

113TH CONGRESS  
1ST SESSION

# H. R. 1385

To amend title VI of the Federal Food, Drug, and Cosmetic Act to ensure the safe use of cosmetics, and for other purposes.

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## IN THE HOUSE OF REPRESENTATIVES

MARCH 21, 2013

Ms. SCHAKOWSKY (for herself, Mr. MARKEY, Mr. BLUMENAUER, Ms. CHU, Mr. CONYERS, Mr. ELLISON, Mr. GRIJALVA, Mr. HASTINGS of Florida, Mr. HUFFMAN, Mr. LOWENTHAL, Mr. MICHAUD, Mr. MORAN, Ms. NORTON, Ms. PINGREE of Maine, Ms. WASSERMAN SCHULTZ, and Ms. SPEIER) introduced the following bill; which was referred to the Committee on Energy and Commerce, and in addition to the Committee on Education and the Workforce, for a period to be subsequently determined by the Speaker, in each case for consideration of such provisions as fall within the jurisdiction of the committee concerned

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## A BILL

To amend title VI of the Federal Food, Drug, and Cosmetic Act to ensure the safe use of cosmetics, 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; TABLE OF CONTENTS.**

4 (a) SHORT TITLE.—This Act may be cited as the  
5 “Safe Cosmetics and Personal Care Products Act of  
6 2013”.

1 (b) TABLE OF CONTENTS.—The table of contents of  
 2 this Act is as follows:

Sec. 1. Short title; table of contents.  
 Sec. 2. Cosmetic regulation.

“SUBCHAPTER A—ADULTERATED AND MISBRANDED COSMETICS

“SUBCHAPTER B—REGULATION OF COSMETICS

“Sec. 611. Definitions.  
 “Sec. 612. Registration of establishments and registration fees.  
 “Sec. 613. Ingredients labels on cosmetics.  
 “Sec. 614. Safety standard and good manufacturing practices.  
 “Sec. 615. Cosmetic and ingredient safety information.  
 “Sec. 616. Lists of ingredients and required responses.  
 “Sec. 617. Treatment of cosmetics based on ingredient lists.  
 “Sec. 618. Treatment of contaminants.  
 “Sec. 619. Cosmetic and ingredient statements.  
 “Sec. 620. Notification, nondistribution, and recall of adulterated or mis-  
 branded cosmetics.  
 “Sec. 621. Petitions.  
 “Sec. 622. Mandatory reporting of serious adverse events.  
 “Sec. 623. Nonconfidential information.  
 “Sec. 624. Animal testing alternatives.  
 “Sec. 625. Product Testing and Review Audit.  
 “Sec. 626. Resources for small businesses.  
 “Sec. 627. Interagency cooperation.  
 “Sec. 628. Savings clause.  
 “Sec. 629. Authorization of appropriations.

Sec. 3. Worker issues.

### 3 SEC. 2. COSMETIC REGULATION.

4 (a) IN GENERAL.—Chapter VI of the Federal Food,  
 5 Drug, and Cosmetic Act (21 U.S.C. 361 et seq.) is amend-  
 6 ed—

7 (1) by inserting before section 601 the fol-  
 8 lowing:

9 **“Subchapter A—Adulterated and Misbranded**  
 10 **Cosmetics”;**

11 and

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

1       **“Subchapter B—Regulation of Cosmetics**

2       **“SEC. 611. DEFINITIONS.**

3       “In this subchapter:

4               “(1) BRAND OWNER.—The term ‘brand owner’  
5       means the entity responsible for bringing a cosmetic  
6       to market.

7               “(2) CONTAMINANT.—The term ‘contaminant’  
8       means unintended substances, such as those that  
9       can originate from sources outside the chemical  
10       pathway, chemical processes, storage of primary sub-  
11       stances, instability of the packaging or harmful by-  
12       products of the manufacturing process.

13               “(3) DOMESTIC ESTABLISHMENT.—The term  
14       ‘domestic establishment’ means an establishment lo-  
15       cated in any State that brings a cosmetic to market.

16               “(4) FOREIGN ESTABLISHMENT.—The term  
17       ‘foreign establishment’ means an establishment that  
18       brings a cosmetic to market and exports those cos-  
19       metics to the United States.

20               “(5) INGREDIENT.—The term ‘ingredient’  
21       means a chemical in a cosmetic, including—

22                       “(A) chemicals that provide a technical or  
23       functional effect;

24                       “(B) chemicals that have no technical or  
25       functional effect in the cosmetic but are present

1 by reason of having been incorporated into the  
2 cosmetic as an ingredient of another cosmetic  
3 ingredient;

4 “(C) processing aids that are present by  
5 reason of having been added to a cosmetic dur-  
6 ing the processing of such cosmetic;

7 “(D) substances that are present by reason  
8 of having been added to a cosmetic during proc-  
9 essing for their technical or functional effect;

10 “(E) the components of a fragrance, fla-  
11 vor, or preservative; and

12 “(F) any individual component that the  
13 Secretary deems an ingredient for purposes of  
14 this chapter.

15 “(6) MANUFACTURER.—The term ‘manufac-  
16 turer’ means the entity that produces ingredients or  
17 combines one or more ingredients to produce a cos-  
18 metic product.

19 “(7) MICROBUSINESS.—The term ‘microbusi-  
20 ness’ means a business—

21 “(A) that is a brand owner as defined in  
22 this subchapter; and

23 “(B) that has annual sales receipts for cos-  
24 metic products that do not exceed \$2,000,000.

1           “(8) PROFESSIONAL USE.—The term ‘profes-  
2           sional use’ means the use of any cosmetic—

3                   “(A) by an employee (within the scope of  
4                   the employment of such employee) of; or

5                   “(B) purchased by a consumer in,  
6           a hair salon, nail salon, beauty salon, spa, or other  
7           establishment that provides cosmetic treatment serv-  
8           ices for humans.

9           “(9) REASONABLE CERTAINTY OF NO HARM.—  
10          With respect to an ingredient or cosmetic, the term  
11          ‘reasonable certainty of no harm’ means that no  
12          harm will be caused to members of the general popu-  
13          lation or any vulnerable population by aggregate ex-  
14          posure to the cosmetic or ingredient, taking into ac-  
15          count possible harmful effects from—

16                   “(A) low-dose exposures to the cosmetic or  
17                   ingredient;

18                   “(B) additive effects resulting from re-  
19                   peated exposure to the cosmetic or ingredient  
20                   over time; or

21                   “(C) cumulative exposure resulting from  
22                   all sources, including both the cosmetic or in-  
23                   gredient and environmental sources.

24          “(10) REPRODUCTIVE OR DEVELOPMENTAL  
25          TOXICITY.—With respect to an ingredient or cos-

1        metic, the term ‘reproductive or developmental tox-  
2        icity’ means that the ingredient or cosmetic can con-  
3        tribute to biologically adverse effects on the develop-  
4        ment of humans or animals, including effects on the  
5        female or male reproductive system, the endocrine  
6        system, fertility, pregnancy, pregnancy outcomes, or  
7        modifications in other functions of the body that are  
8        dependent on the integrity of the reproductive sys-  
9        tem as well normal fetal development.

10        “(11) SERIOUS ADVERSE EVENT.—The term  
11        ‘serious adverse event’ means—

12                “(A) an acute or chronic response that re-  
13                sults in death, a life-threatening experience,  
14                short- or long-term hospitalization, a persistent  
15                or significant disability or incapacity, or a con-  
16                genital anomaly or birth defect; or

17                “(B) requires, based on a reasonable med-  
18                ical judgment, a medical or surgical interven-  
19                tion to prevent an outcome described above.

20        “(12) SUPPLIER.—The term ‘supplier’ means  
21        the entity that supplies ingredients, raw materials,  
22        or specific components of a cosmetic product, includ-  
23        ing packaging.

24        “(13) VULNERABLE POPULATIONS.—The term  
25        ‘vulnerable populations’ includes pregnant women,

1 infants, children, the elderly, and highly exposed  
2 populations, including workers employed by hair sa-  
3 lons, nail salons, beauty salons, spas, other estab-  
4 lishments that provide cosmetic treatment services  
5 for humans, and cosmetic manufacturing plants.

6 **“SEC. 612. REGISTRATION OF ESTABLISHMENTS AND REG-**  
7 **ISTRATION FEES.**

8 “(a) REGISTRATION.—

9 “(1) IN GENERAL.—Beginning 1 year after the  
10 date of the enactment of this subchapter, and annu-  
11 ally thereafter, any brand owner (except for micro-  
12 businesses) engaged in bringing a cosmetic to mar-  
13 ket for use in the United States shall register with  
14 the Secretary and pay to the Secretary the applica-  
15 ble fee, as established under the fee schedule in sub-  
16 section (e).

17 “(2) RULES FOR DOMESTIC AND FOREIGN ES-  
18 TABLISHMENTS.—To be registered under paragraph  
19 (1)—

20 “(A) as a domestic establishment, the  
21 owner, operator, or agent in charge of the do-  
22 mestic establishment shall submit a registration  
23 to the Secretary; or

1           “(B) as a foreign establishment, the owner,  
2           operator, or agent in charge of the foreign es-  
3           tablishment shall—

4                   “(i) submit a registration to the Sec-  
5                   retary; and

6                   “(ii) include with the registration the  
7                   name of the United States agent for the  
8                   foreign establishment.

9           “(3) NEW ESTABLISHMENTS.—Any brand  
10          owner that initially brings a cosmetic to market  
11          after the date on which the requirements of para-  
12          graph (1) apply shall, not later than 60 days after  
13          the date on which the establishment brings a cos-  
14          metic to market, register with the Secretary and pay  
15          the applicable fee, as required under paragraph (1).

16          “(b) SUBMISSION OF REGISTRATION.—

17                   “(1) IN GENERAL.—In order to register under  
18                   subsection (a), an establishment (referred to in this  
19                   section as the ‘registrant’) shall submit to the Sec-  
20                   retary, with respect to any cosmetics that the estab-  
21                   lishment brings to market, all of the following:

22                           “(A) Any information necessary to notify  
23                           the Secretary of the name, address, and legal  
24                           status of each establishment at which, and all



1 trade names under which, the registrant brings  
2 cosmetics to market.

3 “(B) A description of the establishment’s  
4 activities with respect to cosmetics, including a  
5 list of all cosmetic products brought to market  
6 by the establishment and the functions of such  
7 cosmetics.

8 “(C) The gross receipts or sales for the es-  
9 tablishment from cosmetics.

10 “(2) NOTIFICATION OF CHANGES.—When sub-  
11 mitting the annual registration, the registrant shall  
12 notify the Secretary of changes to the information  
13 described in paragraph (1).

14 “(c) PROCEDURE.—Upon receipt of a completed reg-  
15 istration submitted under subsection (a), the Secretary  
16 shall notify the registrant of the receipt of such registra-  
17 tion and assign a registration number to each registered  
18 establishment.

19 “(d) LIST OF REGISTERED ESTABLISHMENTS.—

20 “(1) MAINTENANCE OF LIST.—The Secretary  
21 shall—

22 “(A) compile, maintain, and update as ap-  
23 propriate, a list of establishments that are reg-  
24 istered under this section;

25 “(B) make such list publicly available;

1           “(C) remove from such list the name of  
2 any establishment that fails to register in ac-  
3 cordance with this section; and

4           “(D) indicate on such list any establish-  
5 ment which has had its registration suspended  
6 or cancelled by the Secretary under this section.

7           “(2) APPLICATION OF FOIA.—

8           “(A) REGISTRATION DOCUMENTS.—Any  
9 registration documents submitted pursuant to  
10 this section shall not be subject to disclosure  
11 under section 552 of title 5, United States  
12 Code.

13           “(B) OTHER INFORMATION.—Information  
14 derived from—

15                   “(i) the list under paragraph (1); or

16                   “(ii) registration documents submitted  
17 pursuant to this section,

18 shall not be subject to disclosure under section  
19 552 of title 5, United States Code, except to the  
20 extent that such information discloses the iden-  
21 tity or location of a specific registrant.

22           “(e) FEE SCHEDULE.—A schedule of fees shall be de-  
23 veloped by the Secretary to provide for oversight and en-  
24 forcement of this subchapter. The fee structure shall—

1           “(1) be prorated based on the establishment’s  
2 gross receipts or sales; and

3           “(2) only be assessed on companies with annual  
4 gross receipts or sales of cosmetics that exceed  
5 \$10,000,000.

6           “(f) SUSPENSION AND CANCELLATION OF REGISTRA-  
7 TION.—

8           “(1) CRITERIA FOR SUSPENSION.—Registration  
9 under this section is subject to suspension if the  
10 Secretary finds—

11           “(A) the information submitted by the es-  
12 tablishment for registration under subsection  
13 (a) is incomplete, inaccurate, or out of date;

14           “(B) the establishment fails to notify the  
15 Secretary of changes required under subsection  
16 (b)(2);

17           “(C) the establishment fails to pay reg-  
18 istration fees, as required under subsection (a),  
19 in a timely manner; or

20           “(D) the establishment violates any portion  
21 of this chapter.

22           “(2) SUSPENSION OF REGISTRATION.—If the  
23 Secretary determines that an establishment is sub-  
24 ject to suspension under this subsection and that it

1 is appropriate to suspend the registration of such es-  
2 tablishment, the Secretary shall—

3 “(A) suspend the registration of such es-  
4 tablishment; and

5 “(B) provide a notice of suspension to such  
6 establishment.

7 “(3) CANCELLATION.—If the establishment  
8 fails to correct the issue that resulted in the suspen-  
9 sion under paragraph (2) before the last day of the  
10 30-day period beginning on the date that the estab-  
11 lishment receives notice under such paragraph, the  
12 Secretary may cancel the registration of such estab-  
13 lishment.

14 “(g) RECORDKEEPING.—All establishments that are  
15 required to register under this section shall maintain  
16 records that include a current list of suppliers and manu-  
17 facturers, if the registrant does not manufacture or pack-  
18 age its own product. Those records shall be accessible by  
19 the Secretary upon request for review or audit.

20 **“SEC. 613. INGREDIENTS LABELS ON COSMETICS.**

21 “(a) IN GENERAL.—Subject to subsections (b) and  
22 (c), the Secretary shall require that the label on each pack-  
23 age of cosmetics (including cosmetics distributed for retail  
24 sale and professional use) bears a declaration of the name

1 of each ingredient in such cosmetic in descending order  
2 of predominance.

3 “(b) ADJUSTMENTS FOR LABEL SIZE.—

4 “(1) RULES FOR SMALL PRODUCTS.—Not later  
5 than 6 months after the date of the enactment of  
6 this subchapter, the Secretary shall issue regulations  
7 that apply to any cosmetic for which the product  
8 packaging is not of sufficient size to bear or contain  
9 a label that meets the requirements of subsection  
10 (a).

11 “(2) REQUIREMENTS FOR PUBLIC DISCLO-  
12 SURE.—Such regulations shall establish require-  
13 ments for listing ingredients on the label of such  
14 cosmetics and additional requirements for public dis-  
15 closure of the ingredients in such cosmetics.

16 “(c) SPECIAL RULE FOR CONTAMINANTS.—The Sec-  
17 retary shall require, in the case of a contaminant, that  
18 a contaminant be declared on the label of a cosmetic, in  
19 the same manner as an ingredient under subsection (a),  
20 if the contaminant is present at the lower of the following  
21 levels:

22 “(1) A level that is greater than one part-per-  
23 billion by weight of product formation.

24 “(2) A level that is greater than one percent of  
25 the restriction on the concentration for such con-

1       taminant for such use, as determined by the Sec-  
2       retary under section 616(a)(2).

3       “(d) LABELING OF NANOMATERIALS IN COS-  
4 METICS.—The Secretary may require that—

5               “(1) minerals and other particulate ingredients  
6       be labeled as ‘nano-scale’ on a cosmetic ingredient  
7       label or list if not less than 1 percent of the ingre-  
8       dient particles in the cosmetic are 100 nanometers  
9       or smaller in not less than 1 dimension; and

10              “(2) other ingredients in a cosmetic be des-  
11       ignated with scale-specific information on a cosmetic  
12       ingredient label or list if such ingredients possess  
13       scale-specific hazard properties.

14       “(e) LABELING OF INGREDIENTS IN COSMETICS  
15 SOLD THROUGH INTERNET COMMERCE.—The Secretary  
16 shall require—

17              “(1) in the case of a cosmetic sold on the Web  
18       site of an Internet vendor, that the brand owner of  
19       such cosmetic provide to such Internet vendor a list  
20       of the ingredients of the cosmetic; and

21              “(2) that each Internet vendor display the list  
22       of ingredients of a cosmetic sold by such vendor on  
23       the Web page that is the primary Web page pro-  
24       viding information relating to the sale of such cos-  
25       metic on the Web site of the vendor.

1       “(f) TRADE SECRETS.—Notwithstanding any other  
2 provision of law, an ingredient required to be listed on a  
3 label under this section shall not be treated as a trade  
4 secret.

5       “(g) APPLICATION.—Beginning 18 months after the  
6 date of the enactment of this subchapter, the requirements  
7 of this section shall apply to—

8               “(1) all cosmetics that are available for retail  
9 sale; and

10              “(2) brand owners and Internet vendors of such  
11 cosmetics.

12 **“SEC. 614. SAFETY STANDARD AND GOOD MANUFACTURING**  
13 **PRACTICES.**

14       “(a) SAFETY STANDARD.—

15              “(1) IN GENERAL.—Taking into account the ex-  
16 pected use of a cosmetic, the Secretary shall estab-  
17 lish a safety standard that, with respect to a cos-  
18 metic or an ingredient in a cosmetic provides a rea-  
19 sonable certainty of no harm (as such term is de-  
20 fined in section 611(7)) from exposure to the cos-  
21 metic or ingredient and protects the public from any  
22 known or anticipated adverse health effects associ-  
23 ated with the cosmetic or ingredient.

24              “(2) STANDARDS FOR ESTABLISHING SAFETY  
25 STANDARD.—In establishing the safety standard

1 under paragraph (1), the Secretary shall ensure  
2 that—

3 “(A) the likely level of exposure to all  
4 sources of the ingredient or cosmetic (including  
5 environmental sources) that will result under  
6 the safety standard presents not more than a 1  
7 in a million risk for any adverse health effect  
8 in any vulnerable population at the lower 95th  
9 percentile confidence interval; or

10 “(B) the safety standard results in expo-  
11 sure to the amount or concentration of an in-  
12 gredient or cosmetic that is shown to produce  
13 no adverse health effects, incorporating an mar-  
14 gin of safety of at least 1,000 and considering  
15 the impact of cumulative exposure from all  
16 sources (including environmental sources).

17 “(3) USE OF OTHER FEDERAL STANDARDS.—If  
18 any Federal agency has promulgated a standard for  
19 an ingredient that satisfies the requirements under  
20 paragraph (1), the Secretary may treat such stand-  
21 ard as the safety standard under paragraph (1) for  
22 purposes of such ingredient.

23 “(4) APPLICATION OF SAFETY STANDARD.—  
24 The Secretary may only determine that an ingre-  
25 dient or a cosmetic meets the safety standard under



1 paragraph (1) if there is a reasonable certainty of no  
2 harm from exposure to the ingredient or cosmetic.

3 “(b) GOOD MANUFACTURING PRACTICES.—

4 “(1) IN GENERAL.—The Secretary shall issue  
5 guidance prescribing good manufacturing practices  
6 for cosmetics and ingredients, including quality con-  
7 trol procedures that the Secretary determines are  
8 necessary, and shall update such regulations as nec-  
9 essary.

10 “(2) CONSIDERATION OF SMALL BUSINESS.—In  
11 developing the guidance under paragraph (1), the  
12 Secretary shall consider how such practices will im-  
13 pact small businesses.

14 **“SEC. 615. COSMETIC AND INGREDIENT SAFETY INFORMA-**  
15 **TION.**

16 “(a) REQUIRED SUBMISSION OF ALL SAFETY INFOR-

17 MATION.—  
18 “(1) IN GENERAL.—Brand owners of cosmetics  
19 shall submit to the Secretary (in an electronic for-  
20 mat that the Secretary shall determine) all data and  
21 information that the brand owner can access regard-  
22 ing the safety of the—

23 “(A) ingredients listed on the cosmetic  
24 label under section 613 for a cosmetic; and

25 “(B) cosmetic itself.

1           “(2) REQUIRED INFORMATION.—The required  
2 data and information under paragraph (1) shall in-  
3 clude, for each ingredient in a cosmetic and for the  
4 cosmetic, the following:

5           “(A) Functions and uses.

6           “(B) Data and information on the phys-  
7 ical, chemical, and toxicity of each such ingre-  
8 dient or cosmetic.

9           “(C) Exposure and fate information.

10          “(D) Results of all safety tests that the  
11 brand owner can access or has conducted.

12          “(E) Any other information used to sub-  
13 stantiate the safety of such ingredient and cos-  
14 metic.

15          “(3) DEADLINES.—

16          “(A) INITIAL SUBMISSION.—A brand  
17 owner shall submit the data and information re-  
18 quired under paragraph (1)—

19           “(i) in the case of an ingredient or  
20 cosmetic which is marketed for sale in  
21 interstate commerce on or before the date  
22 of the enactment of this subchapter, not  
23 later than 1 year after such date; and

1           “(ii) in the case of an ingredient or  
2 cosmetic which is not marketed for sale on  
3 or before such date—

4                   “(I) not later than the end of the  
5 14-month period beginning on the  
6 date of the enactment of this sub-  
7 chapter; or

8                   “(II) if the ingredient or cosmetic  
9 is first marketed for sale in interstate  
10 commerce after the end of the period  
11 described in subclause (I), not later  
12 than 60 days after the date on which  
13 such ingredient or cosmetic is first  
14 marketed for sale.

15           “(B) UPDATES.—

16                   “(i) IN GENERAL.—Subject to clause  
17 (ii), a brand owner shall update the data  
18 and information submitted under subpara-  
19 graph (A) annually.

20                   “(ii) ADVERSE HEALTH EFFECTS.—In  
21 the case of information related to an ad-  
22 verse health effect that is suspected to be  
23 caused by an ingredient or a cosmetic, a  
24 brand owner shall update the information

1 not later than 60 days after receiving such  
2 information.

3 “(4) SUPPLIER AND MANUFACTURER INFORMA-  
4 TION.—

5 “(A) USE OF SUPPLIER OR MANUFAC-  
6 Turer INFORMATION.—In order to meet the re-  
7 quirements of paragraph (1) with respect to an  
8 ingredient, a brand owner may submit safety  
9 data and information provided by the supplier  
10 or manufacturer of the ingredient or cosmetic.

11 “(B) SUPPLIER OR MANUFACTURER PRO-  
12 vision OF INFORMATION.—If a brand owner re-  
13 quests that a supplier or manufacturer of an in-  
14 gredient provide to such brand owner any of the  
15 data and information described under para-  
16 graph (2) or under section 617, such supplier  
17 or manufacturer shall provide such data and in-  
18 formation to such brand owner not later than  
19 90 days after receiving such request.

20 “(b) DATABASE.—

21 “(1) INITIAL PUBLICATION.—Not later than 1  
22 year after the date of the enactment of this sub-  
23 chapter, the Secretary shall publish a comprehensive,  
24 publicly accessible database containing all noncon-

1        confidential information (as such term is used under  
2        section 623) submitted under subsection (a)(1).

3            “(2) UPDATES.—Not later than 90 days after  
4        the Secretary receives new or updated information  
5        under subsection (a)(3)(B), the Secretary shall up-  
6        date the database under paragraph (1) with such in-  
7        formation.

8        “(c) REVIEW AND EVALUATION OF INFORMATION.—

9            “(1) IN GENERAL.—Based on the data and in-  
10       information submitted under subsection (a)(1), avail-  
11       able from an authoritative source (as such term is  
12       defined in paragraph (3), including data described  
13       under section 627(b)), and such other information  
14       as the Secretary may have available, the Secretary  
15       shall review and evaluate the safety of cosmetics and  
16       ingredients of cosmetics that are marketed in inter-  
17       state commerce.

18        “(2) CONSIDERATION OF NANOMATERIALS.—

19        The Secretary shall—

20            “(A) monitor developments in the scientific  
21       understanding from any adverse health effects  
22       related to the use of nanotechnology in the for-  
23       mulation of cosmetics (including progress in the  
24       standardization of testing methods and specific  
25       size definitions for nanomaterials); and

1           “(B) consider scale specific hazard prop-  
2           erties of ingredients when reviewing and evalu-  
3           ating the safety of cosmetics and ingredients  
4           under paragraph (1).

5           “(3) AUTHORITATIVE SOURCE DEFINED.—For  
6           purposes of this paragraph, the term ‘authoritative  
7           source’ means—

8           “(A) the Environmental Protection Agen-  
9           cy;

10           “(B) the International Agency for Re-  
11           search on Cancer;

12           “(C) the National Toxicity Program  
13           through the National Institutes of Health;

14           “(D) the California Environmental Protec-  
15           tion Agency; and

16           “(E) any other authoritative international,  
17           Federal, and State entity, as determined by the  
18           Secretary.

19 **“SEC. 616. LISTS OF INGREDIENTS AND REQUIRED RE-**  
20 **SPONSES.**

21           “(a) PLACEMENT ON LIST.—

22           “(1) IN GENERAL.—Based on an initial review  
23           and evaluation of an ingredient under subsection (c),  
24           the Secretary shall place the ingredient on one of the  
25           following lists:

1           “(A) The prohibited and restricted list  
2           under subsection (b).

3           “(B) The safe without limits list under  
4           subsection (c).

5           “(C) The priority assessment list under  
6           subsection (d).

7           “(2) CONSIDERATIONS.—In determining the  
8           placement of an ingredient on a list under sub-  
9           section (a), the Secretary shall consider whether the  
10          ingredient—

11           “(A) reacts with other substances to form  
12           harmful contaminants;

13           “(B) is found to be present in the body  
14           through biomonitoring;

15           “(C) is found in drinking water or air;

16           “(D) is a known or suspected neurological  
17           or immunological toxicant, respiratory  
18           asthmagen, carcinogen, teratogen, or endocrine  
19           disruptor, or have other toxicity concerns (in-  
20           cluding reproductive or developmental toxicity);  
21           or

22           “(E) is known to persist in the environ-  
23           ment or bioaccumulate.

24           “(3) PRIORITIZATION OF INGREDIENTS THAT  
25           ARE FOOD.—In placing ingredients on the lists

1 under paragraph (1), the Secretary shall prioritize  
2 the placement of ingredients that are food (as such  
3 term is defined under section 201(f)) on such lists.

4 “(b) PROHIBITED AND RESTRICTED LIST.—

5 “(1) IN GENERAL.—Not later than 2 years  
6 after the date of the enactment of this subchapter,  
7 the Secretary shall issue, by regulation, a list of in-  
8 gredients that are identified by the Secretary—

9 “(A) as prohibited for use because the Sec-  
10 retary determines that such ingredients are un-  
11 safe for use in cosmetics in any amount because  
12 such ingredients fail to meet the safety stand-  
13 ard under section 614(a); or

14 “(B) as being subject to necessary restric-  
15 tions in use or concentration to allow the use of  
16 the ingredient in a cosmetic to satisfy the safety  
17 standard.

18 “(2) SPECIFICATION OF RESTRICTIONS.—In the  
19 case of any ingredient listed under paragraph  
20 (1)(B), the Secretary shall specify the restrictions on  
21 use or concentration that are necessary to satisfy the  
22 safety standard for such ingredient.

23 “(3) UPDATES.—The Secretary shall, at a min-  
24 imum, annually update the list under paragraph (1),  
25 including any—



1           “(A) determinations under subsection  
2           (d)(3); or

3           “(B) new information that demonstrates  
4           that an ingredient fails to meet the safety  
5           standard, or requires restrictions on use to  
6           meet such standard.

7           “(4) MANUFACTURER REQUIREMENTS.—Not  
8           later than 1 year after the date that an ingredient  
9           is placed on a list under subsection (b), any manu-  
10          facturer using such ingredient in a cosmetic shall re-  
11          formulate such cosmetic to—

12           “(A) eliminate the use of the ingredient, if  
13           it is listed under paragraph (1)(A); or

14           “(B) modify the use of the ingredient if it  
15           is listed under paragraph (1)(B), to meet the  
16           restrictions specified under paragraph (2).

17          “(c) SAFE WITHOUT LIMITS LIST.—

18           “(1) IN GENERAL.—Not later than 2 years  
19           after the date of the enactment of this subchapter,  
20           the Secretary shall issue, by regulation, a list of in-  
21           gredients that the Secretary has determined are safe  
22           for use in cosmetics, without limits or restrictions.

23           “(2) STANDARD FOR INCLUSION IN LIST.—The  
24           Secretary may only include an ingredient on the list  
25           under paragraph (1) if the Secretary determines

1 that the ingredient meets the safety standard under  
2 section 614(a), regardless of—

3 “(A) the type and form of cosmetic the in-  
4 gredient is used in; and

5 “(B) the concentration of the ingredient  
6 that is used in a cosmetic.

7 “(3) UPDATES AND REDETERMINATIONS.—The  
8 Secretary shall annually update the list under para-  
9 graph (1) and may redetermine whether an ingre-  
10 dient distributed in commerce meets the safety  
11 standard if, in the judgment of the Secretary, new  
12 information raises a credible question as to whether  
13 the ingredient continues to meet the safety standard.

14 “(d) PRIORITY ASSESSMENT LIST AND RELATED  
15 SAFETY DETERMINATIONS.—

16 “(1) IN GENERAL.—Not later than 2 years  
17 after the date of the enactment of this subchapter,  
18 the Secretary shall develop and publish a priority as-  
19 sessment list of not less than 300 ingredients—

20 “(A) which, because of a lack of authori-  
21 tative information on the safety of the ingre-  
22 dient, cannot be included on—

23 “(i) the list under subsection (b) (re-  
24 lating to prohibited and restricted ingredi-  
25 ents); or

1                   “(ii) the list under subsection (c) (re-  
2                   lating to ingredients that are safe without  
3                   limits); and

4                   “(B) for which the Secretary has deter-  
5                   mined it is a priority to conduct a safety deter-  
6                   mination under paragraph (3).

7                   “(2) ANNUAL ADDITION OF INGREDIENTS.—  
8                   After the list is developed under paragraph (1), the  
9                   Secretary shall annually add at least 100 additional  
10                  ingredients to such list until all ingredients that are  
11                  used in the formulation or manufacture of cosmetics  
12                  have been added—

13                         “(A) to such list;

14                         “(B) to the list under subsection (b); or

15                         “(C) to the list under subsection (c).

16                   “(3) DETERMINATION OF WHETHER INGREDI-  
17                  DIENT MEETS SAFETY STANDARD.—

18                         “(A) REVIEW OF PRIORITY INGREDI-  
19                         ENTS.—During the 2-year period following the  
20                         date on which an ingredient is placed on the list  
21                         under paragraph (1), the Secretary shall—

22                                 “(i) collect data and information on  
23                                 such ingredient; and

24                                 “(ii) review and evaluate the safety of  
25                                 such ingredient.

1           “(B) DETERMINATION OF LIST PLACE-  
2           MENT.—Not later than the end of the period  
3           under subparagraph (A), the Secretary shall  
4           issue a determination, based on the review and  
5           evaluation under such clause, that—

6                   “(i) the ingredient meets the require-  
7                   ments for inclusion on a list under sub-  
8                   section (b) (relating to prohibited and re-  
9                   stricted ingredients) or subsection (c) (re-  
10                  lating to ingredients that are safe without  
11                  limits); or

12                  “(ii) insufficient information exists to  
13                  place the ingredient on either such list.

14           “(C) GUIDANCE IN THE CASE OF INSUFFI-  
15           CIENT INFORMATION.—If the Secretary deter-  
16           mines under subparagraph (B) that, with re-  
17           spect to an ingredient, insufficient information  
18           exists to place such ingredient on either of the  
19           lists under subsection (b) or subsection (c), the  
20           Secretary shall provide guidance on the data  
21           and information (including minimum data re-  
22           quirements and safety testing protocols) that  
23           the Secretary requires to evaluate whether the  
24           ingredient meets the safety standard under sec-

1           tion 614(a) for purposes of placing such ingre-  
2           dient on such a list.

3           “(D) COMMENT PERIOD.—Upon issuing  
4           the determination under subparagraph (B),  
5           and, if applicable, the guidance under subpara-  
6           graph (C), the Secretary shall provide a period  
7           of not less than 60 days for public comment on  
8           the determination before applying such deter-  
9           mination to an ingredient, except that a shorter  
10          period for comment may be provided if the Sec-  
11          retary—

12                   “(i) finds that it would be in the pub-  
13                   lic interest to have a shorter period; and

14                   “(ii) publicly declares the reasons for  
15                   such finding.

16          “(4) RESPONSE TO INADEQUATE INFORMA-  
17          TION.—Not later than 18 months after the date that  
18          the Secretary issues guidance under paragraph  
19          (3)(C) with respect to an ingredient subject to a de-  
20          termination under paragraph (3)(B), a brand owner  
21          using such ingredient in a cosmetic shall—

22                   “(A) reformulate such cosmetic to elimi-  
23                   nate the use of the ingredient; or

24                   “(B) provide the Secretary with the data  
25                   and information specified in such guidance.

1           “(5) EVALUATION OF ADDITIONAL DATA AND  
2 INFORMATION.—With respect to an ingredient, not  
3 later than 6 months after the Secretary receives the  
4 data and information under paragraph (4)(B) the  
5 Secretary shall review such data and information  
6 and shall make a redetermination under paragraph  
7 (3)(B) for such ingredient, subject to the comment  
8 period under paragraph (3)(D).

9           “(6) LIMITATION.—If the Secretary has not  
10 placed an ingredient on either of the lists under sub-  
11 section (b) and subsection (c) by the end of the 5-  
12 year period beginning on the date that such ingre-  
13 dient is first placed on the list under subsection (d),  
14 beginning on the first day after such period such in-  
15 gredient may not be—

16                   “(A) used in a cosmetic; and

17                   “(B) manufactured, imported, distributed,  
18 or marketed for use in cosmetics.

19 **“SEC. 617. TREATMENT OF COSMETICS BASED ON INGRE-**  
20 **DIENT LISTS.**

21           “(a) IN GENERAL.—Subject to subsections (b)(4)  
22 and (d)(4) of section 616, a brand owner may only dis-  
23 tribute in interstate commerce a cosmetic that meets the  
24 safety standard under section 614(a).

1       “(b) PRESUMPTION RELATED TO THE SAFETY OF  
2 COSMETICS.—

3               “(1) IN GENERAL.—Subject to paragraph (2),  
4 for purposes of subsection (a), the Secretary shall  
5 presume that the following cosmetics meet the safety  
6 standard under section 614(a):

7                       “(A) A cosmetic that is made solely of in-  
8 gredients on the list under section 616(e)(1)  
9 (relating to ingredients that are safe without  
10 limits).

11                      “(B) A cosmetic that is made solely of in-  
12 gredients on the list under section 616(b)(1)(B)  
13 (relating to ingredients subject to restrictions)  
14 and the use of each of such ingredients in such  
15 cosmetic is in compliance with the restrictions  
16 on the use of such ingredients specified under  
17 section 616(b)(2).

18                      “(C) A cosmetic that is made solely of in-  
19 gredients described under subparagraph (A)  
20 and subparagraph (B).

21               “(2) EXCEPTIONS.—The Secretary may require  
22 that a brand owner demonstrate that a cosmetic  
23 meets the safety standard under section 614(a) (in-  
24 cluding by requiring that the brand owner conduct  
25 safety testing, or request such safety testing from

1 relevant suppliers and manufacturers, of a cosmetic  
2 described under paragraph (1)) if the cosmetic—

3 “(A) contains penetration enhancers, sensi-  
4 tizers, estrogenic chemicals, or other similar in-  
5 gredients;

6 “(B) contains ingredients that react with  
7 each other or with other substances to form  
8 harmful byproducts; or

9 “(C) the Secretary has any additional rea-  
10 son to believe that such cosmetic does not meet  
11 the safety standard under section 614(a).

12 “(3) GUIDANCE.—If, under paragraph (2), the  
13 Secretary requires that a brand owner demonstrate  
14 that a cosmetic meets the safety standard under sec-  
15 tion 614(a), the Secretary shall provide the brand  
16 owner with guidance on the data and information  
17 that the Secretary requires to evaluate whether the  
18 cosmetic meets the safety standard under such sec-  
19 tion.

20 “(c) NOTIFICATION OF FAILURE OF SECRETARY TO  
21 ACT.—If the Secretary fails to act by an applicable dead-  
22 line under section 616 or this section, brand owners and  
23 manufacturers of an ingredient or a cosmetic affected by  
24 such failure of the Secretary to act shall issue to the Sec-  
25 retary, the public, and each known customer of the ingre-



1 dient or cosmetic, a written notice that a determination  
2 by the Secretary of the safety of the ingredient for use  
3 in cosmetics is pending.

4 **“SEC. 618. TREATMENT OF CONTAMINANTS.**

5       “(a) PUBLICATION OF LIST.—Not later than 1 year  
6 after the date of the enactment of this subchapter, and  
7 annually thereafter, the Secretary shall publish a list of  
8 contaminants of concern linked to severe acute reactions  
9 or long-term adverse health effects, including—

10           “(1) ingredients used in cosmetics that may  
11       contain contaminants of concern;

12           “(2) combinations of ingredients that may cre-  
13       ate contaminants of concern when such ingredients  
14       interact;

15           “(3) contaminants of concern that may leech  
16       from product packaging into a cosmetic; and

17           “(4) any other contaminant of concern identi-  
18       fied by the Secretary that are present in cosmetics.

19       “(b) EVALUATION; LABELING.—The Secretary shall  
20 use the process described in sections 615 and 616 to evalu-  
21 ate contaminants of concern for possible elimination or re-  
22 striction in cosmetics. The Secretary shall require that a  
23 contaminant on the list under subsection (a) be declared  
24 on the label of a cosmetic, in the same manner as an ingre-  
25 dient under section 613.

1 “(c) REQUIREMENTS FOR TESTING.—

2 “(1) IN GENERAL.—Not later than 1 year after  
3 the date of enactment of this subchapter, the Sec-  
4 retary shall establish, by rule, requirements for test-  
5 ing ingredients and cosmetics for contaminants list-  
6 ed under subsection (a).

7 “(2) CONTENTS.—The requirements under  
8 paragraph (1) shall include—

9 “(A) testing methods and applicable proto-  
10 cols; and

11 “(B) maximum allowable detection limits  
12 for each contaminant in an ingredient or cos-  
13 metic.

14 “(3) UPDATE.—The Secretary shall annually  
15 update the requirements under paragraph (1).

16 “(d) SUPPLIER REQUIREMENTS.—Not later than 1  
17 year after the promulgation of the rule under subsection  
18 (b)(1), a supplier of an ingredient that is used in a cos-  
19 metic shall, with respect to such ingredient—

20 “(1) comply with the requirements under sub-  
21 section (b)(1) for any ingredient listed under sub-  
22 section (a);

23 “(2) conduct similar testing on any ingredient  
24 that—

1           “(A) the supplier expects may be used in  
2           a cosmetic;

3           “(B) the supplier suspects may contain a  
4           contaminant of concern; and

5           “(C) is not listed under subsection (a); and

6           “(3) upon the sale of an ingredient to the man-  
7           ufacturer, provide to the manufacturer specifications  
8           for the ingredient that—

9           “(A) include the levels of contaminants  
10          present in such ingredient; and

11          “(B) are based on the results of the tests  
12          under paragraph (1) and paragraph (2).

13          “(e) BRAND OWNER REQUIREMENTS.—Not later  
14          than 1 year after the promulgation of the rule under sub-  
15          section (b)(1), a brand owner of a cosmetic shall, with re-  
16          spect to each ingredient that the brand owner uses in a  
17          cosmetic—

18          “(1) obtain, from each supplier or manufac-  
19          turer of the ingredient, specifications for the ingre-  
20          dient that include—

21          “(A) the level of each contaminant present  
22          in the ingredient; and

23          “(B) the detection limits of the analytical  
24          test used to detect the contaminant; or

1           “(2) comply with the requirements under para-  
2           graphs (1) and (2) of subsection (c) for the ingre-  
3           dient, in the same manner as if the brand owner  
4           were a supplier.

5   **“SEC. 619. COSMETIC AND INGREDIENT STATEMENTS.**

6           “(a) IN GENERAL.—Beginning 1 year after the date  
7           of the enactment of this subchapter, each brand owner of  
8           a cosmetic intended to be marketed in the United States  
9           shall submit electronically to the Secretary, for each cos-  
10          metic that is intended to be marketed in the United  
11          States, a statement containing—

12           “(1) the registration number of the brand  
13          owner;

14           “(2) the brand name and the product name for  
15          the cosmetic;

16           “(3) the applicable use for the cosmetic;

17           “(4) the ingredient list as it appears on the cos-  
18          metic label or insert, including the particle size  
19          range of any nanoscale cosmetic ingredients;

20           “(5) any warnings and directions for use from  
21          the cosmetic label or insert; and

22           “(6) the title and full contact information for  
23          the individual responsible for submitting and main-  
24          taining such statement.

1       “(b) NEW COSMETICS.—Any brand owner that be-  
2 gins to market a cosmetic after the date of the enactment  
3 of this subchapter shall comply with the requirements of  
4 subsection (a) beginning on the later of the following:

5           “(1) The end of the 18-month period beginning  
6       on the date of the enactment of this subchapter.

7           “(2) The 6-month period after the date on  
8       which the establishment begins to manufacture such  
9       cosmetic.

10       “(c) NOTIFICATION OF CHANGES.—The brand owner  
11 shall notify the Secretary annually of any change to the  
12 information required under subsection (a).

13       “(d) PROCEDURE.—Upon receipt of a completed  
14 statement described under subsection (a), the Secretary  
15 shall notify the brand owner of the receipt of such state-  
16 ment and assign a cosmetic statement number.

17       “(e) LIST.—The Secretary shall compile, maintain,  
18 and update as appropriate, a list of cosmetics for which  
19 statements are submitted under this section.

20       “(f) ACCESS TO SAFETY INFORMATION.—The cos-  
21 metic and ingredient statements collected under this sec-  
22 tion shall be added to the publicly accessible database cre-  
23 ated by the Secretary under section 615(b).

1 **“SEC. 620. NOTIFICATION, NONDISTRIBUTION, AND RECALL**  
2 **OF ADULTERATED OR MISBRANDED COS-**  
3 **METICS.**

4 “(a) NOTIFICATION OF ADULTERATED OR MIS-  
5 BRANDED COSMETICS.—

6 “(1) IN GENERAL.—A responsible party that  
7 has reason to believe that a cosmetic, when intro-  
8 duced into or while in interstate commerce, or while  
9 held for sale (regardless of whether such sale is the  
10 first sale of such cosmetic) after shipment in inter-  
11 state commerce, is adulterated or misbranded in a  
12 manner that presents a reasonable probability that  
13 the use or exposure to the cosmetic (or an ingredient  
14 or component used in any such cosmetic) will cause  
15 a threat of serious adverse event shall notify the  
16 Secretary of the identity and location of the cos-  
17 metic.

18 “(2) MANNER OF NOTIFICATION.—Notification  
19 under paragraph (1) shall be made in such manner  
20 and by such means as the Secretary may require by  
21 regulation or guidance.

22 “(3) RESPONSIBLE PARTY DEFINED.—For pur-  
23 poses of this subsection, the term ‘responsible party’  
24 means a brand owner, manufacturer, packager, re-  
25 tailer, or distributor of the cosmetic.

1       “(b) VOLUNTARY RECALL.—The Secretary may re-  
2 quest that any person who distributes a cosmetic that the  
3 Secretary has reason to believe is adulterated, misbranded,  
4 or otherwise in violation of this Act voluntarily—

5               “(1) recall such cosmetic; and

6               “(2) provide for notice, including to individuals  
7 as appropriate, to persons who may be affected by  
8 the recall.

9       “(c) ORDER TO CEASE DISTRIBUTION.—

10              “(1) IN GENERAL.—If the Secretary has reason  
11 to believe that—

12                      “(A) the use of, or exposure to, a cosmetic  
13 may cause serious adverse event;

14                      “(B) the cosmetic is misbranded; or

15                      “(C) the cosmetic is marketed, manufac-  
16 tured, packaged, or distributed by an unregis-  
17 tered brand owner;

18 the Secretary shall have the authority to issue an  
19 order requiring any person who distributes such cos-  
20 metic to immediately cease distribution of such cos-  
21 metic.

22              “(2) CEASE DISTRIBUTION AND NOTICE.—Any  
23 person who is subject to an order under paragraph  
24 (1) shall immediately cease distribution of such cos-

1        metic and provide notification as required by such  
2        order.

3           “(3) APPEAL.—

4               “(A) 24 HOURS.—A person subject to an  
5        order under paragraph (1) may appeal such  
6        order to the Secretary within 24 hours of the  
7        issuance of such order.

8               “(B) CONTENTS OF APPEAL.—Such appeal  
9        may include a request for an informal hearing  
10       and a description of any efforts to recall such  
11       cosmetic undertaken voluntarily by the person,  
12       including after a request under subsection (b).

13               “(C) INFORMAL HEARING.—Except as pro-  
14       vided in subsection (e), an informal hearing  
15       shall be held as soon as practicable, but not  
16       later than 5 calendar days (or less as deter-  
17       mined by the Secretary) after such an appeal is  
18       filed, unless the parties jointly agree to an ex-  
19       tension.

20               “(D) IMPACT ON RECALL.—If an appeal is  
21       filed under subparagraph (A), the Secretary  
22       may not amend the order to require a recall  
23       under subsection (d) until after the conclusion  
24       of the hearing under subparagraph (C).



1           “(4) VACATION OF ORDER.—If the Secretary  
2 determines that inadequate grounds exist to support  
3 the actions required by the order under paragraph  
4 (1), the Secretary shall vacate the order.

5           “(d) ORDER TO RECALL.—

6           “(1) AMENDMENT.—Except as provided under  
7 subsection (e) and subject to subsection (c)(3)(D), if  
8 the Secretary determines that a recall of a cosmetic  
9 subject to an order under subsection (c) is appro-  
10 priate, the Secretary shall amend the order to re-  
11 quire a recall.

12           “(2) CONTENTS.—An amended order under  
13 paragraph (1) shall—

14           “(A) specify a timetable in which the recall  
15 will occur;

16           “(B) require periodic reports to the Sec-  
17 retary describing the progress of the recall; and

18           “(C) provide for notice, including to indi-  
19 viduals as appropriate, to persons who may be  
20 affected by the recall.

21 In providing for such notice, the Secretary may  
22 allow for the assistance of health professionals, State  
23 or local officials, or other individuals designated by  
24 the Secretary.

1           “(3) NONDELEGATION.—An amended order  
2 under this subsection may only be issued by the Sec-  
3 retary or an official designated by the Secretary, and  
4 may not be delegated to another official or employee.

5           “(4) DETERMINATION.—If the Secretary deter-  
6 mines that inadequate grounds exist to support the  
7 amendment made to the order under paragraph (1),  
8 the Secretary shall remove such amendment from  
9 such order.

10          “(e) EMERGENCY RECALL ORDER.—

11           “(1) IN GENERAL.—If the Secretary has cred-  
12 ible evidence or information that a cosmetic subject  
13 to an order under subsection (c) presents an immi-  
14 nent threat of serious adverse event, the Secretary  
15 may issue an order requiring any person who dis-  
16 tributes such cosmetic—

17           “(A) to immediately recall such cosmetic;  
18 and

19           “(B) to provide for notice, including to in-  
20 dividuals as appropriate, to persons who may be  
21 affected by the recall.

22           “(2) RECALL AND NOTICE.—Any person who is  
23 subject to an emergency recall order under this sub-  
24 section shall immediately recall such cosmetic and  
25 provide notification as required by such order.

1           “(3) APPEAL.—

2                   “(A) 24 HOURS.—Any person subject to  
3           such an order may appeal such order to the  
4           Secretary within 24 hours of the issuance of  
5           such order.

6                   “(B) CONTENTS OF APPEAL.—Such appeal  
7           may include a request for an informal hearing  
8           and a description of any efforts to recall such  
9           cosmetic undertaken voluntarily by the person,  
10          including after a request under subsection (b).

11                   “(C) INFORMAL HEARING.—An informal  
12          hearing shall be held as soon as practicable  
13          after the appeal is filed under subparagraph  
14          (A), but not later than 5 calendar days after  
15          such an appeal is filed, or fewer days (as deter-  
16          mined by the Secretary), unless the parties  
17          jointly agree to an extension.

18                   “(4) VACATION OF ORDER.—If the Secretary  
19          determines that inadequate grounds exist to support  
20          the actions required by the order under paragraph  
21          (1), the Secretary shall vacate the order.

22                   “(5) NONDELEGATION.—An order under this  
23          subsection may only be issued by the Secretary or an  
24          official designated by the Secretary, and may not be  
25          delegated to another official or employee.

1       “(f) NOTICE TO CONSUMERS AND HEALTH OFFI-  
2       CIALS.—The Secretary shall, as the Secretary determines  
3       to be necessary, provide notice of a recall order under this  
4       section to consumers to whom the cosmetic was, or may  
5       have been, distributed and to appropriate State and local  
6       health officials.

7       “(g) SUPPLY CHAIN INFORMATION.—

8               “(1) IN GENERAL.—In the case of a cosmetic  
9       that the Secretary has reason to believe is adulter-  
10       ated, misbranded, or otherwise in violation of this  
11       Act, the Secretary shall request that the brand  
12       owner named on the label of such cosmetic (as re-  
13       quired under section 602(b)(1)) submit all of the fol-  
14       lowing information:

15               “(A) The name and place of business of  
16       the manufacturer, packager, supplier, or dis-  
17       tributor from which such entity received the  
18       cosmetic or ingredients for manufacturing such  
19       cosmetic.

20               “(B) The name and place of business of  
21       any entity (including any retailer) that was pro-  
22       vided with such cosmetic by the entity named  
23       on the label.

24               “(2) COLLECTION OF ADDITIONAL SUPPLY  
25       CHAIN INFORMATION.—In the case of a cosmetic

1 that the Secretary has reason to believe is adulter-  
2 ated, misbranded, or otherwise in violation of this  
3 Act, to the extent necessary to protect the safety of  
4 the public, the Secretary may request that any entity  
5 (including a supplier of an ingredient, manufacturer,  
6 packer, distributor, or retailer) in the supply chain  
7 of such cosmetic submit to the Secretary information  
8 that is similar to the information described under  
9 subparagraphs (A) and (B) of paragraph (1).

10 “(3) MAINTENANCE OF RECORDS.—Any entity  
11 in supply chain of a cosmetic (including the brand  
12 owner named on the label of a cosmetic) shall—

13 “(A) maintain records sufficient to provide  
14 the information described in subparagraphs (A)  
15 and (B) of paragraph (1); and

16 “(B) provide such information to the Sec-  
17 retary upon the request of the Secretary.

18 “(h) SAVINGS CLAUSE.—Nothing contained in this  
19 section shall be construed as limiting the authority of the  
20 Secretary to issue an order to cease distribution of, or to  
21 recall, a cosmetic under any other provision of this Act.

22 **“SEC. 621. PETITIONS.**

23 “(a) IN GENERAL.—The Secretary shall complete  
24 and publish a review, and, if appropriate, immediately re-  
25 vise related, relevant information, including ingredient

1 lists, ingredient restrictions or prohibitions, or ingredient  
2 or cosmetic safety determinations, not later than 6 months  
3 after the date on which the Secretary receives from any  
4 individual or entity a reasonable petition—

5 “(1) to prohibit or restrict an ingredient for use  
6 in cosmetics and list such ingredient on the list  
7 under section 616(b);

8 “(2) to remove an ingredient from the list of in-  
9 gredients that are safe without limits under section  
10 616(c);

11 “(3) to add an ingredient to the priority assess-  
12 ment list under section 616(d); or

13 “(4) to add an ingredient to the list of contami-  
14 nants under section 618.

15 “(b) REASONABLE PETITION.—Not later than 1 year  
16 after the date of the enactment of this Act, the Secretary  
17 shall issue rules specifying the criteria which the Secretary  
18 will use to determine if a petition submitted under this  
19 section is a reasonable petition.

20 **“SEC. 622. MANDATORY REPORTING OF SERIOUS ADVERSE**  
21 **EVENTS.**

22 “(a) SUBMISSION OF REPORT ON SERIOUS ADVERSE  
23 EVENTS.—The Secretary shall require that the brand  
24 owner of a cosmetic whose name appears on the label of  
25 a cosmetic marketed in the United States submit to the

1 Secretary a report containing information received con-  
2 cerning any serious adverse event associated with the use  
3 of the cosmetic.

4 “(b) TIMING OF REPORT.—A report under subsection  
5 (a) shall be submitted to the Secretary not later than 15  
6 business days after information concerning the serious ad-  
7 verse event is received at the place of business of the brand  
8 owner.

9 “(c) CONTENT OF REPORT.—A report under sub-  
10 section (a) shall include the following information, to the  
11 extent to which the brand owner submitting the report has  
12 been able to verify the information:

13 “(1) The identity of the individual experiencing  
14 the adverse health event.

15 “(2) An identifiable report of such effect.

16 “(3) The name of the cosmetic suspected of  
17 causing such effect.

18 “(4) A description of the adverse health event.

19 “(d) PUBLIC AVAILABILITY AND PRIVACY.—

20 “(1) PUBLIC AVAILABILITY.—Subject to para-  
21 graph (2), the serious adverse event reports collected  
22 by the Secretary under this section shall be sub-  
23 mitted electronically and shall be made accessible to  
24 the public.

25 “(2) PRIVACY.—

1           “(A) PERSONALLY IDENTIFIABLE INFOR-  
2 MATION.—Notwithstanding any other provision  
3 of law, personally identifiable information in se-  
4 rious adverse event reports provided to the Sec-  
5 retary under this section, shall not—

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

9                   “(ii) otherwise be disclosed or distrib-  
10 uted to any party without the written con-  
11 sent of the Secretary and the person sub-  
12 mitting such information to the Secretary.

13           “(B) TREATMENT OF INFORMATION  
14 UNDER PRIVACY ACT AND FOIA.—A report sub-  
15 mitted to the Secretary under this section, shall  
16 be considered to be a record about an individual  
17 under section 552a of title 5, United States  
18 Code (commonly referred to as the “Privacy  
19 Act of 1974”) and a medical or similar file the  
20 disclosure of which would constitute a violation  
21 of section 552 of such title 5 (commonly re-  
22 ferred to as the “Freedom of Information  
23 Act”), and shall not be publicly disclosed unless  
24 all personally identifiable information is re-  
25 dacted.



1 **“SEC. 623. NONCONFIDENTIAL INFORMATION.**

2 “(a) INFORMATION AVAILABLE TO PUBLIC.—Subject  
3 to subsection (c) and section 622(d)(2), all nonconfidential  
4 information submitted pursuant to this subchapter shall  
5 be made available to the public, including the following  
6 types of information:

7 “(1) The name, identity, and structure of a  
8 chemical substance, contaminant, or impurity that is  
9 an ingredient.

10 “(2) All information concerning function, expo-  
11 sure, toxicity data, health hazards, and environ-  
12 mental hazards for a cosmetic.

13 “(3) The functions of ingredients in cosmetics.

14 “(4) Fragrance, flavor, and colorants in a cos-  
15 metic.

16 “(b) CONFIDENTIAL INFORMATION.—The concentra-  
17 tion of cosmetic ingredients used in a finished cosmetic  
18 shall be considered confidential business information and  
19 may not be made available to the public under subsection  
20 (a).

21 “(c) PETITION FOR INFORMATION TO REMAIN CON-  
22 FIDENTIAL.—

23 “(1) IN GENERAL.—The Secretary shall create  
24 a process for an entity to petition for nonconfidential  
25 information described in subsection (a) to remain  
26 confidential if the entity shows that there would be

1 a serious negative impact to the entity’s commercial  
2 interests if such information were disclosed to the  
3 public.

4 “(2) LIMITATION.—The Secretary may not ap-  
5 prove a petition under paragraph (1) to the extent  
6 that such petition would prevent the public dislo-  
7 sure of—

8 “(A) the name, identity, and structure of  
9 any chemical substance, contaminant, or impu-  
10 rity that is an ingredient;

11 “(B) all health and safety data related to  
12 that substance, contaminant, or impurity; or

13 “(C) any data used to substantiate the  
14 safety of that substance, contaminant, or impu-  
15 rity.

16 **“SEC. 624. ANIMAL TESTING ALTERNATIVES.**

17 “(a) IN GENERAL.—To minimize the use of animal  
18 testing of ingredients and cosmetics, the Secretary shall—

19 “(1) require, where practicable, alternative test-  
20 ing methods that—

21 “(A) do not involve the use of an animal  
22 to test the chemical substance;

23 “(B) provide information that is equivalent  
24 or superior in scientific quality to the animal  
25 testing method; and

1           “(C) use fewer animals than conventional  
2 animal-based tests when nonanimal methods  
3 are impracticable, including the use of tests  
4 that combine multiple endpoints; and  
5           “(2) encourage, where practicable—

6           “(A) estimation of toxicological properties  
7 of a chemical through the use of testing infor-  
8 mation for one or more structurally similar  
9 chemicals where such estimates provide infor-  
10 mation of sufficient scientific quality;

11           “(B) the formation of industry consortia to  
12 conduct testing to avoid duplication of tests;  
13 and

14           “(C) funding for research and validation of  
15 alternative test methods, in accordance with  
16 this subsection.

17           “(b) LIST OF ALTERNATIVE TESTING METHODS.—  
18 Not later than 1 year after the date of the enactment of  
19 this subchapter, and triennially thereafter, the Secretary  
20 shall publish a list of the alternative testing methods de-  
21 scribed in subsection (a).

22           **“SEC. 625. PRODUCT TESTING AND REVIEW AUDIT.**

23           “The Secretary shall conduct annual audits of ran-  
24 dom samples of cosmetics to assess or test for acute nega-  
25 tive reactions, pathogen hazards, contaminants, leaching

1 of packaging additives, mislabeling, or other relevant  
2 issues of concern (as determined by the Secretary).

3 **“SEC. 626. RESOURCES FOR SMALL BUSINESSES.**

4 “The Secretary shall provide technical support to as-  
5 sist small businesses in carrying out the requirements of  
6 this subchapter.

7 **“SEC. 627. INTERAGENCY COOPERATION.**

8 “(a) INTERAGENCY COUNCIL ON COSMETIC SAFE-  
9 TY.—There is established an Interagency Council on Cos-  
10 metic Safety for the purpose of sharing data and pro-  
11 moting collaboration on cosmetic safety between the Food  
12 and Drug Administration, the National Institute of Envi-  
13 ronmental Health Sciences, the Centers for Disease Con-  
14 trol and Prevention, the Occupational Safety and Health  
15 Administration, and the Environmental Protection Agen-  
16 cy.

17 “(b) USE OF DATA FROM FEDERAL SOURCES.—For  
18 purposes of this subchapter, the Secretary, as appropriate,  
19 shall request and utilize ingredient and cosmetic toxicity,  
20 use, and exposure data from other Federal agencies.

21 **“SEC. 628. SAVINGS CLAUSE.**

22 “Nothing in this Act affects the right of a State or  
23 a political subdivision of a State to adopt or enforce any  
24 regulation, requirement, or standard of performance that  
25 is different from, or in addition to, a regulation, require-

1 ment, liability, or standard for performance established  
2 pursuant to this Act unless compliance with both this Act  
3 and the State or political subdivision of a State regulation,  
4 requirement, or standard of performance is impossible, in  
5 which case the applicable provisions of this Act shall con-  
6 trol.

7 **“SEC. 629. AUTHORIZATION OF APPROPRIATIONS.**

8 “There are authorized to be appropriated such sums  
9 as may be necessary to carry out this subchapter for each  
10 of the fiscal years 2014 through 2018.”.

11 (b) ADULTERATED AND MISBRANDED COSMETICS.—

12 (1) ADULTERATED COSMETICS.—Section 601 of  
13 the Federal Food, Drug, and Cosmetic Act (21  
14 U.S.C. 361) is amended in paragraph (a)—

15 (A) by striking “, except that this provi-  
16 sion shall not apply to coal-tar hair dye” and all  
17 that follows through “or eyebrow dyes”; and

18 (B) by adding at the end the following:

19 “(f) If it is manufactured in a manner that fails  
20 to comply with section 617(a).

21 “(g) If it is imported, distributed, or marketed  
22 and—

23 “(1) it contains an ingredient on the list  
24 under section 616(b)(1)(A), and the manufac-  
25 turer has not complied with section 616(b)(4)

1 with respect to such ingredient and such cos-  
2 metic; or

3 “(2) it contains an ingredient on the list  
4 under section 616(b)(1)(B), such ingredient is  
5 being used in a manner that violates the limit  
6 on use or concentration of such ingredient  
7 under section 616(b)(2), and the manufacturer  
8 has not complied with section 616(b)(4) with  
9 respect to such ingredient and such cosmetic.

10 “(h) If it is marketed by a brand owner that,  
11 with respect to such cosmetic, is required to dem-  
12 onstrate, under section 617(b)(2), that the cosmetic  
13 meets the safety standard and the brand owner has  
14 not yet submitted the required data under section  
15 617(b)(3).”.

16 (2) MISBRANDED COSMETICS.—Section 602 of  
17 the Federal Food, Drug, and Cosmetic Act (21  
18 U.S.C. 362) is amended—

19 (A) in paragraph (a), by inserting “or fails  
20 to meet the requirements of section 613 or  
21 618(b)” before the period; and

22 (B) by adding at the end the following:

23 “(g) If it—

1           “(1) was brought to market by a brand  
2 owner that failed to register and pay the appli-  
3 cable fee as required under section 612;

4           “(2) is brought to market, manufactured,  
5 packaged, distributed, or sold in retail by a  
6 brand owner, manufacturer, packager, dis-  
7 tributor, or retailer, respectively, who fails to  
8 notify the Secretary as required under section  
9 620(a)(1);

10           “(3) is distributed in violation of an order  
11 under section 620(e);

12           “(4) is not recalled as required by an order  
13 under subsection (d) or (e) of section 620;

14           “(5) is manufactured in a manner that  
15 fails to comply with good manufacturing prac-  
16 tices prescribed by the Secretary under section  
17 614(b); or

18           “(6) is brought to market by a brand  
19 owner who fails—

20                   “(A) to submit the statement required  
21 under section 619; or

22                   “(B) notify the Secretary of changes  
23 to information contained in such report, as  
24 required by such section.”.

1           (3) ADDITIONAL PROHIBITIONS.—Section 301  
2 of the Federal Food, Drug, and Cosmetic Act (21  
3 U.S.C. 331) is amended—

4                   (A) in paragraph (e), by inserting “612,”  
5 after “564,” each place it appears; and

6                   (B) by adding at the end the following:

7           “(ccc) The failure of a brand owner, manufac-  
8 turer, or supplier of a cosmetic or an ingredient for  
9 use in a cosmetic to submit and update data and in-  
10 formation as required under section 615(a).

11           “(ddd) The manufacture, importation, distribu-  
12 tion, or marketing of an ingredient for use in a cos-  
13 metic that is on the list under section 616(b)(1)(A).

14           “(eee) The failure of a supplier of an ingredient  
15 for use in a cosmetic—

16                   “(1) to provide data and information as re-  
17 quired by section 615(a)(4)(B); or

18                   “(2) comply with the testing requirements  
19 under section 618(c).

20           “(fff) The failure of a manufacturer to comply  
21 with the requirements of section 618(d).

22           “(ggg) The failure of a brand owner of a cos-  
23 metic to comply with the requirement of reporting  
24 serious adverse events under section 622.”.



1 **SEC. 3. WORKER ISSUES.**

2 (a) IN GENERAL.—The Secretary of Labor shall pro-  
3 mulgate an occupational safety and health standard under  
4 section 6 of the Occupational Safety and Health Act of  
5 1970 (29 U.S.C. 655) that requires the following:

6 (1) MANUFACTURERS AND IMPORTERS.—Each  
7 manufacturer or importer selling any cosmetic for  
8 professional use shall—

9 (A) obtain or develop a material safety  
10 data sheet described in subsection (b) for each  
11 such cosmetic or personal care product that—

12 (i) the manufacturer or importer pro-  
13 duces or imports; and

14 (ii) includes a hazardous chemical, or  
15 a product ingredient associated with any  
16 chemical hazard, that is classified as a  
17 health hazard in accordance with the cri-  
18 teria found in section 1910.1200(d) of title  
19 29 of the Code of Federal Regulations, and  
20 any successor regulations; and

21 (B) make the material safety data sheet  
22 available to distributors and employers, includ-  
23 ing salon owners, in English and, upon request,  
24 in other languages, including Spanish and Viet-  
25 namese.

1           (2) DISTRIBUTORS.—Each distributor of a cos-  
2           metic or personal care product for professional use  
3           shall distribute and provide material safety data  
4           sheets described in subsection (b) in the same man-  
5           ner as a distributor of a chemical hazard is required  
6           to distribute and provide material safety data sheets  
7           under section 1910.1200(g) of title 29, Code of Fed-  
8           eral Regulations, or any successor regulations.

9           (3) EMPLOYERS.—Each employer, including  
10          any operator of a salon, shall—

11                 (A) have a material safety data sheet in  
12                 the workplace for each cosmetic or personal  
13                 care product for professional use that is used in  
14                 the course of the employer’s business;

15                 (B) make such material safety data sheet  
16                 available to all employees of the employer who  
17                 are exposed or use the product to the same ex-  
18                 tent and in the same manner as material safety  
19                 data sheets are required to be made available  
20                 under section 1910.1200(g) of title 29, Code of  
21                 Federal Regulations, or any successor regula-  
22                 tions; and

23                 (C) upon request, provide employees with  
24                 translations of such material safety data sheet

1           in other languages, including Spanish and Viet-  
2           namese.

3           (b) CONTENTS OF MATERIAL SAFETY DATA  
4 SHEET.—A material safety data sheet for a cosmetic or  
5 personal care product for professional use described in this  
6 section shall—

7           (1) contain the information required in a mate-  
8 rial safety data sheet under section 1910.1200(g) of  
9 title 29, Code of Federal Regulations, or any suc-  
10 cessor regulations, for each hazardous chemical, or  
11 product ingredient associated with any chemical haz-  
12 ard, described in subsection (a)(1)(A)(ii); and

13           (2) include the following statement: “This ma-  
14 terial safety data sheet is also available in multiple  
15 languages by contacting the manufacturer, using the  
16 contact information provided on this sheet.”.

17           (c) PROFESSIONAL USE DEFINED.—In this section,  
18 the term “professional use” has the meaning given such  
19 term in section 611(6) of the Federal Food, Drug, and  
20 Cosmetic Act, except to the extent that such term applies  
21 to a product that is sold as a retail product in any of the  
22 establishments listed under such definition.

○