

114TH CONGRESS
1ST SESSION

H. R. 4075

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

IN THE HOUSE OF REPRESENTATIVES

NOVEMBER 18, 2015

Mr. SESSIONS 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 manufacturing establishments, the submission of cosmetic and ingredient statements, and the reporting of serious cosmetic 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 Modernization Amendments of 2015”.

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.**

9 The table of contents for this Act is as follows:

- Sec. 1. Short title and references.
- Sec. 2. Table of contents.
- Sec. 3. Definitions.
- Sec. 4. Registration of cosmetic manufacturing establishments.
- Sec. 5. Cosmetic and ingredient statement.
- Sec. 6. Serious and unexpected adverse event reporting for cosmetics.
- Sec. 7. Good manufacturing practice.
- Sec. 8. Safety substantiation for cosmetic ingredients and nonfunctional constituents.
- Sec. 9. National Cosmetic Regulatory Databank.
- Sec. 10. Special rules.
- Sec. 11. Prohibited acts.
- Sec. 12. National uniformity for cosmetics.
- Sec. 13. Importation.
- Sec. 14. Effective dates.

10 **SEC. 3. DEFINITIONS.**

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

13 **“SEC. 604. DEFINITIONS.**

14 “In this chapter:

15 “(1) COSMETIC.—Notwithstanding section
 16 201(i), for purposes of this section and sections
 17 601(f), 605, 606, 607, 608, and 801(a), the term

1 ‘cosmetic’ includes only articles described in section
2 201(i)(1).

3 “(2) ESTABLISHMENT.—

4 “(A) The term ‘establishment’ means a
5 place of business where a cosmetic is manufac-
6 tured, without further processing outside or
7 within the United States.

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

15 “(C) The term ‘domestic establishment’
16 means an establishment location in any State.

17 “(D) The term ‘foreign establishment’
18 means an establishment location outside the
19 United States.

20 “(3) SAFE; SAFETY.—

21 “(A) The terms ‘safe’ and ‘safety’, with re-
22 spect to a cosmetic, mean the cosmetic does not
23 present a significant risk of serious illness or
24 injury to humans under the conditions of use
25 recommended or suggested in the labeling of

1 the cosmetic, including the limitation of ‘for
2 professional use’ only.

3 “(B) For purposes of subparagraph (A),
4 the term ‘professional’ means an individual
5 who—

6 “(i) is licensed by an official State au-
7 thority to practice in the field of cosme-
8 tology, nail care, barbering, and or esthet-
9 ics; and

10 “(ii) is in compliance with all require-
11 ments of the State for such licensing.”.

12 **SEC. 4. REGISTRATION OF COSMETIC MANUFACTURING ES-**
13 **TABLISHMENTS.**

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

17 **“SEC. 605. REGISTRATION OF COSMETIC MANUFACTURING**
18 **ESTABLISHMENTS.**

19 “(a) IN GENERAL.—

20 “(1) REGISTRATION.—The Secretary shall by
21 regulation require that every domestic and foreign
22 establishment engaged in the manufacture of a cos-
23 metic intended to be sold in the United States that
24 is not exempt under subsection (e) be registered with
25 the Secretary within 60 business days after the first

1 commercial sale of a cosmetic in the United States.
2 If a cosmetic is processed in more than one estab-
3 lishment, registration shall be required under this
4 section only for the establishment that performs the
5 final portion of the manufacturing operation. The
6 single registration shall cover all such cosmetics
7 manufactured by the establishment. The registration
8 shall state only the name of the company or other
9 organization name of the establishment, the city,
10 street address, State, and country of the establish-
11 ment, and the title, email address, and telephone
12 number for the office within the establishment that
13 is responsible for submitting and maintaining the
14 registration. For a foreign establishment, the reg-
15 istration shall include the contact information for
16 the initial United States agent of the establishment.

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

1 number is received by the person who submitted the
2 registration. Where more than one person registers
3 the same establishment, the Secretary shall provide
4 only one unique establishment registration number
5 for the establishment. The unique cosmetic estab-
6 lishment number shall not be required to be included
7 in cosmetic labeling.

8 “(b) MAINTENANCE.—The information required in a
9 registration under subsection (a) or in an existing reg-
10 istration under subsection (e)(1)(A) shall be maintained
11 as current and accurate by the registrant by withdrawing
12 or amending the registration within 60 business days after
13 the information becomes no longer current and accurate.

14 “(c) ENFORCEMENT.—The Secretary shall enforce
15 this section under section 301(ddd) and shall not suspend
16 or revoke a registration under this section.

17 “(d) LIST.—The Secretary shall compile and main-
18 tain an up-to-date and publicly available electronic list of
19 establishments that are registered under this section.

20 “(e) EXEMPTIONS.—

21 “(1) IN GENERAL.—Registration under sub-
22 section (a) shall not be required for any entity based
23 on such entity operating as—

24 “(A) an establishment that as of the date
25 of enactment of this section is registered as a

1 cosmetic establishment under part 710 of title
2 21, Code of Federal Regulations (as in effect on
3 such date);

4 “(B) a beauty shop or salon or spa;

5 “(C) a cosmetic retailer, including any
6 such retailer that is—

7 “(i) an individual sales representative;

8 “(ii) a wholesale or retail distribution
9 or sales facility; or

10 “(iii) a pharmacy or other person or
11 organization that—

12 “(I) compounds cosmetics at a
13 single location and administers, dis-
14 penses, or distributes such cosmetics
15 at retail from that location; and

16 “(II) does not otherwise manu-
17 facture or package cosmetics from
18 that location;

19 “(D) a health care provider, including a
20 hospital or clinic;

21 “(E) a public health agency or other non-
22 profit entity;

23 “(F) a hotel or other entity that provides
24 complimentary cosmetics;

1 “(G) a trade show or other venue where
2 cosmetic samples are provided;

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

7 “(I) a handcrafted soap or cosmetic made
8 in a home, a community facility, or a similar es-
9 tablishment; or

10 “(J) a business with less than \$1,000,000
11 annual net sales of cosmetics.

12 “(2) ADDITIONAL EXEMPTIONS.—The Sec-
13 retary may supplement the list of exemptions under
14 paragraph (1) with additional exemptions for per-
15 sons and activities where the cost of compliance ex-
16 ceeds the safety benefit to the public.”.

17 **SEC. 5. COSMETIC AND INGREDIENT STATEMENT.**

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

21 **“SEC. 606. COSMETIC AND INGREDIENT STATEMENT.**

22 “(a) IN GENERAL.—The Secretary shall by regula-
23 tion require that every domestic establishment and foreign
24 establishment engaged in the manufacture of a cosmetic
25 intended to be sold in the United States submit to the

1 Secretary, for each cosmetic so manufactured in the estab-
2 lishment, except such cosmetics manufactured by entities
3 exempted by section 605(e) from registration under sec-
4 tion 605, within 60 business days after the first commer-
5 cial sale of the cosmetic, a cosmetic and ingredient state-
6 ment. The Secretary shall require the statement to contain
7 only—

8 “(1) the unique establishment registration num-
9 ber of the manufacturing establishment where the
10 cosmetic is manufactured or, if the same cosmetic is
11 manufactured in more than one establishment, the
12 unique establishment registration number of each es-
13 tablishment where it is manufactured;

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

15 “(3) the applicable cosmetic category or cat-
16 egories for the cosmetic;

17 “(4) the ingredients in the cosmetic (in accord-
18 ance with section 701.3 of title 21, Code of Federal
19 Regulations (as in effect on the date of enactment
20 of the Cosmetic Modernization Amendments of 2015
21 and including any successor regulations), and using
22 the name of each ingredient established under sub-
23 section (d), if any), in descending order of predomi-
24 nance by weight, except that—

1 “(A) flavors and fragrances may be des-
2 ignated as such; and

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

5 “(5) the title, email address, and telephone
6 number for the office within the establishment that
7 is responsible for submitting and maintaining the
8 statement.

9 “(b) UNIQUE NUMBER.—The Secretary shall estab-
10 lish and provide to the office submitting a statement re-
11 quired by subsection (a) a unique cosmetic and ingredient
12 statement number within 15 business days after receiving
13 the statement. If the Secretary does not provide a unique
14 cosmetic and ingredient statement number within such 15-
15 business-day period, any requirement under this Act for
16 such number shall be deemed to be inapplicable until the
17 date that is 30 business days after such number is received
18 by the office that submitted the statement. The unique
19 cosmetic and ingredient statement number shall not be re-
20 quired to be included in cosmetic labeling.

21 “(c) CHANGE IN LABELING.—An establishment shall
22 not be required to submit a new or revised statement
23 under subsection (a) because of a change in labeling ex-
24 cept to the extent necessary to maintain the accuracy of

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

3 “(d) NAME OF INGREDIENT.—For purposes of this
4 section and cosmetic ingredient labeling under section
5 701.3 of title 21, Code of Federal Regulations (as in effect
6 on the date of enactment of the Cosmetic Modernization
7 Amendments of 2015 and including any successor regula-
8 tions), the name of a cosmetic ingredient shall be the
9 name, if any, in the most recent edition of the Inter-
10 national Cosmetic Ingredient Dictionary, unless the Sec-
11 retary by regulation establishes a different name for the
12 ingredient.

13 “(e) MAINTENANCE.—The information required in a
14 statement submitted to the Secretary under subsection (a)
15 or in an existing statement under subsection (g)(1) shall
16 be maintained as current and accurate by the office that
17 filed the statement by withdrawing or amending the state-
18 ment within 60 business days after the information be-
19 comes no longer current and accurate, except that no
20 amendment shall be required for a change in the order
21 of predominance of the ingredients or for any other type
22 or category of change for which the costs of amending the
23 statement exceed the safety benefit to the public.

24 “(f) ENFORCEMENT.—The Secretary shall enforce
25 subsections (a) and (e) under section 301(eee) and shall

1 not suspend or revoke a cosmetic and ingredient state-
2 ment.

3 “(g) LIST.—The Secretary shall compile and main-
4 tain an up-to-date and publicly available electronic list of
5 cosmetics and ingredients for which statements are sub-
6 mitted under this section. A statement submitted pursuant
7 to this section shall not be subject to disclosure under sec-
8 tion 552 of title 5, United States Code. The Secretary may
9 make publicly available information derived from such
10 statements that discloses the names of ingredients used
11 in cosmetics and the number of cosmetics in which a spe-
12 cific ingredient is used, but may not make publicly avail-
13 able any information that relates to any ingredient that
14 is exempt from public disclosure under section 720.8 of
15 title 21, Code of Federal Regulations (as in effect on the
16 date of enactment of the Cosmetic Modernization Amend-
17 ments of 2015 and including any successor regulations),
18 or that discloses at what establishment a cosmetic is man-
19 ufactured. At the written request of the director of a State
20 agency responsible for regulating the safety of cosmetics
21 stating good cause therefor, the Secretary may disclose to
22 such official confidential business and trade secret infor-
23 mation contained in a statement and such official and
24 other State employees who have access to such informa-
25 tion shall then be subject to the provisions of section

1 301(j) of this Act, section 552(b) of title 5, United States
 2 Code, and section 1905 of title 18, United States Code,
 3 with respect to such information.

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

6 “(1) for a cosmetic for which as of the date of
 7 enactment of this section a cosmetic ingredient
 8 statement has been submitted to the Secretary
 9 under part 710 of title 21, Code of Federal Regula-
 10 tions (as in effect on the date of enactment of the
 11 Cosmetic Modernization Amendments of 2015);

12 “(2) for a cosmetic ingredient exempt from
 13 public disclosure under section 720.8 of title 21,
 14 Code of Federal Regulations (as in effect on the
 15 date of enactment of the Cosmetic Modernization
 16 Amendments of 2015 and including any successor
 17 regulations); or

18 “(3) by an entity to the extent such entity is
 19 exempted by section 605(e) from registration under
 20 section 605.”.

21 **SEC. 6. SERIOUS AND UNEXPECTED ADVERSE EVENT RE-**
 22 **PORTING FOR COSMETICS.**

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

1 **“SEC. 607. SERIOUS AND UNEXPECTED ADVERSE EVENT RE-**
2 **PORTING FOR COSMETICS.**

3 “(a) IN GENERAL.—The Secretary shall by regula-
4 tion require that a domestic or foreign manufacturer,
5 packer, or distributor whose name appears on the label
6 pursuant to section 602(b)(1) of a cosmetic marketed in
7 the United States submit to the Secretary under sub-
8 section (b) a report containing—

9 “(1) information received concerning any seri-
10 ous and unexpected adverse event in the United
11 States allegedly associated with the use of the cos-
12 metic for which it is reasonably likely that the ad-
13 verse event was caused by the cosmetic when used
14 as recommended or suggested in the labeling; and

15 “(2) a copy of the label for the cosmetic.

16 “(b) SUBMISSION OF REPORTS.—A report on an ad-
17 verse event under subsection (a) shall be submitted to the
18 Secretary not later than 15 business days after informa-
19 tion concerning the adverse event is received at the place
20 of business labeled on the cosmetic pursuant to section
21 602(b)(1).

22 “(c) REQUIRED CONTENTS.—A report under sub-
23 section (a) shall include all of the following information:

24 “(1) An identifiable patient.

25 “(2) An identifiable reporter.

26 “(3) A suspect cosmetic or component thereof.

1 “(4) A serious adverse event.

2 “(d) ADDITIONAL CONTENTS; SUPPLEMENTAL RE-
3 PORTING.—The person submitting a report under sub-
4 section (a) may—

5 “(1) include pertinent information in addition
6 to the information listed in subsection (c); and

7 “(2) after submitting the initial report, supple-
8 ment the report with additional information.

9 “(e) SPECIAL RULES.—

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

14 “(A) shall be considered to be a safety re-
15 port under section 756 that is subject to the
16 provisions of that section; and

17 “(B) shall be considered to be a record
18 about an individual under section 552a of title
19 5, United States Code, and a medical or similar
20 file the disclosure of which would constitute a
21 violation of section 552 of such title 5, and
22 shall not be publicly disclosed unless all person-
23 ally identifiable information is redacted.

1 “(2) NO TREATMENT AS ADMISSION.—The sub-
2 mission of a serious and unexpected adverse event
3 report in compliance with subsection (a)—

4 “(A) shall not be construed as an admis-
5 sion that the cosmetic involved caused or con-
6 tributed to the adverse event; and

7 “(B) may be accompanied by a statement
8 that denies that the report constitutes an ad-
9 mission that the cosmetic involved caused or
10 contributed to the adverse event.

11 “(3) INCLUSION OF STATEMENT IN PUBLIC DIS-
12 CLOSURE.—In releasing any report under subsection
13 (a) or portion thereof for public disclosure, the Sec-
14 retary shall include any statement under paragraph
15 (2)(B).

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

21 “(g) EXEMPTION.—The Secretary may, by regula-
22 tion, establish an exemption to the requirements under
23 subsections (b) and (d) if the Secretary determines that
24 such exemption would have no adverse effect on public
25 health.

1 “(h) DEFINITIONS.—In this section:

2 “(1) The term ‘serious’, with respect to an ad-
3 verse event, means—

4 “(A) resulting in—

5 “(i) death;

6 “(ii) a life-threatening experience;

7 “(iii) inpatient hospitalization;

8 “(iv) a persistent and significant dis-
9 ability or incapacity;

10 “(v) a congenital anomaly or birth de-
11 fect; or

12 “(vi) permanent disfiguration; or

13 “(B) requiring, based on reasonable med-
14 ical judgment, a medical or surgical interven-
15 tion to prevent an outcome described under
16 subparagraph (A).

17 “(2) The term ‘unexpected’, with respect to an
18 adverse event, means not identified on the cosmetic
19 label.”.

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

23 “(g) If it is a cosmetic that is marketed in the United
24 States, unless the label of such cosmetic includes a domes-
25 tic address or domestic phone number through which a

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

5 **SEC. 7. GOOD MANUFACTURING PRACTICE.**

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

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

13 (b) PRINCIPLES AND STANDARDS.—Chapter VI (21
 14 U.S.C. 361 et seq.), as amended by sections 3, 4, 5, and
 15 6, is further amended by adding at the end the following:

16 **“SEC. 608. GOOD MANUFACTURING PRACTICE.**

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

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

1 “(c) GOOD MANUFACTURING PRACTICES OF OTHER
 2 PARTIES.—A manufacturer shall not be responsible under
 3 section 601(f) or this section for the good manufacturing
 4 practice of its suppliers. A distributor shall not be respon-
 5 sible under section 601(f) or this section for the good man-
 6 ufacturing practice of its manufacturers.”.

7 **SEC. 8. SAFETY SUBSTANTIATION FOR COSMETIC INGREDI-**
 8 **ENTS AND NONFUNCTIONAL CONSTITUENTS.**

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

12 **“SEC. 609. COSMETIC INGREDIENTS AND NONFUNCTIONAL**
 13 **CONSTITUENTS THAT ARE SAFE FOR USE IN**
 14 **COSMETICS.**

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

18 “(b) SAFE INGREDIENTS.—Unless and until prohib-
 19 ited or limited by the Secretary by regulation, the fol-
 20 lowing ingredients are deemed to be adequately substan-
 21 tiated for safe use in cosmetics subject to the requirements
 22 of good manufacturing practice:

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

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

4 “(3) Food ingredients that have been deter-
5 mined by the Secretary to be generally recognized as
6 safe for direct addition to food for human consump-
7 tion, within any limits established in such deter-
8 mination.

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

13 “(5) Pharmaceutical excipients and inactive in-
14 gredients approved or permitted by the Secretary,
15 listed on a Food and Drug Administration website
16 for use in drugs for human consumption or for
17 which monographs have been included in the Hand-
18 book of Pharmaceutical Excipients, within any limits
19 established in such lists or monographs.

20 “(6) Cosmetic ingredients that have been re-
21 viewed for safety by a qualified nongovernmental or
22 governmental expert scientific body, including the
23 Cosmetic Ingredient Review Expert Panel, and that
24 are the subject of a monograph published in a peer-

1 reviewed scientific journal, within any limits estab-
2 lished in such monographs.

3 “(7) Fragrance ingredients that have been re-
4 viewed for safety by a qualified nongovernmental or
5 governmental expert scientific body, including the
6 Research Institute of Fragrance Materials Expert
7 Panel, and that are the subject of a monograph pub-
8 lished in a peer-reviewed scientific journal, within
9 any limits established in such monographs.

10 “(8) Cosmetic ingredients approved or per-
11 mitted for use in cosmetics by any of the countries
12 listed in section 802(b)(1)(A) as having an adequate
13 regulatory authority, within any limits established by
14 such regulatory authority.

15 “(c) SAFE NONFUNCTIONAL CONSTITUENTS.—

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

18 “(A) has not been intentionally added as a
19 separate substance; and

20 “(B) serves no technical or cosmetic func-
21 tion in the cosmetic.

22 “(2) ADEQUATE SUBSTANTIATION.—The fol-
23 lowing nonfunctional constituents are deemed to be
24 adequately substantiated for safe use in cosmetics,
25 subject to the requirements of good manufacturing

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

3 “(A) The levels approved or permitted for
4 nonfunctional constituents by the Secretary for
5 color additives for cosmetic use and for food ad-
6 ditives and generally recognized as safe food in-
7 gredients for direct human consumption.

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

13 “(C) The levels approved or permitted for
14 nonfunctional constituents by the Secretary or
15 the United States Pharmacopeia for oral non-
16 prescription drugs.

17 “(D) The levels approved or permitted for
18 nonfunctional constituents by the Environ-
19 mental Protection Agency for direct human
20 consumption in drinking water.

21 “(E) The levels for nonfunctional constitu-
22 ents approved or permitted in cosmetics and
23 human food and food ingredients by any of the
24 countries listed in section 802(b)(1)(A) as hav-
25 ing an adequate regulatory authority.

1 “(d) CENTER.—The Secretary shall establish a pro-
2 gram within the center of the Food and Drug Administra-
3 tion with primary responsibility for regulating cosmetics
4 to evaluate and make determinations, by regulation, on
5 the safe use of cosmetics and ingredients and nonfunc-
6 tional constituents thereof.

7 “(e) APPLICATION; PREEMPTION.—A safety deter-
8 mination accepted or made by the Secretary or established
9 under this section shall apply in every State. No State may
10 establish or enforce a safety determination for a cosmetic
11 or an ingredient or nonfunctional constituent of a cosmetic

12 “(f) EFFECTIVE DATE OF REGULATIONS.—Any reg-
13 ulation or guidance by the Secretary pursuant to this sec-
14 tion concerning the safety of a cosmetic or an ingredient
15 or nonfunctional constituent of a cosmetic shall apply be-
16 ginning no earlier than the date that is 2 years after the
17 date on which such regulation or guidance is issued as
18 final, unless the Secretary determines, after public notice
19 and an opportunity for public comment, that an earlier
20 date of applicability is required to prevent serious adverse
21 health consequences or death to humans.”.

22 **SEC. 9. NATIONAL COSMETIC REGULATORY DATABANK.**

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

1 **“SEC. 610. NATIONAL COSMETIC REGULATORY DATABANK.**

2 “(a) IN GENERAL.—For the purpose of consolidating
3 information pertaining to the regulation of cosmetic safe-
4 ty, the Secretary shall establish and maintain in the center
5 of the Food and Drug Administration with primary re-
6 sponsibility for regulating cosmetics a database, to be
7 known as the National Cosmetic Regulatory Databank,
8 containing—

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

11 “(2) such other information pertaining to the
12 regulation of cosmetics as the Secretary deems ap-
13 propriate.

14 “(b) AVAILABILITY.—In the case of information in
15 the National Cosmetic Regulatory Databank that is not
16 subject to public disclosure under section 552 of title 5,
17 United States Code, the Secretary may nonetheless dis-
18 close such information to the director of a State agency
19 on written request by such director demonstrating good
20 cause for the disclosure. A director receiving information
21 pursuant to the preceding sentence shall agree to limit to
22 the disclosure of such information by State officials and
23 employees to the same extent such disclosure is limited
24 with respect to Federal officials and employees under sec-
25 tion 301(j) of this Act, section 552(b) of title 5, United

1 States Code, and section 1905 of title 18, United States
2 Code, with respect to such information.

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

7 **SEC. 10. SPECIAL RULES.**

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

11 **“SEC. 611. SPECIAL RULES.**

12 “(a) CONTRACTORS.—The person described in sec-
13 tion 607(f) with respect to a cosmetic (referred to in this
14 section as the ‘responsible party’) may, by agreement, au-
15 thorize a manufacturer, distributor, or packer of the cos-
16 metic or a third-party contractor to submit any required
17 report of a serious and unexpected adverse event (as such
18 term is used in section 607) so long as the responsible
19 party directs to the manufacturer, distributor, packer, or
20 third-party contractor all such adverse events associated
21 with such cosmetic that are reported to the responsible
22 party through the address or telephone number described
23 in section 607(f).

24 “(b) EXEMPTIONS.—The Secretary, on the Sec-
25 retary’s own initiative or in response to a petition, may

1 establish exemptions from the requirements of sections
2 601(f), 605, 606, 607, and 608—

3 “(1) for the efficient and cost-effective imple-
4 mentation of such requirements; or

5 “(2) where the cost of compliance exceeds the
6 safety benefit to the public.”.

7 (b) COSMETIC DEFINITION.—Section 201(i) (21
8 U.S.C. 321(i)) is amended by adding at the end the fol-
9 lowing: “An article described in subparagraph (1) that is
10 intended only for topical external use to alter the appear-
11 ance by temporarily affecting the structure or any function
12 of the human skin, and that is not the subject of an ap-
13 proved new drug application under section 505, shall, for
14 purposes of this Act, be treated only as a cosmetic and
15 not a drug.”.

16 (c) COLOR ADDITIVES.—Section 721(f) (21 U.S.C.
17 379e(f)) is amended—

18 (1) by striking “(f) The Secretary shall” and
19 inserting “(f)(1) The Secretary shall”; and

20 (2) by adding at the end the following:

21 “(2) A color additive, including mixtures thereof, in-
22 tended for use in externally applied cosmetics and not in
23 the area of the eye is exempt from the requirements of
24 this section if it is generally recognized, among experts
25 qualified by scientific training and experience to evaluate

1 its safety, as having been shown through scientific proce-
2 dures to be safe under the conditions of its intended use.
3 Notwithstanding the preceding sentence, the Secretary
4 may by regulation require certification of batches under
5 subsection (c) for any such color additive.”.

6 **SEC. 11. PROHIBITED ACTS.**

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

9 “(ddd) The failure to register a cosmetic establish-
10 ment as required under section 605 or to maintain the
11 registration current and accurate.

12 “(eee) The failure to submit a cosmetic and ingre-
13 dient statement as required under section 606 or to main-
14 tain the statement current and accurate.

15 “(fff) The failure to submit a serious and unexpected
16 adverse event report, or to include on the label of a cos-
17 metic the domestic telephone number, email address, or
18 mailing address through which a report of a serious ad-
19 verse event may be received, as required under section
20 607.”.

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

24 **SEC. 12. NATIONAL UNIFORMITY FOR COSMETICS.**

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

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

4 (2) by amending subsection (a) to read as fol-
5 lows:

6 “(a) IN GENERAL.—Except as provided in subsection
7 (b) or (d) of this section, no State or political subdivision
8 of a State may establish or continue in effect any require-
9 ment for labeling or packaging of a cosmetic.”;

10 (3) by amending subsection (c) to read as fol-
11 lows:

12 “(c) COSMETIC SAFETY.—No State or political sub-
13 division of a State may establish or continue in effect any
14 law, regulation, order, or other requirement—

15 “(1) relating directly or indirectly to, or relying
16 upon, a human health or safety evaluation of a non-
17 functional cosmetic constituent, cosmetic ingredient,
18 or cosmetic (as defined in section 201(i)(1)), or re-
19 lating in any way to the safety standard and the
20 human health-based requirements, evaluations, and
21 determinations under chapter VI, the Poison Preven-
22 tion Packaging Act of 1970, or the Fair Packaging
23 and Labeling Act; or

24 “(2) relating directly or indirectly to registra-
25 tion or listing of cosmetic facilities, establishments,

1 cosmetics, or cosmetic ingredients, reporting of any
2 information relating to cosmetics including adverse
3 event reporting, cosmetic manufacturing processes
4 or standards including good manufacturing practice,
5 cosmetic labels or labeling including any general or
6 health related warnings or public statement, or the
7 requirement of any fees on cosmetic establishments,
8 cosmetics, ingredients, or nonfunctional constitu-
9 ents.”; and

10 (4) by repealing subsection (e).

11 **SEC. 13. IMPORTATION.**

12 Section 801(a) (21 U.S.C. 381(a)) is amended by
13 adding at the end the following: “If a cosmetic is being
14 imported or offered for import into the United States and
15 the importer does not present both the unique cosmetic
16 establishment registration number required under section
17 605 for the establishment that performs the final portion
18 of the manufacturing operation and the unique cosmetic
19 and ingredient statement number required under section
20 606 for the cosmetic, or the registration or statement
21 number is not correct and accurate, the cosmetic shall be
22 denied entry.”.

23 **SEC. 14. EFFECTIVE DATES.**

24 (a)(1) The amendments made by sections 4, 5, 6, and
25 13 of this Act apply beginning on the later date of—

1 (A) the date that is one year after the Sec-
2 retary of Health and Human Services promulgates
3 final regulations implementing such amendments; or

4 (B) the date that is one year after the Sec-
5 retary of Health and Human Services publishes a
6 notice in the Federal Register determining that an
7 effective electronic system has been established and
8 is fully operational for—

9 (i) the submission of cosmetic manufac-
10 turing establishment registrations, cosmetic and
11 ingredient statements, and reports of serious
12 cosmetic adverse events; and

13 (ii) the National Cosmetic Regulatory
14 Databank.

15 (2) Until the date applicable under paragraph (1),
16 the voluntary establishment registration and voluntary in-
17 gredient listing programs established in parts 710 and 720
18 of title 21, Code of Federal Regulations (as in effect on
19 the date of enactment of this Act), shall remain effective
20 and shall be fully implemented by the Secretary of Health
21 and Human Services.

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

1 (c) Notwithstanding subsections (a) and (b), the
2 amendments made by sections 5 and 7 shall not apply with
3 respect to a cosmetic manufacturer with less than
4 \$5,000,000 of annual net sales of cosmetics until the later
5 of—

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

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

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

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

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