

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

A BILL

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

1 *Be it enacted by the Senate and House of Representa-*
2 *tives of the United States of America in Congress assembled,*

3 **SECTION 1. SHORT TITLE; TABLE OF CONTENTS.**

4 (a) **SHORT TITLE.**—This Act may be cited as the
5 “Cosmetics Safety Enhancement Act of 2012”.

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

- Sec. 1. Short title; table of contents.
- Sec. 2. Registration of cosmetic facilities; listing of cosmetic products; fees.
- Sec. 3. Cosmetic product safety substantiation.
- Sec. 4. Serious adverse event reports for cosmetics.
- Sec. 5. Maintenance and access to records.
- Sec. 6. Good manufacturing practices for cosmetics.

Sec. 7. Mandatory recall authority.

Sec. 8. Effective dates.

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

3 (a) PROHIBITED ACT.—Section 301(dd) of the Fed-
 4 eral Food, Drug, and Cosmetic Act (21 U.S.C. 331(dd))
 5 is amended by striking the period at the end and adding
 6 “, the failure to register in accordance with section 604(a),
 7 or the failure to list a cosmetic product in accordance with
 8 section 604(b)”.

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

12 “(f) If it was manufactured, packed, or held in a fa-
 13 cility that is not duly registered under section 604(a), or
 14 if it is a cosmetic product that is not listed in accordance
 15 with section 604(b).”.

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

19 **“SEC. 604. REGISTRATION OF COSMETIC FACILITIES AND**
 20 **COSMETIC PRODUCT LISTING.**

21 “(a) REGISTRATION.—

22 “(1) IN GENERAL.—The Secretary shall by reg-
 23 ulation require that any facility engaged in manufac-
 24 turing, packing, or holding a cosmetic product or a

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

4 “(2) REGISTRATION.—

5 “(A) TIMING.—A registration under para-
6 graph (1) shall be submitted to the Secretary
7 not later than December 31 of each year.

8 “(B) FORMAT; CONTENTS.—Each registra-
9 tion under paragraph (1) shall be submitted
10 using an electronic format, as specified in regu-
11 lations or guidance issued by the Secretary, and
12 shall include the following information:

13 “(i) The facility’s name and full ad-
14 dress, which address shall identify the pre-
15 cise physical location of the facility.

16 “(ii) The identity of the facility, in-
17 cluding the unique facility identifier, if
18 any, previously assigned by the Secretary
19 to the facility under paragraph (3).

20 “(iii) All business trading names used
21 by the facility.

22 “(iv) The product category or cat-
23 egories of each cosmetic product or cos-
24 metic formulation manufactured, packed,
25 or held at the facility.

1 “(v) The type of activity conducted at
2 the facility (such as manufacturing, pack-
3 ing, or holding).

4 “(vi) The name, title, street address,
5 telephone number, and, if available, the
6 email address of the emergency contact for
7 the facility.

8 “(vii) In the case of a foreign facility,
9 the name, street address, telephone num-
10 ber, emergency contact information, and, if
11 available, the email address of the United
12 States agent for the facility.

13 “(viii) The name, title, street address,
14 telephone number, and, if available, email
15 address of the individual submitting the
16 registration.

17 “(ix) Additional information per-
18 taining to the facility or to the cosmetic
19 products or cosmetic formulations manu-
20 factured, packed, or held at the facility, as
21 the Secretary may require by regulation.

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

1 than 30 days after the date of such change un-
2 less otherwise specified by the Secretary.

3 “(3) PROCEDURE.—Upon receipt of a com-
4 pleted registration under paragraph (1), the Sec-
5 retary shall notify the registrant of the receipt of
6 such registration. At the time of the initial registra-
7 tion of any cosmetic facility under this section, the
8 Secretary shall assign a unique facility identifier to
9 the facility.

10 “(4) LIST.—

11 “(A) IN GENERAL.—The Secretary shall
12 compile and maintain an up-to-date list of fa-
13 cilities that are registered under this section.

14 “(B) REMOVAL.—The Secretary shall—

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

18 “(ii) initiate proceedings in accord-
19 ance with paragraph (6) to cancel the reg-
20 istration of any facility that—

21 “(I) fails to re-register under this
22 section; or

23 “(II) fails to pay the registration
24 fee required under section 744.

1 “(C) PUBLIC AVAILABILITY.—The list of
2 registered facilities maintained pursuant to sub-
3 paragraph (A) and any registration documents
4 submitted pursuant to this subsection shall not
5 be subject to disclosure under section 552 of
6 title 5, United States Code. Information derived
7 from such list or registration documents shall
8 not be subject to disclosure under section 552
9 of title 5, United States Code, to the extent
10 that such information discloses the identity or
11 location of a specific registered facility.

12 “(5) SUSPENSION OF REGISTRATION.—

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

18 “(B) NOTICE OF SUSPENSION.—Susten-
19 sion of a registration under this section shall be
20 preceded by—

21 “(i) notice, as defined in guidance or
22 regulations issued by the Secretary, to the
23 facility of the intent to suspend the reg-
24 istration; and

1 “(ii) an opportunity for an informal
2 hearing concerning the suspension of the
3 such registration for such facility.

4 “(C) REINSTATEMENT.—A registration
5 that is suspended under this section may be re-
6 instated pursuant to criteria published by the
7 Secretary in the Federal Register and on a pub-
8 lic Web site of the Food and Drug Administra-
9 tion.

10 “(6) CANCELLATION OF REGISTRATION.—

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

16 “(i) the registration was not updated
17 in accordance with this section or other-
18 wise contains false, incomplete, or inac-
19 curate information; or

20 “(ii) the required registration fee
21 under section 744 has not been paid within
22 30 days after the date due.

23 “(B) NOTICE OF CANCELLATION.—Can-
24 cellation shall be preceded by notice to the facil-

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

3 “(C) TIMELY UPDATE OR CORRECTION.—

4 If the registration for the facility is updated or
5 corrected and the required registration fee is
6 paid no later than 7 days after notice is pro-
7 vided under subparagraph (B), the Secretary
8 shall not cancel such registration.

9 “(b) COSMETIC PRODUCT LISTING.—

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

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

18 “(A) The unique facility identifier (as-
19 signed under subsection (a)(3)) of the facility
20 where the cosmetic product is manufactured or
21 packed, or, if the same cosmetic product is
22 manufactured or packed in more than one facil-
23 ity, unique facility identifier of each facility
24 where it is manufactured or packed.

1 “(B) The brand name and the full name
2 for the cosmetic product as it appears on the
3 label.

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

7 “(D) The applicable cosmetic category for
8 the cosmetic product.

9 “(E) The ingredients in the cosmetic prod-
10 uct in descending order of predominance by
11 weight, with each ingredient identified by the
12 name adopted in regulations promulgated by
13 the Secretary, if any, or by the common or
14 usual name of the ingredient.

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

17 “(G) Such additional information per-
18 taining to the cosmetic product as the Secretary
19 may require by regulation.

20 “(3) ADDITIONAL REQUIREMENTS.—

21 “(A) CERTIFICATION.—The filing for a
22 cosmetic product under paragraph (1) shall in-
23 clude a certification, submitted by the respon-
24 sible person, that such list includes all cosmetic
25 products owned by such person.

1 “(B) CHANGES TO INFORMATION.—The
2 responsible person shall notify the Secretary
3 within 60 days of—

4 “(i) any change to the information re-
5 quired to be in such product list; or

6 “(ii) the discontinuation of the manu-
7 facture of a cosmetic product.

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

12 “(A) notify the responsible person identi-
13 fied in such list that the list has been received;
14 and

15 “(B) assign a cosmetic product number to
16 any listed product not previously assigned a
17 cosmetic product listing number.

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

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

23 “(1) COSMETIC FORMULATION.—The term ‘cos-
24 metic formulation’ means a preparation of cosmetic

1 raw materials with a qualitatively and quantitatively
2 set composition.

3 “(2) COSMETIC PRODUCT.—The term ‘cosmetic
4 product’ means a finished cosmetic that has under-
5 gone all stages of production, including packaging in
6 its final container for shipment and application of a
7 product label.

8 “(3) FACILITY.—

9 “(A)(i) The term ‘facility’ includes any fac-
10 tory, warehouse, or establishment facility (in-
11 cluding a factory, warehouse, or establishment
12 of an importer) that manufactures, packs, or
13 holds cosmetic products or cosmetic formula-
14 tions.

15 “(ii) Such term does not include—

16 “(I) beauty shops and salons;

17 “(II) pharmacies and other cosmetic
18 product retailers, including individual sales
19 representatives and retail distribution fa-
20 cilities;

21 “(III) hospitals, physicians’ offices,
22 and health care clinics;

23 “(IV) public health agencies and other
24 nonprofit entities that provide cosmetics
25 directly to the consumer;

1 “(V) hotels and other entities that
2 provide complimentary cosmetics to guests;

3 “(VI) trade shows and other venues
4 where cosmetic product samples are pro-
5 vided free of charge; and

6 “(VII) entities that manufacture or
7 compound cosmetic products solely for use
8 in research, teaching, or pilot plant pro-
9 duction and not for sale.

10 “(B) The term ‘domestic facility’ means a
11 facility located in any State.

12 “(C)(i) The term ‘foreign facility’ means a
13 facility that manufactures, packs, or holds cos-
14 metics that are exported to the United States
15 without further processing or packaging outside
16 the United States.

17 “(ii) A cosmetic may not be considered to
18 have undergone further processing or packaging
19 for purposes of clause (i) solely on the basis
20 that labeling was added or that any similar ac-
21 tivity of a de minimis nature was carried out
22 with respect to the cosmetic.

23 “(4) RESPONSIBLE PERSON.—The term ‘re-
24 sponsible person’ means a person (as defined in sec-
25 tion 201(e)) that is the owner of a cosmetic product

1 intended for introduction into United States com-
2 merce.”.

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

7 **“PART 7—FEES RELATING TO COSMETICS**

8 **“SEC. 744. FACILITY REGISTRATION FEE.**

9 “(a) IN GENERAL.—

10 “(1) ASSESSMENT AND COLLECTION.—Begin-
11 ning in fiscal year 2013, the Secretary shall assess
12 and collect an annual fee for the registration of a fa-
13 cility under section 604(a).

14 “(2) PAYABLE DATE.—A fee under this section
15 shall be payable—

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

19 “(B) for any other facility—

20 “(i) for fiscal year 2013, not later
21 than the sooner of—

22 “(I) 90 days after the date of the
23 enactment of this part; or

24 “(II) the date of re-registration;
25 and

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

3 “(b) FREE AMOUNTS.—

4 “(1) IN GENERAL.—The registration fee under
5 subsection (a) shall be—

6 “(A) for fiscal year 2013, \$500; and

7 “(B) for fiscal year 2014 and each subse-
8 quent fiscal year, the fee for fiscal year 2013 as
9 adjusted under subsection (c).

10 “(2) ANNUAL FEE SETTING.—The Secretary
11 shall, not later than 60 days before the start of fis-
12 cal year 2014 and each subsequent fiscal year, es-
13 tablish, for the next fiscal year, registration fees
14 under subsection (a), as described in paragraph (1).

15 “(c) INFLATION ADJUSTMENT.—For fiscal year 2014
16 and subsequent fiscal years, the revenues established in
17 subsection (b) shall be adjusted by the Secretary by notice,
18 published in the Federal Register, for a fiscal year to re-
19 flect the sum of one plus—

20 “(1) the average annual change in the cost, per
21 full-time equivalent position of the Food and Drug
22 Administration, of all personnel compensation and
23 benefits paid with respect to such positions for the
24 first 3 years of the preceding 4 fiscal years multi-
25 plied by the proportion of personnel compensation

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

4 “(2) the average annual change that occurred
5 in the Consumer Price Index for urban consumers
6 (Washington-Baltimore, DC–MD–VA–WV; Not Sea-
7 sonally Adjusted; All items; Annual Index) for the
8 first 3 years of the preceding 4 years of available
9 data multiplied by the proportion of all costs other
10 than personnel compensation and benefits costs to
11 total costs of cosmetic safety activities for the first
12 3 years of the preceding 4 fiscal years.

13 The adjustment made each fiscal year under this sub-
14 section will be added on a compounded basis to the sum
15 of all adjustments made each fiscal year after fiscal year
16 2013 under this subsection.

17 “(d) LIMITATIONS.—

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

1 penses of the cosmetic products programs of the
2 Food and Drug Administration for fiscal year 2012
3 (excluding the amount of fees appropriated for such
4 fiscal year) multiplied by the adjustment factor ap-
5 plicable to the fiscal year involved.

6 “(2) AUTHORITY.—If the Secretary does not
7 assess fees under subsection (a) during any portion
8 of a fiscal year because of paragraph (1) and if at
9 a later date in such fiscal year the Secretary may as-
10 sess such fees, the Secretary may assess and collect
11 such fees, without any modification in the rate, for
12 registration under section 604 at any time in such
13 fiscal year.

14 “(3) ADJUSTMENT FACTOR.—In this sub-
15 section, the term ‘adjustment factor’ applicable to a
16 fiscal year is the Consumer Price Index for all urban
17 consumers (all items; United States city average) for
18 October of the preceding fiscal year divided by such
19 Index for October 2011.

20 “(e) CREDITING AND AVAILABILITY OF FEES.—

21 “(1) IN GENERAL.—Fees authorized under sub-
22 section (a) shall be collected and available for obliga-
23 tion only to the extent and in the amount provided
24 in advance in appropriations Acts. Such fees are au-
25 thorized to remain available until expended. Such

1 sums as may be necessary may be transferred from
2 the Food and Drug Administration salaries and ex-
3 penses appropriation account without fiscal year lim-
4 itation to such appropriation account for salaries
5 and expenses with such fiscal year limitation.

6 “(2) COLLECTIONS AND APPROPRIATIONS
7 ACTS.—The fees authorized by this section—

8 “(A) shall be retained in each fiscal year in
9 an amount not to exceed the amount specified
10 in appropriation Acts, or otherwise made avail-
11 able for obligation, for such fiscal year; and

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

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

18 “(f) COLLECTION OF UNPAID FEES.—In any case
19 where the Secretary does not receive payment of a fee as-
20 sessed under subsection (a) within 30 days after it is due,
21 such fee shall be treated as a claim of the United States
22 Government subject to subchapter II of chapter 37 of title
23 31, United States Code.

24 “(g) CONSTRUCTION.—This section may not be con-
25 strued to require that the number of full-time equivalent

1 positions in the Department of Health and Human Serv-
2 ices, for officers, employees, and advisory committees not
3 engaged in cosmetic safety activities, be reduced to offset
4 the number of officers, employees, and advisory commit-
5 tees so engaged.

6 “(h) ANNUAL FISCAL REPORTS.—Beginning with
7 fiscal year 2014, not later than 120 days after the end
8 of each fiscal year for which fees are collected under this
9 section, the Secretary shall prepare and submit to the
10 Committee on Energy and Commerce of the House of
11 Representatives and the Committee on Health, Education,
12 Labor, and Pensions of the Senate a report on the imple-
13 mentation of the authority for such fees during such fiscal
14 year and the use, by the Food and Drug Administration,
15 of the fees collected for such fiscal year.

16 “(i) DEFINITIONS.—In this section:

17 “(1) The term ‘costs of cosmetic safety activi-
18 ties’ means the expenses incurred in connection with
19 cosmetic safety activities for—

20 “(A) officers and employees of the Food
21 and Drug Administration, contractors of the
22 Food and Drug Administration, advisory com-
23 mittees, and costs related to such officers, em-
24 ployees, and committees and to contracts with
25 such contractors;

1 “(B) laboratory capacity;

2 “(C) management of information, and the
3 acquisition, maintenance, and repair of tech-
4 nology resources;

5 “(D) leasing, maintenance, renovation, and
6 repair of facilities and acquisition, maintenance,
7 and repair of fixtures, furniture, scientific
8 equipment, and other necessary materials and
9 supplies; and

10 “(E) collecting fees under this section and
11 accounting for resources allocated for cosmetic
12 safety activities.

13 “(2) The term ‘cosmetic safety activities’ means
14 activities of the Food and Drug Administration re-
15 lated to ensuring the safety of cosmetics sold for use
16 in the United States, as authorized by this Act.”.

17 (e) TRANSITIONAL PROVISIONS.—

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

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

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

3 **SEC. 3. COSMETIC PRODUCT SAFETY SUBSTANTIATION.**

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

8 “(g) If it is a cosmetic product for which any require-
9 ment of section 605 (relating to safety substantiation) is
10 not met.”.

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

15 **“SEC. 605. COSMETIC PRODUCT SAFETY SUBSTANTIATION.**

16 “(a) IN GENERAL.—The responsible person shall—

17 “(1) before introduction or delivery for intro-
18 duction into interstate commerce of a cosmetic prod-
19 uct, establish a file containing scientific evidence
20 pertaining to such product’s safety; and

21 “(2) maintain such file for no less than 5 years
22 after the date on which such person ceases to intro-
23 duce such article into interstate commerce.

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

1 “(1) consist of studies, tests, data, or other in-
2 formation known to the responsible person that re-
3 lates to the cosmetic product’s safety; and

4 “(2) demonstrate that such cosmetic product is
5 safe.

6 “(c) REQUESTS BY SECRETARY; ACCESS TO
7 RECORDS.—In response to a request by the Secretary, the
8 responsible person shall promptly supply to the Secretary
9 a copy of the file required under subsection (a). Such per-
10 son shall also permit an officer or employee duly des-
11 ignated by the Secretary, upon presentation of appropriate
12 credentials, to have access at reasonable times to records
13 required to be maintained under this section for the pur-
14 pose of inspection and copying.

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

16 “(1) The term ‘cosmetic product’ has the mean-
17 ing given to such term in section 604(c).

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

24 “(3) The term ‘responsible person’ has the
25 meaning given to such term in section 604(c).”.

1 **SEC. 4. SERIOUS ADVERSE EVENT REPORTS FOR COS-**
2 **METICS.**

3 (a) PROHIBITED ACTS.—Section 301 of the Federal
4 Food, Drug, and Cosmetic Act (21 U.S.C. 331) is amend-
5 ed—

6 (1) in subsection (e)—

7 (A) by striking “or 761” and inserting
8 “761, or 606”; and

9 (B) by inserting “606,” before “909,”; and

10 (2) in subsection (ii)—

11 (A) by striking “760 or 761” and inserting
12 “760, 761, or 606”;

13 (B) by striking “or the” and inserting “,
14 the”; and

15 (C) by striking the period at the end and
16 inserting “, or the falsification of a report sub-
17 mitted under section 606 to the Secretary.”.

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

21 “(f) If it is a cosmetic product that is marketed in
22 the United States, unless the label of such cosmetic prod-
23 uct includes a domestic address, including the street ad-
24 dress or P.O. box, city, State, and zip code, or a domestic
25 telephone number, including the area code, through which
26 the responsible person (as described in section 606(a)(1))

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

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

7 **“SEC. 606. SERIOUS ADVERSE EVENT REPORTS FOR COS-**
8 **METICS.**

9 “(a)(1) IN GENERAL.—The manufacturer, packer, or
10 distributor of a cosmetic product distributed in the United
11 States (referred to in this section as the ‘responsible per-
12 son’) shall submit to the Secretary under subsection (b)
13 a report containing any information that such responsible
14 person received concerning any serious adverse event that
15 occurs in the United States and that is associated with
16 the use of the cosmetic product in the United States, ac-
17 companied by a copy of the label on or within the retail
18 packaging of such cosmetic product.

19 “(2) RETAILER.—A retailer whose name appears on
20 the label of a cosmetic product and who is also a dis-
21 tributor of such product may agree in writing that the
22 manufacturer of the cosmetic product shall submit the re-
23 ports required by paragraph (1) for any cosmetic product
24 so long as the retailer directs to the manufacturer all in-

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

3 “(b) SUBMISSION OF REPORTS.—

4 “(1) IN GENERAL.—A report under subsection
5 (a) shall be submitted to the Secretary no later than
6 15 business days after information concerning the
7 adverse event is received at the place of business
8 that is indicated on the label of the cosmetic, as re-
9 quired under section 602(b)(1).

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

17 “(A) The identity of the individual experi-
18 encing the adverse event.

19 “(B) The identity of the individual report-
20 ing the adverse event to the responsible person.

21 “(C) The identity of the cosmetic product
22 associated with the adverse event.

23 “(D) A detailed description of the adverse
24 event.

1 “(3) ADDITIONAL INFORMATION.—The respon-
2 sible person submitting a report under subsection
3 (a) may include any additional information and
4 shall, within 15 business days of receiving any new
5 information related to the serious adverse event re-
6 port, submit such new information to the Secretary.

7 “(c) MAINTENANCE AND INSPECTION OF
8 RECORDS.—

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

14 “(2) RECORDS INSPECTION.—The responsible
15 person shall permit an officer or employee duly des-
16 ignated by the Secretary, upon presentation of ap-
17 propriate credentials, to have access, at reasonable
18 times, to records required to be maintained under
19 this subsection for the purpose of inspection and
20 copying.

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

25 “(1) a safety report under section 756;

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

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

8 “(e) DEFINITIONS.—In this section:

9 “(1) The term ‘serious’, with respect to an ad-
10 verse event associated with a cosmetic product,
11 means—

12 “(A) resulting in—

13 “(i) death;

14 “(ii) a life-threatening experience;

15 “(iii) inpatient hospitalization;

16 “(iv) a disability, disfigurement, or in-
17 capacity; or

18 “(v) a congenital anomaly or birth de-
19 fect; or

20 “(B) requiring, based on reasonable med-
21 ical judgment, a medical or surgical interven-
22 tion to prevent an outcome described in sub-
23 paragraph (A).

24 “(2) The term ‘cosmetic product’ has the mean-
25 ing given to such term in section 604(c).

1 “(3) The term ‘retailer’ means a person that
2 sells or otherwise provides a cosmetic product di-
3 rectly to a consumer.”.

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

7 (1) in subsection (a), by striking “760 or 761”
8 each place it appears and inserting “760, 761, or
9 606”; and

10 (2) in subsection (b), by striking “760 or 761”
11 each place it appears and inserting “760, 761, or
12 606”.

13 **SEC. 5. MAINTENANCE AND ACCESS TO RECORDS.**

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

18 **“SEC. 607. MAINTENANCE AND ACCESS TO RECORDS.**

19 “(a) RECORDS ACCESS.—

20 “(1) RECORDS ACCESS DURING AN INSPEC-
21 TION.—

22 “(A) IN GENERAL.—Each person who
23 manufactures, packs, or holds a cosmetic prod-
24 uct in the United States or for import into the
25 United States shall, at the request of an officer

1 or employee duly designated by the Secretary,
2 permit such officer or employee, upon presen-
3 tation of appropriate credentials, at reasonable
4 times, within reasonable limits, and in a reason-
5 able manner, to have access to and copy all
6 records relating to whether the cosmetic may be
7 adulterated, misbranded, or otherwise in viola-
8 tion of this Act, including all records collected
9 or developed to comply with section 605 (relat-
10 ing to cosmetic product safety substantiation)
11 or 606 (relating to serious adverse event re-
12 ports).

13 “(B) SCOPE OF RECORDS.—The require-
14 ment under subparagraph (A) applies to all
15 records relating to the manufacture, packing, or
16 holding of such cosmetic product maintained by
17 or on behalf of such person in any format and
18 at any location.

19 “(C) IMMEDIATE AVAILABILITY WITH NO-
20 TICE.—Records not required to be made avail-
21 able immediately on commencement of an in-
22 spection under subparagraph (A) shall nonethe-
23 less be made available immediately on com-
24 mencement of such an inspection if, a reason-
25 able time before such inspection, the Secretary

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

9 “(2) ADDITIONAL AUTHORITIES TO ACCESS
10 RECORDS REMOTELY; SUBMISSION OF RECORDS TO
11 THE SECRETARY.—

12 “(A) REMOTE ACCESS IN EMERGENCIES.—

13 If the Secretary has a reasonable belief that a
14 cosmetic product has caused one or more seri-
15 ous adverse events (as such term is used in sec-
16 tion 606), the Secretary may require each per-
17 son who manufactures, packs, or holds such
18 cosmetic product, or any cosmetic product that
19 the Secretary determines may be affected in a
20 similar manner, to submit to the Secretary all
21 records reasonably related to such cosmetic
22 product as soon as is reasonably practicable,
23 after receiving written notice (including by no-
24 tice served personally and outside normal busi-
25 ness hours to an agent identified under clause

1 (vi) or (vii) of section 604(a)(2)(B) of such re-
2 quirement).

3 “(B) ELECTRONIC SUBMISSION.—If the
4 records required to be submitted to the Sec-
5 retary under subparagraph (A) are available in
6 electronic format, such records shall be sub-
7 mitted electronically unless the Secretary speci-
8 fies otherwise in the notice under such subpara-
9 graph.

10 “(b) REGULATIONS CONCERNING RECORD-
11 KEEPING.—The Secretary shall, by regulation, establish
12 requirements regarding the establishment and mainte-
13 nance, for not longer than 2 years, of records by persons
14 who manufacture, pack, or hold cosmetics in the United
15 States or for import into the United States, which records
16 are needed by the Secretary for inspection to allow the
17 Secretary to determine that the cosmetic is in compliance
18 with applicable laws and regulations; to identify the pre-
19 vious sources and the subsequent recipients of a cosmetic,
20 including its packaging; or for other purposes the Sec-
21 retary deems necessary to protect public health. The Sec-
22 retary shall take into account the size of a business in
23 promulgating regulations under this subsection.”.

1 (b) CONFORMING AMENDMENTS.—Section 704(a) of
2 the Federal Food, Drug, and Cosmetic Act (21 U.S.C.
3 374(a)) is amended—

4 (1) in paragraph (1)—

5 (A) by inserting after the second sentence
6 the following: “In the case of any person who
7 manufactures, packs, or holds cosmetics, the in-
8 spection shall extend to all records and other
9 information described in or required under sec-
10 tion 607 bearing on whether a cosmetic is adul-
11 terated, misbranded, or otherwise in violation of
12 this Act.”; and

13 (B) in the fourth sentence—

14 (i) by striking “the preceding sen-
15 tence” and inserting “either of the pre-
16 ceding two sentences”;

17 (ii) by striking “and” after “or chap-
18 ter IX”; and

19 (iii) by inserting after “section
20 505(j))” the following: “, and formulas for
21 a cosmetic, financial data, pricing data,
22 personnel data, research data, or sales
23 data (other than shipment data regarding
24 sales) related to a cosmetic”; and

1 (2) INTERNATIONAL STANDARDS.—In promul-
2 gating such regulations, the Secretary of Health and
3 Human Services, acting through the Commissioner
4 of Food and Drugs, shall review international stand-
5 ards for cosmetic product good manufacturing prac-
6 tice that are in existence on the date of enactment
7 of this Act to ensure that such regulations are con-
8 sistent, to the extent the Secretary determines prac-
9 ticable and appropriate, with such standards.

10 **SEC. 7. MANDATORY RECALL AUTHORITY.**

11 (a) PROHIBITED ACT.—Section 301(xx) of the Fed-
12 eral Food, Drug, and Cosmetic Act (21 U.S.C. 331(xx))
13 is amended by inserting “or 608” after “The refusal or
14 failure to follow an order under section 423”.

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

19 **“SEC. 608. MANDATORY RECALL AUTHORITY.**

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

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

3 “(b) PREHEARING ORDER TO CEASE DISTRIBUTION
4 AND GIVE NOTICE.—

5 “(1) IN GENERAL.—If a responsible person re-
6 fuses to or does not voluntarily cease distribution or
7 recall such cosmetic within the time and in the man-
8 ner prescribed by the Secretary (if so prescribed),
9 the Secretary may, by order require, as the Sec-
10 retary deems necessary, such person to—

11 “(A) immediately cease distribution of
12 such cosmetic; and

13 “(B) as applicable, immediately notify all
14 persons—

15 “(i) manufacturing, packing, or hold-
16 ing such cosmetic, and

17 “(ii) to which such cosmetic has been
18 distributed, transported, or sold,

19 to immediately cease distribution of such cos-
20 metic.

21 “(2) DETERMINATION TO LIMIT AREAS AF-
22 FECTED.—If the Secretary requires a responsible
23 person to cease distribution under paragraph (1)(A)
24 of a cosmetic identified in subsection (a), the Sec-
25 retary may limit the size of the geographic area and

1 the markets affected by such cessation if such limi-
2 tation would not compromise the public health.

3 “(c) HEARING ON ORDER.—The Secretary shall pro-
4 vide a responsible person subject to an order under sub-
5 section (b) with an opportunity for an informal hearing,
6 to be held as soon as possible, but not later than 2 days
7 after the issuance of the order, on the actions required
8 by the order and on why the cosmetic that is the subject
9 of the order should not be recalled.

10 “(d) POST-HEARING RECALL ORDER AND MODIFICA-
11 TION OF ORDER.—

12 “(1) AMENDMENT OF ORDER.—If, after pro-
13 viding opportunity for an informal hearing under
14 subsection (c), the Secretary determines that re-
15 moval of the cosmetic from commerce is necessary,
16 the Secretary shall, as appropriate—

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

19 “(B) specify a timetable in which the recall
20 shall occur;

21 “(C) require periodic reports to the Sec-
22 retary describing the progress of the recall; and

23 “(D) provide notice to consumers to whom
24 such cosmetic was, or may have been, distrib-
25 uted.

1 “(2) VACATING OF ORDER.—If, after such hear-
2 ing, the Secretary determines that adequate grounds
3 do not exist to continue the actions required by the
4 order, or that such actions should be modified, the
5 Secretary shall vacate the order or modify the order.

6 “(e) COOPERATION AND CONSULTATION.—The Sec-
7 retary shall work with State and local public health offi-
8 cials in carrying out this section, as appropriate.

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

11 “(1) ensure that a press release is published re-
12 garding the recall, as well as alerts and public no-
13 tices, as appropriate, in order to provide notifica-
14 tion—

15 “(A) of the recall to consumers and retail-
16 ers to whom such cosmetic was, or may have
17 been, distributed; and

18 “(B) that includes, at a minimum—

19 “(i) the name of the cosmetic subject
20 to the recall;

21 “(ii) a description of the risk associ-
22 ated with such cosmetic; and

23 “(iii) to the extent practicable, infor-
24 mation for consumers about similar cos-
25 metics that are not affected by the recall;

1 “(2) shall consider providing a list to the public
2 of retail consignees receiving products involved in a
3 Class I recall, as determined appropriate by the Sec-
4 retary; and

5 “(3) if available, publish on the Internet Web
6 site of the Food and Drug Administration an image
7 of the cosmetic that is the subject of the press re-
8 lease described in (1).

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

13 “(h) EFFECT.—Nothing in this section shall affect
14 the authority of the Secretary to request or participate
15 in a voluntary recall, or to issue an order to cease distribu-
16 tion or to recall under any other provision of this Act or
17 under the Public Health Service Act.

18 “(i) RESPONSIBLE PERSON DEFINED.—In this sec-
19 tion, the term ‘responsible person’ has the meaning given
20 to such term in section 604(c).”.

21 **SEC. 8. EFFECTIVE DATES.**

22 (a) The amendments made by sections 2(a), 3, 4, 5,
23 and 7 shall take effect 18 months after the date of enact-
24 ment of this Act.

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

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