

112TH CONGRESS
2^D SESSION

H. R. 4395

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

IN THE HOUSE OF REPRESENTATIVES

APRIL 18, 2012

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

A BILL

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

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 AND REFERENCES.**

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

1 (b) REFERENCES TO THE FEDERAL FOOD, DRUG,
 2 AND COSMETIC ACT.—Except as otherwise specified,
 3 whenever in this Act an amendment is expressed in terms
 4 of an amendment to a section or other provision, the ref-
 5 erence shall be considered to be made to a section or other
 6 provision of the Federal Food, Drug, and Cosmetic Act
 7 (21 U.S.C. 301 et seq.).

8 **SEC. 2. TABLE OF CONTENTS.**

- Sec. 1. Short title and references.
- Sec. 2. Table of contents.
- Sec. 3. Registration of cosmetic manufacturing establishments.
- Sec. 4. Cosmetic and ingredient statement.
- Sec. 5. Serious and unexpected adverse event reporting for cosmetics.
- Sec. 6. Good manufacturing practice for cosmetics.
- Sec. 7. Tolerances for nonfunctional constituents in cosmetics.
- Sec. 8. Cosmetic ingredient review.
- Sec. 9. Cosmetic ingredient safety.
- Sec. 10. National cosmetic regulatory databank.
- Sec. 11. Cosmetic records inspection.
- Sec. 12. Rules of construction.
- Sec. 13. Conforming amendments.
- Sec. 14. National uniformity for cosmetics.
- Sec. 15. Importation.
- Sec. 16. Authorization of appropriations.
- Sec. 17. Effective dates.

9 **SEC. 3. REGISTRATION OF COSMETIC MANUFACTURING ES-**
 10 **TABLISHMENTS.**

11 Chapter VI is amended by adding at the end the fol-
 12 lowing:

13 **“SEC. 604. REGISTRATION OF COSMETIC MANUFACTURING**
 14 **ESTABLISHMENTS.**

15 “(a) IN GENERAL.—

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

1 gaged in the manufacture of a cosmetic intended to
2 be marketed in the United States be registered with
3 the Secretary within 60 days after beginning such
4 manufacture. If a cosmetic is processed in more
5 than one establishment, registration shall be re-
6 quired only for the establishment that performs the
7 final portion of the manufacturing operation. The
8 registration shall state the name of the company or
9 other organization, the city, street address, State,
10 and country of the establishment, and the title,
11 email address, and telephone number for the office
12 within the establishment that is responsible for sub-
13 mitting and maintaining the registration.

14 “(2) The Secretary shall establish and provide
15 to the registrant a unique cosmetic establishment
16 registration number within 15 business days after
17 receiving the registration. Where more than one per-
18 son registers the same manufacturing establishment,
19 the Secretary shall provide only one unique estab-
20 lishment registration number for the establishment.

21 “(b) MAINTENANCE.—The information required in a
22 registration under subsection (a) or in an existing reg-
23 istration under subsection (e) shall be maintained as cur-
24 rent and accurate by the registrant by withdrawing or

1 amending the registration within 60 days after the infor-
2 mation becomes no longer current and accurate.

3 “(c) LIST.—The Secretary shall compile and main-
4 tain an up-to-date and publicly available electronic list of
5 establishments that are registered under this section.

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

8 “(1) The term ‘establishment’ is a place of
9 business where a cosmetic is manufactured, without
10 further processing outside or within the United
11 States.

12 “(2)(A) The term ‘domestic establishment’
13 means an establishment location in any State.

14 “(B) The term ‘foreign establishment’ means
15 an establishment location outside the States from
16 which a cosmetic is exported to the United States.

17 “(3) A cosmetic shall not be considered to have
18 undergone further processing for purposes of para-
19 graph (1) solely on the basis that packaging or other
20 labeling was added or that any similar activity of a
21 de minimis nature was carried out with respect to
22 the cosmetic.

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

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

3 “(f) SUSPENSION OF REGISTRATION.—

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

9 “(2) NOTICE OF SUSPENSION.—Suspension of a
10 registration under this section shall be preceded
11 by—

12 “(A) notice to the establishment of the in-
13 tent to suspend the registration; and

14 “(B) an opportunity for an informal hear-
15 ing concerning the suspension.

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

19 “(4) PROCEDURES.—The Secretary shall by
20 regulations establish procedures for the implementa-
21 tion of this subsection.

22 “(g) CANCELLATION OF REGISTRATION.—

23 “(1) IN GENERAL.—Not earlier than 10 days
24 after providing notice under paragraph (2), the Sec-
25 retary may cancel a registration under this section

1 if the Secretary determines that the registration was
2 not updated in accordance with this section or other-
3 wise is not current and accurate.

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

8 “(3) TIMELY UPDATE OR CORRECTION.—If the
9 registration for the establishment is updated or cor-
10 rected no later than 7 days after notice is provided
11 under paragraph (2), the Secretary shall not cancel
12 the registration.”.

13 **SEC. 4. COSMETIC AND INGREDIENT STATEMENT.**

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

16 **“SEC. 605. COSMETIC AND INGREDIENT STATEMENT.**

17 “(a) IN GENERAL.—The Secretary shall by regula-
18 tion require that every domestic and foreign establishment
19 engaged in the manufacture of a cosmetic intended to be
20 marketed in the United States submit to the Secretary,
21 for each cosmetic manufactured in the establishment,
22 within 60 days after beginning manufacture of the prod-
23 uct, a cosmetic and ingredient statement containing—

24 “(1) the unique establishment registration num-
25 ber of the manufacturing establishment where the

1 cosmetic is manufactured or, if the same cosmetic
2 product is manufactured in more than one establish-
3 ment, the unique establishment registration number
4 of each establishment where it is manufactured;

5 “(2) the brand name or names for the cosmetic;

6 “(3) the applicable cosmetic category or cat-
7 egories for the cosmetic;

8 “(4) the ingredients in the cosmetic (in accord-
9 ance with section 701.3 of title 21, Code of Federal
10 Regulations, and using the name of each ingredient
11 established under subsection (b), if any), in descend-
12 ing order of predominance by weight, except that—

13 “(A) flavors and fragrances may be des-
14 ignated as such; and

15 “(B) all variations in color, flavor, or fra-
16 grance may be included in one statement; and

17 “(5) the title, email address, and telephone
18 number for the office within the establishment that
19 is responsible for filing and maintaining the state-
20 ment.

21 The Secretary shall establish and provide to the person
22 submitting the statement a unique cosmetic and ingre-
23 dient statement number within 15 business days after re-
24 ceiving the statement.

1 “(b) NAME OF INGREDIENT.—For purposes of this
2 section and cosmetic ingredient labeling under section
3 701.3 of title 21, Code of Federal Regulations, the name
4 of a cosmetic ingredient shall be the name, if any, in the
5 most recent edition of the International Cosmetic Ingre-
6 dient Dictionary, unless the Secretary, after public notice
7 and an opportunity for public comment, by regulation or
8 guidance establishes a different name for the ingredient.

9 “(c) MAINTENANCE.—The information required in a
10 statement submitted to the Secretary under subsection (a)
11 or in an existing statement under subsection (e)(1) shall
12 be maintained as current and accurate by the person who
13 filed the statement by withdrawing or amending the state-
14 ment within 60 days after the information becomes no
15 longer current and accurate, except that no amendment
16 shall be required for a change in the order of predomi-
17 nance of the ingredients or for any other type or category
18 of change for which the Secretary determines that the
19 costs of amending the statement exceed the benefits.

20 “(d) LIST.—The Secretary shall compile and main-
21 tain an up-to-date and publicly available electronic list of
22 cosmetics and ingredients for which statements are sub-
23 mitted under this section. A statement submitted pursuant
24 to this section shall not be subject to disclosure under sec-
25 tion 552 of title 5, United States Code. The Secretary may

1 make publicly available information derived from such
2 statements that discloses the names of ingredients used
3 in cosmetic products and the number of cosmetic products
4 in which a specific ingredient is used but may not make
5 publicly available any information that relates to any in-
6 gredient that is exempt from public disclosure under sec-
7 tion 720.8 of title 21, Code of Federal Regulations, or that
8 discloses at what establishment a cosmetic is manufac-
9 tured. At the request of the director of a State agency
10 responsible for regulating the safety of cosmetics, the Sec-
11 retary may disclose to such official confidential business
12 and trade secret information contained in a statement and
13 such official and other State employees who have access
14 to such information shall then be subject to the provisions
15 of section 301(j), subsection 552(b) of title 5, United
16 States Code, and section 1905 of title 18, United States
17 Code, with respect to such information.

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

20 “(1) a cosmetic for which as of the date of en-
21 actment of this section a cosmetic ingredient state-
22 ment has been submitted to the Secretary under
23 part 710 of title 21, Code of Federal Regulations; or

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

4 **SEC. 5. SERIOUS AND UNEXPECTED ADVERSE EVENT RE-**
5 **PORTING FOR COSMETICS.**

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

8 **“SEC. 606. SERIOUS AND UNEXPECTED ADVERSE EVENT RE-**
9 **PORTING FOR COSMETICS.**

10 “(a) IN GENERAL.—The Secretary shall by regula-
11 tion require that a domestic or foreign manufacturer,
12 packer, or distributor whose name appears on the label
13 pursuant to section 602(b)(1) of a cosmetic marketed in
14 the United States submit to the Secretary under sub-
15 section (b) a report containing information received con-
16 cerning a serious and unexpected adverse event in the
17 United States allegedly associated with the use of the
18 product.

19 “(b) SUBMISSION OF REPORTS.—A serious and unex-
20 pected adverse event report shall be submitted to the Sec-
21 retary no later than 15 business days after information
22 concerning the adverse event is received at the place of
23 business labeled on the product under section 602(b)(1).

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

4 “(1) an identifiable patient;

5 “(2) an identifiable reporter;

6 “(3) a suspect cosmetic product; and

7 “(4) a serious and unexpected adverse event.

8 The person submitting the report may include in the sub-
9 mission any additional pertinent information and may
10 supplement the report with additional information at a
11 later time.

12 “(d) DEFINITIONS.—

13 “(1) A ‘serious’ adverse event is one that—

14 “(A) results in—

15 “(i) death;

16 “(ii) a life-threatening experience;

17 “(iii) inpatient hospitalization;

18 “(iv) a persistent and significant dis-
19 ability or incapacity; or

20 “(v) congenital anomaly or birth de-
21 fect; or

22 “(B) requires, based on reasonable medical
23 judgment, a medical or surgical intervention to
24 prevent an outcome described under subpara-
25 graph (A).

1 “(2) An ‘unexpected’ adverse event is one that
2 is not identified in the current labeling for the cos-
3 metic.

4 “(e) RULES OF CONSTRUCTION.—

5 “(1) A serious and unexpected adverse event re-
6 port (including all information submitted in the ini-
7 tial report or added later) submitted to the Sec-
8 retary under subsection (a) is—

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

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

13 “(ii) a medical or similar file the disclosure
14 of which would constitute a violation of section
15 552(b)(6) of such title 5, and shall not be pub-
16 licly disclosed.

17 “(2) The submission of a serious and unex-
18 pected adverse event report in compliance with sub-
19 section (a) shall not constitute an admission that the
20 cosmetic involved caused or contributed to the ad-
21 verse event.

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

1 **SEC. 6. GOOD MANUFACTURING PRACTICE FOR COS-**
2 **METICS.**

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

5 **“SEC. 607. GOOD MANUFACTURING PRACTICES FOR COS-**
6 **METICS.**

7 “The Secretary shall, after public notice and an op-
8 portunity for public comment, by regulation establish good
9 manufacturing practices for the methods used in, or the
10 facilities or controls used for, the manufacture, processing,
11 filling, or packaging of cosmetics. In issuing such regula-
12 tions or guidance, the Secretary shall review international
13 standards for cosmetic good manufacturing practices to
14 ensure that such regulations or guidance are consistent,
15 to the extent the Secretary determines practicable and ap-
16 propriate, with such standards.”.

17 **SEC. 7. TOLERANCES FOR NONFUNCTIONAL CONSTITU-**
18 **ENTS IN COSMETICS.**

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

21 **“SEC. 608. TOLERANCES FOR NONFUNCTIONAL CONSTITU-**
22 **ENTS IN COSMETICS.**

23 “(a) IN GENERAL.—The Secretary may on the Sec-
24 retary’s own initiative, and shall in response to a petition
25 submitted by an interested person, including a State,
26 under subsection (b) or in accordance with the provisions

1 under subsection (c), after public notice and an oppor-
2 tunity for public comment, establish by regulation or guid-
3 ance a tolerance level for a nonfunctional constituent in
4 cosmetics. For purposes of this section, a ‘nonfunctional
5 constituent’ in a cosmetic is any substance that is an ancil-
6 lary part of an ingredient or the manufacturing process,
7 has not been added as a separate substance, and serves
8 no cosmetic function in the cosmetic. The Secretary shall
9 establish such a tolerance at a level that is necessary for
10 the protection of the public health using generally recog-
11 nized principles of scientific risk assessment. In issuing
12 such a regulation or guidance, the Secretary shall take
13 into consideration the level that is reasonably achievable
14 through good manufacturing practices and shall review
15 tolerance levels for such nonfunctional constituent estab-
16 lished by authoritative scientific or regulatory organiza-
17 tions to ensure that such regulation or guidance is con-
18 sistent, to the extent the Secretary determines practicable
19 and appropriate, with such other tolerance levels.

20 “(b) PROCEDURE.—

21 “(1)(A)(i) If the review of a nonfunctional con-
22 stituent is being conducted on the Secretary’s own
23 initiative or under subsection (c), the Secretary shall
24 initiate the proceeding by publishing in the Federal
25 Register a proposed regulation or guidance. The

1 Secretary shall provide 180 days for public com-
2 ment.

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

7 “(B)(i) If the review of a nonfunctional con-
8 stituent is being conducted in response to a petition
9 submitted by an interested person, the Secretary
10 shall publish the petition in the Federal Register for
11 public comment not later than 60 days after receipt
12 of the petition. All appendices to the petition shall
13 be made available on the Secretary’s website. The
14 Secretary shall provide 180 days for public com-
15 ment.

16 “(ii) Any such petition shall specify the non-
17 functional constituent, the proposed tolerance level,
18 and the scientific data and information on which the
19 proposed tolerance level is based.

20 “(iii) Not later than 180 days after the end of
21 the period for public comment, the Secretary shall
22 publish in the Federal Register a proposed regula-
23 tion or guidance for public comment. The Secretary
24 shall provide 90 days for public comment.

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

5 “(C) The Secretary may on the Secretary’s own
6 initiative, and shall in response to a petition sub-
7 mitted by an interested person, reconsider any toler-
8 ance level established under subparagraph (A) or
9 (B), using the same procedure established in this
10 paragraph (1).

11 “(D) Any regulation or guidance, including any
12 revised regulation or guidance, shall apply to cos-
13 metics first shipped in interstate commerce begin-
14 ning two years after the date of issue of the regula-
15 tion or guidance, unless the Secretary determines,
16 after public notice and an opportunity for public
17 comment, that an earlier effective date is required to
18 prevent serious adverse health consequences or
19 death.

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

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

4 “(c) PRIORITY LIST.—Within 180 days after the date
5 of enactment, the Secretary shall establish a publicly avail-
6 able electronic priority list of nonfunctional constituents
7 in cosmetics for review under this section. The Secretary
8 shall begin and complete a review of at least one such pri-
9 ority nonfunctional constituent every 365 days.

10 “(d) APPLICATION.—A tolerance level established by
11 the Secretary under this section shall apply in every
12 State.”.

13 **SEC. 8. COSMETIC INGREDIENT REVIEW.**

14 Chapter VI, as amended by sections 3, 4, 5, 6, and
15 7, is amended by adding at the end the following:

16 **“SEC. 609. COSMETIC INGREDIENT REVIEW.**

17 “(a) PANEL’S RECOMMENDATION.—The Cosmetic
18 Ingredient Review Expert Panel determination in an ap-
19 proved final report that a cosmetic ingredient—

20 “(1) is safe for use in cosmetic products with-
21 out the need for specified conditions of use;

22 “(2) is safe for use in cosmetic products under
23 specified conditions for use;

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

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

5 “(5) is the subject of any other type of deter-
6 mination by the Cosmetic Ingredient Review Expert
7 Panel, shall be deemed to constitute a recommenda-
8 tion that the Secretary accept that determination for
9 purposes of implementing and enforcing this chapter
10 in accordance with the effective dates established
11 under subsection (d).

12 “(b) SECRETARY’S DETERMINATION.—The Secretary
13 shall be deemed to accept that determination and rec-
14 ommendation unless the Secretary at any time determines,
15 by regulation or guidance, after public notice and an op-
16 portunity for public comment, to make a different deter-
17 mination. A determination and recommendation described
18 in subsection (a) that is deemed to be accepted by the Sec-
19 retary shall be implemented and enforced by the Secretary
20 by banning any use of any ingredient that does not con-
21 form to the specified safe conditions of use under sub-
22 section (a)(2) and any ingredient described under sub-
23 section (a)(3) or (4).

24 “(c) PROPRIETARY DATA.—The determination de-
25 scribed in subsection (a)(4) shall not apply to a person

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

7 “(d) EFFECTIVE DATES.—Subsection (b) shall be ef-
8 fective—

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

13 “(2) two years after the date of approval of the
14 final report for ingredients that are the subject of an
15 approved final report after the date of enactment of
16 this subsection.

17 “(e) SECRETARY’S REPRESENTATIVE.—The Sec-
18 retary shall appoint a representative who shall be a mem-
19 ber of and shall participate in the deliberations of the Cos-
20 metic Ingredient Review Expert Panel.

21 “(f) APPLICATION.—A safety determination accepted
22 or made by the Secretary under this section shall apply
23 in every State.”.

1 **SEC. 9. COSMETIC INGREDIENT SAFETY.**

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

4 **“SEC. 610. COSMETIC INGREDIENT SAFETY.**

5 “(a) IN GENERAL.—

6 “(1) The Secretary may on the Secretary’s own
7 initiative, and shall in response to a petition sub-
8 mitted by an interested person, including a State,
9 under subsection (b) or in accordance with the provi-
10 sions under subsection (c), evaluate the safety of any
11 ingredient intended for use as or in a cosmetic prod-
12 uct and, after public notice and an opportunity for
13 public comment, establish by regulation or guidance
14 the conditions, if any, under which the ingredient is
15 safe for human use.

16 “(2) In evaluating the safety of any such ingre-
17 dient, the Secretary shall apply generally recognized
18 principles of scientific risk assessment and shall take
19 into account—

20 “(A) the conditions of use recommended or
21 suggested in the labeling;

22 “(B) any relevant safety evaluation con-
23 ducted by the Cosmetic Ingredient Review Ex-
24 pert Panel; and

1 “(C) all relevant unpublished and pub-
2 lished safety data and information, including
3 human exposure during marketing.

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

10 “(b) PROCEDURE.—

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

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

21 “(B)(i) If the review of an ingredient is being
22 conducted in response to a petition submitted by an
23 interested person, the Secretary shall publish the pe-
24 tition in the Federal Register for public comment
25 not later than 60 days after receipt of the petition.

1 All appendices to the petition shall be made available
2 on the Secretary’s website. The Secretary shall pro-
3 vide 180 days for public comment.

4 “(ii) Any such petition shall specify the ingre-
5 dient, the uses for which the ingredient is intended,
6 any proposed conditions of safe use, and the sci-
7 entific data and information, including human expo-
8 sure during marketing, on which the proposed condi-
9 tions are based.

10 “(iii) Not later than 180 days after the end of
11 the period for public comment, the Secretary shall
12 publish in the Federal Register a proposed regula-
13 tion or guidance for public comment. The Secretary
14 shall provide 90 days for public comment.

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

19 “(C) The Secretary may on the Secretary’s own
20 initiative, and shall in response to a petition sub-
21 mitted by an interested person, reconsider any con-
22 ditions for safe use established under subparagraph
23 (A) or (B), using the same procedure established in
24 this paragraph (1).

1 “(D) Any regulation or guidance, including any
2 revised regulation or guidance, shall apply to cos-
3 metics first shipped in interstate commerce begin-
4 ning two years after the date of issuance of the reg-
5 ulation or guidance, unless the Secretary determines,
6 after public notice and an opportunity for public
7 comment, that an earlier effective date is required to
8 prevent serious adverse health consequences or
9 death.

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

19 “(c) PRIORITY LIST.—Within 180 days after the date
20 of enactment, the Secretary shall establish a publicly avail-
21 able electronic priority list of cosmetic ingredients. The
22 Secretary shall begin and complete a review of at least
23 one such priority cosmetic ingredient every 365 days.

1 “(d) APPLICATION.—A safety determination accepted
2 or made by the Secretary under this section shall apply
3 in every State.”.

4 **SEC. 10. NATIONAL COSMETIC REGULATORY DATABANK.**

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

7 **“SEC. 613. NATIONAL COSMETIC REGULATORY DATABANK.**

8 “In order to consolidate all information pertaining to
9 regulation of the safety of cosmetics in one place for use
10 by State officials responsible for the regulation of cos-
11 metics and by the general public, the Secretary shall es-
12 tablish and maintain in the Center for Food Safety and
13 Applied Nutrition (or any successor organization of such
14 Center) of the Food and Drug Administration an elec-
15 tronic National Cosmetic Regulatory Databank that shall
16 contain the information submitted to the Secretary under
17 sections 604, 605, and 606, and such other information
18 pertaining to the regulation of cosmetics as the Secretary
19 shall deem appropriate. Information in the National Cos-
20 metic Regulatory Databank that is not subject to public
21 disclosure under section 552 of title 5, United States
22 Code, may be disclosed on request to the director of a
23 State agency responsible for regulating the safety of cos-
24 metics, and such official and other State employees who
25 have access to such information shall then be subject to

1 the provisions of section 301(j), subsection 552(b) of title
2 5, United States Code, and section 1905 of title 18,
3 United States Code, with respect to such information. In-
4 formation available in the National Cosmetic Regulatory
5 Databank shall not be subject to State laws on submission
6 of that information, whether in the same or a different
7 format.”.

8 **SEC. 11. COSMETIC RECORDS INSPECTION.**

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

12 **“SEC. 614. COSMETIC RECORDS INSPECTION.**

13 “If the Secretary has a reasonable belief that a cos-
14 metic product, and any other related cosmetic product
15 that the Secretary reasonably believes is affected in the
16 same manner, is adulterated and presents a threat of seri-
17 ous adverse health consequences or death to humans, each
18 person who manufactures, processes, packs, distributes,
19 receives, holds, or imports such article shall, at the request
20 of an officer or employee duly designated by the Secretary,
21 permit such officer or employee, upon presentation of ap-
22 propriate credentials and a written notice to such person
23 setting forth the basis for the Secretary’s belief, at reason-
24 able times and within reasonable limits and in a reason-
25 able manner, to have access to and copy records that are

1 needed to assist the Secretary in determining whether the
2 cosmetic product is adulterated and presents a threat of
3 serious adverse health consequences or death to humans.
4 The Secretary shall prevent the disclosure of trade secret
5 or confidential information obtained by the Secretary pur-
6 suant to this section. This section does not extend to cos-
7 metic product formulas, financial data, pricing data, per-
8 sonnel data, research data, or sales data other than ship-
9 ment data.”.

10 **SEC. 12. RULES OF CONSTRUCTION.**

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

14 **“SEC. 615. RULES OF CONSTRUCTION.**

15 “(a) **COSMETIC PRODUCTS.**—Whenever the term cos-
16 metic or cosmetics is used in sections 604, 605, 606, or
17 607, it shall be deemed to refer only to a cosmetic product
18 or cosmetic products. A cosmetic product that is subject
19 to the caution legend in section 601(a) shall not be subject
20 to the provisions of sections 608, 609, or 610.

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

1 by a person who contracts to perform that function for
2 the person who is required to register or make the submis-
3 sion.

4 “(c) EXEMPTIONS.—The Secretary may, in the Sec-
5 retary’s discretion, establish exemptions from the require-
6 ments in this title for the efficient and cost-effective imple-
7 mentation of these provisions.

8 “(d) SAFETY.—For purposes of chapter VI, a cos-
9 metic shall be deemed to be safe if it does not present
10 a risk of significant illness or injury to humans under the
11 conditions of use recommended or suggested in the label-
12 ing.”.

13 **SEC. 13. CONFORMING AMENDMENTS.**

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

16 “(aaa) The failure to reg-
17 ister a cosmetic establishment re-
18 quired to be registered under sec-
19 tion 604 or to maintain the reg-
20 istration current and accurate.

21 “(bbb) The failure to submit
22 a cosmetic and ingredient state-
23 ment required under section 605
24 or to maintain the statement cur-
25 rent and accurate.

1 “(ccc) The failure to submit
2 a serious and unexpected adverse
3 event report or to include on a
4 label the domestic telephone
5 number through which a report
6 of a serious and unexpected ad-
7 verse event may be received, as
8 required under section 606.

9 “(ddd) The failure to comply
10 with cosmetic good manufac-
11 turing practices established
12 under section 607.

13 “(eee) The failure to comply
14 with a tolerance for a nonfunc-
15 tional constituent in cosmetics es-
16 tablished under section 608.

17 “(fff) The failure to comply
18 with a determination with respect
19 to the safety of a cosmetic ingre-
20 dient under section 609 or sec-
21 tion 610.

22 “(ggg) For a cosmetic prod-
23 uct that is being imported or of-
24 fered for import, the failure of
25 the importer to present both the

1 unique cosmetic establishment
2 registration number established
3 by the Secretary under section
4 604(a) and the unique cosmetic
5 and ingredient statement number
6 established by the Secretary
7 under section 605(a).”.

8 (b) Section 301(j) is amended by inserting “605, 609,
9 613,” after “573,”.

10 **SEC. 14. NATIONAL UNIFORMITY FOR COSMETICS.**

11 Section 752 is amended—

12 (1) by amending the section heading to read as
13 follows: “**NATIONAL UNIFORMITY FOR COS-**
14 **METICS**”;

15 (2) in subsection (b), by inserting “or (f)” after
16 “subsection (a)”; and

17 (3) by adding at the end the following:

18 “(f) **COSMETIC SAFETY.**—

19 “(1) **IN GENERAL.**—Subject to paragraphs (2)
20 and (3), no State or political subdivision of a State
21 may establish or continue in effect any law, regula-
22 tion, order, or other requirement relating to cosmetic
23 constituents, cosmetic ingredients, or cosmetic prod-
24 ucts—

1 “(A) that is different from, in addition to,
2 or otherwise not identical to, the provisions of
3 chapter VI and the requirements and deter-
4 minations established or accepted by the Sec-
5 retary thereunder; or

6 “(B) relating to registration, listing, or
7 fees for establishments, products, ingredients,
8 or constituents, or to submission of reports.

9 “(2) STATE PETITIONS.—Not later than 180
10 days after the date of the enactment of this sub-
11 section, a State may petition the Secretary under
12 section 609 or 610 to establish as a national stand-
13 ard a tolerance for a nonfunctional constituent or a
14 safety requirement for a cosmetic ingredient that ex-
15 ists in a State law or a duly promulgated State reg-
16 ulation that is effective on the date of enactment of
17 this subsection. Pending completion of the process
18 established under section 608 or 610, the State re-
19 quirement shall remain in effect for that State.
20 Upon completion of the process established under
21 section 608 or 610, the final regulation or guidance
22 published by the Secretary in the Federal Register
23 shall be the national safety standard for the con-
24 stituent or ingredient.

1 “(3) REQUIREMENTS ADOPTED BY STATE PUB-
2 LIC INITIATIVE OR REFERENDUM.—This subsection
3 shall not apply to a State requirement adopted by a
4 State public initiative or referendum enacted prior to
5 the enactment of this subsection.”.

6 **SEC. 15. IMPORTATION.**

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

9 “If a cosmetic product is being imported or offered
10 for import into the United States and the importer does
11 not present both the unique cosmetic establishment reg-
12 istration number established under section 604 and the
13 unique cosmetic and ingredient statement number estab-
14 lished under section 605, or the registration number or
15 statement number is not correct and accurate, the cos-
16 metic product shall be denied entry.”.

17 **SEC. 16. AUTHORIZATION OF APPROPRIATIONS.**

18 Chapter VI, as amended by sections 3, 4, 5, 6, 7,
19 8, 9, 10, 11, and 12, is amended by adding at the end
20 the following:

21 **“SEC. 616. AUTHORIZATION OF APPROPRIATIONS.**

22 “To carry out this chapter and section 752, there is
23 authorized to be appropriated \$11,700,000 for each of fis-
24 cal years 2014 through 2018. The Secretary shall annu-
25 ally allocate for personnel and functions for the regulation

1 of cosmetics during the period of such fiscal years at least
2 \$11,700,000 out of the total funds appropriated for the
3 Food and Drug Administration, 10 full-time equivalent
4 personnel in the Office of Regulatory Affairs, and 1 full-
5 time equivalent lawyer in the Office of Chief Counsel.”.

6 **SEC. 17. EFFECTIVE DATES.**

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

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

12 (2) one year after the Secretary of Health and
13 Human Services publishes a notice in the Federal
14 Register determining that an effective electronic sys-
15 tem has been established and is operational for the
16 submission of cosmetic manufacturing establishment
17 registrations, cosmetic and ingredient filings, reports
18 of serious and unexpected cosmetic adverse events,
19 good manufacturing practices for cosmetics, and the
20 National Cosmetic Regulatory Databank.

21 (b) The remaining sections of this Act shall be effec-
22 tive on the date of the enactment of this Act.

○