

115TH CONGRESS  
2D SESSION

# H. R. 6903

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

SEPTEMBER 26, 2018

Ms. SCHAKOWSKY 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 2018”.

7 (b) **TABLE OF CONTENTS.**—The table of contents of  
8 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 misbranded cosmetics.

“Sec. 621. Petitions.

“Sec. 622. Mandatory reporting of serious adverse events.

“Sec. 623. Nonconfidential information.

“Sec. 624. Ban on use of animal testing.

“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.

1 **SEC. 2. COSMETIC REGULATION.**

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

5 (1) by inserting before section 601 the fol-  
6 lowing:

7 **“Subchapter A—Adulterated and Misbranded**  
8 **Cosmetics”;**

9 and

10 (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 a technical or  
25                      functional effect in the cosmetic, including the

1 components of intentionally added fragrance in-  
2 gredients and colorants and intentional break-  
3 down products of an added chemical that also  
4 have a functional or technical effect in the cos-  
5 metic;

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

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

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

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

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

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

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

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

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

5                   “(A) by an employee (within the scope of  
6           the employment of such employee) of; or

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

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

18                   “(A) low-dose exposures to the cosmetic or  
19          ingredient;

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

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

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

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

14           “(A) an acute or chronic response that re-  
15 sults in death, a life-threatening experience,  
16 short- or long-term hospitalization, a persistent  
17 or significant disability or incapacity, a con-  
18 genital anomaly or birth defect, serious and  
19 persistent rashes or infections, significant hair  
20 loss, permanent or significant alteration of ap-  
21 pearance, or impacts to maternal health, includ-  
22 ing placenta previa, gestational diabetes, and  
23 miscarriage;



1 the Secretary and pay to the Secretary the applica-  
2 ble fee, as established under the fee schedule in sub-  
3 section (e).

4 “(2) RULES FOR DOMESTIC AND FOREIGN ES-  
5 TABLISHMENTS.—To be registered under paragraph  
6 (1)—

7 “(A) as a domestic establishment, the  
8 owner, operator, or agent in charge of the do-  
9 mestic establishment shall submit a registration  
10 to the Secretary; or

11 “(B) as a foreign establishment, the owner,  
12 operator, or agent in charge of the foreign es-  
13 tablishment shall—

14 “(i) submit a registration to the Sec-  
15 retary; and

16 “(ii) include with the registration the  
17 name of the United States agent for the  
18 foreign establishment.

19 “(3) NEW ESTABLISHMENTS.—Any brand  
20 owner that initially brings a cosmetic to market  
21 after the date on which the requirements of para-  
22 graph (1) apply shall, not later than 60 days after  
23 the date on which the establishment brings a cos-  
24 metic to market, register with the Secretary and pay  
25 the applicable fee, as required under paragraph (1).



1 “(b) SUBMISSION OF REGISTRATION.—

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

7 “(A) Any information necessary to notify  
8 the Secretary of the name, address, and legal  
9 status of each establishment at which, and all  
10 trade names under which, the registrant brings  
11 cosmetics to market.

12 “(B) A description of the establishment’s  
13 activities with respect to cosmetics, including a  
14 list of all cosmetic products brought to market  
15 by the establishment and the functions of such  
16 cosmetics.

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

19 “(2) NOTIFICATION OF CHANGES.—When sub-  
20 mitting the annual registration, the registrant shall  
21 notify the Secretary of changes to the information  
22 described in paragraph (1).

23 “(c) PROCEDURE.—Upon receipt of a completed reg-  
24 istration submitted under subsection (a), the Secretary  
25 shall notify the registrant of the receipt of such registra-

1 tion and assign a registration number to each registered  
2 establishment.

3 “(d) LIST OF REGISTERED ESTABLISHMENTS.—

4 “(1) MAINTENANCE OF LIST.—The Secretary  
5 shall—

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

9 “(B) make such list publicly available, in-  
10 cluding by posting such list on the public Web  
11 site of the Food and Drug Administration;

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

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

18 “(2) APPLICATION OF FOIA.—

19 “(A) REGISTRATION DOCUMENTS.—Any  
20 registration documents submitted pursuant to  
21 this section shall not be subject to disclosure  
22 under section 552 of title 5, United States  
23 Code.

24 “(B) OTHER INFORMATION.—Information  
25 derived from—

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

2 “(ii) registration documents submitted  
3 pursuant to this section,

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

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

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

13 “(2) only be assessed on companies with annual  
14 gross receipts or sales of cosmetics that exceed  
15 \$10,000,000.

16 “(f) SUSPENSION AND CANCELLATION OF REGISTRA-  
17 TION.—

18 “(1) CRITERIA FOR SUSPENSION.—Registration  
19 under this section is subject to suspension if the  
20 Secretary finds—

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

1           “(B) the establishment fails to notify the  
2           Secretary of changes required under subsection  
3           (b)(2);

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

7           “(D) the establishment violates any portion  
8           of this chapter.

9           “(2) SUSPENSION OF REGISTRATION.—If the  
10          Secretary determines that an establishment is sub-  
11          ject to suspension under this subsection and that it  
12          is appropriate to suspend the registration of such es-  
13          tablishment, the Secretary shall—

14                 “(A) suspend the registration of such es-  
15                 tablishment; and

16                 “(B) provide a notice of suspension to such  
17                 establishment.

18           “(3) CANCELLATION.—If the establishment  
19          fails to correct the issue that resulted in the suspen-  
20          sion under paragraph (2) before the last day of the  
21          30-day period beginning on the date that the estab-  
22          lishment receives notice under such paragraph, the  
23          Secretary may cancel the registration of such estab-  
24          lishment.

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

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

8       “(a) IN GENERAL.—Subject to subsections (b) and  
9 (c), the Secretary shall require that the label on each pack-  
10 age of cosmetics (including cosmetics for retail sale and  
11 including cosmetics for professional use) bears a declara-  
12 tion of the name of each ingredient in such cosmetic in  
13 descending order of predominance.

14       “(b) ADJUSTMENTS FOR LABEL SIZE.—

15               “(1) RULES FOR SMALL PRODUCTS.—Not later  
16 than 6 months after the date of the enactment of  
17 this subchapter, the Secretary shall issue regulations  
18 that apply to any cosmetic for which the product  
19 packaging is not of sufficient size to bear or contain  
20 a label that meets the requirements of subsection  
21 (a).

22               “(2) REQUIREMENTS FOR PUBLIC DISCLO-  
23 SURE.—Such regulations shall establish require-  
24 ments for listing ingredients on the label of such

1 cosmetics and additional requirements for public dis-  
2 closure of the ingredients in such cosmetics.

3 “(c) SPECIAL RULE FOR CONTAMINANTS.—The Sec-  
4 retary shall require, in the case of a contaminant, that  
5 a contaminant be declared on the label of a cosmetic, in  
6 the same manner as an ingredient under subsection (a),  
7 if the contaminant is present at the lower of the following  
8 levels:

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

11 “(2) A level that is greater than one percent of  
12 the restriction on the concentration for such con-  
13 taminant for such use, as determined by the Sec-  
14 retary under section 616(a)(2).

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

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

22 “(2) other ingredients in a cosmetic be des-  
23 ignated with scale-specific information on a cosmetic  
24 ingredient label or list if such ingredients possess  
25 scale-specific hazard properties.

1       “(e) LABELING OF INGREDIENTS IN COSMETICS  
2 SOLD THROUGH INTERNET COMMERCE.—The Secretary  
3 shall require—

4           “(1) in the case of a cosmetic sold on the Web  
5 site of an Internet vendor, that the brand owner of  
6 such cosmetic provide to such Internet vendor a list  
7 of the ingredients of the cosmetic; and

8           “(2) that each Internet vendor display the list  
9 of ingredients of a cosmetic sold by such vendor on  
10 the Web page that is the primary Web page pro-  
11 viding information relating to the sale of such cos-  
12 metic on the Web site of the vendor.

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

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

20           “(1) all cosmetics that are available for retail  
21 sale (including such cosmetics for professional use);  
22 and

23           “(2) brand owners and Internet vendors of such  
24 cosmetics.

1 **“SEC. 614. SAFETY STANDARD AND GOOD MANUFACTURING**  
2 **PRACTICES.**

3 “(a) SAFETY STANDARD.—

4 “(1) IN GENERAL.—Taking into account the ex-  
5 pected use of a cosmetic, the Secretary shall estab-  
6 lish a safety standard that, with respect to a cos-  
7 metic or an ingredient in a cosmetic provides a rea-  
8 sonable certainty of no harm (as such term is de-  
9 fined in section 611(9)) from exposure to the cos-  
10 metic or ingredient and protects the public from any  
11 known or anticipated adverse health effects associ-  
12 ated with the cosmetic or ingredient.

13 “(2) STANDARDS FOR ESTABLISHING SAFETY  
14 STANDARD.—In establishing the safety standard  
15 under paragraph (1), the Secretary shall ensure  
16 that—

17 “(A) the likely level of exposure to all  
18 sources of the ingredient or cosmetic (including  
19 environmental sources) that will result under  
20 the safety standard presents not more than a  
21 one in a million risk for any adverse health ef-  
22 fect in any vulnerable population at the lower  
23 95th percentile confidence interval; or

24 “(B) the safety standard results in expo-  
25 sure to the amount or concentration of an in-  
26 gredient or cosmetic that is shown to produce



1 no adverse health effects, incorporating an mar-  
2 gin of safety of at least 1,000 and considering  
3 the impact of cumulative exposure from all  
4 sources (including environmental sources).

5 “(3) USE OF OTHER FEDERAL STANDARDS.—If  
6 any Federal agency has promulgated a standard for  
7 an ingredient that satisfies the requirements under  
8 paragraph (1), the Secretary may treat such stand-  
9 ard as the safety standard under paragraph (1) for  
10 purposes of such ingredient.

11 “(4) APPLICATION OF SAFETY STANDARD.—  
12 The Secretary may only determine that an ingre-  
13 dient or a cosmetic meets the safety standard under  
14 paragraph (1) if there is a reasonable certainty of no  
15 harm from exposure to the ingredient or cosmetic.

16 “(b) GOOD MANUFACTURING PRACTICES.—

17 “(1) IN GENERAL.—The Secretary shall issue  
18 guidance prescribing good manufacturing practices  
19 for cosmetics and ingredients, including quality con-  
20 trol procedures that the Secretary determines are  
21 necessary, and shall update such regulations as nec-  
22 essary.

23 “(2) CONSIDERATION OF SMALL BUSINESS.—In  
24 developing the guidance under paragraph (1), the

1 Secretary shall consider how such practices will im-  
2 pact small businesses.

3 **“SEC. 615. COSMETIC AND INGREDIENT SAFETY INFORMA-**  
4 **TION.**

5 “(a) REQUIRED SUBMISSION OF ALL SAFETY INFOR-  
6 MATION.—

7 “(1) IN GENERAL.—Brand owners of cosmetics  
8 shall submit to the Secretary (in an electronic for-  
9 mat that the Secretary shall determine) all data and  
10 information that the brand owner can access regard-  
11 ing the safety of the—

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

14 “(B) cosmetic itself.

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

19 “(A) Functions and uses.

20 “(B) Data and information on the phys-  
21 ical, chemical, and toxicity of each such ingre-  
22 dient or cosmetic.

23 “(C) Exposure and fate information.

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

1           “(E) Any other information used to sub-  
2           stantiate the safety of such ingredient and cos-  
3           metic.

4           “(3) DEADLINES.—

5           “(A) INITIAL SUBMISSION.—A brand  
6           owner shall submit the data and information re-  
7           quired under paragraph (1)—

8                   “(i) in the case of an ingredient or  
9                   cosmetic which is marketed for sale in  
10                  interstate commerce on or before the date  
11                  of the enactment of this subchapter, not  
12                  later than 1 year after such date; and

13                  “(ii) in the case of an ingredient or  
14                  cosmetic which is not marketed for sale on  
15                  or before such date—

16                          “(I) not later than the end of the  
17                          14-month period beginning on the  
18                          date of the enactment of this sub-  
19                          chapter; or

20                          “(II) if the ingredient or cosmetic  
21                          is first marketed for sale in interstate  
22                          commerce after the end of the period  
23                          described in subclause (I), not later  
24                          than 60 days after the date on which

1           such ingredient or cosmetic is first  
2           marketed for sale.

3           “(B) UPDATES.—

4           “(i) IN GENERAL.—Subject to clause  
5           (ii), a brand owner shall update the data  
6           and information submitted under subpara-  
7           graph (A) annually.

8           “(ii) ADVERSE HEALTH EFFECTS.—In  
9           the case of information related to an ad-  
10          verse health effect that is suspected to be  
11          caused by an ingredient or a cosmetic, a  
12          brand owner shall update the information  
13          not later than 60 days after receiving such  
14          information.

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

17          “(A) USE OF SUPPLIER OR MANUFAC-  
18          TURER INFORMATION.—In order to meet the re-  
19          quirements of paragraph (1) with respect to an  
20          ingredient, a brand owner may submit safety  
21          data and information provided by the supplier  
22          or manufacturer of the ingredient or cosmetic.

23          “(B) SUPPLIER OR MANUFACTURER PRO-  
24          VISION OF INFORMATION.—If a brand owner re-  
25          quests that a supplier or manufacturer of an in-

1           ingredient provide to such brand owner any of the  
2           data and information described under para-  
3           graph (2) or under section 617, such supplier  
4           or manufacturer shall provide such data and in-  
5           formation to such brand owner not later than  
6           90 days after receiving such request.

7           “(b) DATABASE.—

8           “(1) INITIAL PUBLICATION.—Not later than 1  
9           year after the date of the enactment of this sub-  
10          chapter, the Secretary shall publish a comprehensive  
11          database that—

12                   “(A) is publicly accessible, including on the  
13                   public Web site of the Food and Drug Adminis-  
14                   tration; and

15                   “(B) contains all nonconfidential informa-  
16                   tion (as such term is used under section 623)  
17                   submitted under subsection (a)(1).

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

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

24                   “(1) IN GENERAL.—Based on the data and in-  
25                   formation submitted under subsection (a)(1), avail-

1       able from an authoritative source (as such term is  
2       defined in paragraph (3), including data described  
3       under section 627(b)), and such other information  
4       as the Secretary may have available, the Secretary  
5       shall review and evaluate the safety of cosmetics and  
6       ingredients of cosmetics that are marketed in inter-  
7       state commerce.

8               “(2) CONSIDERATION OF NANOMATERIALS.—

9       The Secretary shall—

10               “(A) monitor developments in the scientific  
11               understanding from any adverse health effects  
12               related to the use of nanotechnology in the for-  
13               mulation of cosmetics (including progress in the  
14               standardization of testing methods and specific  
15               size definitions for nanomaterials); and

16               “(B) consider scale specific hazard prop-  
17               erties of ingredients when reviewing and evalu-  
18               ating the safety of cosmetics and ingredients  
19               under paragraph (1).

20               “(3) AUTHORITATIVE SOURCE DEFINED.—For  
21       purposes of this paragraph, the term ‘authoritative  
22       source’ means—

23               “(A) the Environmental Protection Agen-  
24       cy;

1           “(B) the International Agency for Re-  
2 search on Cancer;

3           “(C) the National Toxicity Program  
4 through the National Institutes of Health;

5           “(D) the California Environmental Protec-  
6 tion Agency; and

7           “(E) any other authoritative international,  
8 Federal, and State entity, as determined by the  
9 Secretary.

10 **“SEC. 616. LISTS OF INGREDIENTS AND REQUIRED RE-  
11 SPONSES.**

12           “(a) PLACEMENT ON LIST.—

13           “(1) IN GENERAL.—Based on an initial review  
14 and evaluation of an ingredient under subsection (c),  
15 the Secretary shall place the ingredient on one of the  
16 following lists:

17           “(A) The prohibited and restricted list  
18 under subsection (b).

19           “(B) The safe without limits list under  
20 subsection (c).

21           “(C) The priority assessment list under  
22 subsection (d).

23           “(2) CONSIDERATIONS.—In determining the  
24 placement of an ingredient on a list under sub-

1 section (a), the Secretary shall consider whether the  
2 ingredient—

3 “(A) reacts with other substances to form  
4 harmful contaminants;

5 “(B) is found to be present in the body  
6 through biomonitoring;

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

8 “(D) is a known or suspected neurological  
9 or immunological toxicant, respiratory asth-  
10 magen, carcinogen, teratogen, or endocrine  
11 disruptor, or have other toxicity concerns (in-  
12 cluding reproductive or developmental toxicity);  
13 or

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

16 “(3) PRIORITIZATION OF INGREDIENTS THAT  
17 ARE FOOD.—In placing ingredients on the lists  
18 under paragraph (1), the Secretary shall prioritize  
19 the placement of ingredients that are food (as such  
20 term is defined under section 201(f)) on such lists.

21 “(b) PROHIBITED AND RESTRICTED LIST.—

22 “(1) IN GENERAL.—The Secretary shall issue,  
23 by regulation, a list of ingredients that are identified  
24 by the Secretary—



1           “(A) as prohibited for use because the Sec-  
2           retary determines that such ingredients are un-  
3           safe for use in cosmetics in any amount because  
4           such ingredients fail to meet the safety stand-  
5           ard under section 614(a); or

6           “(B) as being subject to necessary restric-  
7           tions in use or concentration to allow the use of  
8           the ingredient in a cosmetic to satisfy the safety  
9           standard.

10          “(2) INITIAL LIST.—

11                 “(A) DEEMED PROHIBITED INGREDI-  
12                 ENTS.—Effective as of the date of enactment of  
13                 this subchapter, the following ingredients are  
14                 deemed to be listed pursuant to paragraph  
15                 (1)(A) as prohibited for use:

16                         “(i) Benzophenones (benzophenone,  
17                         benzophenone-1, benzophenone-3 aka  
18                         oxybenzone).

19                         “(ii) Octinoxate.

20                         “(iii) Butylated Hydroxyanisole and  
21                         Butylated Hydroxytoluen.

22                         “(iv) Coal tar dyes (P-phenylenedia-  
23                         mine).

24                         “(v) Cocamide Diethanolamine.

1                   “(vi) Dibutylated Phthalate (Phthal-  
2                   ates DBP), Bis(2-ethylhexyl) Phthalate  
3                   (DEHP).

4                   “(vii) Toluene.

5                   “(viii) Styrene or Styrene acrylates.

6                   “(ix) Formaldehydes (Methylene gly-  
7                   col/methanediol/formaldehyde) and Form-  
8                   aldehyde-releasing preservatives (DMDM  
9                   hydantoin, diazolidinyl urea, imidazolidinyl  
10                  urea, methenamine, quaternium-15, and  
11                  sodium hydroxymethylglycinate).

12                  “(x) Triclosan.

13                  “(xi) Lead acetate or other lead com-  
14                  pounds.

15                  “(xii) Parabens (isopropylparaben, iso-  
16                  butylparaben, pheyparaben, benzylpara-  
17                  ben, pentylparaben, propylparaben and  
18                  butylparaben).

19                  “(B) FIRST INGREDIENTS LISTED BY REG-  
20                  ULATION.—Not later than 2 years after the  
21                  date of enactment of this subchapter, the Sec-  
22                  retary shall promulgate by final regulation the  
23                  list required by subparagraphs (A) and (B) of  
24                  paragraph (1), to supplement the ingredients

1           deemed by subparagraph (A) of this paragraph  
2           to be listed pursuant to paragraph (1)(A).

3           “(3) SPECIFICATION OF RESTRICTIONS.—In the  
4           case of any ingredient listed under paragraph  
5           (1)(B), the Secretary shall specify the restrictions on  
6           use or concentration that are necessary to satisfy the  
7           safety standard for such ingredient.

8           “(4) UPDATES.—After promulgating the initial  
9           list pursuant to paragraph (2)(B), the Secretary  
10          shall, at a minimum, annually update the list under  
11          paragraph (1), including any—

12                   “(A) determinations under subsection  
13                   (d)(3); or

14                   “(B) new information that demonstrates  
15                   that an ingredient fails to meet the safety  
16                   standard, or requires restrictions on use to  
17                   meet such standard.

18          “(5) MANUFACTURER REQUIREMENTS.—Not  
19          later than 1 year after the date that an ingredient  
20          is placed on a list under this subsection, any manu-  
21          facturer using such ingredient in a cosmetic shall re-  
22          formulate such cosmetic to—

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

1           “(B) modify the use of the ingredient if it  
2           is listed under paragraph (1)(B), to meet the  
3           restrictions specified under paragraph (3).

4           “(c) SAFE WITHOUT LIMITS 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 the Secretary has determined are safe  
9           for use in cosmetics, without limits or restrictions.

10          “(2) STANDARD FOR INCLUSION IN LIST.—The  
11          Secretary may only include an ingredient on the list  
12          under paragraph (1) if the Secretary determines  
13          that the ingredient meets the safety standard under  
14          section 614(a), regardless of—

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

17                 “(B) the concentration of the ingredient  
18                 that is used in a cosmetic.

19          “(3) UPDATES AND REDETERMINATIONS.—The  
20          Secretary shall annually update the list under para-  
21          graph (1) and may redetermine whether an ingre-  
22          dient distributed in commerce meets the safety  
23          standard if, in the judgment of the Secretary, new  
24          information raises a credible question as to whether  
25          the ingredient continues to meet the safety standard.

1       “(d) PRIORITY ASSESSMENT LIST AND RELATED  
2 SAFETY DETERMINATIONS.—

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

7           “(A) which, because of a lack of authori-  
8 tative information on the safety of the ingre-  
9 dient, cannot be included on—

10           “(i) the list under subsection (b) (re-  
11 lating to prohibited and restricted ingredi-  
12 ents); or

13           “(ii) the list under subsection (c) (re-  
14 lating to ingredients that are safe without  
15 limits); and

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

19       “(2) ANNUAL ADDITION OF INGREDIENTS.—  
20 After the list is developed under paragraph (1), the  
21 Secretary shall annually add at least 100 additional  
22 ingredients to such list until all ingredients that are  
23 used in the formulation or manufacture of cosmetics  
24 have been added—

25           “(A) to such list;

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

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

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

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

9 “(i) collect data and information on  
10 such ingredient; and

11 “(ii) review and evaluate the safety of  
12 such ingredient.

13 “(B) DETERMINATION OF LIST PLACE-  
14 MENT.—Not later than the end of the period  
15 under subparagraph (A), the Secretary shall  
16 issue a determination, based on the review and  
17 evaluation under such clause, that—

18 “(i) the ingredient meets the require-  
19 ments for inclusion on a list under sub-  
20 section (b) (relating to prohibited and re-  
21 stricted ingredients) or subsection (c) (re-  
22 lating to ingredients that are safe without  
23 limits); or

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

1           “(C) GUIDANCE IN THE CASE OF INSUFFI-  
2           CIENT INFORMATION.—If the Secretary deter-  
3           mines under subparagraph (B) that, with re-  
4           spect to an ingredient, insufficient information  
5           exists to place such ingredient on either of the  
6           lists under subsection (b) or subsection (c), the  
7           Secretary shall provide guidance on the data  
8           and information (including minimum data re-  
9           quirements and safety testing protocols) that  
10          the Secretary requires to evaluate whether the  
11          ingredient meets the safety standard under sec-  
12          tion 614(a) for purposes of placing such ingre-  
13          dient on such a list.

14          “(D) COMMENT PERIOD.—Upon issuing  
15          the determination under subparagraph (B),  
16          and, if applicable, the guidance under subpara-  
17          graph (C), the Secretary shall provide a period  
18          of not less than 60 days for public comment on  
19          the determination before applying such deter-  
20          mination to an ingredient, except that a shorter  
21          period for comment may be provided if the Sec-  
22          retary—

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

1                   “(ii) publicly declares the reasons for  
2                   such finding.

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

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

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

13                  “(5) EVALUATION OF ADDITIONAL DATA AND  
14                  INFORMATION.—With respect to an ingredient, not  
15                  later than 6 months after the Secretary receives the  
16                  data and information under paragraph (4)(B) the  
17                  Secretary shall review such data and information  
18                  and shall make a redetermination under paragraph  
19                  (3)(B) for such ingredient, subject to the comment  
20                  period under paragraph (3)(D).

21                  “(6) LIMITATION.—If the Secretary has not  
22                  placed an ingredient on either of the lists under sub-  
23                  section (b) and subsection (c) by the end of the 5-  
24                  year period beginning on the date that such ingre-  
25                  dient is first placed on the list under subsection (d),



1 beginning on the first day after such period such in-  
2 gredient may not be—

3 “(A) used in a cosmetic; and

4 “(B) manufactured, imported, distributed,  
5 or marketed for use in cosmetics.

6 **“SEC. 617. TREATMENT OF COSMETICS BASED ON INGRE-  
7 DIENT LISTS.**

8 “(a) IN GENERAL.—Subject to subsections (b)(5)  
9 and (d)(4) of section 616, a brand owner may only dis-  
10 tribute in interstate commerce a cosmetic that meets the  
11 safety standard under section 614(a).

12 “(b) PRESUMPTION RELATED TO THE SAFETY OF  
13 COSMETICS.—

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

18 “(A) A cosmetic that is made solely of in-  
19 gredients on the list under section 616(c)(1)  
20 (relating to ingredients that are safe without  
21 limits).

22 “(B) A cosmetic that is made solely of in-  
23 gredients on the list under section 616(b)(1)(B)  
24 (relating to ingredients subject to restrictions)  
25 and the use of each of such ingredients in such

1 cosmetic is in compliance with the restrictions  
2 on the use of such ingredients specified under  
3 section 616(b)(3).

4 “(C) A cosmetic that is made solely of in-  
5 gredients described under subparagraph (A)  
6 and subparagraph (B).

7 “(2) EXCEPTIONS.—The Secretary may require  
8 that a brand owner demonstrate that a cosmetic  
9 meets the safety standard under section 614(a) (in-  
10 cluding by requiring that the brand owner conduct  
11 safety testing, or request such safety testing from  
12 relevant suppliers and manufacturers, of a cosmetic  
13 described under paragraph (1)) if the cosmetic—

14 “(A) contains penetration enhancers, sensi-  
15 tizers, estrogenic chemicals, or other similar in-  
16 gredients;

17 “(B) contains ingredients that react with  
18 each other or with other substances to form  
19 harmful byproducts; or

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

23 “(3) GUIDANCE.—If, under paragraph (2), the  
24 Secretary requires that a brand owner demonstrate  
25 that a cosmetic meets the safety standard under sec-

1       tion 614(a), the Secretary shall provide the brand  
2       owner with guidance on the data and information  
3       that the Secretary requires to evaluate whether the  
4       cosmetic meets the safety standard under such sec-  
5       tion.

6       “(c) NOTIFICATION OF FAILURE OF SECRETARY TO  
7       ACT.—If the Secretary fails to act by an applicable dead-  
8       line under section 616 or this section, brand owners and  
9       manufacturers of an ingredient or a cosmetic affected by  
10      such failure of the Secretary to act shall issue to the Sec-  
11      retary, the public, and each known customer of the ingre-  
12      dient or cosmetic, a written notice that a determination  
13      by the Secretary of the safety of the ingredient for use  
14      in cosmetics is pending.

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

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

21              “(1) ingredients used in cosmetics that may  
22              contain contaminants of concern;

23              “(2) combinations of ingredients that may cre-  
24              ate contaminants of concern when such ingredients  
25              interact;

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

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

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

12          “(c) REQUIREMENTS FOR TESTING.—

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

18                 “(2) CONTENTS.—The requirements under  
19                 paragraph (1) shall include—

20                         “(A) testing methods and applicable proto-  
21                         cols; and

22                         “(B) maximum allowable detection limits  
23                         for each contaminant in an ingredient or cos-  
24                         metic.

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

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

7           “(1) comply with the requirements under sub-  
8           section (b)(1) for any ingredient listed under sub-  
9           section (a);

10           “(2) conduct similar testing on any ingredient  
11           that—

12           “(A) the supplier expects may be used in  
13           a cosmetic;

14           “(B) the supplier suspects may contain a  
15           contaminant of concern; and

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

17           “(3) upon the sale of an ingredient to the man-  
18           ufacturer, provide to the manufacturer specifications  
19           for the ingredient that—

20           “(A) include the levels of contaminants  
21           present in such ingredient; and

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

24           “(e) BRAND OWNER REQUIREMENTS.—Not later  
25           than 1 year after the promulgation of the rule under sub-

1 section (b)(1), a brand owner of a cosmetic shall, with re-  
2 spect to each ingredient that the brand owner uses in a  
3 cosmetic—

4 “(1) obtain, from each supplier or manufac-  
5 turer of the ingredient, specifications for the ingre-  
6 dient that include—

7 “(A) the level of each contaminant present  
8 in the ingredient; and

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

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

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

16 “(a) IN GENERAL.—Beginning 1 year after the date  
17 of the enactment of this subchapter, each brand owner of  
18 a cosmetic intended to be marketed in the United States  
19 shall submit electronically to the Secretary, for each cos-  
20 metic that is intended to be marketed in the United  
21 States, a statement containing—

22 “(1) the registration number of the brand  
23 owner;

24 “(2) the brand name and the product name for  
25 the cosmetic;

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

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

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

7           “(6) the title and full contact information for  
8           the individual responsible for submitting and main-  
9           taining such statement.

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

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

16                 “(2) The 6-month period after the date on  
17                 which the establishment begins to manufacture such  
18                 cosmetic.

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

22          “(d) PROCEDURE.—Upon receipt of a completed  
23         statement described under subsection (a), the Secretary  
24         shall notify the brand owner of the receipt of such state-  
25         ment and assign a cosmetic statement number.

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

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

8       **“SEC. 620. NOTIFICATION, NONDISTRIBUTION, AND RECALL**  
9                               **OF ADULTERATED OR MISBRANDED COS-**  
10                              **METICS.**

11       “(a) NOTIFICATION OF ADULTERATED OR MIS-  
12 BRANDED COSMETICS.—

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



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

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

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

13                 “(1) recall such cosmetic; and

14                 “(2) provide for notice, including to individuals  
15                 as appropriate, to persons who may be affected by  
16                 the recall.

17          “(c) ORDER TO CEASE DISTRIBUTION.—

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

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

22                         “(B) the cosmetic is misbranded; or

23                         “(C) the cosmetic is marketed, manufac-  
24                         tured, packaged, or distributed by an unregis-  
25                         tered brand owner;

1 the Secretary shall have the authority to issue an  
2 order requiring any person who distributes such cos-  
3 metic to immediately cease distribution of such cos-  
4 metic.

5 “(2) CEASE DISTRIBUTION AND NOTICE.—Any  
6 person who is subject to an order under paragraph  
7 (1) shall immediately cease distribution of such cos-  
8 metic and provide notification as required by such  
9 order.

10 “(3) APPEAL.—

11 “(A) 24 HOURS.—A person subject to an  
12 order under paragraph (1) may appeal such  
13 order to the Secretary within 24 hours of the  
14 issuance of such order.

15 “(B) CONTENTS OF APPEAL.—Such appeal  
16 may include a request for an informal hearing  
17 and a description of any efforts to recall such  
18 cosmetic undertaken voluntarily by the person,  
19 including after a request under subsection (b).

20 “(C) INFORMAL HEARING.—Except as pro-  
21 vided in subsection (e), an informal hearing  
22 shall be held as soon as practicable, but not  
23 later than 5 calendar days (or less as deter-  
24 mined by the Secretary) after such an appeal is

1 filed, unless the parties jointly agree to an ex-  
2 tension.

3 “(D) IMPACT ON RECALL.—If an appeal is  
4 filed under subparagraph (A), the Secretary  
5 may not amend the order to require a recall  
6 under subsection (d) until after the conclusion  
7 of the hearing under subparagraph (C).

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

12 “(d) ORDER TO RECALL.—

13 “(1) AMENDMENT.—Except as provided under  
14 subsection (e) and subject to subsection (c)(3)(D), if  
15 the Secretary determines that a recall of a cosmetic  
16 subject to an order under subsection (c) is appro-  
17 priate, the Secretary shall amend the order to re-  
18 quire a recall.

19 “(2) CONTENTS.—An amended order under  
20 paragraph (1) shall—

21 “(A) specify a timetable in which the recall  
22 will occur;

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

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

4           In providing for such notice, the Secretary may  
5           allow for the assistance of health professionals, State  
6           or local officials, or other individuals designated by  
7           the Secretary.

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

12          “(4) DETERMINATION.—If the Secretary deter-  
13          mines that inadequate grounds exist to support the  
14          amendment made to the order under paragraph (1),  
15          the Secretary shall remove such amendment from  
16          such order.

17          “(e) EMERGENCY RECALL ORDER.—

18          “(1) IN GENERAL.—If the Secretary has cred-  
19          ible evidence or information that a cosmetic subject  
20          to an order under subsection (e) presents an immi-  
21          nent threat of serious adverse event, the Secretary  
22          may issue an order requiring any person who dis-  
23          tributes such cosmetic—

24                  “(A) to immediately recall such cosmetic;  
25                  and

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

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

8           “(3) APPEAL.—

9           “(A) 24 HOURS.—Any person subject to  
10          such an order may appeal such order to the  
11          Secretary within 24 hours of the issuance of  
12          such order.

13          “(B) CONTENTS OF APPEAL.—Such appeal  
14          may include a request for an informal hearing  
15          and a description of any efforts to recall such  
16          cosmetic undertaken voluntarily by the person,  
17          including after a request under subsection (b).

18          “(C) INFORMAL HEARING.—An informal  
19          hearing shall be held as soon as practicable  
20          after the appeal is filed under subparagraph  
21          (A), but not later than 5 calendar days after  
22          such an appeal is filed, or fewer days (as deter-  
23          mined by the Secretary), unless the parties  
24          jointly agree to an extension.

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

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

15           “(g) SUPPLY CHAIN INFORMATION.—

16           “(1) IN GENERAL.—In the case of a cosmetic  
17 that the Secretary has reason to believe is adulter-  
18 ated, misbranded, or otherwise in violation of this  
19 Act, the Secretary shall request that the brand  
20 owner named on the label of such cosmetic (as re-  
21 quired under section 602(b)(1)) submit all of the fol-  
22 lowing information:

23           “(A) The name and place of business of  
24 the manufacturer, packager, supplier, or dis-  
25 tributor from which such entity received the

1 cosmetic or ingredients for manufacturing such  
2 cosmetic.

3 “(B) The name and place of business of  
4 any entity (including any retailer) that was pro-  
5 vided with such cosmetic by the entity named  
6 on the label.

7 “(2) COLLECTION OF ADDITIONAL SUPPLY  
8 CHAIN INFORMATION.—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, to the extent necessary to protect the safety of  
12 the public, the Secretary may request that any entity  
13 (including a supplier of an ingredient, manufacturer,  
14 packer, distributor, or retailer) in the supply chain  
15 of such cosmetic submit to the Secretary information  
16 that is similar to the information described under  
17 subparagraphs (A) and (B) of paragraph (1).

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

21 “(A) maintain records sufficient to provide  
22 the information described in subparagraphs (A)  
23 and (B) of paragraph (1); and

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

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

5 **“SEC. 621. PETITIONS.**

6       “(a) IN GENERAL.—The Secretary shall complete  
7 and publish a review, and, if appropriate, immediately re-  
8 vise related, relevant information, including ingredient  
9 lists, ingredient restrictions or prohibitions, or ingredient  
10 or cosmetic safety determinations, not later than 6 months  
11 after the date on which the Secretary receives from any  
12 individual or entity a reasonable petition—

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

16               “(2) to remove an ingredient from the list of in-  
17 gredients that are safe without limits under section  
18 616(c);

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

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

23       “(b) REASONABLE PETITION.—Not later than 1 year  
24 after the date of the enactment of this Act, the Secretary  
25 shall issue rules specifying the criteria which the Secretary



1 will use to determine if a petition submitted under this  
2 section is a reasonable petition.

3 **“SEC. 622. MANDATORY REPORTING OF SERIOUS ADVERSE**  
4 **EVENTS.**

5 “(a) SUBMISSION OF REPORT ON SERIOUS ADVERSE  
6 EVENTS.—The Secretary shall require that the brand  
7 owner of a cosmetic whose name appears on the label of  
8 a cosmetic marketed in the United States submit to the  
9 Secretary a report containing information received con-  
10 cerning any serious adverse event associated with the use  
11 of the cosmetic.

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

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

21 “(1) The identity of the individual experiencing  
22 the adverse health event.

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

24 “(3) The name of the cosmetic suspected of  
25 causing such effect.

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

2           “(d) PUBLIC AVAILABILITY AND PRIVACY.—

3           “(1) PUBLIC AVAILABILITY.—Subject to para-  
4 graph (2), the serious adverse event reports collected  
5 by the Secretary under this section shall be sub-  
6 mitted electronically and shall be made accessible to  
7 the public.

8           “(2) PRIVACY.—

9           “(A) PERSONALLY IDENTIFIABLE INFOR-  
10 MATION.—Notwithstanding any other provision  
11 of law, personally identifiable information in se-  
12 rious adverse event reports provided to the Sec-  
13 retary under this section, shall not—

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

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

21           “(B) TREATMENT OF INFORMATION  
22 UNDER PRIVACY ACT AND FOIA.—A report sub-  
23 mitted to the Secretary under this section, shall  
24 be considered to be a record about an individual  
25 under section 552a of title 5, United States

1 Code (commonly referred to as the “Privacy  
2 Act of 1974”) and a medical or similar file the  
3 disclosure of which would constitute a violation  
4 of section 552 of such title 5 (commonly re-  
5 ferred to as the “Freedom of Information  
6 Act”), and shall not be publicly disclosed unless  
7 all personally identifiable information is re-  
8 dacted.

9 **“SEC. 623. NONCONFIDENTIAL INFORMATION.**

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

15 “(1) The name, identity, and structure of a  
16 chemical substance, contaminant, or impurity that is  
17 an ingredient.

18 “(2) All information concerning function, expo-  
19 sure, toxicity data, health hazards, and environ-  
20 mental hazards for a cosmetic.

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

22 “(4) Fragrance, flavor, and colorants in a cos-  
23 metic.

24 “(b) CONFIDENTIAL INFORMATION.—The concentra-  
25 tion of cosmetic ingredients used in a finished cosmetic

1 shall be considered confidential business information and  
2 may not be made available to the public under subsection  
3 (a).

4 “(c) PETITION FOR INFORMATION TO REMAIN CON-  
5 FIDENTIAL.—

6 “(1) IN GENERAL.—The Secretary shall create  
7 a process for an entity to petition for nonconfidential  
8 information described in subsection (a) to remain  
9 confidential if the entity shows that there would be  
10 a serious negative impact to the entity’s commercial  
11 interests if such information were disclosed to the  
12 public.

13 “(2) LIMITATION.—The Secretary may not ap-  
14 prove a petition under paragraph (1) to the extent  
15 that such petition would prevent the public disclo-  
16 sure of—

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

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

22 “(C) any data used to substantiate the  
23 safety of that substance, contaminant, or impu-  
24 rity.

1 **“SEC. 624. BAN ON USE OF ANIMAL TESTING.**

2       “(a) BAN.—Beginning on the date of enactment of  
3 this subchapter, it shall be unlawful for any entity to con-  
4 duct, directly or pursuant to contract, animal testing for  
5 the purpose of developing a cosmetic for sale in or affect-  
6 ing interstate commerce.

7       “(b) LIMITATION ON CONSIDERATION OF DATA.—  
8 The Secretary shall not take into consideration any animal  
9 testing on a finished cosmetic product or an ingredient  
10 that occurs on or after the date of enactment of this sub-  
11 chapter with respect to any determination as to whether  
12 a cosmetic or ingredient meets the safety standard under  
13 section 614(a).

14       “(c) EXCEPTION.—Subsections (a) and (b) shall not  
15 apply with respect to animal testing if—

16               “(1) the animal testing is for the purpose of de-  
17 termining whether an ingredient, or the relevant cat-  
18 egory of ingredients, meets the safety standard  
19 under section 614(a); and

20               “(2) the Secretary determines that the safety of  
21 the ingredient, or the relevant category of ingredi-  
22 ents, cannot be established using a non-animal test-  
23 ing method that is validated by the Interagency Co-  
24 ordinating Committee on the Validation of Alter-  
25 native Methods.

1       “(d) VALIDATED, ELIGIBLE NON-ANIMAL TESTING  
2 METHODS.—

3           “(1) LIST.—The Secretary shall develop, main-  
4       tain, and make publicly available a list of non-animal  
5       testing methods that—

6           “(A) are validated by the Interagency Co-  
7       ordinating Committee on the Validation of Al-  
8       ternative Methods; and

9           “(B) are eligible for use pursuant to the  
10       exception described in subsection (c).

11       “(2) INITIAL LIST; UPDATES.—The Secretary  
12       shall—

13           “(A) not later than 1 year after the date  
14       of enactment of this subchapter, publish the ini-  
15       tial list under paragraph (1); and

16           “(B) annually thereafter, update such list.

17       “(e) GRANTS.—The Secretary shall award grants for  
18       the development of testing methods that may be used to  
19       replace animal testing pursuant to the exception described  
20       in subsection (c).

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

22       ““The Secretary shall conduct annual audits of ran-  
23       dom samples of cosmetics to assess or test for acute nega-  
24       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)(5)



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)(3), and the manufacturer  
8 has not complied with section 616(b)(5) 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(c);

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           “(hhh) The conduct of animal testing in viola-  
2           tion of section 624.”.

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

4           (a) IN GENERAL.—The Secretary of Labor shall pro-  
5           mulgate an occupational safety and health standard under  
6           section 6 of the Occupational Safety and Health Act of  
7           1970 (29 U.S.C. 655) that requires the following:

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

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

14                                   (i) the manufacturer or importer pro-  
15                                   duces or imports; and

16                                   (ii) includes a hazardous chemical, or  
17                                   a product ingredient associated with any  
18                                   chemical hazard, that is classified as a  
19                                   health hazard in accordance with the cri-  
20                                   teria found in section 1910.1200(d) of title  
21                                   29 of the Code of Federal Regulations, and  
22                                   any successor regulations; and

23                           (B) make the material safety data sheet  
24                           available on the manufacturer or importer’s  
25                           Web site (in addition to any other required

1 manner of making such sheet available) to dis-  
2 tributors and employers, including salon own-  
3 ers, in English, Spanish, Vietnamese, and, upon  
4 request, other languages.

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

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

15 (A) have a material safety data sheet in  
16 the workplace for each cosmetic or personal  
17 care product for professional use that is used in  
18 the course of the employer’s business;

19 (B) make such material safety data sheet  
20 available to all employees of the employer who  
21 are exposed or use the product to the same ex-  
22 tent and in the same manner as material safety  
23 data sheets are required to be made available  
24 under section 1910.1200(g) of title 29, Code of

1 Federal Regulations, or any successor regula-  
2 tions; and

3 (C) upon request, provide employees with  
4 translations of such material safety data sheet  
5 in other languages, including Spanish and Viet-  
6 nameese.

7 (b) CONTENTS OF MATERIAL SAFETY DATA  
8 SHEET.—A material safety data sheet for a cosmetic or  
9 personal care product for professional use described in this  
10 section shall—

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

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

21 (c) PROFESSIONAL USE DEFINED.—In this section,  
22 the term “professional use” has the meaning given such  
23 term in section 611(8) of the Federal Food, Drug, and  
24 Cosmetic Act except to the extent that such term applies

- 1 to a product that is sold as a retail product in any of the
- 2 establishments listed under such definition.

○