2012

Mr. LANCE introduced the following bill; which was referred to the Committee on Energy and Commerce

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A BILL

To amend the Federal Food, Drug, and Cosmetic Act to establish new procedures and requirements for the registration of cosmetic product manufacturing establishments, the submission of cosmetic product and ingredient statements, and the reporting of serious and unexpected cosmetic product adverse events, 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 AND REFERENCES.

(a) SHORT TITLE.—This Act may be cited as the "Cosmetic Safety Amendments Act of 2012".

(b) REFERENCES TO THE FEDERAL FOOD, DRUG, AND COSMETIC ACT.—Except as otherwise specified, whenever in this Act an amendment is expressed in terms of an amendment to a section or other provision, the reference shall be considered to be made to a section or other provision of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.).

SEC. 2. TABLE OF CONTENTS.

SEC. 3. REGISTRATION OF COSMETIC MANUFACTURING ESTABLISHMENTS.

Chapter VI is amended by adding at the end the following:

"SEC. 604. REGISTRATION OF COSMETIC MANUFACTURING ESTABLISHMENTS.

"(a) IN GENERAL.—

"(1) The Secretary shall by regulation require that every domestic and foreign establishment en-

gaged in the manufacture of a cosmetic intended to be marketed in the United States be registered with the Secretary within 60 days after beginning such manufacture. If a cosmetic is processed in more than one establishment, registration shall be required only for the establishment that performs the final portion of the manufacturing operation. The registration shall state the name of the company or other organization, the city, street address, State, and country of the establishment, and the title, email address, and telephone number for the office within the establishment that is responsible for submitting and maintaining the registration.

''(2) The Secretary shall establish and provide to the registrant a unique cosmetic establishment registration number within 15 business days after receiving the registration. Where more than one person registers the same manufacturing establishment, the Secretary shall provide only one unique establishment registration number for the establishment.

''(b) MAINTENANCE.—The information required in a registration under subsection (a) or in an existing registration under subsection (e) shall be maintained as current and accurate by the registrant by withdrawing or

amending the registration within 60 days after the information becomes no longer current and accurate.

''(c) LIST.—The Secretary shall compile and maintain an up-to-date and publicly available electronic list of establishments that are registered under this section.

''(d) DEFINITIONS.—For purposes of this chapter the following definitions apply:

''(1) The term 'establishment' is a place of business where a cosmetic is manufactured, without further processing outside or within the United States.

''(2)(A) The term 'domestic establishment' means an establishment location in any State.

''(B) The term 'foreign establishment' means an establishment location outside the States from which a cosmetic is exported to the United States.

''(3) A cosmetic shall not be considered to have undergone further processing for purposes of paragraph (1) solely on the basis that packaging or other labeling was added or that any similar activity of a de minimis nature was carried out with respect to the cosmetic.

''(e) EXEMPTIONS.—Registration under subsection (a) shall not be required for any establishment that as of the date of enactment of this section is registered as a

cosmetic establishment under part 710 of title 21, Code of Federal Regulations.

''(f) SUSPENSION OF REGISTRATION.—

''(1) IN GENERAL.—The Secretary may suspend the registration of any facility under this section for a violation of this Act that presents a significant risk of serious adverse health consequences or death to humans.

''(2) NOTICE OF SUSPENSION.—Suspension of a registration under this section shall be preceded by—

''(A) notice to the establishment of the intent to suspend the registration; and

''(B) an opportunity for an informal hearing concerning the suspension.

''(3) REINSTATEMENT.—A registration that is suspended under this section may be reinstated by the Secretary.

''(4) PROCEDURES.—The Secretary shall by regulations establish procedures for the implementation of this subsection.

''(g) CANCELLATION OF REGISTRATION.—

''(1) IN GENERAL.—Not earlier than 10 days after providing notice under paragraph (2), the Secretary may cancel a registration under this section

if the Secretary determines that the registration was not updated in accordance with this section or otherwise is not current and accurate.

''(2) NOTICE OF CANCELLATION.—Cancellation shall be preceded by notice to the establishment of the intent to cancel the registration and the basis for such cancellation.

''(3) TIMELY UPDATE OR CORRECTION.—If the registration for the establishment is updated or corrected no later than 7 days after notice is provided under paragraph (2), the Secretary shall not cancel the registration.''.

SEC. 4. COSMETIC AND INGREDIENT STATEMENT.

Chapter VI, as amended by section 3, is amended by adding at the end the following:

''SEC. 605. COSMETIC AND INGREDIENT STATEMENT.

''(a) IN GENERAL.—The Secretary shall by regulation require that every domestic and foreign establishment engaged in the manufacture of a cosmetic intended to be marketed in the United States submit to the Secretary, for each cosmetic manufactured in the establishment, within 60 days after beginning manufacture of the product, a cosmetic and ingredient statement containing—

''(1) the unique establishment registration number of the manufacturing establishment where the

cosmetic is manufactured or, if the same cosmetic product is manufactured in more than one establishment, the unique establishment registration number of each establishment where it is manufactured;

''(2) the brand name or names for the cosmetic;

''(3) the applicable cosmetic category or categories for the cosmetic;

''(4) the ingredients in the cosmetic (in accordance with section 701.3 of title 21, Code of Federal Regulations, and using the name of each ingredient established under subsection (b), if any), in descending order of predominance by weight, except that—

''(A) flavors and fragrances may be designated as such; and

''(B) all variations in color, flavor, or fragrance may be included in one statement; and

''(5) the title, email address, and telephone number for the office within the establishment that is responsible for filing and maintaining the statement.

The Secretary shall establish and provide to the person submitting the statement a unique cosmetic and ingredient statement number within 15 business days after receiving the statement.

''(b) NAME OF INGREDIENT.—For purposes of this section and cosmetic ingredient labeling under section 701.3 of title 21, Code of Federal Regulations, the name of a cosmetic ingredient shall be the name, if any, in the most recent edition of the International Cosmetic Ingredient Dictionary, unless the Secretary, after public notice and an opportunity for public comment, by regulation or guidance establishes a different name for the ingredient.

''(c) MAINTENANCE.—The information required in a statement submitted to the Secretary under subsection (a) or in an existing statement under subsection (e)(1) shall be maintained as current and accurate by the person who filed the statement by withdrawing or amending the statement within 60 days after the information becomes no longer current and accurate, except that no amendment shall be required for a change in the order of predominance of the ingredients or for any other type or category of change for which the Secretary determines that the costs of amending the statement exceed the benefits.

''(d) LIST.—The Secretary shall compile and maintain an up-to-date and publicly available electronic list of cosmetics and ingredients for which statements are submitted under this section. A statement submitted pursuant to this section shall not be subject to disclosure under section 552 of title 5, United States Code. The Secretary may

make publicly available information derived from such statements that discloses the names of ingredients used in cosmetic products and the number of cosmetic products in which a specific ingredient is used but may not make publicly available any information that relates to any ingredient that is exempt from public disclosure under section 720.8 of title 21, Code of Federal Regulations, or that discloses at what establishment a cosmetic is manufactured. At the request of the director of a State agency responsible for regulating the safety of cosmetics, the Secretary may disclose to such official confidential business and trade secret information contained in a statement and such official and other State employees who have access to such information shall then be subject to the provisions of section 301(j), subsection 552(b) of title 5, United States Code, and section 1905 of title 18, United States Code, with respect to such information.

''(e) EXEMPTIONS.—Submission of a statement under subsection (a) shall not be required for—

''(1) a cosmetic for which as of the date of enactment of this section a cosmetic ingredient statement has been submitted to the Secretary under part 710 of title 21, Code of Federal Regulations; or

''(2) a cosmetic ingredient exempt from public disclosure under section 720.8 of title 21, Code of Federal Regulations.''.

SEC. 5. SERIOUS AND UNEXPECTED ADVERSE EVENT REPORTING FOR COSMETICS.

Chapter VI, as amended by sections 3 and 4, is amended by adding at the end the following:

''SEC. 606. SERIOUS AND UNEXPECTED ADVERSE EVENT REPORTING FOR COSMETICS.

''(a) IN GENERAL.—The Secretary shall by regulation require that a domestic or foreign manufacturer, packer, or distributor whose name appears on the label pursuant to section 602(b)(1) of a cosmetic marketed in the United States submit to the Secretary under subsection (b) a report containing information received concerning a serious and unexpected adverse event in the United States allegedly associated with the use of the product.

''(b) SUBMISSION OF REPORTS.—A serious and unexpected adverse event report shall be submitted to the Secretary no later than 15 business days after information concerning the adverse event is received at the place of business labeled on the product under section 602(b)(1).

''(c) CONTENTS.—No such report shall be submitted unless the person submitting the report has been able to verify—

''(1) an identifiable patient;

''(2) an identifiable reporter;

''(3) a suspect cosmetic product; and

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

The person submitting the report may include in the submission any additional pertinent information and may supplement the report with additional information at a later time.

''(d) DEFINITIONS.—

''(1) A 'serious' adverse event is one that—

''(A) results in—

''(i) death;

''(ii) a life-threatening experience;

''(iii) inpatient hospitalization;

''(iv) a persistent and significant disability or incapacity; or

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

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

''(2) An 'unexpected' adverse event is one that is not identified in the current labeling for the cosmetic.

''(e) RULES OF CONSTRUCTION.—

''(1) A serious and unexpected adverse event report (including all information submitted in the initial report or added later) submitted to the Secretary under subsection (a) is—

''(A) a safety report under section 756 that is subject to the provisions of that section;

''(B)(i) a record about an individual under section 552a of title 5, United States Code; and

''(ii) a medical or similar file the disclosure of which would constitute a violation of section 552(b)(6) of such title 5, and shall not be publicly disclosed.

''(2) The submission of a serious and unexpected adverse event report in compliance with subsection (a) shall not constitute an admission that the cosmetic involved caused or contributed to the adverse event.

''(f) The label of a cosmetic shall bear the domestic telephone number through which the person whose name and place of business appear on the label may receive a report of a serious and unexpected adverse event.''.

SEC. 6. GOOD MANUFACTURING PRACTICE FOR COSMETICS.

Chapter VI, as amended by sections 3, 4, and 5, is amended by adding at the end the following:

"SEC. 607. GOOD MANUFACTURING PRACTICES FOR COSMETICS.

''The Secretary shall, after public notice and an opportunity for public comment, by regulation establish good manufacturing practices for the methods used in, or the facilities or controls used for, the manufacture, processing, filling, or packaging of cosmetics. In issuing such regulations or guidance, the Secretary shall review international standards for cosmetic good manufacturing practices to ensure that such regulations or guidance are consistent, to the extent the Secretary determines practicable and appropriate, with such standards.''.

SEC. 7. TOLERANCES FOR NONFUNCTIONAL CONSTITUENTS IN COSMETICS.

Chapter VI, as amended by sections 3, 4, 5, and 6, is amended by adding at the end the following:

"SEC. 608. TOLERANCES FOR NONFUNCTIONAL CONSTITUENTS IN COSMETICS.

''(a) IN GENERAL.—The Secretary may on the Secretary's own initiative, and shall in response to a petition submitted by an interested person, including a State, under subsection (b) or in accordance with the provisions

under subsection (c), after public notice and an opportunity for public comment, establish by regulation or guidance a tolerance level for a nonfunctional constituent in cosmetics. For purposes of this section, a 'nonfunctional constituent' in a cosmetic is any substance that is an ancillary part of an ingredient or the manufacturing process, has not been added as a separate substance, and serves no cosmetic function in the cosmetic. The Secretary shall establish such a tolerance at a level that is necessary for the protection of the public health using generally recognized principles of scientific risk assessment. In issuing such a regulation or guidance, the Secretary shall take into consideration the level that is reasonably achievable through good manufacturing practices and shall review tolerance levels for such nonfunctional constituent established by authoritative scientific or regulatory organizations to ensure that such regulation or guidance is consistent, to the extent the Secretary determines practicable and appropriate, with such other tolerance levels.

''(b) PROCEDURE.—

''(1)(A)(i) If the review of a nonfunctional constituent is being conducted on the Secretary's own initiative or under subsection (c), the Secretary shall initiate the proceeding by publishing in the Federal Register a proposed regulation or guidance. The

Secretary shall provide 180 days for public comment.

''(ii) Not later than 180 days after the end of the period for public comment, the Secretary shall publish in the Federal Register a final regulation or guidance.

''(B)(i) If the review of a nonfunctional constituent is being conducted in response to a petition submitted by an interested person, the Secretary shall publish the petition in the Federal Register for public comment not later than 60 days after receipt of the petition. All appendices to the petition shall be made available on the Secretary's website. The Secretary shall provide 180 days for public comment.

''(ii) Any such petition shall specify the nonfunctional constituent, the proposed tolerance level, and the scientific data and information on which the proposed tolerance level is based.

''(iii) Not later than 180 days after the end of the period for public comment, the Secretary shall publish in the Federal Register a proposed regulation or guidance for public comment. The Secretary shall provide 90 days for public comment.

''(iv) Not later than 90 days after the end of the period for public comment, the Secretary shall publish in the Federal Register a final regulation or guidance.

''(C) The Secretary may on the Secretary's own initiative, and shall in response to a petition submitted by an interested person, reconsider any tolerance level established under subparagraph (A) or (B), using the same procedure established in this paragraph (1).

''(D) Any regulation or guidance, including any revised regulation or guidance, shall apply to cosmetics first shipped in interstate commerce beginning two years after the date of issue of the regulation or guidance, unless the Secretary determines, after public notice and an opportunity for public comment, that an earlier effective date is required to prevent serious adverse health consequences or death.

''(2) The failure of the Secretary to comply with any applicable time period requirement under paragraph (1) shall constitute final agency action for purposes of judicial review. If the court conducting such review determines that the Secretary has failed to comply with the requirement, the court shall

order the Secretary to comply within a time period determined by the court to be appropriate, but in no event later than 90 days following the court's order.

''(c) PRIORITY LIST.—Within 180 days after the date of enactment, the Secretary shall establish a publicly available electronic priority list of nonfunctional constituents in cosmetics for review under this section. The Secretary shall begin and complete a review of at least one such priority nonfunctional constituent every 365 days.

''(d) APPLICATION.—A tolerance level established by the Secretary under this section shall apply in every State.''.

SEC. 8. COSMETIC INGREDIENT REVIEW.

Chapter VI, as amended by sections 3, 4, 5, 6, and 7, is amended by adding at the end the following:

''SEC. 609. COSMETIC INGREDIENT REVIEW.

''(a) PANEL'S RECOMMENDATION.—The Cosmetic Ingredient Review Expert Panel determination in an approved final report that a cosmetic ingredient—

''(1) is safe for use in cosmetic products without the need for specified conditions of use;

''(2) is safe for use in cosmetic products under specified conditions for use;

''(3) is not safe for use in a cosmetic product under any conditions of use;

''(4) requires more information in order to make a determination whether the ingredient is safe for use in a cosmetic product under any conditions of use; or

''(5) is the subject of any other type of determination by the Cosmetic Ingredient Review Expert Panel, shall be deemed to constitute a recommendation that the Secretary accept that determination for purposes of implementing and enforcing this chapter in accordance with the effective dates established under subsection (d).

''(b) SECRETARY'S DETERMINATION.—The Secretary shall be deemed to accept that determination and recommendation unless the Secretary at any time determines, by regulation or guidance, after public notice and an opportunity for public comment, to make a different determination. A determination and recommendation described in subsection (a) that is deemed to be accepted by the Secretary shall be implemented and enforced by the Secretary by banning any use of any ingredient that does not conform to the specified safe conditions of use under subsection (a)(2) and any ingredient described under subsection (a)(3) or (4).

''(c) PROPRIETARY DATA.—The determination described in subsection (a)(4) shall not apply to a person

using the ingredient who has adequate safety substantiation and provides that substantiation to the Secretary as confidential business or trade secret information that shall not be publicly disclosed under section 301(j) of this Act or sections 552(b)(4) of title 5 or 1905 of title 18, United States Code.

''(d) EFFECTIVE DATES.—Subsection (b) shall be effective—

''(1) three years after the date of enactment for ingredients that are the subject of an approved final report as of the date of enactment of this subsection; and

''(2) two years after the date of approval of the final report for ingredients that are the subject of an approved final report after the date of enactment of this subsection.

''(e) SECRETARY'S REPRESENTATIVE.—The Secretary shall appoint a representative who shall be a member of and shall participate in the deliberations of the Cosmetic Ingredient Review Expert Panel.

''(f) APPLICATION.—A safety determination accepted or made by the Secretary under this section shall apply in every State.''.

SEC. 9. COSMETIC INGREDIENT SAFETY.

Chapter VI, as amended by sections 3, 4, 5, 6, 7, and 8, is amended by adding at the end the following:

"SEC. 610. COSMETIC INGREDIENT SAFETY.

''(a) IN GENERAL.—

''(1) The Secretary may on the Secretary's own initiative, and shall in response to a petition submitted by an interested person, including a State, under subsection (b) or in accordance with the provisions under subsection (c), evaluate the safety of any ingredient intended for use as or in a cosmetic product and, after public notice and an opportunity for public comment, establish by regulation or guidance the conditions, if any, under which the ingredient is safe for human use.

''(2) In evaluating the safety of any such ingredient, the Secretary shall apply generally recognized principles of scientific risk assessment and shall take into account—

''(A) the conditions of use recommended or suggested in the labeling;

''(B) any relevant safety evaluation conducted by the Cosmetic Ingredient Review Expert Panel; and

"(C) all relevant unpublished and published safety data and information, including human exposure during marketing.

The Secretary shall determine the conditions for the use of the ingredient that are necessary for safe use, or that the ingredient is safe for use without the need for specified conditions of use, or that there are no conditions under which the ingredient can be safely used.

"(b) PROCEDURE.—

"(1)(A)(i) If the review of an ingredient is being conducted on the Secretary's own initiative or under subsection (c), the Secretary shall initiate the proceeding by publishing in the Federal Register a proposed regulation or guidance. The Secretary shall provide 180 days for public comment.

"(ii) Not later than 180 days after the end of the period for public comment, the Secretary shall publish in the Federal Register a final regulation or guidance.

"(B)(i) If the review of an ingredient is being conducted in response to a petition submitted by an interested person, the Secretary shall publish the petition in the Federal Register for public comment not later than 60 days after receipt of the petition.

All appendices to the petition shall be made available on the Secretary's website. The Secretary shall provide 180 days for public comment.

''(ii) Any such petition shall specify the ingredient, the uses for which the ingredient is intended, any proposed conditions of safe use, and the scientific data and information, including human exposure during marketing, on which the proposed conditions are based.

''(iii) Not later than 180 days after the end of the period for public comment, the Secretary shall publish in the Federal Register a proposed regulation or guidance for public comment. The Secretary shall provide 90 days for public comment.

''(iv) Not later than 90 days after the end of the period for public comment, the Secretary shall publish in the Federal Register a final regulation or guidance.

''(C) The Secretary may on the Secretary's own initiative, and shall in response to a petition submitted by an interested person, reconsider any conditions for safe use established under subparagraph (A) or (B), using the same procedure established in this paragraph (1).

''(D) Any regulation or guidance, including any revised regulation or guidance, shall apply to cosmetics first shipped in interstate commerce beginning two years after the date of issuance of the regulation or guidance, unless the Secretary determines, after public notice and an opportunity for public comment, that an earlier effective date is required to prevent serious adverse health consequences or death.

''(2) The failure of the Secretary to comply with any applicable time period requirement under paragraph (1) shall constitute final agency action for purposes of judicial review. If the court conducting such review determines that the Secretary has failed to comply with the requirement, the court shall order the Secretary to comply within a time period determined by the court to be appropriate, but in no event later than 90 days following the court's order.

''(c) PRIORITY LIST.—Within 180 days after the date of enactment, the Secretary shall establish a publicly available electronic priority list of cosmetic ingredients. The Secretary shall begin and complete a review of at least one such priority cosmetic ingredient every 365 days.

''(d) APPLICATION.—A safety determination accepted or made by the Secretary under this section shall apply in every State.''.

SEC. 10. NATIONAL COSMETIC REGULATORY DATABANK.

Chapter VI, as amended by sections 3, 4, 5, 6, 7, 8, and 9, is amended by adding at the end the following:

''SEC. 613. NATIONAL COSMETIC REGULATORY DATABANK.

''In order to consolidate all information pertaining to regulation of the safety of cosmetics in one place for use by State officials responsible for the regulation of cosmetics and by the general public, the Secretary shall establish and maintain in the Center for Food Safety and Applied Nutrition (or any successor organization of such Center) of the Food and Drug Administration an electronic National Cosmetic Regulatory Databank that shall contain the information submitted to the Secretary under sections 604, 605, and 606, and such other information pertaining to the regulation of cosmetics as the Secretary shall deem appropriate. Information in the National Cosmetic Regulatory Databank that is not subject to public disclosure under section 552 of title 5, United States Code, may be disclosed on request to the director of a State agency responsible for regulating the safety of cosmetics, and such official and other State employees who have access to such information shall then be subject to

the provisions of section 301(j), subsection 552(b) of title 5, United States Code, and section 1905 of title 18, United States Code, with respect to such information. Information available in the National Cosmetic Regulatory Databank shall not be subject to State laws on submission of that information, whether in the same or a different format.''.

SEC. 11. COSMETIC RECORDS INSPECTION.

Chapter VI, as amended by sections 3, 4, 5, 6, 7, 8, 9, and 10, is amended by adding at the end the following:

''SEC. 614. COSMETIC RECORDS INSPECTION.

''If the Secretary has a reasonable belief that a cosmetic product, and any other related cosmetic product that the Secretary reasonably believes is affected in the same manner, is adulterated and presents a threat of serious adverse health consequences or death to humans, each person who manufactures, processes, packs, distributes, receives, holds, or imports such article 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 setting forth the basis for the Secretary's belief, at reasonable times and within reasonable limits and in a reasonable manner, to have access to and copy records 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. The Secretary shall prevent the disclosure of trade secret or confidential information obtained by the Secretary pursuant to this section. This section does not extend to cosmetic product formulas, financial data, pricing data, personnel data, research data, or sales data other than shipment data.''.

SEC. 12. RULES OF CONSTRUCTION.

Chapter VI, as amended by sections 3, 4, 5, 6, 7, 8, 9, 10, and 11, is amended by adding at the end the following:

''SEC. 615. RULES OF CONSTRUCTION.

''(a) COSMETIC PRODUCTS.—Whenever the term cosmetic or cosmetics is used in sections 604, 605, 606, or 607, it shall be deemed to refer only to a cosmetic product or cosmetic products. A cosmetic product that is subject to the caution legend in section 601(a) shall not be subject to the provisions of sections 608, 609, or 610.

''(b) CONTRACTORS.—A requirement for registration of a cosmetic establishment under section 604, submission of a cosmetic and ingredient statement under section 605, or submission of a serious and unexpected adverse event report for a cosmetic under section 606, may be satisfied

by a person who contracts to perform that function for the person who is required to register or make the submission.

''(c) EXEMPTIONS.—The Secretary may, in the Secretary's discretion, establish exemptions from the requirements in this title for the efficient and cost-effective implementation of these provisions.

''(d) SAFETY.—For purposes of chapter VI, a cosmetic shall be deemed to be safe if it does not present a risk of significant illness or injury to humans under the conditions of use recommended or suggested in the labeling.''.

SEC. 13. CONFORMING AMENDMENTS.

(a) Section 301 is amended by adding at the end the following:

''(aaa) The failure to register a cosmetic establishment required to be registered under section 604 or to maintain the registration current and accurate.

''(bbb) The failure to submit a cosmetic and ingredient statement required under section 605 or to maintain the statement current and accurate.

"(ccc) The failure to submit a serious and unexpected adverse event report or to include on a label the domestic telephone number through which a report of a serious and unexpected adverse event may be received, as required under section 606.

"(ddd) The failure to comply with cosmetic good manufacturing practices established under section 607.

"(eee) The failure to comply with a tolerance for a nonfunctional constituent in cosmetics established under section 608.

"(fff) The failure to comply with a determination with respect to the safety of a cosmetic ingredient under section 609 or section 610.

"(ggg) For a cosmetic product that is being imported or offered for import, the failure of the importer to present both the

unique cosmetic establishment registration number established by the Secretary under section 604(a) and the unique cosmetic and ingredient statement number established by the Secretary under section 605(a).''.

(b) Section 301(j) is amended by inserting ''605, 609, 613,'' after ''573,''.

SEC. 14. NATIONAL UNIFORMITY FOR COSMETICS.

Section 752 is amended—

(1) by amending the section heading to read as follows: ''**NATIONAL UNIFORMITY FOR COSMETICS**'';

(2) in subsection (b), by inserting ''or (f)'' after ''subsection (a)''; and

(3) by adding at the end the following:

''(f) COSMETIC SAFETY.—

''(1) IN GENERAL.—Subject to paragraphs (2) and (3), no State or political subdivision of a State may establish or continue in effect any law, regulation, order, or other requirement relating to cosmetic constituents, cosmetic ingredients, or cosmetic products—

"(A) that is different from, in addition to, or otherwise not identical to, the provisions of chapter VI and the requirements and determinations established or accepted by the Secretary thereunder; or

"(B) relating to registration, listing, or fees for establishments, products, ingredients, or constituents, or to submission of reports.

"(2) STATE PETITIONS.—Not later than 180 days after the date of the enactment of this subsection, a State may petition the Secretary under section 609 or 610 to establish as a national standard a tolerance for a nonfunctional constituent or a safety requirement for a cosmetic ingredient that exists in a State law or a duly promulgated State regulation that is effective on the date of enactment of this subsection. Pending completion of the process established under section 608 or 610, the State requirement shall remain in effect for that State. Upon completion of the process established under section 608 or 610, the final regulation or guidance published by the Secretary in the Federal Register shall be the national safety standard for the constituent or ingredient.

''(3) REQUIREMENTS ADOPTED BY STATE PUBLIC INITIATIVE OR REFERENDUM.—This subsection shall not apply to a State requirement adopted by a State public initiative or referendum enacted prior to the enactment of this subsection.''.

SEC. 15. IMPORTATION.

Section 801(a) is amended by adding at the end the following:

''If a cosmetic product is being imported or offered for import into the United States and the importer does not present both the unique cosmetic establishment registration number established under section 604 and the unique cosmetic and ingredient statement number established under section 605, or the registration number or statement number is not correct and accurate, the cosmetic product shall be denied entry.''.

SEC. 16. AUTHORIZATION OF APPROPRIATIONS.

Chapter VI, as amended by sections 3, 4, 5, 6, 7, 8, 9, 10, 11, and 12, is amended by adding at the end the following:

''SEC. 616. AUTHORIZATION OF APPROPRIATIONS.

''To carry out this chapter and section 752, there is authorized to be appropriated $11,700,000 for each of fiscal years 2014 through 2018. The Secretary shall annually allocate for personnel and functions for the regulation

of cosmetics during the period of such fiscal years at least $11,700,000 out of the total funds appropriated for the Food and Drug Administration, 10 full-time equivalent personnel in the Office of Regulatory Affairs, and 1 full-time equivalent lawyer in the Office of Chief Counsel.''.

SEC. 17. EFFECTIVE DATES.

(a) Sections 3, 4, 5, 6, and 15 of this Act shall be effective on the later date of—

(1) one year after the Secretary of Health and Human Services promulgates final regulations or guidance implementing these sections; or

(2) one year after the Secretary of Health and Human Services publishes a notice in the Federal Register determining that an effective electronic system has been established and is operational for the submission of cosmetic manufacturing establishment registrations, cosmetic and ingredient filings, reports of serious and unexpected cosmetic adverse events, good manufacturing practices for cosmetics, and the National Cosmetic Regulatory Databank.

(b) The remaining sections of this Act shall be effective on the date of the enactment of this Act.

○