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(Original Signature of Member)

114TH CONGRESS
1ST SESSION

H. R. _____

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

Mr. SESSIONS introduced the following bill; which was referred to the Committee on _____

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,*

1 **SECTION 1. SHORT TITLE AND REFERENCES.**

2 (a) SHORT TITLE.—This Act may be cited as the
3 “Cosmetic Modernization Amendments of 2015”.

4 (b) REFERENCES TO THE FEDERAL FOOD, DRUG,
5 AND COSMETIC ACT.—Except as otherwise specified,
6 whenever in this Act an amendment is expressed in terms
7 of an amendment to a section or other provision, the ref-
8 erence shall be considered to be made to a section or other
9 provision of the Federal Food, Drug, and Cosmetic Act
10 (21 U.S.C. 301 et seq.).

11 **SEC. 2. TABLE OF CONTENTS.**

12 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.

13 **SEC. 3. DEFINITIONS.**

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

16 **“SEC. 604. DEFINITIONS.**

17 “In this chapter:

1 “(1) COSMETIC.—Notwithstanding section
2 201(i), for purposes of this section and sections
3 601(f), 605, 606, 607, 608, and 801(a), the term
4 ‘cosmetic’ includes only articles described in section
5 201(i)(1).

6 “(2) ESTABLISHMENT.—

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

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

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

20 “(D) The term ‘foreign establishment’
21 means an establishment location outside the
22 United States.

23 “(3) SAFE; SAFETY.—

24 “(A) The terms ‘safe’ and ‘safety’, with re-
25 spect to a cosmetic, mean the cosmetic does not

1 present a significant risk of serious illness or
2 injury to humans under the conditions of use
3 recommended or suggested in the labeling of
4 the cosmetic, including the limitation of ‘for
5 professional use’ only.

6 “(B) For purposes of subparagraph (A),
7 the term ‘professional’ means an individual
8 who—

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

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

15 **SEC. 4. REGISTRATION OF COSMETIC MANUFACTURING ES-**
16 **TABLISHMENTS.**

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

20 **“SEC. 605. REGISTRATION OF COSMETIC MANUFACTURING**
21 **ESTABLISHMENTS.**

22 “(a) IN GENERAL.—

23 “(1) REGISTRATION.—The Secretary shall by
24 regulation require that every domestic and foreign
25 establishment engaged in the manufacture of a cos-

1 metic intended to be sold in the United States that
2 is not exempt under (e) be registered with the Sec-
3 retary within 60 business days after the first com-
4 mercial sale of a cosmetic in the United States. If
5 a cosmetic is processed in more than one establish-
6 ment, registration shall be required under this sec-
7 tion only for the establishment that performs the
8 final portion of the manufacturing operation. The
9 single registration shall cover all such cosmetics
10 manufactured by the establishment. The registration
11 shall state only the name of the company or other
12 organization name of the establishment, the city,
13 street address, State, and country of the establish-
14 ment, and the title, email address, and telephone
15 number for the office within the establishment that
16 is responsible for submitting and maintaining the
17 registration. For a foreign establishment, the reg-
18 istration shall include the contact information for
19 the initial United States agent of the establishment.

20 “(2) UNIQUE NUMBER.—The Secretary shall
21 establish and provide to each registrant under this
22 section a unique cosmetic establishment registration
23 number within 15 business days after receiving the
24 registration. If the Secretary does not provide a
25 unique cosmetic establishment registration number

1 within such 15 business days, any requirement
2 under this Act for such number shall be deemed to
3 be inapplicable until 30 business days after such
4 number is received by the person who submitted the
5 registration. Where more than one person registers
6 the same establishment, the Secretary shall provide
7 only one unique establishment registration number
8 for the establishment. The unique cosmetic estab-
9 lishment number shall not be required to be included
10 in cosmetic labeling.

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

17 “(c) ENFORCEMENT.—The Secretary shall enforce
18 this section under section 301(ddd) and shall not suspend
19 or revoke a registration under this section.

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

23 “(e) EXEMPTIONS.—

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

4 “(A) an establishment that as of the date
5 of enactment of this section is registered as a
6 cosmetic establishment under part 710 of title
7 21, Code of Federal Regulations (as in effect on
8 such date);

9 “(B) a beauty shop or salon or spa;

10 “(C) a cosmetic retailer, including any
11 such retailer that is—

12 “(i) an individual sales representative;

13 “(ii) a wholesale or retail distribution
14 or sales facility; or

15 “(iii) a pharmacy or other person or
16 organization that—

17 “(I) compounds cosmetics at a
18 single location and administers, dis-
19 penses, or distributes such cosmetics
20 at retail from that location; and

21 “(II) does not otherwise manu-
22 facture or package cosmetics from
23 that location;

24 “(D) a health care provider, including a
25 hospital or clinic;

1 “(E) a public health agency or other non-
2 profit entity;

3 “(F) a hotel or other entity that provides
4 complimentary cosmetics;

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

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

11 “(I) a handcrafted soap or cosmetic made
12 in a home, a community facility, or a similar es-
13 tablishment; or

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

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

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

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

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

2 “(a) IN GENERAL.—The Secretary shall by regula-
3 tion require that every domestic establishment and foreign
4 establishment engaged in the manufacture of a cosmetic
5 intended to be sold in the United States submit to the
6 Secretary, for each cosmetic so manufactured in the estab-
7 lishment, except such cosmetics manufactured by entities
8 exempted by section 605(e) from registration under sec-
9 tion 605, within 60 business days after the first commer-
10 cial sale of the cosmetic, a cosmetic and ingredient state-
11 ment. The Secretary shall require the statement to contain
12 only—

13 “(1) the unique establishment registration num-
14 ber of the manufacturing establishment where the
15 cosmetic is manufactured or, if the same cosmetic is
16 manufactured in more than one establishment, the
17 unique establishment registration number of each es-
18 tablishment where it is manufactured;

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

20 “(3) the applicable cosmetic category or cat-
21 egories for the cosmetic;

22 “(4) the ingredients in the cosmetic (in accord-
23 ance with section 701.3 of title 21, Code of Federal
24 Regulations (as in effect on the date of enactment
25 of the Cosmetic Modernization Amendments of 2015
26 and including any successor regulations) and using

1 the name of each ingredient established under sub-
2 section (d), if any), in descending order of predomi-
3 nance by weight, except that—

4 “(A) flavors and fragrances may be des-
5 ignated as such; and

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

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

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

24 “(c) CHANGE IN LABELING.—An establishment shall
25 not be required to submit a new or revised statement

1 under subsection (a) because of a change in labeling ex-
2 cept to the extent necessary to maintain the accuracy of
3 the information included in a statement under subsection
4 (a).

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

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

1 “(f) ENFORCEMENT.—The Secretary shall enforce
2 subsections (a) and (e) under section 301(eee) and shall
3 not suspend or revoke a cosmetic and ingredient state-
4 ment.

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

1 other State employees who have access to such informa-
2 tion shall then be subject to the provisions of section
3 301(j) of this Act, subsection 552(b) of title 5, United
4 States Code, and section 1905 of title 18, United States
5 Code, with respect to such information.

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

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

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

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

1 **SEC. 6. SERIOUS AND UNEXPECTED ADVERSE EVENT RE-**
2 **PORTING FOR COSMETICS.**

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

6 **“SEC. 607. SERIOUS AND UNEXPECTED ADVERSE EVENT RE-**
7 **PORTING FOR COSMETICS.**

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

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

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

21 “(b) SUBMISSION OF REPORTS.—A report on an ad-
22 verse event under subsection (a) shall be submitted to the
23 Secretary not later than 15 business days after informa-
24 tion concerning the adverse event is received at the place
25 of business labeled on the cosmetic pursuant to section
26 602(b)(1).

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

3 “(1) An identifiable patient.

4 “(2) An identifiable reporter.

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

6 “(4) A serious adverse event.

7 “(d) ADDITIONAL CONTENTS; SUPPLEMENTAL RE-
8 PORTING.—The person submitting a report under sub-
9 section (a) may—

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

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

14 “(e) SPECIAL RULES.—

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

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

22 “(B) shall be considered to be a record
23 about an individual under section 552a of title
24 5, United States Code, and a medical or similar
25 file the disclosure of which would constitute a

1 violation of section 552 of such title 5, and
2 shall not be publicly disclosed unless all person-
3 ally identifiable information is redacted.

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

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

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

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

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

24 “(g) EXEMPTION.—The Secretary may, by regula-
25 tion, establish an exemption to the requirements under

1 paragraphs (b) and (d) if the Secretary determines that
2 such exemption would have no adverse effect on public
3 health.

4 “(h) DEFINITIONS.—In this section:

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

7 “(A) resulting in—

8 “(i) death;

9 “(ii) a life-threatening experience;

10 “(iii) inpatient hospitalization;

11 “(iv) a persistent and significant dis-
12 ability or incapacity;

13 “(v) a congenital anomaly or birth de-
14 fect; or

15 “(vi) permanent disfiguration; or

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

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

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

1 “(g) If it is a cosmetic that is marketed in the United
2 States, unless the label of such cosmetic includes a domes-
3 tic address or domestic phone number through which a
4 report of a serious and unexpected adverse event (as such
5 term is used in section 607) associated with the use of
6 such cosmetic may be submitted to the person described
7 in section 607(f).”.

8 **SEC. 7. GOOD MANUFACTURING PRACTICE.**

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

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

16 (b) PRINCIPLES AND STANDARDS.—Chapter VI (21
17 U.S.C. 361 et seq.), as amended by sections 3, 4, 5, and
18 6, is further amended by adding at the end the following:

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

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

24 “(b) NOTICE AND COMMENT.—A regulation under
25 subsection (a) shall be promulgated only after providing

1 notice and an opportunity for comment in accordance with
2 chapter 5 of title 5, United States Code.

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

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

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

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

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

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

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

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

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

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

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

23 “(6) Cosmetic ingredients that have been re-
24 viewed for safety by a qualified nongovernmental or
25 governmental expert scientific body, including the

1 Cosmetic Ingredient Review Expert Panel, and that
2 are the subject of a monograph published in a peer-
3 reviewed scientific journal, within any limits estab-
4 lished in such monographs.

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

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

17 “(c) SAFE NONFUNCTIONAL CONSTITUENTS.—

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

20 “(A) has not been intentionally added as a
21 separate substance; and

22 “(B) serves no technical or cosmetic func-
23 tion in the cosmetic.

24 “(2) ADEQUATE SUBSTANTIATION.—The fol-
25 lowing nonfunctional constituents are deemed to be

1 adequately substantiated for safe use in cosmetics,
2 subject to the requirements of good manufacturing
3 practice and any limits or bans established by the
4 Secretary by regulation:

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

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

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

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

23 “(E) The levels for nonfunctional constitu-
24 ents approved or permitted in cosmetics and
25 human food and food ingredients by any of the

1 countries listed in section 802(b)(1)(A) as hav-
2 ing an adequate regulatory authority.

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

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

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

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

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

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

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

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

15 “(2) such other information pertaining to the
16 regulation of cosmetics as the Secretary deems ap-
17 propriate.

18 “(b) AVAILABILITY.—In the case of information in
19 the National Cosmetic Regulatory Databank that is not
20 subject to public disclosure under section 552 of title 5,
21 United States Code, the Secretary may nonetheless dis-
22 close such information to the director of a State agency
23 on written request by such director demonstrating good
24 cause for the disclosure. A director receiving information
25 pursuant to the preceding sentence shall agree to limit to
26 the disclosure of such information by State officials and

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

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

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

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

14 **“SEC. 611. SPECIAL RULES.**

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

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

3 “(b) EXEMPTIONS.—The Secretary, on the Sec-
4 retary’s own initiative or in response to a petition, may
5 establish exemptions from the requirements of sections
6 601(f), 605, 606, 607, and 608—

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

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

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

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

22 (1) by striking “(f) The Secretary shall” and
23 inserting “(f)(1) The Secretary shall”; and

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

1 “(2) A color additive, including mixtures thereof, in-
2 tended for use in externally applied cosmetics and not in
3 the area of the eye is exempt from the requirements of
4 this section if it is generally recognized, among experts
5 qualified by scientific training and experience to evaluate
6 its safety, as having been shown through scientific proce-
7 dures to be safe under the conditions of its intended use.
8 Notwithstanding the preceding sentence, the Secretary
9 may by regulation require certification of batches under
10 subsection (c) for any such color additive.”.

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

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

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

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

20 “(fff) The failure to submit a serious and unexpected
21 adverse event report, or to include on the label of a cos-
22 metic the domestic telephone number, email address, or
23 mailing address through which a report of a serious ad-
24 verse event may be received, as required under section
25 607.”.

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

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

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

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

9 (2) by amending subsection (a) to read as fol-
10 lows:

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

15 (3) by amending subsection (c) to read as fol-
16 lows:

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

20 “(1) relating directly or indirectly to, or relying
21 upon, a human health or safety evaluation of a non-
22 functional cosmetic constituent, cosmetic ingredient,
23 or cosmetic (as defined in section 201(i)(1)), or re-
24 lating in any way to the safety standard and the
25 human health-based requirements, evaluations, and

1 determinations under chapter VI, the Poison Preven-
2 tion Packaging Act of 1970, or the Fair Packaging
3 and Labeling Act; or

4 “(2) relating directly or indirectly to registra-
5 tion or listing of cosmetic facilities, establishments,
6 cosmetics, or cosmetic ingredients, reporting of any
7 information relating to cosmetics including adverse
8 event reporting, cosmetic manufacturing processes
9 or standards including good manufacturing practice,
10 cosmetic labels or labeling including any general or
11 health related warnings or public statement, or the
12 requirement of any fees on cosmetic establishments,
13 cosmetics, ingredients, or nonfunctional constitu-
14 ents.”; and

15 (4) by repealing subsection (e).

16 **SEC. 13. IMPORTATION.**

17 Section 801(a) (21 U.S.C. 381(a)) is amended by
18 adding at the end the following: “If a cosmetic is being
19 imported or offered for import into the United States and
20 the importer does not present both the unique cosmetic
21 establishment registration number required under section
22 605 for the establishment that performs the final portion
23 of the manufacturing operation and the unique cosmetic
24 and ingredient statement number required under section
25 606 for the cosmetic, or the registration or statement

1 number is not correct and accurate, the cosmetic shall be
2 denied entry.”.

3 **SEC. 14. EFFECTIVE DATES.**

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

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

9 (B) the date that is one year after the Sec-
10 retary of Health and Human Services publishes a
11 notice in the Federal Register determining that an
12 effective electronic system has been established and
13 is fully operational for—

14 (i) the submission of cosmetic manufac-
15 turing establishment registrations, cosmetic and
16 ingredient statements, and reports of serious
17 cosmetic adverse events; and

18 (ii) the National Cosmetic Regulatory
19 Databank.

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

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

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

6 (c) Notwithstanding subsections (a) and (b), the
7 amendments made by sections 5 and 7 shall not apply with
8 respect to a cosmetic manufacturer with less than
9 \$5,000,000 of annual net sales of cosmetics until the later
10 of—

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

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

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

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