I

112TH CONGRESS
2D SESSION

H. R. 4262

To amend the Federal Food, Drug, and Cosmetic Act to improve the safety of cosmetics.

IN THE HOUSE OF REPRESENTATIVES

MARCH 26, 2012

Mr. PALLONE (for himself and Mr. DINGELL) 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 improve the safety of cosmetics.

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

SECTION 1. SHORT TITLE; TABLE OF CONTENTS.

(a) SHORT TITLE.—This Act may be cited as the ''Cosmetics Safety Enhancement Act of 2012''.

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

SEC. 2. REGISTRATION OF COSMETIC FACILITIES; LISTING OF COSMETIC PRODUCTS; FEES.

(a) PROHIBITED ACT.—Section 301(dd) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 331(dd)) is amended by striking the period at the end and adding ", the failure to register in accordance with section 604(a), or the failure to list a cosmetic product in accordance with section 604(b)".

(b) ADULTERATION.—Section 601 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 361) is amended by adding at the end the following:

"(f) If it was manufactured, packed, or held in a facility that is not duly registered under section 604(a), or if it is a cosmetic product that is not listed in accordance with section 604(b).".

(c) ANNUAL REGISTRATION.—Chapter VI of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 361 et seq) is amended by adding at the end the following:

"SEC. 604. REGISTRATION OF COSMETIC FACILITIES AND COSMETIC PRODUCT LISTING.

"(a) REGISTRATION.—

"(1) IN GENERAL.—The Secretary shall by regulation require that any facility engaged in manufacturing, packing, or holding a cosmetic product or a

cosmetic formulation be registered annually with the Secretary. To be so registered, any such facility shall pay the registration fee required under section 744.

''(2) REGISTRATION.—

''(A) TIMING.—A registration under paragraph (1) shall be submitted to the Secretary not later than December 31 of each year.

''(B) FORMAT; CONTENTS.—Each registration under paragraph (1) shall be submitted using an electronic format, as specified in regulations or guidance issued by the Secretary, and shall include the following information:

''(i) The facility's name and full address, which address shall identify the precise physical location of the facility.

''(ii) The identity of the facility, including the unique facility identifier, if any, previously assigned by the Secretary to the facility under paragraph (3).

''(iii) All business trading names used by the facility.

''(iv) The product category or categories of each cosmetic product or cosmetic formulation manufactured, packed, or held at the facility.

''(v) The type of activity conducted at the facility (such as manufacturing, packing, or holding).

''(vi) The name, title, street address, telephone number, and, if available, the email address of the emergency contact for the facility.

''(vii) In the case of a foreign facility, the name, street address, telephone number, emergency contact information, and, if available, the email address of the United States agent for the facility.

''(viii) The name, title, street address, telephone number, and, if available, email address of the individual submitting the registration.

''(ix) Additional information pertaining to the facility or to the cosmetic products or cosmetic formulations manufactured, packed, or held at the facility, as the Secretary may require by regulation.

''(C) CHANGES TO INFORMATION.—The registrant shall notify the Secretary of any change to the information described in clauses (i) through (ix) of subparagraph (B) not later

than 30 days after the date of such change unless otherwise specified by the Secretary.

''(3) PROCEDURE.—Upon receipt of a completed registration under paragraph (1), the Secretary shall notify the registrant of the receipt of such registration. At the time of the initial registration of any cosmetic facility under this section, the Secretary shall assign a unique facility identifier to the facility.

''(4) LIST.—

''(A) IN GENERAL.—The Secretary shall compile and maintain an up-to-date list of facilities that are registered under this section.

''(B) REMOVAL.—The Secretary shall—

''(i) remove from such list the name of any facility whose registration under this section is suspended or cancelled; and

''(ii) initiate proceedings in accordance with paragraph (6) to cancel the registration of any facility that—

''(I) fails to re-register under this section; or

''(II) fails to pay the registration fee required under section 744.

''(C) PUBLIC AVAILABILITY.—The list of registered facilities maintained pursuant to subparagraph (A) and any registration documents submitted pursuant to this subsection shall not be subject to disclosure under section 552 of title 5, United States Code. Information derived from such list or registration documents shall not be subject to disclosure under section 552 of title 5, United States Code, to the extent that such information discloses the identity or location of a specific registered facility.

''(5) SUSPENSION OF REGISTRATION.—

''(A) IN GENERAL.—The Secretary may suspend the registration of any facility under this section for a violation of this Act that could result in serious adverse health consequences or death to humans or animals.

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

''(i) notice, as defined in guidance or regulations issued by the Secretary, to the facility of the intent to suspend the registration; and

"(ii) an opportunity for an informal hearing concerning the suspension of the such registration for such facility.

"(C) REINSTATEMENT.—A registration that is suspended under this section may be reinstated pursuant to criteria published by the Secretary in the Federal Register and on a public Web site of the Food and Drug Administration.

"(6) CANCELLATION OF REGISTRATION.—

"(A) IN GENERAL.—Not earlier than 10 days after providing notice under subparagraph (B), the Secretary may cancel a registration under this section if the Secretary determines that—

"(i) the registration was not updated in accordance with this section or otherwise contains false, incomplete, or inaccurate information; or

"(ii) the required registration fee under section 744 has not been paid within 30 days after the date due.

"(B) NOTICE OF CANCELLATION.—Cancellation shall be preceded by notice to the facil-

ity of the intent to cancel the registration and the basis for such cancellation.

"(C) TIMELY UPDATE OR CORRECTION.—If the registration for the facility is updated or corrected and the required registration fee is paid no later than 7 days after notice is provided under subparagraph (B), the Secretary shall not cancel such registration.

"(b) COSMETIC PRODUCT LISTING.—

"(1) IN GENERAL.—Not later than March 31 of each year, every responsible person shall file with the Secretary a list, in such form as the Secretary may prescribe, of each cosmetic product owned by such person and distributed in the United States.

"(2) CONTENTS.—For each cosmetic product, the list required by paragraph (1) shall include the following information:

"(A) The unique facility identifier (assigned under subsection (a)(3)) of the facility where the cosmetic product is manufactured or packed, or, if the same cosmetic product is manufactured or packed in more than one facility, unique facility identifier of each facility where it is manufactured or packed.

''(B) The brand name and the full name for the cosmetic product as it appears on the label.

''(C) The cosmetic product listing number, if any, previously assigned by the Secretary under paragraph (4) to the cosmetic product.

''(D) The applicable cosmetic category for the cosmetic product.

''(E) The ingredients in the cosmetic product in descending order of predominance by weight, with each ingredient identified by the name adopted in regulations promulgated by the Secretary, if any, or by the common or usual name of the ingredient.

''(F) The title and full contact information of each individual submitting the list.

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

''(3) ADDITIONAL REQUIREMENTS.—

''(A) CERTIFICATION.—The filing for a cosmetic product under paragraph (1) shall include a certification, submitted by the responsible person, that such list includes all cosmetic products owned by such person.

''(B) CHANGES TO INFORMATION.—The responsible person shall notify the Secretary within 60 days of—

''(i) any change to the information required to be in such product list; or

''(ii) the discontinuation of the manufacture of a cosmetic product.

''(4) NOTIFICATION TO OWNER; ASSIGNMENT OF COSMETIC PRODUCT NUMBER.—Upon receipt of a list for a cosmetic product under paragraph (1), the Secretary shall—

''(A) notify the responsible person identified in such list that the list has been received; and

''(B) assign a cosmetic product number to any listed product not previously assigned a cosmetic product listing number.

''(5) UP-TO-DATE LIST.—The Secretary shall compile and maintain an up-to-date list of cosmetic products distributed in the United States, including the ingredients of each such product.

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

''(1) COSMETIC FORMULATION.—The term 'cosmetic formulation' means a preparation of cosmetic

raw materials with a qualitatively and quantitatively set composition.

''(2) COSMETIC PRODUCT.—The term 'cosmetic product' means a finished cosmetic that has undergone all stages of production, including packaging in its final container for shipment and application of a product label.

''(3) FACILITY.—

''(A)(i) The term 'facility' includes any factory, warehouse, or establishment facility (including a factory, warehouse, or establishment of an importer) that manufactures, packs, or holds cosmetic products or cosmetic formulations.

''(ii) Such term does not include—

''(I) beauty shops and salons;

''(II) pharmacies and other cosmetic product retailers, including individual sales representatives and retail distribution facilities;

''(III) hospitals, physicians' offices, and health care clinics;

''(IV) public health agencies and other nonprofit entities that provide cosmetics directly to the consumer;

''(V) hotels and other entities that provide complimentary cosmetics to guests;

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

''(VII) entities that manufacture or compound cosmetic products solely for use in research, teaching, or pilot plant production and not for sale.

''(B) The term 'domestic facility' means a facility located in any State.

''(C)(i) The term 'foreign facility' means a facility that manufactures, packs, or holds cosmetics that are exported to the United States without further processing or packaging outside the United States.

''(ii) A cosmetic may not be considered to have undergone further processing or packaging for purposes of clause (i) 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.

''(4) RESPONSIBLE PERSON.—The term 'responsible person' means a person (as defined in section 201(e)) that is the owner of a cosmetic product

intended for introduction into United States commerce.''.

(d) REGISTRATION FEE.—Chapter VII of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 371 et seq.) is amended by adding at the end of subchapter C the following:

''PART 7—FEES RELATING TO COSMETICS

''SEC. 744. FACILITY REGISTRATION FEE.

''(a) IN GENERAL.—

''(1) ASSESSMENT AND COLLECTION.—Beginning in fiscal year 2013, the Secretary shall assess and collect an annual fee for the registration of a facility under section 604(a).

''(2) PAYABLE DATE.—A fee under this section shall be payable—

''(A) for a facility that was not registered under section 604 for the preceding fiscal year, on the date of registration; and

''(B) for any other facility—

''(i) for fiscal year 2013, not later than the sooner of—

''(I) 90 days after the date of the enactment of this part; or

''(II) the date of re-registration; and

''(ii) for a subsequent fiscal year, on the date of re-registration.

''(b) FEE AMOUNTS.—

''(1) IN GENERAL.—The registration fee under subsection (a) shall be—

''(A) for fiscal year 2013, $500; and

''(B) for fiscal year 2014 and each subsequent fiscal year, the fee for fiscal year 2013 as adjusted under subsection (c).

''(2) ANNUAL FEE SETTING.—The Secretary shall, not later than 60 days before the start of fiscal year 2014 and each subsequent fiscal year, establish, for the next fiscal year, registration fees under subsection (a), as described in paragraph (1).

''(c) INFLATION ADJUSTMENT.—For fiscal year 2014 and subsequent fiscal years, the revenues established in subsection (b) shall be adjusted by the Secretary by notice, published in the Federal Register, for a fiscal year to reflect the sum of one plus—

''(1) the average annual change in the cost, per full-time equivalent position of the Food and Drug Administration, of all personnel compensation and benefits paid with respect to such positions for the first 3 years of the preceding 4 fiscal years multiplied by the proportion of personnel compensation

and benefits costs to total costs of cosmetic safety activities for the first 3 years of the preceding 4 years; and

''(2) the average annual change that occurred in the Consumer Price Index for urban consumers (Washington-Baltimore, DC–MD–VA–WV; Not Seasonally Adjusted; All items; Annual Index) for the first 3 years of the preceding 4 years of available data multiplied by the proportion of all costs other than personnel compensation and benefits costs to total costs of cosmetic safety activities for the first 3 years of the preceding 4 fiscal years.

The adjustment made each fiscal year under this subsection will be added on a compounded basis to the sum of all adjustments made each fiscal year after fiscal year 2013 under this subsection.

''(d) LIMITATIONS.—

''(1) IN GENERAL.—Fees under subsection (a) shall be refunded for a fiscal year beginning after fiscal year 2013 unless appropriations for salaries and expenses of the cosmetic products programs of the Food and Drug Administration for such fiscal year (excluding the amount of fees appropriated for such fiscal year) are equal to or greater than the amount of appropriations for the salaries and ex-

penses of the cosmetic products programs of the Food and Drug Administration for fiscal year 2012 (excluding the amount of fees appropriated for such fiscal year) multiplied by the adjustment factor applicable to the fiscal year involved.

''(2) AUTHORITY.—If the Secretary does not assess fees under subsection (a) during any portion of a fiscal year because of paragraph (1) and if at a later date in such fiscal year the Secretary may assess such fees, the Secretary may assess and collect such fees, without any modification in the rate, for registration under section 604 at any time in such fiscal year.

''(3) ADJUSTMENT FACTOR.—In this subsection, the term 'adjustment factor' applicable to a fiscal year is the Consumer Price Index for all urban consumers (all items; United States city average) for October of the preceding fiscal year divided by such Index for October 2011.

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

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

sums as may be necessary may be transferred from the Food and Drug Administration salaries and expenses appropriation account without fiscal year limitation to such appropriation account for salaries and expenses with such fiscal year limitation.

''(2) COLLECTIONS AND APPROPRIATIONS ACTS.—The fees authorized by this section—

''(A) shall be retained in each fiscal year in an amount not to exceed the amount specified in appropriation Acts, or otherwise made available for obligation, for such fiscal year; and

''(B) shall only be collected and available to defray the costs of cosmetic safety activities.

''(3) AUTHORIZATION OF APPROPRIATIONS.—For each of fiscal years 2013 through 2017, there are authorized to be appropriated for fees under this section such sums as may be necessary.

''(f) COLLECTION OF UNPAID FEES.—In any case where the Secretary does not receive payment of a fee assessed under subsection (a) within 30 days after it is due, such fee shall be treated as a claim of the United States Government subject to subchapter II of chapter 37 of title 31, United States Code.

''(g) CONSTRUCTION.—This section may not be construed to require that the number of full-time equivalent

positions in the Department of Health and Human Services, for officers, employees, and advisory committees not engaged in cosmetic safety activities, be reduced to offset the number of officers, employees, and advisory committees so engaged.

''(h) ANNUAL FISCAL REPORTS.—Beginning with fiscal year 2014, not later than 120 days after the end of each fiscal year for which fees are collected under this section, the Secretary shall prepare and submit to the Committee on Energy and Commerce of the House of Representatives and the Committee on Health, Education, Labor, and Pensions of the Senate a report on the implementation of the authority for such fees during such fiscal year and the use, by the Food and Drug Administration, of the fees collected for such fiscal year.

''(i) DEFINITIONS.—In this section:

''(1) The term 'costs of cosmetic safety activities' means the expenses incurred in connection with cosmetic safety activities for—

''(A) officers and employees of the Food and Drug Administration, contractors of the Food and Drug Administration, advisory committees, and costs related to such officers, employees, and committees and to contracts with such contractors;

''(B) laboratory capacity;

''(C) management of information, and the acquisition, maintenance, and repair of technology resources;

''(D) leasing, maintenance, renovation, and repair of facilities and acquisition, maintenance, and repair of fixtures, furniture, scientific equipment, and other necessary materials and supplies; and

''(E) collecting fees under this section and accounting for resources allocated for cosmetic safety activities.

''(2) The term 'cosmetic safety activities' means activities of the Food and Drug Administration related to ensuring the safety of cosmetics sold for use in the United States, as authorized by this Act.''.

(e) TRANSITIONAL PROVISIONS.—

(1) FEES.—The Secretary of Health and Human Services shall first impose the fee established under section 744 of the Federal Food, Drug, and Cosmetic Act, as added by subsection (d), for fiscal years beginning with fiscal year 2013.

(2) SUNSET DATE.—Section 744 of the Federal Food, Drug, and Cosmetic Act, as added by subsection (d), does not authorize the assessment or col-

lection of a fee for registration under section 604 of such Act occurring after fiscal year 2017.

SEC. 3. COSMETIC PRODUCT SAFETY SUBSTANTIATION.

(a) ADULTERATION.—Section 601 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 361), as amended by section 2(b), is further amended by adding at the end the following:

''(g) If it is a cosmetic product for which any requirement of section 605 (relating to safety substantiation) is not met.''.

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

''SEC. 605. COSMETIC PRODUCT SAFETY SUBSTANTIATION.

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

''(1) before introduction or delivery for introduction into interstate commerce of a cosmetic product, establish a file containing scientific evidence pertaining to such product's safety; and

''(2) maintain such file for no less than 5 years after the date on which such person ceases to introduce such article into interstate commerce.

''(b) SCIENTIFIC EVIDENCE.—The scientific evidence required by subsection (a)(1) shall—

''(1) consist of studies, tests, data, or other information known to the responsible person that relates to the cosmetic product's safety; and

''(2) demonstrate that such cosmetic product is safe.

''(c) REQUESTS BY SECRETARY; ACCESS TO RECORDS.—In response to a request by the Secretary, the responsible person shall promptly supply to the Secretary a copy of the file required under subsection (a). Such person shall also permit an officer or employee duly designated by the Secretary, upon presentation of appropriate credentials, to have access at reasonable times to records required to be maintained under this section for the purpose of inspection and copying.

''(d) DEFINITIONS.—For the purposes of this section:

''(1) The term 'cosmetic product' has the meaning given to such term in section 604(c).

''(2) The term 'safe', with respect to a cosmetic product, means that evidence in the file established under subsection (a)(1) demonstrates that there is a reasonable certainty that no harm will result from the use of the cosmetic product under the intended conditions of use for such cosmetic product.

''(3) The term 'responsible person' has the meaning given to such term in section 604(c).''.

SEC. 4. SERIOUS ADVERSE EVENT REPORTS FOR COSMETICS.

(a) PROHIBITED ACTS.—Section 301 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 331) is amended—

(1) in subsection (e)—

(A) by striking ''or 761'' and inserting ''761, or 606''; and

(B) by inserting ''606,'' before ''909,''; and

(2) in subsection (ii)—

(A) by striking ''760 or 761'' and inserting ''760, 761, or 606'';

(B) by striking ''or the'' and inserting '', the''; and

(C) by striking the period at the end and inserting '', or the falsification of a report submitted under section 606 to the Secretary.''.

(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:

''(f) If it is a cosmetic product that is marketed in the United States, unless the label of such cosmetic product includes a domestic address, including the street address or P.O. box, city, State, and zip code, or a domestic telephone number, including the area code, through which the responsible person (as described in section 606(a)(1))

may receive a report of a serious adverse event associated with the use of such cosmetic product.''.

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

''SEC. 606. SERIOUS ADVERSE EVENT REPORTS FOR COSMETICS.

''(a)(1) IN GENERAL.—The manufacturer, packer, or distributor of a cosmetic product distributed in the United States (referred to in this section as the 'responsible person') shall submit to the Secretary under subsection (b) a report containing any information that such responsible person received concerning any serious adverse event that occurs in the United States and that is associated with the use of the cosmetic product in the United States, accompanied by a copy of the label on or within the retail packaging of such cosmetic product.

''(2) RETAILER.—A retailer whose name appears on the label of a cosmetic product and who is also a distributor of such product may agree in writing that the manufacturer of the cosmetic product shall submit the reports required by paragraph (1) for any cosmetic product so long as the retailer directs to the manufacturer all in-

formation relating to each adverse event associated with such cosmetic product that is provided to the retailer.

''(b) SUBMISSION OF REPORTS.—

''(1) IN GENERAL.—A report under subsection (a) 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 that is indicated on the label of the cosmetic, as required under section 602(b)(1).

''(2) CONTENTS.—A report under subsection (a) shall be submitted to the Secretary in a format, and shall contain the information, defined by the Secretary in guidance or by regulation, including the following information, to the extent to which such information has been provided to the responsible person:

''(A) The identity of the individual experiencing the adverse event.

''(B) The identity of the individual reporting the adverse event to the responsible person.

''(C) The identity of the cosmetic product associated with the adverse event.

''(D) A detailed description of the adverse event.

''(3) ADDITIONAL INFORMATION.—The responsible person submitting a report under subsection (a) may include any additional information and shall, within 15 business days of receiving any new information related to the serious adverse event report, submit such new information to the Secretary.

''(c) MAINTENANCE AND INSPECTION OF RECORDS.—

''(1) MAINTENANCE.—The responsible person shall maintain records of all information received by such person relating to each serious adverse event for a period of 6 years from initial receipt of such information.

''(2) RECORDS INSPECTION.—The responsible person shall permit an officer or employee duly designated by the Secretary, upon presentation of appropriate credentials, to have access, at reasonable times, to records required to be maintained under this subsection for the purpose of inspection and copying.

''(d) RELATION TO OTHER PROVISIONS.—A report under subsection (a) (including all information submitted in the initial report or added later) shall be considered to be—

''(1) a safety report under section 756;

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

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

''(e) DEFINITIONS.—In this section:

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

''(A) resulting in—

''(i) death;

''(ii) a life-threatening experience;

''(iii) inpatient hospitalization;

''(iv) a disability, disfigurement, or incapacity; or

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

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

''(2) The term 'cosmetic product' has the meaning given to such term in section 604(c).

''(3) The term 'retailer' means a person that sells or otherwise provides a cosmetic product directly to a consumer.''.

(d) IMPORTED COSMETIC PRODUCTS.—Section 801 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 381) is amended—

(1) in subsection (a), by striking ''760 or 761'' each place it appears and inserting ''760, 761, or 606''; and

(2) in subsection (b), by striking ''760 or 761'' each place it appears and inserting ''760, 761, or 606''.

SEC. 5. MAINTENANCE AND ACCESS TO RECORDS.

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

''SEC. 607. MAINTENANCE AND ACCESS TO RECORDS.

''(a) RECORDS ACCESS.—

''(1) RECORDS ACCESS DURING AN INSPECTION.—

''(A) IN GENERAL.—Each person who manufactures, packs, or holds a cosmetic product in the United States or for import into the United States shall, at the request of an officer

or employee duly designated by the Secretary, permit such officer or employee, upon presentation of appropriate credentials, at reasonable times, within reasonable limits, and in a reasonable manner, to have access to and copy all records relating to whether the cosmetic may be adulterated, misbranded, or otherwise in violation of this Act, including all records collected or developed to comply with section 605 (relating to cosmetic product safety substantiation) or 606 (relating to serious adverse event reports).

''(B) SCOPE OF RECORDS.—The requirement under subparagraph (A) applies to all records relating to the manufacture, packing, or holding of such cosmetic product maintained by or on behalf of such person in any format and at any location.

''(C) IMMEDIATE AVAILABILITY WITH NOTICE.—Records not required to be made available immediately on commencement of an inspection under subparagraph (A) shall nonetheless be made available immediately on commencement of such an inspection if, a reasonable time before such inspection, the Secretary

by letter provides written notice to the person and identifies the records to be made available during such inspection. Nothing in this subparagraph shall be construed as permitting a person to refuse to produce records required under and in accordance with subparagraph (A) due to failure of the Secretary to provide notice under this paragraph.

''(2) ADDITIONAL AUTHORITIES TO ACCESS RECORDS REMOTELY; SUBMISSION OF RECORDS TO THE SECRETARY.—

''(A) REMOTE ACCESS IN EMERGENCIES.—If the Secretary has a reasonable belief that a cosmetic product has caused one or more serious adverse events (as such term is used in section 606), the Secretary may require each person who manufactures, packs, or holds such cosmetic product, or any cosmetic product that the Secretary determines may be affected in a similar manner, to submit to the Secretary all records reasonably related to such cosmetic product as soon as is reasonably practicable, after receiving written notice (including by notice served personally and outside normal business hours to an agent identified under clause

(vi) or (vii) of section 604(a)(2)(B) of such requirement).

''(B) ELECTRONIC SUBMISSION.—If the records required to be submitted to the Secretary under subparagraph (A) are available in electronic format, such records shall be submitted electronically unless the Secretary specifies otherwise in the notice under such subparagraph.

''(b) REGULATIONS CONCERNING RECORDKEEPING.—The Secretary shall, by regulation, establish requirements regarding the establishment and maintenance, for not longer than 2 years, of records by persons who manufacture, pack, or hold cosmetics in the United States or for import into the United States, which records are needed by the Secretary for inspection to allow the Secretary to determine that the cosmetic is in compliance with applicable laws and regulations; to identify the previous sources and the subsequent recipients of a cosmetic, including its packaging; or for other purposes the Secretary deems necessary to protect public health. The Secretary shall take into account the size of a business in promulgating regulations under this subsection.''.

(b) CONFORMING AMENDMENTS.—Section 704(a) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 374(a)) is amended—

(1) in paragraph (1)—

(A) by inserting after the second sentence the following: ''In the case of any person who manufactures, packs, or holds cosmetics, the inspection shall extend to all records and other information described in or required under section 607 bearing on whether a cosmetic is adulterated, misbranded, or otherwise in violation of this Act.''; and

(B) in the fourth sentence—

(i) by striking ''the preceding sentence'' and inserting ''either of the preceding two sentences'';

(ii) by striking ''and'' after ''or chapter IX''; and

(iii) by inserting after ''section 505(j))'' the following: '', and formulas for a cosmetic, financial data, pricing data, personnel data, research data, or sales data (other than shipment data regarding sales) related to a cosmetic''; and

(2) in paragraph (2), by striking ''third sentence'' and inserting ''fourth sentence''.

(c) NO EFFECT ON OTHER PROVISIONS.—This section shall not be construed to limit the authority of the Secretary to require the establishment and maintenance of records under any other provision of this Act.

SEC. 6. GOOD MANUFACTURING PRACTICES FOR COSMETICS.

(a) IN GENERAL.—Section 601 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 361), as amended by section 3(a), is further amended by adding at the end the following:

''(h) If the methods used in, or the facilities or controls used for, its manufacture, packing, or holding do not conform to current good manufacturing practice, as prescribed by the Secretary in regulations, to ensure that the cosmetic is safe and otherwise in compliance with this Act.''.

(b) REGULATIONS.—

(1) PROMULGATION.—The Secretary of Health and Human Services, acting through the Commissioner of Food and Drugs, shall promulgate regulations to carry out section 601(h) of the Federal Food, Drug, and Cosmetic Act, as added by subsection (a).

(2) INTERNATIONAL STANDARDS.—In promulgating such regulations, the Secretary of Health and Human Services, acting through the Commissioner of Food and Drugs, shall review international standards for cosmetic product good manufacturing practice that are in existence on the date of enactment of this Act to ensure that such regulations are consistent, to the extent the Secretary determines practicable and appropriate, with such standards.

SEC. 7. MANDATORY RECALL AUTHORITY.

(a) PROHIBITED ACT.—Section 301(xx) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 331(xx)) is amended by inserting ''or 608'' after ''The refusal or failure to follow an order under section 423''.

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

''SEC. 608. MANDATORY RECALL AUTHORITY.

''(a) VOLUNTARY PROCEDURES.—If the Secretary determines that there is a reasonable probability that a cosmetic is adulterated under section 601 and the use of, or exposure to, such cosmetic will cause serious adverse health consequences or death to humans, the Secretary

shall provide each responsible person with an opportunity to cease distribution and recall such cosmetic.

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

''(1) IN GENERAL.—If a responsible person refuses to or does not voluntarily cease distribution or recall such cosmetic within the time and in the manner prescribed by the Secretary (if so prescribed), the Secretary may, by order require, as the Secretary deems necessary, such person to—

''(A) immediately cease distribution of such cosmetic; and

''(B) as applicable, immediately notify all persons—

''(i) manufacturing, packing, or holding such cosmetic, and

''(ii) to which such cosmetic has been distributed, transported, or sold,

to immediately cease distribution of such cosmetic.

''(2) DETERMINATION TO LIMIT AREAS AFFECTED.—If the Secretary requires a responsible person to cease distribution under paragraph (1)(A) of a cosmetic identified in subsection (a), the Secretary may limit the size of the geographic area and

the markets affected by such cessation if such limitation would not compromise the public health.

''(c) HEARING ON ORDER.—The Secretary shall provide a responsible person subject to an order under subsection (b) with an opportunity for an informal hearing, to be held as soon as possible, but not later than 2 days after the issuance of the order, on the actions required by the order and on why the cosmetic that is the subject of the order should not be recalled.

''(d) POST-HEARING RECALL ORDER AND MODIFICATION OF ORDER.—

''(1) AMENDMENT OF ORDER.—If, after providing opportunity for an informal hearing under subsection (c), the Secretary determines that removal of the cosmetic from commerce is necessary, the Secretary shall, as appropriate—

''(A) amend the order to require recall of such cosmetic or other appropriate action;

''(B) specify a timetable in which the recall shall occur;

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

''(D) provide notice to consumers to whom such cosmetic was, or may have been, distributed.

''(2) VACATING OF ORDER.—If, after such hearing, the Secretary determines that adequate grounds do not exist to continue the actions required by the order, or that such actions should be modified, the Secretary shall vacate the order or modify the order.

''(e) COOPERATION AND CONSULTATION.—The Secretary shall work with State and local public health officials in carrying out this section, as appropriate.

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

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

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

''(B) that includes, at a minimum—

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

''(ii) a description of the risk associated with such cosmetic; and

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

''(2) shall consider providing a list to the public of retail consignees receiving products involved in a Class I recall, as determined appropriate by the Secretary; and

''(3) if available, publish on the Internet Web site of the Food and Drug Administration an image of the cosmetic that is the subject of the press release described in (1).

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

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

''(i) RESPONSIBLE PERSON DEFINED.—In this section, the term 'responsible person' has the meaning given to such term in section 604(c).''.

SEC. 8. EFFECTIVE DATES.

(a) The amendments made by sections 2(a), 3, 4, 5, and 7 shall take effect 18 months after the date of enactment of this Act.

(b) The amendments made by sections 2(b) and 6 shall take effect 3 years after the date of enactment of this Act.

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