

112TH CONGRESS
1ST SESSION

H. R. 2359

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

IN THE HOUSE OF REPRESENTATIVES

JUNE 24, 2011

Ms. SCHAKOWSKY (for herself, Mr. MARKEY, Ms. BALDWIN, Mr. MORAN, Ms. WOOLSEY, Mr. BLUMENAUER, Ms. CHU, Mr. GUTIERREZ, Ms. LEE of California, Mr. FRANK of Massachusetts, and Ms. WASSERMAN SCHULTZ) 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

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 Act of 2011”.

6 (b) TABLE OF CONTENTS.—The table of contents of
7 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 adverse health effects.
 “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.

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) DOMESTIC ESTABLISHMENT.—The term
5 ‘domestic establishment’ means an establishment lo-
6 cated in any State that manufactures or packages
7 cosmetics.

8 “(2) FOREIGN ESTABLISHMENT.—The term
9 ‘foreign establishment’ means an establishment that
10 manufactures or packages cosmetics that are ex-
11 ported to the United States.

12 “(3) MANUFACTURER.—The term ‘manufac-
13 turer’ only includes manufacturers that determine
14 the final formulation of a cosmetic.

15 “(4) INGREDIENT.—

16 “(A) IN GENERAL.—The term ‘ingredient’
17 means a chemical in a cosmetic, including—

18 “(i) chemicals that provide a technical
19 or functional effect;

20 “(ii) chemicals that have no technical
21 or functional effect in the cosmetic but are
22 present by reason of having been incor-
23 porated into the cosmetic as an ingredient
24 of another cosmetic ingredient;

1 “(iii) processing aids that are present
2 by reason of having been added to a cos-
3 metic during the processing of such cos-
4 metic;

5 “(iv) substances that are present by
6 reason of having been added to a cosmetic
7 during processing for their technical or
8 functional effect;

9 “(v) the components of a fragrance,
10 flavor, or preservative; and

11 “(vi) any individual component of a
12 petroleum-derived, animal-derived, or other
13 ingredient that the Secretary deems an in-
14 gredient for purposes of this chapter.

15 “(B) TREATMENT OF CONTAMINANTS.—
16 For purposes of sections 614 through 617, the
17 term ‘ingredient’ also includes—

18 “(i) contaminants present at levels
19 above technically feasible detection limits;
20 and

21 “(ii) contaminants that may leach
22 from container materials or form via reac-
23 tions over the shelf life of a cosmetic and
24 that may be present at levels above tech-
25 nically feasible detection limits.

1 “(5) MICROBUSINESS.—The term ‘microbusi-
2 ness’ means a business—

3 “(A) that is engaged in the manufacturing
4 or packaging of cosmetics; and

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

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

9 “(A) by an employee (within the scope of
10 the employment of such employee) of; or

11 “(B) purchased by a consumer in,
12 a hair salon, nail salon, beauty salon, spa, or other
13 establishment that provides cosmetic treatment serv-
14 ices for humans.

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

22 “(A) low-dose exposures to the cosmetic or
23 ingredient; or

1 “(B) additive effects resulting from re-
2 peated exposure to the cosmetic or ingredient
3 over time; or

4 “(C) cumulative exposure resulting from
5 all sources, including both the cosmetic or in-
6 gredient and environmental sources.

7 “(8) REPRODUCTIVE OR DEVELOPMENTAL TOX-
8 ICITY.—With respect to an ingredient or cosmetic,
9 the term ‘reproductive or developmental toxicity’
10 means that the ingredient or cosmetic can contribute
11 to biologically adverse effects on the development of
12 humans or animals, including effects on the female
13 or male reproductive system, the endocrine system,
14 fertility, pregnancy, pregnancy outcomes, or modi-
15 fications in other functions of the body that are de-
16 pendent on the integrity of the reproductive system
17 as well normal fetal development.

18 “(9) VULNERABLE POPULATIONS.—The term
19 ‘vulnerable populations’ includes pregnant women,
20 infants, children, the elderly, people with com-
21 promised immune systems, and highly exposed popu-
22 lations, including workers employed by hair salons,
23 nail salons, beauty salons, spas, other establishments
24 that provide cosmetic treatment services for humans,
25 and cosmetic manufacturing plants.

1 **“SEC. 612. REGISTRATION OF ESTABLISHMENTS AND REG-**
2 **ISTRATION FEES.**

3 “(a) REGISTRATION.—

4 “(1) IN GENERAL.—Beginning 1 year after the
5 date of the enactment of this subchapter, and annu-
6 ally thereafter, any establishment (except for micro-
7 businesses) engaged in manufacturing or packaging
8 cosmetics for use in the United States shall register
9 with the Secretary and pay to the Secretary the ap-
10 plicable fee, as established under the fee schedule in
11 subsection (e).

12 “(2) RULES FOR DOMESTIC AND FOREIGN ES-
13 TABLISHMENTS.—To be registered under paragraph
14 (1)—

15 “(A) as a domestic establishment, the
16 owner, operator, or agent in charge of the do-
17 mestic establishment shall submit a registration
18 to the Secretary; or

19 “(B) as a foreign establishment, the owner,
20 operator, or agent in charge of the foreign es-
21 tablishment shall—

22 “(i) submit a registration to the Sec-
23 retary; and

24 “(ii) include with the registration the
25 name of the United States agent for the
26 foreign establishment.

1 “(3) NEW ESTABLISHMENTS.—Any establish-
2 ment that begins to manufacture or package a cos-
3 metic after the date on which the requirements of
4 paragraph (1) apply shall, not later than 60 days
5 after the date on which the establishment began to
6 manufacture or package such cosmetic, register with
7 the Secretary and pay the applicable fee, as required
8 under paragraph (1).

9 “(b) SUBMISSION OF REGISTRATION.—

10 “(1) IN GENERAL.—In order to register under
11 subsection (a), an establishment (referred to in this
12 section as the ‘registrant’) shall submit to the Sec-
13 retary, with respect to any cosmetics that the estab-
14 lishment manufactures or package, all of the fol-
15 lowing:

16 “(A) Any information necessary to notify
17 the Secretary of the name, address, and legal
18 status of each establishment at which, and all
19 trade names under which, the registrant manu-
20 factures or package cosmetics.

21 “(B) A description of the establishment’s
22 activities with respect to cosmetics, including a
23 list of all cosmetic products manufactured or
24 packaged by the establishment and the func-
25 tions of such cosmetics.

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

3 “(D) The name and address of any com-
4 pany that supplies the establishment, if the es-
5 tablishment manufactures cosmetics, with any
6 ingredient and the name of the ingredient sup-
7 plied to such establishment by such supplier.

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

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

17 “(d) LIST OF REGISTERED ESTABLISHMENTS.—

18 “(1) MAINTENANCE OF LIST.—The Secretary
19 shall—

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

23 “(B) make such list publically available;
24 and

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

4 “(2) APPLICATION OF FOIA.—

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

10 “(B) OTHER INFORMATION.—Information
11 derived from—

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

13 “(ii) registration documents submitted
14 pursuant to this section,

15 shall not be subject to disclosure under section
16 552 of title 5, United States Code, except to the
17 extent that such information discloses the iden-
18 tity or location of a specific registrant.

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

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

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

4 “(f) SUSPENSION AND CANCELLATION OF REGISTRA-
5 TION.—

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

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

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

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

18 “(D) the establishment violates any portion
19 of this chapter.

20 “(2) SUSPENSION OF REGISTRATION.—If the
21 Secretary determines that an establishment is sub-
22 ject to suspension under subsection (f) and that it
23 is appropriate to suspend the registration of such es-
24 tablishment, the Secretary shall—

1 “(A) suspend the registration of such es-
2 tablishment; and

3 “(B) provide a notice of suspension to such
4 establishment.

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

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

13 “(a) IN GENERAL.—Subject to subsections (b) and
14 (c), the Secretary shall require that the label on each pack-
15 age of cosmetics (including cosmetics distributed for retail
16 sale and professional use) bears a declaration of the name
17 of each ingredient in such cosmetic in descending order
18 of predominance.

19 “(b) ADJUSTMENTS FOR LABEL SIZE.—

20 “(1) RULES FOR SMALL PRODUCTS.—Not later
21 than 6 months after the date of the enactment of
22 this subchapter, the Secretary shall issue regulations
23 that apply to any cosmetic for which the product
24 packaging is not of sufficient size to bear or contain

1 a label that meets the requirements of subsection
2 (a).

3 “(2) REQUIREMENTS FOR PUBLIC DISCLO-
4 SURE.—Such regulations shall establish require-
5 ments for listing ingredients on the label of such
6 cosmetics and additional requirements for public dis-
7 closure of the ingredients in such cosmetics.

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

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

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

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

22 “(1) minerals and other particulate ingredients
23 be labeled as ‘nano-scale’ on a cosmetic ingredient
24 label or list if not less than 1 percent of the ingre-

1 dient particles in the cosmetic are 100 nanometers
2 or smaller in not less than 1 dimension; and

3 “(2) other ingredients in a cosmetic be des-
4 ignated with scale-specific information on a cosmetic
5 ingredient label or list if such ingredients possess
6 scale-specific hazard properties.

7 “(e) LABELING OF INGREDIENTS IN COSMETICS
8 SOLD THROUGH INTERNET COMMERCE.—The Secretary
9 shall require—

10 “(1) in the case of a cosmetic sold on the Web
11 site of an Internet vendor, that the manufacturers
12 and distributors of such cosmetic provide to such
13 Internet vendor a list of the ingredients of the cos-
14 metic; and

15 “(2) that each Internet vendor display the list
16 of ingredients of a cosmetic sold by such vendor on
17 the Web page that is the primary Web page pro-
18 viding information relating to the sale of such cos-
19 metic on the Web site of the vendor.

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

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

4 “(1) all cosmetics that are available for retail
5 sale; and

6 “(2) manufacturers, distributors, and Internet
7 vendors of such cosmetics.

8 **“SEC. 614. SAFETY STANDARD AND GOOD MANUFACTURING**
9 **PRACTICES.**

10 “(a) SAFETY STANDARD.—

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

20 “(2) STANDARDS FOR ESTABLISHING SAFETY
21 STANDARD.—In establishing the safety standard
22 under paragraph (1), the Secretary shall ensure
23 that—

24 “(A) the likely level of exposure to all
25 sources of the ingredient or cosmetic (including

1 environmental sources) that will result under
2 the safety standard presents not more than a 1
3 in a million risk for any adverse health effect
4 in any vulnerable population at the lower 95th
5 percentile confidence interval; or

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

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

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

24 “(b) GOOD MANUFACTURING PRACTICES.—

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

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

11 **“SEC. 615. COSMETIC AND INGREDIENT SAFETY INFORMA-**
 12 **TION.**

13 “(a) REQUIRED SUBMISSION OF ALL SAFETY INFOR-
 14 MATION.—

15 “(1) IN GENERAL.—Manufacturers of cosmetics
 16 and ingredients shall submit to the Secretary (in an
 17 electronic format that the Secretary shall determine)
 18 all data and information that the manufacturer can
 19 access regarding the safety of the—

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

22 “(B) cosmetic itself.

23 “(2) REQUIRED INFORMATION.—The required
 24 data and information under paragraph (1) shall in-

1 include, for each ingredient in a cosmetic and for the
2 cosmetic, the following:

3 “(A) Functions and uses.

4 “(B) Data and information on the phys-
5 ical, chemical, and toxicological properties of
6 each such ingredient or cosmetic.

7 “(C) Exposure and fate information.

8 “(D) Results of all safety tests that the
9 manufacturer can access or has conducted.

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

13 “(3) DEADLINES.—

14 “(A) INITIAL SUBMISSION.—A manufac-
15 turer shall submit the data and information re-
16 quired under paragraph (1)—

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

22 “(ii) in the case of an ingredient or
23 cosmetic which is not marketed for sale on
24 or before such date—

1 “(I) not later than the end of the
2 14-month period beginning on the
3 date of the enactment of this sub-
4 chapter; or

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

12 “(B) UPDATES.—

13 “(i) IN GENERAL.—Subject to clause
14 (ii), a manufacturer shall update the data
15 and information submitted under subpara-
16 graph (A) annually.

17 “(ii) ADVERSE HEALTH EFFECTS.—In
18 the case of information related to an ad-
19 verse health effect that is suspected to be
20 caused by an ingredient or a cosmetic, a
21 manufacturer shall update the information
22 not later than 60 days after receiving such
23 information.

24 “(4) SUPPLIER INFORMATION.—

1 “(A) USE OF SUPPLIER INFORMATION.—

2 In order to meet the requirements of paragraph
3 (1) with respect to an ingredient, a manufac-
4 turer may submit safety data and information
5 provided by the supplier of the ingredient.

6 “(B) SUPPLIER PROVISION OF INFORMA-

7 TION.—If a manufacturer requests that a sup-
8 plier of an ingredient provide to such manufac-
9 turer any of the data and information described
10 under paragraph (2), such supplier shall pro-
11 vide such data and information to such manu-
12 facturer not later than 90 days after receiving
13 such request.

14 “(b) DATABASE.—

15 “(1) INITIAL PUBLICATION.—Not later than 1
16 year after the date of the enactment of this sub-
17 chapter, the Secretary shall publish a comprehensive,
18 publicly accessible database containing all noncon-
19 fidential information (as such term is used under
20 section 623) submitted under subsection (a)(1).

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

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

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

11 “(2) CONSIDERATION OF NANOMATERIALS.—

12 The Secretary shall—

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

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

23 “(3) AUTHORITATIVE SOURCE DEFINED.—For
24 purposes of this paragraph, the term ‘authoritative
25 source’ means—

1 “(A) the Environmental Protection Agen-
2 cy;

3 “(B) the International Agency for Re-
4 search on Cancer;

5 “(C) the National Toxicity Program
6 through the National Institutes of Health;

7 “(D) the California Environmental Protec-
8 tion Agency; and

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

12 **“SEC. 616. LISTS OF INGREDIENTS AND REQUIRED RE-**
13 **SPONSES.**

14 “(a) PLACEMENT ON LIST.—

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

19 “(A) The prohibited and restricted list
20 under subsection (b).

21 “(B) The safe without limits list under
22 subsection (c).

23 “(C) The priority assessment list under
24 subsection (d).

1 “(2) CONSIDERATIONS.—In determining the
2 placement of an ingredient on a list under sub-
3 section (a), the Secretary shall consider whether the
4 ingredient—

5 “(A) reacts with other substances to form
6 harmful contaminants;

7 “(B) is found to be present in the body
8 through biomonitoring;

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

10 “(D) is a known or suspected neurological
11 or immunological toxicant, respiratory
12 asthmagen, carcinogen, teratogen, or endocrine
13 disruptor, or have other toxicological concerns
14 (including reproductive or developmental tox-
15 icity); or

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

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

23 “(b) PROHIBITED AND RESTRICTED LIST.—

24 “(1) IN GENERAL.—Not later than 2 years
25 after the date of the enactment of this subchapter,

1 the Secretary shall issue, by regulation, a list of in-
2 gredients that are identified by the Secretary—

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

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

12 “(2) SPECIFICATION OF RESTRICTIONS.—In the
13 case of any ingredient listed under paragraph
14 (1)(B), the Secretary shall specify the restrictions on
15 use or concentration that are necessary to satisfy the
16 safety standard for such ingredient.

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

20 “(A) determinations under subsection
21 (d)(3); or

22 “(B) new information that demonstrates
23 that an ingredient fails to meet the safety
24 standard, or requires restrictions on use to
25 meet such standard.

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

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

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

11 “(c) SAFE WITHOUT LIMITS LIST.—

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

17 “(2) STANDARD FOR INCLUSION IN LIST.—The
18 Secretary may only include an ingredient on the list
19 under paragraph (1) if the Secretary determines
20 that the ingredient meets the safety standard under
21 section 614(a), regardless of—

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

24 “(B) the concentration of the ingredient
25 that is used in a cosmetic.

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

8 “(d) PRIORITY ASSESSMENT LIST AND RELATED
9 SAFETY DETERMINATIONS.—

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

14 “(A) which, because of a lack of authori-
15 tative information on the safety of the ingre-
16 dient, cannot be included on—

17 “(i) the list under subsection (b) (re-
18 lating to prohibited and restricted ingredi-
19 ents); or

20 “(ii) the list under subsection (c) (re-
21 lating to ingredients that are safe without
22 limits); and

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

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

7 “(A) to such list;

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

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

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

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

16 “(i) collect data and information on
17 such ingredient; and

18 “(ii) review and evaluate the safety of
19 such ingredient.

20 “(B) DETERMINATION OF LIST PLACE-
21 MENT.—Not later than the end of the period
22 under subparagraph (A), the Secretary shall
23 issue a determination, based on the review and
24 evaluation under such clause, that—

1 “(i) the ingredient meets the require-
2 ments for inclusion on a list under sub-
3 section (b) (relating to prohibited and re-
4 stricted ingredients) or subsection (c) (re-
5 lating to ingredients that are safe without
6 limits); or

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

9 “(C) GUIDANCE IN THE CASE OF INSUFFI-
10 CIENT INFORMATION.—If the Secretary deter-
11 mines under subparagraph (B) that, with re-
12 spect to an ingredient, insufficient information
13 exists to place such ingredient on either of the
14 lists under subsection (b) or subsection (c), the
15 Secretary shall provide guidance to manufactur-
16 ers on the data and information (including min-
17 imum data requirements and safety testing pro-
18 tocols) that the Secretary requires to evaluate
19 whether the ingredient meets the safety stand-
20 ard under section 614(a) for purposes of plac-
21 ing such ingredient on such a list.

22 “(D) COMMENT PERIOD.—Upon issuing
23 the determination under subparagraph (B),
24 and, if applicable, the guidance under subpara-
25 graph (C), the Secretary shall provide a period

1 of not less than 60 days for public comment on
2 the determination before applying such deter-
3 mination to an ingredient, except that a shorter
4 period for comment may be provided if the Sec-
5 retary—

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

8 “(ii) publically declares the reasons
9 for such finding.

10 “(4) MANUFACTURER RESPONSE TO INAD-
11 EQUATE INFORMATION.—Not later than 18 months
12 after the date that the Secretary issues guidance
13 under paragraph (3)(C) with respect to an ingre-
14 dient subject to a determination under paragraph
15 (3)(B), a manufacturer using such ingredient in a
16 cosmetic shall—

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

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

21 “(5) EVALUATION OF ADDITIONAL DATA AND
22 INFORMATION.—With respect to an ingredient, not
23 later than 6 months after a manufacturer provides
24 the Secretary with the data and information under
25 paragraph (4)(B) the Secretary shall review such

1 data and information and shall make a redetermina-
2 tion under paragraph (3)(B) for such ingredient,
3 subject to the comment period under paragraph
4 (3)(D).

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

12 “(A) used in a cosmetic; and

13 “(B) manufactured, imported, distributed,
14 or marketed for use in cosmetics.

15 **“SEC. 617. TREATMENT OF COSMETICS BASED ON INGRE-**
16 **DIENT LISTS.**

17 “(a) IN GENERAL.—Subject to subsections (b)(4)
18 and (d)(4) of section 616, a manufacturer may only manu-
19 facture a cosmetic for distribution in interstate commerce
20 if such cosmetic meets the safety standard under section
21 614(a).

22 “(b) PRESUMPTION RELATED TO THE SAFETY OF
23 COSMETICS.—

24 “(1) IN GENERAL.—Subject to paragraph (2),
25 for purposes of subsection (a), the Secretary shall

1 presume that the following cosmetics meet the safety
2 standard under section 614(a):

3 “(A) A cosmetic that is made solely of in-
4 gredients on the list under section 616(e)(1)
5 (relating to ingredients that are safe without
6 limits).

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

14 “(C) A cosmetic that is made solely of in-
15 gredients described under subparagraph (A)
16 and subparagraph (B).

17 “(2) EXCEPTIONS.—The Secretary may require
18 that a manufacturer demonstrate that a cosmetic
19 meets the safety standard under section 614(a) (in-
20 cluding by requiring that the manufacturer conduct
21 safety testing of a cosmetic described under para-
22 graph (1)) if the cosmetic—

23 “(A) contains penetration enhancers, sensi-
24 tizers, estrogenic chemicals, or other similar in-
25 gredients;

1 “(B) contains ingredients that react with
2 each other or with other substances to form
3 harmful byproducts; or

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

7 “(3) GUIDANCE.—If, under paragraph (2), the
8 Secretary requires that a manufacturer demonstrate
9 that a cosmetic meets the safety standard under sec-
10 tion 614(a), the Secretary shall provide the manu-
11 facturer with guidance on the data and information
12 that the Secretary requires to evaluate whether the
13 cosmetic meets the safety standard under such sec-
14 tion.

15 “(c) NOTIFICATION OF FAILURE OF SECRETARY TO
16 ACT.—If the Secretary fails to act by an applicable dead-
17 line under section 616 or this section, a manufacturer of
18 an ingredient or a cosmetic affected by such failure of the
19 Secretary to act shall issue to the Secretary, the public,
20 and each known customer of the ingredient or cosmetic,
21 a written notice that a determination by the Secretary of
22 the safety of the ingredient for use in cosmetics is pending.

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

2 “(a) PUBLICATION OF LIST.—Not later than 1 year
3 after the date of the enactment of this subchapter, and
4 annually thereafter, the Secretary shall publish a list of—

5 “(1) ingredients used in cosmetics that may
6 contain contaminants;

7 “(2) combinations of ingredients that may cre-
8 ate contaminants when such ingredients interact;

9 “(3) contaminants that may leech from product
10 packaging into a cosmetic; and

11 “(4) any other contaminant of cosmetics identi-
12 fied by the Secretary.

13 “(b) REQUIREMENTS FOR TESTING.—

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

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

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

23 “(B) maximum allowable detection limits
24 for each contaminant in an ingredient.

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

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

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

8 “(2) conduct similar testing on any ingredient
9 that—

10 “(A) the supplier expects may be used in
11 a cosmetic;

12 “(B) the supplier suspects may contain a
13 contaminant; and

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

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

18 “(A) include the levels of contaminants
19 present in such ingredient; and

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

22 “(d) MANUFACTURER REQUIREMENTS.—Not later
23 than 1 year after the promulgation of the rule under sub-
24 section (b)(1), a manufacturer of a cosmetic shall, with

1 respect to each ingredient that the manufacturer uses in
2 a cosmetic—

3 “(1) obtain, from each supplier of the ingre-
4 dient, specifications for the ingredient that include—

5 “(A) the level of each contaminant present
6 in the ingredient; and

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

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

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

14 “(a) IN GENERAL.—Beginning 1 year after the date
15 of the enactment of this subchapter, each establishment
16 engaged in the manufacture of a cosmetic intended to be
17 marketed in the United States shall submit electronically
18 to the Secretary, for each cosmetic manufactured in the
19 establishment that is intended to be marketed in the
20 United States, a statement containing—

21 “(1) the registration number of the manufac-
22 turing establishment where the cosmetic is manufac-
23 tured or, if the same cosmetic is manufactured in
24 more than 1 establishment, the registration number
25 of each establishment where it is manufactured;

1 “(2) the registration number of the establish-
2 ment responsible for distributing the cosmetic;

3 “(3) the brand name and the product name for
4 the cosmetic;

5 “(4) the applicable use for the cosmetic;

6 “(5) the ingredient list as it appears on the cos-
7 metic label or insert, including the particle size
8 range of any nanoscale cosmetic ingredients;

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

11 “(7) the title and full contact information for
12 the individual responsible for submitting and main-
13 taining such statement.

14 “(b) NEW COSMETICS.—Any establishment that be-
15 gins to manufacture a cosmetic after the date of the enact-
16 ment of this subchapter shall comply with the require-
17 ments of subsection (a) beginning on the later of the fol-
18 lowing:

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

21 “(2) The 6-month period after the date on
22 which the establishment begins to manufacture such
23 cosmetic.

1 “(c) NOTIFICATION OF CHANGES.—The establish-
2 ment shall notify the Secretary annually of any change
3 to the information required under subsection (a).

4 “(d) PROCEDURE.—Upon receipt of a completed
5 statement described under subsection (a), the Secretary
6 shall notify the establishment of the receipt of such state-
7 ment and assign a cosmetic statement number.

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

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

15 **“SEC. 620. NOTIFICATION, NONDISTRIBUTION, AND RECALL**
16 **OF ADULTERATED OR MISBRANDED COS-**
17 **METICS.**

18 “(a) NOTIFICATION OF ADULTERATED OR MIS-
19 BRANDED COSMETICS.—

20 “(1) IN GENERAL.—A responsible party that
21 has reason to believe that a cosmetic, when intro-
22 duced into or while in interstate commerce, or while
23 held for sale (regardless of whether such sale is the
24 first sale of such cosmetic) after shipment in inter-
25 state commerce, is adulterated or misbranded in a

1 manner that presents a reasonable probability that
2 the use or exposure to the cosmetic (or an ingredient
3 or component used in any such cosmetic) will cause
4 a threat of serious adverse health effects or death to
5 humans shall notify the Secretary of the identity and
6 location of the cosmetic.

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

11 “(3) RESPONSIBLE PARTY DEFINED.—For pur-
12 poses of this subsection, the term ‘responsible party’
13 means a manufacturer, packager, retailer, or dis-
14 tributor of the cosmetic.

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

19 “(1) recall such cosmetic; and

20 “(2) provide for notice, including to individuals
21 as appropriate, to persons who may be affected by
22 the recall.

23 “(c) ORDER TO CEASE DISTRIBUTION.—

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

1 “(A) the use of, or exposure to, a cosmetic
2 may cause serious adverse health effects or
3 death to humans;

4 “(B) the cosmetic is misbranded; or

5 “(C) the cosmetic is manufactured, pack-
6 aged, or distributed by an unregistered facility;
7 the Secretary shall have the authority to issue an
8 order requiring any person who distributes such cos-
9 metic to immediately cease distribution of such cos-
10 metic.

11 “(2) CEASE DISTRIBUTION AND NOTICE.—Any
12 person who is subject to an order under paragraph
13 (1) shall immediately cease distribution of such cos-
14 metic and provide notification as required by such
15 order.

16 “(3) APPEAL.—

17 “(A) 24 HOURS.—A person subject to an
18 order under paragraph (1) may appeal such
19 order to the Secretary within 24 hours of the
20 issuance of such order.

21 “(B) CONTENTS OF APPEAL.—Such appeal
22 may include a request for an informal hearing
23 and a description of any efforts to recall such
24 cosmetic undertaken voluntarily by the person,
25 including after a request under subsection (b).

1 “(C) INFORMAL HEARING.—Except as pro-
2 vided in subsection (e), an informal hearing
3 shall be held as soon as practicable, but not
4 later than 5 calendar days (or less as deter-
5 mined by the Secretary) after such an appeal is
6 filed, unless the parties jointly agree to an ex-
7 tension.

8 “(D) IMPACT ON RECALL.—If an appeal is
9 filed under subparagraph (A), the Secretary
10 may not amend the order to require a recall
11 under subsection (d) until after the conclusion
12 of the hearing under subparagraph (C).

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

17 “(d) ORDER TO RECALL.—

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

24 “(2) CONTENTS.—An amended order under
25 paragraph (1) shall—

1 “(A) specify a timetable in which the recall
2 will occur;

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

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

8 In providing for such notice, the Secretary may
9 allow for the assistance of health professionals, State
10 or local officials, or other individuals designated by
11 the Secretary.

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

16 “(4) DETERMINATION.—If the Secretary deter-
17 mines that inadequate grounds exist to support the
18 amendment made to the order under paragraph (1),
19 the Secretary shall remove such amendment from
20 such order.

21 “(e) EMERGENCY RECALL ORDER.—

22 “(1) IN GENERAL.—If the Secretary has cred-
23 ible evidence or information that a cosmetic subject
24 to an order under subsection (c) presents an immi-
25 nent threat of serious adverse health effects or death

1 to humans, the Secretary may issue an order requir-
2 ing any person who distributes such cosmetic—

3 “(A) to immediately recall such cosmetic;

4 and

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

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

12 “(3) APPEAL.—

13 “(A) 24 HOURS.—Any person subject to
14 such an order may appeal such order to the
15 Secretary within 24 hours of the issuance of
16 such order.

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

22 “(C) INFORMAL HEARING.—An informal
23 hearing shall be held as soon as practicable
24 after the appeal is filed under subparagraph
25 (A), but not later than 5 calendar days after

1 such an appeal is filed, or fewer days (as deter-
2 mined by the Secretary), unless the parties
3 jointly agree to an extension.

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

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

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

18 “(g) SUPPLY CHAIN INFORMATION.—

19 “(1) IN GENERAL.—In the case of a cosmetic
20 that the Secretary has reason to believe is adulter-
21 ated, misbranded, or otherwise in violation of this
22 Act, the Secretary shall request that the entity
23 named on the label of such cosmetic (as required
24 under section 602(b)(1)) submit all of the following
25 information:

1 “(A) The name and place of business of
2 the manufacturer, packer, or distributor from
3 which such entity received the cosmetic or in-
4 gredients for manufacturing such cosmetic.

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

9 “(2) COLLECTION OF ADDITIONAL SUPPLY
10 CHAIN INFORMATION.—In the case of a cosmetic
11 that the Secretary has reason to believe is adulter-
12 ated, misbranded, or otherwise in violation of this
13 Act, to the extent necessary to protect the safety of
14 the public, the Secretary may request that any entity
15 (including a supplier of an ingredient, manufacturer,
16 packer, distributor, or retailer) in the supply chain
17 of such cosmetic submit to the Secretary information
18 that is similar to the information described under
19 subparagraphs (A) and (B) of paragraph (1).

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

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

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

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

7 **“SEC. 621. PETITIONS.**

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

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

18 “(2) to remove an ingredient from the list of in-
19 gredients that are safe without limits under section
20 616(c);

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

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

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

6 **“SEC. 622. MANDATORY REPORTING OF ADVERSE HEALTH**
7 **EFFECTS.**

8 “(a) SUBMISSION OF REPORT ON ADVERSE HEALTH
9 EFFECTS.—The Secretary shall require that the manufac-
10 turer, packager, or distributor of a cosmetic whose name
11 appears on the label of a cosmetic marketed in the United
12 States submit to the Secretary a report containing infor-
13 mation received concerning any adverse health effect asso-
14 ciated with the use of the cosmetic.

15 “(b) TIMING OF REPORT.—A report under subsection
16 (a) shall be submitted to the Secretary not later than 15
17 business days after information concerning the adverse
18 health effect is received at the place of business of the
19 manufacturer, packager, or distributor.

20 “(c) CONTENT OF REPORT.—A report under sub-
21 section (a) shall include the following information, to the
22 extent to which the manufacturer, packager, or distributor
23 submitting the report has been able to verify the informa-
24 tion:

1 “(1) The identity of the individual experiencing
2 the adverse health effect.

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

4 “(3) The name of the cosmetic suspected of
5 causing such effect.

6 “(4) A description of the adverse health effect.

7 “(d) PUBLIC AVAILABILITY AND PRIVACY.—

8 “(1) PUBLIC AVAILABILITY.—Subject to para-
9 graph (2), the adverse health effect reports collected
10 by the Secretary under this section shall be sub-
11 mitted electronically and shall be made accessible to
12 the public.

13 “(2) PRIVACY.—

14 “(A) PERSONALLY IDENTIFIABLE INFOR-
15 MATION.—Notwithstanding any other provision
16 of law, personally identifiable information in ad-
17 verse health effect reports provided to the Sec-
18 retary under this section, shall not—

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

22 “(ii) otherwise be disclosed or distrib-
23 uted to any party without the written con-
24 sent of the Secretary and the person sub-
25 mitting such information to the Secretary.

1 “(B) TREATMENT OF INFORMATION
2 UNDER PRIVACY ACT AND FOIA.—An adverse
3 health effect report submitted to the Secretary
4 under this section, shall be considered to be a
5 record about an individual under section 552a
6 of title 5, United States Code (commonly re-
7 ferred to as the “Privacy Act of 1974”) and a
8 medical or similar file the disclosure of which
9 would constitute a violation of section 552 of
10 such title 5 (commonly referred to as the
11 “Freedom of Information Act”), and shall not
12 be publicly disclosed unless all personally identi-
13 fiable information is redacted.

14 **“SEC. 623. NONCONFIDENTIAL INFORMATION.**

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

20 “(1) The name, identity, and structure of a
21 chemical substance, contaminant, or impurity that is
22 an ingredient.

23 “(2) All information concerning function, expo-
24 sure, health hazards, and environmental hazards for
25 a cosmetic., and

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

2 “(4) Fragrance, flavor, and colorants in a cos-
3 metic

4 “(b) CONFIDENTIAL INFORMATION.—The concentra-
5 tion of cosmetic ingredients used in a finished cosmetic
6 shall be considered confidential business information and
7 may not be made available to the public under subsection
8 (a).

9 “(c) PETITION FOR INFORMATION TO REMAIN CON-
10 FIDENTIAL.—

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

18 “(2) LIMITATION.—The Secretary may not ap-
19 prove a petition under paragraph (1) to the extent
20 that such petition would prevent the public disclo-
21 sure of—

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

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

3 “(C) any data used to substantiate the
4 safety of that substance, contaminant, or impu-
5 rity.

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

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

9 “(1) require, where practicable, alternative test-
10 ing methods that—

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

13 “(B) provide information that is equivalent
14 or superior in scientific quality to the animal
15 testing method; and

16 “(C) use fewer animals than conventional
17 animal-based tests when nonanimal methods
18 are impracticable, including the use of tests
19 that combine multiple endpoints; and

20 “(2) encourage, where practicable—

21 “(A) estimation of toxicological properties
22 of a chemical through the use of testing infor-
23 mation for 1 or more structurally similar chemi-
24 cals where such estimates provide information
25 of sufficient scientific quality;

1 “(B) the formation of industry consortia to
2 conduct testing to avoid duplication of tests;
3 and

4 “(C) funding for research and validation of
5 alternative test methods, in accordance with
6 this subsection.

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

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

13 “The Secretary shall conduct annual audits of ran-
14 dom samples of cosmetics to assess or test for acute nega-
15 tive reactions, pathogen hazards, contaminants, leaching
16 of packaging additives, mislabeling, or other relevant
17 issues of concern (as determined by the Secretary).

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

19 “The Secretary shall provide technical support to as-
20 sist small businesses in carrying out the requirements of
21 this subchapter.

22 **“SEC. 627. INTERAGENCY COOPERATION.**

23 “(a) INTERAGENCY COUNCIL ON COSMETIC SAFE-
24 TY.—There is established an Interagency Council on Cos-
25 metic Safety for the purpose of sharing data and pro-

1 moting collaboration on cosmetic safety between the Food
2 and Drug Administration, the National Institute of Envi-
3 ronmental Health Sciences, the Centers for Disease Con-
4 trol and Prevention, the Occupational Safety and Health
5 Administration, and the Environmental Protection Agen-
6 cy.

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

11 **“SEC. 628. SAVINGS CLAUSE.**

12 “Nothing in this subchapter shall affect the right of
13 a State, political subdivision of a State, or tribe to adopt
14 or enforce any regulation, requirement, liability, or stand-
15 ard of performance that is more stringent than a regula-
16 tion, requirement, liability, or standard of performance es-
17 tablished by this subchapter, including requiring the provi-
18 sion of a warning of risk, illness, or injury.

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

20 “There are authorized to be appropriated such sums
21 as may be necessary to carry out this subchapter for each
22 of the fiscal years 2012 through 2016.”.

23 (b) ADULTERATED AND MISBRANDED COSMETICS.—

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

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

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

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

10 “(g) If it is imported, distributed, or marketed
11 and—

12 “(1) it contains an ingredient on the list
13 under section 616(b)(1)(A), and the manufac-
14 turer has not complied with section 616(b)(4)
15 with respect to such ingredient and such cos-
16 metic; or

17 “(2) it contains an ingredient on the list
18 under section 616(b)(1)(B), such ingredient is
19 being used in a manner that violates the limit
20 on use or concentration of such ingredient
21 under section 616(b)(2), and the manufacturer
22 has not complied with section 616(b)(4) with
23 respect to such ingredient and such cosmetic.

24 “(h) If it is manufactured by a manufacturer
25 that, with respect to such cosmetic, is required to

1 demonstrate, under section 617(b)(2), that the cos-
2 metic meets the safety standard and the manufac-
3 turer has not yet submitted the required data under
4 section 617(b)(3).”.

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

8 (A) in paragraph (a), by inserting “ or
9 fails to meet the requirements of section 613”
10 before the period; and

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

12 “(g) If it—

13 “(1) was manufactured, packaged, or dis-
14 tributed by an entity that failed to register and
15 pay the applicable fee as required under section
16 612;

17 “(2) is manufactured, packaged, distrib-
18 uted, or sold in retail by a manufacturer, pack-
19 ager, distributor, or retailer, respectively, who
20 fails to notify the Secretary as required under
21 section 620(a)(1);

22 “(3) is distributed in violation of an order
23 under section 620(c);

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

1 “(5) is manufactured in a manner that
2 fails to comply with good manufacturing prac-
3 tices prescribed by the Secretary under section
4 614(b); or

5 “(6) is manufactured by a manufacturer
6 who fails—

7 “(A) to submit the statement required
8 under section 619; or

9 “(B) notify the Secretary of changes
10 to information contained in such report, as
11 required by such section.”.

12 (3) **ADDITIONAL PROHIBITIONS.**—Section 301
13 of the Federal Food, Drug, and Cosmetic Act (21
14 U.S.C. 331) is amended by adding at the end the
15 following:

16 “(aaa) The failure of a manufacturer of a cos-
17 metic or an ingredient for use in a cosmetic to sub-
18 mit and update data and information as required
19 under section 615(a).

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

23 “(ccc) The failure of a supplier of an ingredient
24 for use in a cosmetic—

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

3 “(2) comply with the testing requirements
4 under section 618(c).

5 “(ddd) The failure of a manufacturer to comply
6 with the requirements of section 618(d).

7 “(eee) The failure of a manufacturer, packager,
8 or distributor of a cosmetic to comply with the re-
9 quirement of reporting adverse health effects under
10 section 622.”.

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

12 (a) IN GENERAL.—The Secretary of Labor shall pro-
13 mulgate an occupational safety and health standard under
14 section 6 of the Occupational Safety and Health Act of
15 1970 (29 U.S.C. 655) that requires the following:

16 (1) MANUFACTURERS AND IMPORTERS.—Each
17 manufacturer or importer selling any cosmetic for
18 professional use shall—

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

22 (i) the manufacturer or importer pro-
23 duces or imports; and

24 (ii) includes a hazardous chemical, or
25 a product ingredient associated with any

1 chemical hazard, that is classified as a
2 health hazard in accordance with the cri-
3 teria found in section 1910.1200(d) of title
4 29 of the Code of Federal Regulations, and
5 any successor regulations; and

6 (B) make the material safety data sheet
7 available to distributors and employers, includ-
8 ing salon owners, in English and, upon request,
9 in other languages, including Spanish and Viet-
10 nameese.

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

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

21 (A) have a material safety data sheet in
22 the workplace for each cosmetic or personal
23 care product for professional use that is used in
24 the course of the employer’s business;

1 (B) make such material safety data sheet
2 available to all employees of the employer who
3 are exposed or use the product to the same ex-
4 tent and in the same manner as material safety
5 data sheets are required to be made available
6 under section 1910.1200(g) of title 29, Code of
7 Federal Regulations, or any successor regula-
8 tions; and

9 (C) upon request, provide employees with
10 translations of such material safety data sheet
11 in other languages, including Spanish and Viet-
12 nameese.

13 (b) CONTENTS OF MATERIAL SAFETY DATA
14 SHEET.—A material safety data sheet for a cosmetic or
15 personal care product for professional use described in this
16 section shall—

17 (1) contain the information required in a mate-
18 rial safety data sheet under section 1910.1200(g) of
19 title 29, Code of Federal Regulations, or any suc-
20 cessor regulations, for each hazardous chemical, or
21 product ingredient associated with any chemical haz-
22 ard, described in subsection (a)(1)(A)(ii); and

23 (2) include the following statement: “This ma-
24 terial safety data sheet is also available in multiple

1 languages by contacting the manufacturer, using the
2 contact information provided on this sheet.”.

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

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