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115TH CONGRESS
1ST SESSION

H. R. 575

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

IN THE HOUSE OF REPRESENTATIVES

JANUARY 13, 2017

Mr. SESSIONS 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 manufacturing establishments, the submission of cosmetic and ingredient statements, and the reporting of serious cosmetic 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 Modernization Amendments of 2017".

(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.

The table of contents for this Act is as follows:

SEC. 3. DEFINITIONS.

Chapter VI (21 U.S.C. 361 et seq.) is amended by adding at the end the following:

"SEC. 604. DEFINITIONS.

''In this chapter:

''(1) COSMETIC.—Notwithstanding section 201(i), for purposes of this section and sections 601(f), 605, 606, 607, 608, and 801(a), the term

'cosmetic' includes only articles described in section 201(i)(1).

''(2) ESTABLISHMENT.—

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

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

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

''(D) The term 'foreign establishment' means an establishment location outside the United States.

''(3) SAFE; SAFETY.—

''(A) The terms 'safe' and 'safety', with respect to a cosmetic, mean the cosmetic does not present a significant risk of serious illness or injury to humans under the conditions of use recommended or suggested in the labeling of

the cosmetic, including the limitation of 'for professional use' only.

''(B) For purposes of subparagraph (A), the term 'professional' means an individual who—

''(i) is licensed by an official State authority to practice in the field of cosmetology, nail care, barbering, and or esthetics; and

''(ii) is in compliance with all requirements of the State for such licensing.''.

SEC. 4. REGISTRATION OF COSMETIC MANUFACTURING ESTABLISHMENTS.

Chapter VI (21 U.S.C. 361 et seq.), as amended by section 3, is further amended by adding at the end the following:

''SEC. 605. REGISTRATION OF COSMETIC MANUFACTURING ESTABLISHMENTS.

''(a) IN GENERAL.—

''(1) REGISTRATION.—The Secretary shall by regulation require that every domestic and foreign establishment engaged in the manufacture of a cosmetic intended to be sold in the United States that is not exempt under subsection (e) be registered with the Secretary within 60 business days after the first

commercial sale of a cosmetic in the United States. If a cosmetic is processed in more than one establishment, registration shall be required under this section only for the establishment that performs the final portion of the manufacturing operation. The single registration shall cover all such cosmetics manufactured by the establishment. The registration shall state only the name of the company or other organization name of the establishment, 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. For a foreign establishment, the registration shall include the contact information for the initial United States agent of the establishment.

''(2) UNIQUE NUMBER.—The Secretary shall establish and provide to each registrant under this section a unique cosmetic establishment registration number within 15 business days after receiving the registration. If the Secretary does not provide a unique cosmetic establishment registration number within such 15 business days, any requirement under this Act for such number shall be deemed to be inapplicable until 30 business days after such

number is received by the person who submitted the registration. Where more than one person registers the same establishment, the Secretary shall provide only one unique establishment registration number for the establishment. The unique cosmetic establishment number shall not be required to be included in cosmetic labeling.

''(b) MAINTENANCE.—The information required in a registration under subsection (a) or in an existing registration under subsection (e)(1)(A) shall be maintained as current and accurate by the registrant by withdrawing or amending the registration within 60 business days after the information becomes no longer current and accurate.

''(c) ENFORCEMENT.—The Secretary shall enforce this section under section 301(eee) and shall not suspend or revoke a registration under this section.

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

''(e) EXEMPTIONS.—

''(1) IN GENERAL.—Registration under subsection (a) shall not be required for any entity based on such entity operating as—

''(A) an 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 (as in effect on such date);

"(B) a beauty shop or salon or spa;

"(C) a cosmetic retailer, including any such retailer that is—

"(i) an individual sales representative;

"(ii) a wholesale or retail distribution or sales facility; or

"(iii) a pharmacy or other person or organization that—

"(I) compounds cosmetics at a single location and administers, dispenses, or distributes such cosmetics at retail from that location; and

"(II) does not otherwise manufacture or package cosmetics from that location;

"(D) a health care provider, including a hospital or clinic;

"(E) a public health agency or other nonprofit entity;

"(F) a hotel or other entity that provides complimentary cosmetics;

''(G) a trade show or other venue where cosmetic samples are provided;

''(H) an establishment that manufactures, prepares, compounds, or processes cosmetics for use in research, teaching, or chemical analysis or pilot plant production;

''(I) a handcrafted soap or cosmetic made in a home, a community facility, or a similar establishment; or

''(J) a business with less than $1,000,000 of annual net revenue from cosmetics.

''(2) ADDITIONAL EXEMPTIONS.—The Secretary may supplement the list of exemptions under paragraph (1) with additional exemptions for persons and activities where the cost of compliance exceeds the safety benefit to the public.''.

SEC. 5. COSMETIC AND INGREDIENT STATEMENT.

Chapter VI (21 U.S.C. 361 et seq.), as amended by sections 3 and 4, is further amended by adding at the end the following:

''SEC. 606. COSMETIC AND INGREDIENT STATEMENT.

''(a) IN GENERAL.—The Secretary shall by regulation require that every domestic establishment and foreign establishment engaged in the manufacture of a cosmetic intended to be sold in the United States submit to the

Secretary, for each cosmetic so manufactured in the establishment, except such cosmetics manufactured by entities exempted by section 605(e) from registration under section 605, within 60 business days after the first commercial sale of the cosmetic, a cosmetic and ingredient statement. The Secretary shall require the statement to contain only—

''(1) the unique establishment registration number of the manufacturing establishment where the cosmetic is manufactured or, if the same cosmetic 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 (as in effect on the date of enactment of the Cosmetic Modernization Amendments of 2017 and including any successor regulations), and using the name of each ingredient established under subsection (d), 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 submitting and maintaining the statement.

''(b) UNIQUE NUMBER.—The Secretary shall establish and provide to the office submitting a statement required by subsection (a) a unique cosmetic and ingredient statement number within 15 business days after receiving the statement. If the Secretary does not provide a unique cosmetic and ingredient statement number within such 15-business-day period, any requirement under this Act for such number shall be deemed to be inapplicable until the date that is 30 business days after such number is received by the office that submitted the statement. The unique cosmetic and ingredient statement number shall not be required to be included in cosmetic labeling.

''(c) CHANGE IN LABELING.—An establishment shall not be required to submit a new or revised statement under subsection (a) because of a change in labeling except to the extent necessary to maintain the accuracy of

the information included in a statement under subsection (a).

''(d) NAME OF INGREDIENT.—For purposes of this section and cosmetic ingredient labeling under section 701.3 of title 21, Code of Federal Regulations (as in effect on the date of enactment of the Cosmetic Modernization Amendments of 2017 and including any successor 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 by regulation establishes a different name for the ingredient.

''(e) MAINTENANCE.—The information required in a statement submitted to the Secretary under subsection (a) or in an existing statement under subsection (g)(1) shall be maintained as current and accurate by the office that filed the statement by withdrawing or amending the statement within 60 business 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 costs of amending the statement exceed the safety benefit to the public.

''(f) ENFORCEMENT.—The Secretary shall enforce subsections (a) and (e) under section 301(fff) and shall

not suspend or revoke a cosmetic and ingredient statement.

''(g) 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 cosmetics and the number of cosmetics 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 (as in effect on the date of enactment of the Cosmetic Modernization Amendments of 2017 and including any successor regulations), or that discloses at what establishment a cosmetic is manufactured. At the written request of the director of a State agency responsible for regulating the safety of cosmetics stating good cause therefor, 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) of this Act, section 552(b) of title 5, United States Code, and section 1905 of title 18, United States Code, with respect to such information.

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

''(1) for 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 (as in effect on the date of enactment of the Cosmetic Modernization Amendments of 2017);

''(2) for a cosmetic ingredient exempt from public disclosure under section 720.8 of title 21, Code of Federal Regulations (as in effect on the date of enactment of the Cosmetic Modernization Amendments of 2017 and including any successor regulations); or

''(3) by an entity to the extent such entity is exempted by section 605(e) from registration under section 605.''.

SEC. 6. SERIOUS AND UNEXPECTED ADVERSE EVENT REPORTING FOR COSMETICS.

(a) IN GENERAL.—Chapter VI (21 U.S.C. 361 et seq.), as amended by sections 3, 4, and 5, is further amended by adding at the end the following:

"SEC. 607. 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—

''(1) information received concerning any serious and unexpected adverse event in the United States allegedly associated with the use of the cosmetic for which it is reasonably likely that the adverse event was caused by the cosmetic when used as recommended or suggested in the labeling; and

''(2) a copy of the label for the cosmetic.

''(b) SUBMISSION OF REPORTS.—A report on an adverse event 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 labeled on the cosmetic pursuant to section 602(b)(1).

''(c) REQUIRED CONTENTS.—A report under subsection (a) shall include all of the following information:

''(1) An identifiable patient.

''(2) An identifiable reporter.

''(3) A suspect cosmetic or component thereof.

''(4) A serious adverse event.

''(d) ADDITIONAL CONTENTS; SUPPLEMENTAL REPORTING.—The person submitting a report under subsection (a) may—

''(1) include pertinent information in addition to the information listed in subsection (c); and

''(2) after submitting the initial report, supplement the report with additional information.

''(e) SPECIAL RULES.—

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

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

''(B) shall be considered to be a record about an individual under section 552a of title 5, United States Code, and a medical or similar file the disclosure of which would constitute a violation of section 552 of such title 5, and shall not be publicly disclosed unless all personally identifiable information is redacted.

''(2) NO TREATMENT AS ADMISSION.—The submission of a serious and unexpected adverse event report in compliance with subsection (a)—

''(A) shall not be construed as an admission that the cosmetic involved caused or contributed to the adverse event; and

''(B) may be accompanied by a statement that denies that the report constitutes an admission that the cosmetic involved caused or contributed to the adverse event.

''(3) INCLUSION OF STATEMENT IN PUBLIC DISCLOSURE.—In releasing any report under subsection (a) or portion thereof for public disclosure, the Secretary shall include any statement under paragraph (2)(B).

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

''(g) EXEMPTION.—The Secretary may, by regulation, establish an exemption to the requirements under subsections (b) and (d) if the Secretary determines that such exemption would have no adverse effect on public health.

''(h) DEFINITIONS.—In this section:

''(1) The term 'serious', with respect to an adverse event, means—

''(A) resulting in—

''(i) death;

''(ii) a life-threatening experience;

''(iii) inpatient hospitalization;

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

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

''(vi) permanent disfiguration; or

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

''(2) The term 'unexpected', with respect to an adverse event, means not identified on the cosmetic label.''.

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

''(g) If it is a cosmetic that is marketed in the United States, unless the label of such cosmetic includes a domestic address or domestic phone number through which a

report of a serious and unexpected adverse event (as such term is used in section 607) associated with the use of such cosmetic may be submitted to the person described in section 607(f).''.

SEC. 7. GOOD MANUFACTURING PRACTICE.

(a) PROHIBITION.—Section 601 (21 U.S.C. 361) is amended by adding at the end the following:

''(f) If it has been manufactured under conditions that do not satisfy the principles and standards for good manufacturing practice established under section 608 and as a result presents a significant risk of serious adverse health consequences or death to humans.''.

(b) PRINCIPLES AND STANDARDS.—Chapter VI (21 U.S.C. 361 et seq.), as amended by sections 3, 4, 5, and 6, is further amended by adding at the end the following:

''SEC. 608. GOOD MANUFACTURING PRACTICE.

''(a) IN GENERAL.—The Secretary may by regulation establish principles and standards for good manufacturing practice for the manufacture of cosmetics in accordance with paragraphs (a) and (d) of section 601.

''(b) NOTICE AND COMMENT.—A regulation under subsection (a) shall be promulgated only after providing notice and an opportunity for comment in accordance with chapter 5 of title 5, United States Code.

''(c) GOOD MANUFACTURING PRACTICES OF OTHER PARTIES.—A manufacturer shall not be responsible under section 601(f) or this section for the good manufacturing practice of its suppliers. A distributor shall not be responsible under section 601(f) or this section for the good manufacturing practice of its manufacturers.''.

SEC. 8. SAFETY SUBSTANTIATION FOR COSMETIC INGREDIENTS AND NONFUNCTIONAL CONSTITUENTS.

Chapter VI (21 U.S.C. 361 et seq.), as amended by sections 3, 4, 5, 6, and 7, is further amended by adding at the end the following:

''SEC. 609. COSMETIC INGREDIENTS AND NONFUNCTIONAL CONSTITUENTS THAT ARE SAFE FOR USE IN COSMETICS.

''(a) IN GENERAL.—A manufacturer or distributor of a cosmetic may rely on this section to substantiate the safety of such cosmetic.

''(b) SAFE INGREDIENTS.—Unless and until prohibited or limited by the Secretary by regulation, the following ingredients are deemed to be adequately substantiated for safe use in cosmetics subject to the requirements of good manufacturing practice:

''(1) Color additives approved by the Secretary for use in cosmetics, within any limits established in such approval.

''(2) Food additives approved by the Secretary for direct addition to food for human consumption, within any limits established in such approval.

''(3) Food ingredients that have been determined by the Secretary to be generally recognized as safe for direct addition to food for human consumption, within any limits established in such determination.

''(4) Food ingredients for which monographs have been included in the Food Chemicals Codex for direct addition to food for human consumption, within any limits established in such monographs.

''(5) Pharmaceutical excipients and inactive ingredients approved or permitted by the Secretary, listed on a Food and Drug Administration website for use in drugs for human consumption or for which monographs have been included in the Handbook of Pharmaceutical Excipients, within any limits established in such lists or monographs.

''(6) Cosmetic ingredients that have been reviewed for safety by a qualified nongovernmental or governmental expert scientific body, including the Cosmetic Ingredient Review Expert Panel, and that are the subject of a monograph published in a peer-

reviewed scientific journal, within any limits established in such monographs.

''(7) Fragrance ingredients that have been reviewed for safety by a qualified nongovernmental or governmental expert scientific body, including the Research Institute of Fragrance Materials Expert Panel, and that are the subject of a monograph published in a peer-reviewed scientific journal, within any limits established in such monographs.

''(8) Cosmetic ingredients approved or permitted for use in cosmetics by any of the countries listed in section 802(b)(1)(A) as having an adequate regulatory authority, within any limits established by such regulatory authority.

''(c) SAFE NONFUNCTIONAL CONSTITUENTS.—

''(1) DEFINITION.—A nonfunctional constituent in a cosmetic is any substance that—

''(A) has not been intentionally added as a separate substance; and

''(B) serves no technical or cosmetic function in the cosmetic.

''(2) ADEQUATE SUBSTANTIATION.—The following nonfunctional constituents are deemed to be adequately substantiated for safe use in cosmetics, subject to the requirements of good manufacturing

practice and any limits or bans established by the Secretary by regulation:

"(A) The levels approved or permitted for nonfunctional constituents by the Secretary for color additives for cosmetic use and for food additives and generally recognized as safe food ingredients for direct human consumption.

"(B) The levels approved or permitted for nonfunctional constituents by the Secretary for cosmetics and for food and food ingredients for direct human consumption in compliance policy guides, guidance, and website statements.

"(C) The levels approved or permitted for nonfunctional constituents by the Secretary or the United States Pharmacopeia for oral nonprescription drugs.

"(D) The levels approved or permitted for nonfunctional constituents by the Environmental Protection Agency for direct human consumption in drinking water.

"(E) The levels for nonfunctional constituents approved or permitted in cosmetics and human food and food ingredients by any of the countries listed in section 802(b)(1)(A) as having an adequate regulatory authority.

''(d) CENTER.—The Secretary shall establish a program within the center of the Food and Drug Administration with primary responsibility for regulating cosmetics to evaluate and make determinations, by regulation, on the safe use of cosmetics and ingredients and nonfunctional constituents thereof.

''(e) APPLICATION; PREEMPTION.—A safety determination accepted or made by the Secretary or established under this section shall apply in every State. No State may establish or enforce a safety determination for a cosmetic or an ingredient or nonfunctional constituent of a cosmetic.

''(f) EFFECTIVE DATE OF REGULATIONS.—Any regulation or guidance by the Secretary pursuant to this section concerning the safety of a cosmetic or an ingredient or nonfunctional constituent of a cosmetic shall apply beginning no earlier than the date that is 2 years after the date on which such regulation or guidance is issued as final, unless the Secretary determines, after public notice and an opportunity for public comment, that an earlier date of applicability is required to prevent serious adverse health consequences or death to humans.''.

SEC. 9. NATIONAL COSMETIC REGULATORY DATABANK.

Chapter VI (21 U.S.C. 361 et seq.), as amended by sections 3, 4, 5, 6, 7, and 8, is further amended by adding at the end the following:

"SEC. 610. NATIONAL COSMETIC REGULATORY DATABANK.

"(a) IN GENERAL.—For the purpose of consolidating information pertaining to the regulation of cosmetic safety, the Secretary shall establish and maintain in the center of the Food and Drug Administration with primary responsibility for regulating cosmetics a database, to be known as the National Cosmetic Regulatory Databank, containing—

"(1) the information submitted to the Secretary under sections 605, 606, 607, and 609; and

"(2) such other information pertaining to the regulation of cosmetics as the Secretary deems appropriate.

"(b) AVAILABILITY.—In the case of information in the National Cosmetic Regulatory Databank that is not subject to public disclosure under section 552 of title 5, United States Code, the Secretary may nonetheless disclose such information to the director of a State agency on written request by such director demonstrating good cause for the disclosure. A director receiving information pursuant to the preceding sentence shall agree to limit to the disclosure of such information by State officials and

employees to the same extent such disclosure is limited with respect to Federal officials and employees under section 301(j) of this Act, section 552(b) of title 5, United States Code, and section 1905 of title 18, United States Code, with respect to such information.

''(c) PREEMPTION.—No State or political subdivision thereof may require submission of information that is available in the National Cosmetic Regulatory Databank, whether in the same or a different format.''.

SEC. 10. SPECIAL RULES.

(a) CERTAIN RULES.—Chapter VI (21 U.S.C. 361 et seq.), as amended by sections 3, 4, 5, 6, 7, 8, and 9, is further amended by adding at the end the following:

''SEC. 611. SPECIAL RULES.

''(a) CONTRACTORS.—The person described in section 607(f) with respect to a cosmetic (referred to in this section as the 'responsible party') may, by agreement, authorize a manufacturer, distributor, or packer of the cosmetic or a third-party contractor to submit any required report of a serious and unexpected adverse event (as such term is used in section 607) so long as the responsible party directs to the manufacturer, distributor, packer, or third-party contractor all such adverse events associated with such cosmetic that are reported to the responsible

party through the address or telephone number described in section 607(f).

''(b) EXEMPTIONS.—The Secretary, on the Secretary's own initiative or in response to a petition, may establish exemptions from the requirements of sections 601(f), 605, 606, 607, and 608—

''(1) for the efficient and cost-effective implementation of such requirements; or

''(2) where the cost of compliance exceeds the safety benefit to the public.''.

(b) COSMETIC DEFINITION.—Section 201(i) (21 U.S.C. 321(i)) is amended by adding at the end the following: ''An article described in subparagraph (1) that is intended only for topical external use to alter the appearance by temporarily affecting the structure or any function of the human skin, and that is not the subject of an approved new drug application under section 505, shall, for purposes of this Act, be treated only as a cosmetic and not a drug.''.

(c) COLOR ADDITIVES.—Section 721(f) (21 U.S.C. 379e(f)) is amended—

(1) by striking ''(f) The Secretary shall'' and inserting ''(f)(1) The Secretary shall''; and

(2) by adding at the end the following:

''(2) A color additive, including mixtures thereof, intended for use in externally applied cosmetics and not in the area of the eye is exempt from the requirements of this section if it is generally recognized, among experts qualified by scientific training and experience to evaluate its safety, as having been shown through scientific procedures to be safe under the conditions of its intended use. Notwithstanding the preceding sentence, the Secretary may by regulation require certification of batches under subsection (c) for any such color additive.''.

SEC. 11. PROHIBITED ACTS.

(a) IN GENERAL.—Section 301 (21 U.S.C. 331) is amended by adding at the end the following:

''(eee) The failure to register a cosmetic establishment as required under section 605 or to maintain the registration current and accurate.

''(fff) The failure to submit a cosmetic and ingredient statement as required under section 606 or to maintain the statement current and accurate.

''(ggg) The failure to submit a serious and unexpected adverse event report, or to include on the label of a cosmetic the domestic telephone number, email address, or mailing address through which a report of a serious adverse event may be received, as required under section 607.''.

(b) INFORMATION SECURITY.—Section 301(j) (21 U.S.C. 331(j)) is amended by inserting ''605, 606, 609,'' after ''573,''.

SEC. 12. NATIONAL UNIFORMITY FOR COSMETICS.

Section 752 (21 U.S.C. 379s) is amended—

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

(2) by amending subsection (a) to read as follows:

''(a) IN GENERAL.—Except as provided in subsection (b) or (d) of this section, no State or political subdivision of a State may establish or continue in effect any requirement for labeling or packaging of a cosmetic.'';

(3) by amending subsection (c) to read as follows:

''(c) COSMETIC SAFETY.—No State or political subdivision of a State may establish or continue in effect any law, regulation, order, or other requirement—

''(1) relating directly or indirectly to, or relying upon, a human health or safety evaluation of a nonfunctional cosmetic constituent, cosmetic ingredient, or cosmetic (as defined in section 201(i)(1)), or relating in any way to the safety standard and the human health-based requirements, evaluations, and

determinations under chapter VI, the Poison Prevention Packaging Act of 1970, or the Fair Packaging and Labeling Act; or

''(2) relating directly or indirectly to registration or listing of cosmetic facilities, establishments, cosmetics, or cosmetic ingredients, reporting of any information relating to cosmetics including adverse event reporting, cosmetic manufacturing processes or standards including good manufacturing practice, cosmetic labels or labeling including any general or health related warnings or public statement, or the requirement of any fees on cosmetic establishments, cosmetics, ingredients, or nonfunctional constituents.''; and

(4) by repealing subsection (e).

SEC. 13. IMPORTATION.

Section 801(a) (21 U.S.C. 381(a)) is amended by adding at the end the following: ''If a cosmetic is being imported or offered for import into the United States and the importer does not present both the unique cosmetic establishment registration number required under section 605 for the establishment that performs the final portion of the manufacturing operation and the unique cosmetic and ingredient statement number required under section 606 for the cosmetic, or the registration or statement

number is not correct and accurate, the cosmetic shall be denied entry.''.

SEC. 14. EFFECTIVE DATES.

(a)(1) The amendments made by sections 4, 5, 6, and 13 of this Act apply beginning on the later date of—

(A) the date that is one year after the Secretary of Health and Human Services promulgates final regulations implementing such amendments; or

(B) the date that is 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 fully operational for—

(i) the submission of cosmetic manufacturing establishment registrations, cosmetic and ingredient statements, and reports of serious cosmetic adverse events; and

(ii) the National Cosmetic Regulatory Databank.

(2) Until the date applicable under paragraph (1), the voluntary establishment registration and voluntary ingredient listing programs established in parts 710 and 720 of title 21, Code of Federal Regulations (as in effect on the date of enactment of this Act), shall remain effective

and shall be fully implemented by the Secretary of Health and Human Services.

(b) The amendments made by sections 7 and 8 apply beginning on the date that is two years after the date of enactment of this Act.

(c) Notwithstanding subsections (a) and (b), the amendments made by sections 5 and 7 shall not apply with respect to a cosmetic manufacturer with less than $5,000,000 of annual net sales of cosmetics until the later of—

(1)(A) with respect to the amendment made by section 5, the date that is 36 months after the date otherwise applicable under subsection (a); and

(B) with respect to the amendments made by section 7, the date that is 36 months after the date otherwise applicable under subsection (b); and

(2) such later date as may be determined by the Secretary of Health and Human Services.

(d) Except as provided in subsections (a) through (c), this Act takes effect on the date of enactment of this Act.

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