

115TH CONGRESS
1ST SESSION

S. 2003

To modernize the regulation of cosmetics.

IN THE SENATE OF THE UNITED STATES

OCTOBER 25, 2017

Mr. HATCH introduced the following bill; which was read twice and referred
to the Committee on Health, Education, Labor, and Pensions

A BILL

To modernize the regulation of cosmetics.

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

3 **SECTION 1. SHORT TITLE.**

4 This Act may be cited as the “FDA Cosmetic Safety
5 and Modernization Act”.

6 **SEC. 2. ADVERSE EVENT REPORTING.**

7 (a) IN GENERAL.—Subchapter H of chapter VII of
8 the Federal Food, Drug, and Cosmetic Act (21 U.S.C.
9 379aa et seq.) is amended by adding at the end the fol-
10 lowing:

1 **“SEC. 762. SERIOUS ADVERSE EVENT REPORTING FOR COS-**
2 **METICS.**

3 “(a) DEFINITIONS.—In this section:

4 “(1) The term ‘adverse event’ means any
5 health-related event associated with the use of a cos-
6 metic that is adverse.

7 “(2) The term ‘serious adverse event’ means an
8 adverse event that—

9 “(A) results in—

10 “(i) death;

11 “(ii) a life-threatening experience;

12 “(iii) inpatient hospitalization;

13 “(iv) a persistent or significant dis-
14 ability, incapacity, or disfigurement;

15 “(v) a congenital abnormality or birth
16 defect; or

17 “(vi) permanent alteration of appear-
18 ance other than as intended, under condi-
19 tions of use that are customary or usual;
20 or

21 “(B) requires, based on reasonable medical
22 judgment, a medical or surgical intervention to
23 prevent an outcome described in subparagraph
24 (A).

1 “(3) The term ‘serious adverse event report’
2 means a report that is required to be submitted to
3 the Secretary under subsection (b).

4 “(b) REPORTING REQUIREMENT.—The manufac-
5 turer or distributor of a cosmetic whose name appears on
6 the label of such cosmetic pursuant to section 602 (re-
7 ferred to in this section as a ‘responsible person’) shall
8 submit to the Secretary any report received of a serious
9 adverse event associated with such cosmetic when used in
10 the United States, accompanied by a copy of the label on
11 or within the retail packaging of such cosmetic.

12 “(c) SUBMISSION OF REPORTS.—

13 “(1) TIMING OF REPORTS.—The responsible
14 person shall submit to the Secretary a serious ad-
15 verse event report no later than 15 business days
16 after the report is received.

17 “(2) NEW MEDICAL INFORMATION.—The re-
18 sponsible person shall submit to the Secretary any
19 new and material medical information, related to a
20 submitted serious adverse event report that is re-
21 ceived by the responsible person within 1 year of the
22 initial report, no later than 15 business days after
23 such information is received by such responsible per-
24 son.

1 “(3) CONSOLIDATION OF REPORTS.—The Sec-
2 retary shall provide for systems to enable responsible
3 persons to submit a single report that includes du-
4 plicate reports of, or new medical information re-
5 lated to, a serious adverse event.

6 “(4) EXEMPTION.—The Secretary may estab-
7 lish an exemption to the requirements under para-
8 graphs (1) and (2) if—

9 “(A) the Secretary receives a report in ac-
10 cordance with section 760; or

11 “(B) after providing notice and an oppor-
12 tunity for comment from interested parties, the
13 Secretary determines that such exemption
14 would have no significant adverse effect on pub-
15 lic health.

16 “(d) CONTENT OF REPORT.—Each serious adverse
17 event report under this section shall be submitted to the
18 Secretary, and may be accompanied by additional informa-
19 tion.

20 “(e) MAINTENANCE AND INSPECTION OF
21 RECORDS.—

22 “(1) MAINTENANCE.—The responsible person
23 shall maintain records related to each report of a se-
24 rious adverse event received by the responsible per-
25 son for a period of 6 years.

1 “(2) RECORDS INSPECTION.—

2 “(A) IN GENERAL.—The responsible per-
3 son shall permit an authorized person to have
4 access to records required to be maintained
5 under this section during an inspection pursu-
6 ant to section 704.

7 “(B) AUTHORIZED PERSON.—For pur-
8 poses of this paragraph, the term ‘authorized
9 person’ means an officer or employee of the De-
10 partment of Health and Human Services, who
11 has—

12 “(i) appropriate credentials, as deter-
13 mined by the Secretary; and

14 “(ii) been duly designated by the Sec-
15 retary to have access to the records re-
16 quired under this section.

17 “(f) PROTECTED INFORMATION.—A serious adverse
18 event report submitted to the Secretary under this section,
19 including any new medical information submitted under
20 subsection (c)(2), or an adverse event report voluntarily
21 submitted to the Secretary shall be considered to be—

22 “(1) a safety report under section 756 and may
23 be accompanied by a statement, which shall be a
24 part of any report that is released for public disclo-
25 sure, that denies that the report or the records con-

1 stitute an admission that the product involved
2 caused or contributed to the adverse event; and

3 “(2) a record about an individual under section
4 552a of title 5, United States Code (commonly re-
5 ferred to as the ‘Privacy Act of 1974’), and a med-
6 ical or similar file the disclosure of which would con-
7 stitute a violation of section 552 of such title 5
8 (commonly referred to as the ‘Freedom of Informa-
9 tion Act’), and shall not be publicly disclosed unless
10 all personally identifiable information is redacted.

11 “(g) RULE OF CONSTRUCTION.—The submission of
12 any adverse event report under this section shall not be
13 construed as an admission that the cosmetic involved
14 caused or contributed to the adverse event.

15 “(h) PREEMPTION.—

16 “(1) IN GENERAL.—No State or local govern-
17 ment shall establish or continue in effect any law,
18 regulation, order, or other requirement related to a
19 mandatory system for adverse event reports for cos-
20 metics.

21 “(2) EFFECT OF SECTION.—

22 “(A) IN GENERAL.—Nothing in this sec-
23 tion shall affect the authority of the Secretary
24 to provide adverse event reports and informa-
25 tion to any health, food, or drug officer or em-

1 ployee of any State, territory, or political sub-
2 division of a State or territory, under a memo-
3 randum of understanding between the Secretary
4 and such State, territory, or political subdivi-
5 sion.

6 “(B) PERSONALLY-IDENTIFIABLE INFOR-
7 MATION.—Notwithstanding any other provision
8 of law, personally-identifiable information in ad-
9 verse event reports provided by the Secretary to
10 any health, food, or drug officer or employee of
11 any State, territory, or political subdivision of a
12 State or territory, shall not—

13 “(i) be made publicly available pursu-
14 ant to any State or other law requiring dis-
15 closure of information or records; or

16 “(ii) otherwise be disclosed or distrib-
17 uted to any party without the written con-
18 sent of the Secretary and the person sub-
19 mitting such information to the Secretary.

20 “(C) USE OF SAFETY REPORTS.—Nothing
21 in this section shall permit a State, territory, or
22 political subdivision of a State or territory, to
23 use any safety report received from the Sec-
24 retary in a manner inconsistent with subsection
25 (g) or section 756.

1 “(i) AUTHORIZATION OF APPROPRIATIONS.—There
 2 are authorized to be appropriated to carry out this section
 3 such sums as may be necessary.”.

4 (b) CONFORMING AMENDMENTS.—The Federal
 5 Food, Drug, and Cosmetic Act (21 U.S.C. 321 et seq.)
 6 is amended—

7 (1) in section 301(ii) (21 U.S.C. 331(ii)), by
 8 striking “section 760 or 761” each place it appears
 9 and inserting “section 760, 761, or 762”; and

10 (2) in section 801 (21 U.S.C. 381), by striking
 11 “section 760 or 761” each place it appears in sub-
 12 sections (a) and (b) and inserting “section 760, 761,
 13 or 762”.

14 **SEC. 3. ADULTERATED COSMETICS.**

15 Section 601(a) of the Federal Food, Drug, and Cos-
 16 metic Act (21 U.S.C. 361(a)) is amended—

17 (1) by inserting “, or consists in whole or in
 18 part of,” after “bears or contains”; and

19 (2) by striking “usual, except that this” and in-
 20 serting “usual. For purposes of this clause, a cos-
 21 metic may be adulterated regardless of whether it is
 22 known which particular substance or substances may
 23 render the cosmetic injurious to users under the con-
 24 ditions of use prescribed in the labeling thereof, or

1 under such conditions of use as are customary or
2 usual. This”.

3 **SEC. 4. LABELING.**

4 Section 602 of the Federal Food, Drug, and Cosmetic
5 Act (21 U.S.C. 362) is amended by adding at the end the
6 following:

7 “(g) If it is a cosmetic that is marketed in the United
8 States, unless its label includes a domestic address, do-
9 mestic phone number, or Internet address through which
10 the responsible person (as described in section 762) can
11 receive a report of a serious adverse event with respect
12 to such cosmetic product.”.

13 **SEC. 5. REGISTRATION OF COSMETIC FACILITIES.**

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

17 **“SEC. 604. REGISTRATION OF COSMETIC FACILITIES.**

18 “(a) REGISTRATION.—

19 “(1) IN GENERAL.—The Secretary shall by reg-
20 ulation require the manufacturer or distributor
21 whose name appears on the label of a cosmetic mar-
22 keted in the United States to register all facilities
23 engaged in manufacturing of such cosmetic with the
24 Secretary. To be registered—

1 “(A) for a domestic facility, the responsible
2 person, owner, or agent in charge of the facility
3 shall submit a registration to the Secretary; and

4 “(B) for a foreign facility, the responsible
5 person, owner, or agent in charge of the facility
6 shall submit a registration to the Secretary and
7 shall include with the registration the name of
8 the United States agent for the facility.

9 “(2) REGISTRATION.—

10 “(A) IN GENERAL.—An entity (referred to
11 in this section as the ‘registrant’) shall submit
12 a registration under paragraph (1) to the Sec-
13 retary containing information necessary to no-
14 tify the Secretary of the name and address of
15 each facility at which, and all the trade names
16 under which, the registrant conducts business,
17 the e-mail address for the responsible person
18 (as described in section 762(b)) of the facility
19 or, in the case of a foreign facility, the United
20 States agent for the facility.

21 “(B) AVAILABILITY OF INFORMATION.—
22 The Secretary shall require—

23 “(i) the information submitted under
24 subparagraph (A) to be maintained and
25 available, at the request of the Secretary,

1 for a period to be determined by the Sec-
2 retary; and

3 “(ii) the name and address of each fa-
4 cility with which the registrant contracts
5 related to cosmetic manufacturing, proc-
6 essing, distributing, or other activities, as
7 the Secretary determines appropriate, to be
8 maintained and available at the request of
9 the Secretary, for a period to be deter-
10 mined by the Secretary.

11 “(C) ADDITIONAL REQUIREMENTS.—The
12 registration shall contain an assurance that—

13 “(i) the Secretary will be permitted to
14 inspect the facility at the times and in the
15 manner permitted by this Act; and

16 “(ii) the registrant will notify the Sec-
17 retary in a timely manner of changes to
18 the information submitted.

19 “(3) REGISTRATION RENEWAL.—A registrant
20 that has submitted a registration under paragraph
21 (1) shall submit to the Secretary a renewal registra-
22 tion containing the information described in para-
23 graph (2) every 2 years during a period of time as
24 determined by the Secretary. The Secretary shall
25 provide for an abbreviated registration renewal proc-

1 ess for any registrant that has not had any changes
2 to such information since the registrant submitted
3 the preceding registration or registration renewal for
4 the facility involved.

5 “(4) PROCEDURE.—Upon receipt of a com-
6 pleted registration described in paragraph (1), the
7 Secretary shall notify the registrant of the receipt of
8 such registration and assign a registration number
9 to each registered facility.

10 “(5) LIST.—The Secretary shall compile and
11 maintain an up-to-date list of facilities that are reg-
12 istered under this section. Such list and any reg-
13 istration documents submitted pursuant to this sub-
14 section shall not be subject to disclosure under sec-
15 tion 552 of title 5, United States Code. Information
16 derived from such list or registration documents
17 shall not be subject to disclosure under section 552
18 of title 5, United States Code, to the extent that it
19 discloses the identity or location of a specific reg-
20 istered person.

21 “(b) SUSPENSION OF REGISTRATION.—

22 “(1) IN GENERAL.—If the Secretary determines
23 that cosmetics manufactured or processed by a facil-
24 ity registered under this section has a reasonable
25 probability of causing serious adverse health con-

1 sequences or death to humans, the Secretary may by
2 order suspend the registration of any facility that is
3 responsible for such reasonable probability or that
4 knew of, or had reason to know of, such reasonable
5 probability related to such cosmetics.

6 “(2) HEARING ON SUSPENSION.—The Secretary
7 shall provide the registrant subject to an order
8 under paragraph (1) with an opportunity for an in-
9 formal hearing, to be held as soon as possible but
10 not later than 2 business days after the issuance of
11 the order or such other time period, as agreed upon
12 by the Secretary and the registrant, on the actions
13 required for reinstatement of registration and why
14 the registration that is subject to the suspension
15 should be reinstated. The Secretary shall reinstate a
16 registration if the Secretary determines, based on
17 evidence presented, that adequate grounds do not
18 exist to continue the suspension of the registration.

19 “(3) POST-HEARING CORRECTIVE ACTION PLAN;
20 VACATING OF ORDER.—

21 “(A) CORRECTIVE ACTION PLAN.—If, after
22 providing opportunity for an informal hearing
23 under paragraph (2), the Secretary determines
24 that the suspension of registration remains nec-
25 essary, the Secretary shall require the reg-

1 istrant to submit a corrective action plan to
2 demonstrate how the registrant plans to correct
3 the conditions found by the Secretary. The Sec-
4 retary shall review such plan not later than 14
5 days after the submission of the corrective ac-
6 tion plan or such other time period as deter-
7 mined by the Secretary, in consultation with the
8 registrant.

9 “(B) VACATING OF ORDER.—Upon a de-
10 termination by the Secretary that adequate
11 grounds do not exist to continue the suspension
12 actions required by the order, or that such ac-
13 tions should be modified, the Secretary shall
14 promptly vacate the order and reinstate the reg-
15 istration of the facility subject to the order or
16 modify the order, as appropriate.

17 “(4) EFFECT OF SUSPENSION.—If the registra-
18 tion of a facility is suspended under this subsection,
19 no person shall import or export cosmetics into the
20 United States from such facility, offer to import or
21 export cosmetics into the United States from such
22 facility, or otherwise introduce cosmetics from such
23 facility into interstate or intrastate commerce in the
24 United States.

25 “(5) REGULATIONS.—

1 “(A) IN GENERAL.—The Secretary shall
2 promulgate regulations to implement this sub-
3 section.

4 “(B) ELECTRONIC REGISTRATION RE-
5 QUIREMENT.—The Secretary may require that
6 registration under this section be submitted in
7 an electronic format.

8 “(6) APPLICATION DATE.—Facilities shall not
9 be subject to the requirements of this subsection
10 prior to the date that is 180 days after the date on
11 which the Secretary issues final regulations under
12 paragraph (5).

13 “(7) NO DELEGATION.—The authority con-
14 ferred by this subsection to issue an order to sus-
15 pend a registration or vacate an order of suspension
16 shall not be delegated to any officer or employee
17 other than the Commissioner.

18 “(c) FACILITY.—For purposes of this section:

19 “(1) The term ‘facility’—

20 “(A) includes any factory or other estab-
21 lishment that is engaged in the manufacturing
22 or processing of a cosmetic or cosmetics; and

23 “(B) does not include—

24 “(i) beauty salons, spas, retailers (in-
25 cluding individual sales representatives,

1 wholesale distributors, or pharmacy loca-
2 tions);

3 “(ii) homes where persons are en-
4 gaged in making handcrafted soaps or
5 other cosmetics; or

6 “(iii) any business with less than
7 \$1,000,000 in annual net revenue in the
8 previous year, other than any such busi-
9 ness that is engaged in the manufacturing
10 or processing of products intended to be
11 injected under the skin, including tattoo
12 ink.

13 “(2) The term ‘domestic facility’ means a facil-
14 ity located in any of the States or Territories.

15 “(3) The term ‘foreign facility’ means a facility
16 located outside of the United States or Territories,
17 but only if the cosmetics from such facility are ex-
18 ported to the United States without further manu-
19 facturing outside the United States or Territories.

20 “(d) RULE OF CONSTRUCTION.—Nothing in this sec-
21 tion shall be construed to authorize the Secretary to re-
22 quire an application, review, or licensing process for a fa-
23 cility to be registered, except with respect to the reinstate-
24 ment of a registration that is suspended under subsection
25 (b).

1 “(e) PREEMPTION.—No State or political subdivision
 2 of a State may establish or continue in effect any law,
 3 regulation, order, or other requirement with respect to the
 4 registration of facilities engaged in the manufacturing or
 5 processing of a cosmetic or cosmetics that is different from
 6 the requirements under this section.”.

7 **SEC. 6. GOOD MANUFACTURING PRACTICES.**

8 (a) GOOD MANUFACTURING PRACTICE STAND-
 9 ARDS.—Chapter VI of the Federal Food, Drug, and Cos-
 10 metic Act (21 U.S.C. 361 et seq.), as amended by section
 11 5, is further amended by adding at the end the following:

12 **“SEC. 605. GOOD MANUFACTURING PRACTICES.**

13 “(a) ESTABLISHMENT OF GOOD MANUFACTURING
 14 PRACTICES.—

15 “(1) IN GENERAL.—The Secretary shall by reg-
 16 ulation establish good manufacturing practices for
 17 cosmetics in accordance with paragraphs (a) and (d)
 18 of section 601. Such regulations—

19 “(A) shall be modeled after comparable
 20 good manufacturing practice standards for cos-
 21 metics in effect at the time of promulgation;

22 “(B) may not impose standards for which
 23 there is no current and generally available ana-
 24 lytical methodology;

1 “(C) may ensure that cosmetics do not
2 cause serious adverse health consequences or
3 death;

4 “(D) shall be intended to protect the pub-
5 lic health; and

6 “(E) shall not apply to entities described
7 in clauses (i) and (ii) of section 604(c)(1)(B).

8 “(2) CONSIDERATIONS.—In promulgating regu-
9 lations under paragraph (1), the Secretary shall con-
10 sider facilities that are subject to other, similar reg-
11 ulations, as appropriate.

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

16 “(c) SMALL BUSINESSES.—

17 “(1) APPLICABILITY TO SMALL BUSINESSES.—
18 The Secretary shall provide for an additional year
19 after the effective date of the regulations under sub-
20 section (a) for small businesses (as described in sec-
21 tion 604(c)(1)(B)(iii)) to comply with the good man-
22 ufacturing practices established in accordance with
23 subsection (a), and issue guidance for small busi-
24 nesses for purposes of compliance with this section.

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

18 SEC. 7. IDENTIFICATION AND REVIEW OF COSMETIC IN-
19 GREDIENTS.

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1 **“SEC. 606. IDENTIFICATION AND REVIEW OF COSMETIC IN-**
2 **GREDIENTS.**

3 “(a) IDENTIFICATION OF INGREDIENTS AND NON-
4 FUNCTIONAL CONSTITUENTS TO BE REVIEWED.—Each
5 year, the Secretary, in consultation with industry and con-
6 sumer groups, and taking into consideration ingredients
7 identified by a State or political subdivision as presenting
8 a public health concern, shall identify cosmetic ingredi-
9 ents, as appropriate, that may present a public health con-
10 cern to be reviewed for safety, including a class or classes
11 of ingredients, or a non-functional constituent or class of
12 non-functional constituents. The Secretary shall publish in
13 the Federal Register a list of the ingredients or non-func-
14 tional constituents, or classes of ingredients or constitu-
15 ents identified for review, and solicit public input and pro-
16 vide the public notice and a period of 60 days to comment
17 on any such ingredient, constituent, or class. The Sec-
18 retary may identify a cosmetic ingredient or ingredients,
19 as appropriate, to be reviewed for safety outside such an-
20 nual process.

21 “(b) ADMINISTRATIVE ORDERS AND STANDARDS.—

22 “(1) PUBLICATION OF DETERMINATIONS AND
23 FINDINGS.—

24 “(A) PROPOSED ORDERS.—If the Sec-
25 retary determines that there is adequate sci-
26 entific evidence to support a determination that

1 there is reasonable certainty that an ingredient,
2 class of ingredients, non-functional constituent,
3 or class of non-functional constituents is safe
4 for use, not safe for use, or not safe for speci-
5 fied conditions of use, the Secretary shall post
6 on the Internet website of the Food and Drug
7 Administration a proposed administrative order
8 consistent with such determination.

9 “(B) FINDINGS OF INADEQUATE EVI-
10 DENCE.—If the Secretary determines that there
11 is inadequate scientific evidence to support a
12 determination described in subparagraph (A),
13 the Secretary shall post on the Internet website
14 of the Food and Drug Administration such
15 findings, together with a rationale for the find-
16 ings.

17 “(C) ADDITIONAL EVIDENCE.—Nothing in
18 this paragraph shall prevent the Secretary from
19 considering additional scientific information or
20 safety data related to the ingredient that is sub-
21 mitted to the Secretary.

22 “(2) FINAL ORDERS.—

23 “(A) IN GENERAL.—After allowing not less
24 than 90 days for public comment on a proposed
25 order under paragraph (1)(A) and a period for

1 consideration of any such comments, if the Sec-
2 retary determines that there is adequate sci-
3 entific evidence to make a final determination
4 on the safety of the applicable ingredient, class
5 of ingredients, non-functional constituent, or
6 class of non-functional constituents, the Sec-
7 retary shall issue a final administrative order
8 that there is reasonable certainty that—

9 “(i) the ingredient, class of ingredi-
10 ents, non-functional constituent, or class of
11 non-functional constituents is safe for use;

12 “(ii) the ingredient, class of ingredi-
13 ents, non-functional constituent, or class of
14 non-functional constituents is not safe for
15 any use; or

16 “(iii) the ingredient, class of ingredi-
17 ents, non-functional constituent, or class of
18 non-functional constituents is not safe
19 under specified conditions of use.

20 “(B) FINAL ACTION.—A final administra-
21 tive order under subparagraph (A) shall be con-
22 sidered final agency action for purposes of judi-
23 cial review.

24 “(3) STANDARDS.—A determination that an in-
25 gredient, class of ingredients, non-functional con-

1 stituent, or class of non-functional constituents is
 2 not safe under specified conditions of use may speci-
 3 fy conditions of use such as—

4 “(A) the amount or concentration of such
 5 ingredient;

6 “(B) the populations which may specifi-
 7 cally use such ingredient or not use such ingre-
 8 dient;

9 “(C) the area of the human body on which
 10 or near which such ingredient should not be
 11 used; or

12 “(D) such other conditions that may affect
 13 the safety of the cosmetic as a whole or in part.

14 “(c) COSMETIC SAFETY STANDARD.—For purposes
 15 of this Act, including reviews for safety under this section
 16 and section 607, a cosmetic is safe if there is reasonable
 17 certainty that the cosmetic is not injurious to users under
 18 conditions of use prescribed in labeling or under such con-
 19 ditions of use as are customary or usual.

20 “(d) PREEMPTION.—Upon identification of a cos-
 21 metic ingredient or non-functional constituent by the Sec-
 22 retary under subsection (a), no State or local government
 23 may establish or continue in effect any law, regulation,
 24 order, or other requirement with respect to such ingre-
 25 dient or non-functional constituent, except that a State or

1 local government may continue in effect such a require-
2 ment that was in full effect with respect to such ingredient
3 on the date of enactment of the FDA Cosmetic Safety and
4 Modernization Act, or that is exempted from preemption
5 under section 752(b) of the Federal Food, Drug, and Cos-
6 metic Act.

7 “(e) DEFINITIONS.—For purposes of this Act—

8 “(1) the term ‘non-functional constituent’
9 means a substance or chemical, or other contami-
10 nant, that was not intentionally added or included in
11 the formula of a cosmetic product and serves no
12 technical purpose, but may be present as a break-
13 down product or by-product of manufacturing; and

14 “(2) the term ‘cosmetic’ means a cosmetic prod-
15 uct in finished form consistent with section
16 201(i)(1).

17 “(f) RULE OF CONSTRUCTION.—This section shall
18 not be construed to affect the right of a person to lawfully
19 market a cosmetic product that is or that contains an in-
20 gredient, class of ingredients, non-functional constituent,
21 or class of non-functional constituents while such sub-
22 stance is under review or has been identified for review
23 by the Secretary for safety.

1 “(g) AUTHORIZATION OF APPROPRIATIONS.—To
 2 carry out this section, there are authorized to be appro-
 3 priated such sums as may be necessary.”.

4 **SEC. 8. ACCREDITED THIRD-PARTY REVIEW.**

5 Chapter VI of the Federal Food, Drug, and Cosmetic
 6 Act (21 U.S.C. 361 et seq.), as amended by section 7,
 7 is further amended by adding at the end the following:

8 **“SEC. 607. ACCREDITED THIRD-PARTY REVIEW.**

9 “(a) IN GENERAL.—The Secretary may accredit per-
 10 sons to review and assess for safety cosmetic ingredients
 11 or non-functional constituents identified by the Secretary
 12 under section 606(a) and make recommendations to the
 13 Secretary for proposed administrative orders under section
 14 606(b)(1)(A).

15 “(b) ACCREDITATION AND REVIEW.—Not later than
 16 2 years after the date of enactment of the FDA Cosmetic
 17 Safety and Modernization Act, the Secretary shall promul-
 18 gate regulations establishing—

19 “(1) a process to accredit third parties for pur-
 20 poses of reviewing cosmetic ingredients, classes of
 21 ingredients, non-functional constituents, and classes
 22 of non-functional constituents identified by the Sec-
 23 retary under section 606(a); and

24 “(2) criteria and qualifications for such accredi-
 25 tation of third parties.

1 “(c) REQUIREMENTS REGARDING REVIEW.—In mak-
2 ing a recommendation to the Secretary under subsection
3 (a), an accredited third party shall notify the Secretary
4 in writing of the reasons for the recommendation, and pro-
5 vide relevant scientific literature or data, as the Secretary
6 requires.

7 “(d) REVIEW AND ADMINISTRATIVE ORDER.—The
8 Secretary shall establish a process by which to review rec-
9 ommendations from such accredited third party and to de-
10 termine whether an Administrative Order is appropriate.
11 Not later than 180 calendar days after the date on which
12 the Secretary receives a recommendation from an accred-
13 ited third party pertaining to a cosmetic ingredient or non-
14 functional ingredient identified by the Secretary under
15 section 606(a), the Secretary shall issue a proposed ad-
16 ministrative order, or issue a public rationale on the Sec-
17 retary’s determination not to issue a proposed administra-
18 tive order.

19 “(e) QUALIFICATIONS.—An accredited third party
20 shall, at a minimum, meet the following requirements:

21 “(1) Such third party may not be affiliated with
22 a government entity.

23 “(2) Such third party shall be an independent
24 organization that is not owned or controlled by a
25 manufacturer, supplier, or vendor of cosmetics and

1 that has no financial affiliation with such a manu-
2 facturer, supplier, or vendor.

3 “(3) Such third party shall be a legally con-
4 stituted entity permitted to conduct the activities for
5 which it seeks accreditation.

6 “(4) Such third party shall not engage in the
7 design, manufacturer, promotion, or sale of cos-
8 metics.

9 “(5) Such third party shall have scientific ex-
10 pertise in ingredient safety, toxicology, or chemical
11 safety.

12 “(6) The operations of such third party shall be
13 in accordance with generally accepted professional
14 and ethical business practices and such third party
15 shall agree in writing that it will—

16 “(A) certify that reported information ac-
17 curately reflects data reviewed;

18 “(B) limit work to that within its com-
19 petence and capacity;

20 “(C) treat proprietary, confidential, and
21 commercial information received, including
22 records, reports, and recommendations, as con-
23 fidential information;

1 “(D) promptly respond and attempt to re-
 2 solve complaints regarding the activities for
 3 which it is accredited; and

4 “(E) protect against the use, in carrying
 5 out subsection (a) with respect to a cosmetic, of
 6 any officer or employee of the entity who has a
 7 financial conflict of interest regarding the cos-
 8 metic, and annually make available to the pub-
 9 lic disclosures of the extent to which the entity,
 10 and the officers and employees of the entity,
 11 have maintained compliance with requirements
 12 under this subparagraph relating to financial
 13 conflicts of interest.

14 “(f) RULE OF CONSTRUCTION.—Nothing in this sec-
 15 tion is intended to affect the Secretary’s authority to enter
 16 into contracts with non-accredited third parties for pur-
 17 poses of cosmetic safety review.”.

18 **SEC. 9. REPORTING.**

19 Chapter VI of the Federal Food, Drug, and Cosmetic
 20 Act (21 U.S.C. 361 et seq.), as amended by section 8,
 21 is further amended by adding at the end the following:

22 **“SEC. 608. COSMETIC INGREDIENT REPORT.**

23 “(a) ANNUAL REPORT TO CONGRESS.—The Commis-
 24 sioner shall submit an annual report to the appropriate

1 committees of Congress that includes a report or summary
2 of—

3 “(1) the ingredients or non-functional constitu-
4 ents that the Commissioner has identified for review
5 under section 606(a);

6 “(2) the ingredients or non-functional constitu-
7 ents for which the Commissioner has issued a pro-
8 posed order, a final order, or a finding of incomplete
9 evidence under section 606(b);

10 “(3) the ongoing ingredient or non-functional
11 constituents being reviewed for safety at the time of
12 submission of the report, reviews the Commissioner
13 has determined to be needed, and reviews for which
14 Commissioner is contracting with an accredited third
15 party;

16 “(4) a summary of serious adverse event re-
17 ports submitted under section 762, and the associ-
18 ated product category and serious adverse health
19 consequence for each such report; and

20 “(5) enforcement actions, if any, the Commis-
21 sioner has taken as a result of serious adverse event
22 reports or facility inspections, including warning let-
23 ters, untitled letters, suspension of registration, or
24 any other type of action.”.

1 **SEC. 10. GAO REPORT.**

2 Not later than 2 years after the date of enactment
3 of this Act, the Comptroller General of the United States
4 shall analyze, and submit a report to Congress on—

5 (1) the types of ingredients or non-functional
6 constituents that the Food and Drug Administration
7 has identified for purposes of a safety review under
8 section 606 of the Federal Food, Drug, and Cos-
9 metic Act (as added by section 7) and the factors or
10 methods, if any, that such agency considers in deter-
11 mining the need for a safety review;

12 (2) the level of coordination between the Food
13 and Drug Administration and the States in identi-
14 fying ingredients that may present a public health
15 concern for review, and the process by which the
16 Food and Drug Administration considers public
17 input as part of identifying ingredients that may
18 present a public health concern;

19 (3) how the Food and Drug Administration ac-
20 counts for reports of serious adverse events under
21 section 762 of the Federal Food, Drug, and Cos-
22 metic Act (as added by section 2) to inform cosmetic
23 related inspections;

24 (4) the frequency and type of inspections con-
25 ducted by the Food and Drug Administration, in-
26 cluding inspections in response to reports of serious

1 adverse events, and an analysis of the outcome and
2 related facility compliance;

3 (5) the time between identifying ingredients to
4 be reviewed for safety under section 606(a) of the
5 Federal Food, Drug, and Cosmetic Act and issuance
6 of final administrative orders under section
7 606(b)(2) of such Act;

8 (6) ingredients, if any, that the Food and Drug
9 Administration took action to include on the prohib-
10 ited and restricted ingredients list of the Food and
11 Drug Administration, and a summary of ingredients
12 with respect to which such agency has issued an ad-
13 ministrative order; and

14 (7) the Food and Drug Administration's use of
15 accredited third parties for purposes of cosmetic in-
16 gredient safety reviews in accordance with section
17 607 of the Federal Food, Drug, and Cosmetic Act
18 (as added by section 8).

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