

111TH CONGRESS
2^D SESSION

H. R. 5786

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

JULY 20, 2010

Ms. SCHAKOWSKY (for herself, Mr. MARKEY of Massachusetts, and Ms. BALDWIN) introduced the following bill; which was referred to the Committee on Energy and Commerce, and in addition to the Committee on Education and Labor, 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.**

4 This Act may be cited as the “Safe Cosmetics Act
5 of 2010”.

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:

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

12 **“SEC. 611. DEFINITIONS.**

13 “In this subchapter:

14 “(1) INGREDIENT.—The term ‘ingredient’
15 means a chemical in a cosmetic, including—

16 “(A) chemicals that provide a technical or
17 functional effect;

18 “(B) chemicals that have no technical or
19 functional effect in the cosmetic but are present
20 by reason of having been incorporated into the
21 cosmetic as an ingredient of another cosmetic
22 ingredient;

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

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

4 “(E) contaminants present at levels above
5 technically feasible detection limits;

6 “(F) contaminants that may leach from
7 container materials or form via reactions over
8 the shelf life of a cosmetic and that may be
9 present at levels above technically feasible de-
10 tection limits;

11 “(G) the components of a fragrance, fla-
12 vor, or preservative declared individually by
13 their appropriate label names; and

14 “(H) any individual component of a botan-
15 ical, petroleum-derived, animal-derived, or other
16 ingredient that the Secretary determines be
17 considered an ingredient.

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

20 “(A) by an employee (within the scope of
21 the employment of such employee) of; or

22 “(B) purchased by a consumer in,
23 a hair salon, nail salon, beauty salon, spa, or other
24 establishment that provides cosmetic treatment serv-
25 ices for humans.

1 “(3) REASONABLE CERTAINTY.—The term ‘rea-
2 sonable certainty’, when used in establishing a safety
3 standard (as defined in paragraph (5)) for an ingre-
4 dient or cosmetic—

5 “(A) means that no harm will be caused by
6 aggregate exposure for a member of a vulner-
7 able population to that ingredient or cosmetic;
8 and

9 “(B) corresponds to the lower dose derived
10 from—

11 “(i) data demonstrating that exposure
12 to all sources of the ingredient or cosmetic
13 present not more than a 1 in a million risk
14 for any adverse effect in the population of
15 concern, at the lower 95th percentile con-
16 fidence bound; or

17 “(ii) the amount of an ingredient or
18 cosmetic shown to produce no adverse ef-
19 fects, incorporating an uncertainty factor
20 of at least 1,000 and considering all
21 sources of exposure.

22 “(4) REPRODUCTIVE AND DEVELOPMENTAL
23 TOXICITY.—With respect to an ingredient or cos-
24 metic, the term ‘reproductive and developmental tox-
25 icity’ means that the ingredient or cosmetic causes

1 biologically adverse effects on the reproductive sys-
2 tems of female or male humans or animals, includ-
3 ing alterations to the female or male reproductive
4 system development, the related endocrine system,
5 fertility, pregnancy, pregnancy outcomes, or modi-
6 fications in other functions that are dependent on
7 the integrity of the reproductive system.

8 “(5) SAFETY STANDARD.—

9 “(A) IN GENERAL.—The term ‘safety
10 standard’ means—

11 “(i) with respect to an ingredient,
12 when the route of exposure is directly rel-
13 evant to a particular cosmetic use, a stand-
14 ard that—

15 “(I) provides a reasonable cer-
16 tainty that no harm will result from
17 aggregate exposure to the cosmetic or
18 ingredient, including impacts on vul-
19 nerable populations, taking into ac-
20 count possible harmful effects from
21 low dose exposures to the cosmetic or
22 ingredient or from additive effects,
23 where such evidence exists; and

24 “(II) is requisite to protect the
25 public welfare from any known or an-

1 anticipated adverse effects associated
2 with the cosmetic or ingredient; and

3 “(ii) with respect to a cosmetic, when
4 the route of exposure is directly relevant to
5 the use of the cosmetic, a standard that a
6 cosmetic fails to meet if—

7 “(I) the cosmetic would fail to
8 meet the standard under clause (i) if
9 the cosmetic was treated in the same
10 manner as an ingredient under such
11 clause; or

12 “(II) one or more ingredients in
13 the cosmetic fail to meet such stand-
14 ard.

15 “(B) DETERMINATION OF SAFETY.—A
16 cosmetic or ingredient shall fail to meet the
17 safety standard under subparagraph (A)—

18 “(i) unless the Secretary determines
19 that there is a reasonable certainty that no
20 harm will result from aggregate exposure
21 to the ingredient or cosmetic, including im-
22 pacts on highly exposed or vulnerable pop-
23 ulations, taking into account, where evi-
24 dence exists, possible harmful effects
25 from—

1 “(I) low dose exposures to the
2 cosmetic or ingredient; or

3 “(II) additive effects; or

4 “(ii) if the Secretary determines nec-
5 essary to protect the public welfare from
6 any known or anticipated adverse effects
7 associated with the cosmetic or ingredient.

8 “(6) VULNERABLE POPULATIONS.—The term
9 ‘vulnerable populations’ includes pregnant women,
10 infants, children, the elderly, people with com-
11 promised immune systems, and highly exposed popu-
12 lations, including workers employed by establish-
13 ments listed under paragraph (2) and cosmetic man-
14 ufacturing plants.

15 **“SEC. 612. REGISTRATION OF ESTABLISHMENTS AND REG-**
16 **ISTRATION FEES.**

17 “(a) DEFINITIONS.—In this section:

18 “(1) DOMESTIC ESTABLISHMENT.—The term
19 ‘domestic establishment’ means an establishment lo-
20 cated in any State that manufactures, packages, or
21 distributes cosmetics.

22 “(2) FOREIGN ESTABLISHMENT.—

23 “(A) IN GENERAL.—The term ‘foreign es-
24 tablishment’ means an establishment that man-
25 ufactures, packages, or distributes cosmetics

1 that are exported to the United States without
2 further processing or packaging outside the
3 United States.

4 “(B) NOT CONSIDERED TO HAVE UNDER-
5 GONE FURTHER PROCESSING OR PACKAGING.—
6 A cosmetic may not be considered to have un-
7 dergone further processing or packaging for
8 purposes of subparagraph (A) solely on the
9 basis that labeling was added or that any simi-
10 lar activity of a de minimis nature was carried
11 out with respect to the cosmetic.

12 “(b) REGISTRATION.—The Secretary shall require
13 that any establishment engaged in manufacturing, pack-
14 aging, or distributing cosmetics for use in the United
15 States register annually with the Secretary. To be reg-
16 istered—

17 “(1) as a domestic establishment, the owner,
18 operator, or agent in charge of the domestic estab-
19 lishment shall submit a registration to the Secretary;
20 or

21 “(2) as a foreign establishment, the owner, op-
22 erator, or agent in charge of the foreign establish-
23 ment—

24 “(A) shall submit a registration to the Sec-
25 retary; and

1 “(B) shall include with the registration the
2 name of the United States agent for the foreign
3 establishment.

4 “(c) SUBMISSION OF REGISTRATION.—

5 “(1) IN GENERAL.—An establishment (referred
6 to in this section as the ‘registrant’) shall submit a
7 registration under subsection (b) to the Secretary
8 containing, with respect to any cosmetics that the
9 establishment manufactures, packages, or distrib-
10 utes—

11 “(A) any information necessary to notify
12 the Secretary of the name and address of each
13 establishment at which, and all trade names
14 under which, the registrant manufactures,
15 packages, or distributes cosmetics;

16 “(B) a description of the establishment’s
17 activities with respect to cosmetics;

18 “(C) the number of workers employed at
19 the establishment;

20 “(D) the gross receipts of sales; and

21 “(E) the name and address of any com-
22 pany that supplies the establishment, if the es-
23 tablishment manufactures cosmetics, with any
24 ingredient (including preservatives, fragrances,
25 or any other chemical component of a finished

1 cosmetic product) and the name of the ingre-
2 dient supplied to such establishment by such
3 supplier.

4 “(2) NOTIFICATION OF CHANGES.—

5 “(A) IN GENERAL.—The registrant shall
6 notify the Secretary in a timely manner of
7 changes to the information described in para-
8 graph (1).

9 “(B) DEADLINE FOR CERTAIN
10 CHANGES.—The registrant shall notify the Sec-
11 retary of any change in the products, function,
12 or legal status of each establishment at which
13 the registrant manufactures, packages, or dis-
14 tributes cosmetics (including cessation of busi-
15 ness activities) not later than 60 days after the
16 date of such change.

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

22 “(e) LIST OF REGISTERED ESTABLISHMENTS.—

23 “(1) MAINTENANCE OF LIST.—The Secretary
24 shall compile and maintain an up-to-date list of es-
25 tablishments that are registered under this section.

1 “(2) REMOVAL AND SUSPENSION.—The Sec-
2 retary shall remove from the list under paragraph
3 (1) the name of any establishment that fails to re-
4 register in accordance with this section and shall
5 treat such removal as a suspension of the establish-
6 ment’s registration.

7 “(3) APPLICATION OF FOIA.—

8 “(A) LIST.—The list under paragraph (1)
9 shall be subject to disclosure under section 552
10 of title 5, United States Code.

11 “(B) REGISTRATION DOCUMENTS.—Any
12 registration documents submitted pursuant to
13 this section shall not be subject to disclosure
14 under section 552 of title 5, United States
15 Code.

16 “(C) OTHER INFORMATION.—Information
17 derived from—

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

19 “(ii) registration documents submitted
20 pursuant to this section,

21 shall not be subject to disclosure under section
22 552 of title 5, United States Code, except to the
23 extent that such information discloses the iden-
24 tity or location of a specific registrant.

1 “(f) FEE SCHEDULE.—A schedule of fees shall be de-
2 veloped by the Secretary to provide for oversight and en-
3 forcement of this subchapter. The fee structure shall—

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

6 “(2) only be assessed on companies with annual
7 gross receipts or sales of more than \$1,000,000.

8 “(g) REGISTRATION CANCELLATION.—The Secretary
9 may cancel the registration of any establishment under
10 this section—

11 “(1) if the information submitted by the estab-
12 lishment for such registration is incomplete, inac-
13 curate, or out-of-date; or

14 “(2) if a registered establishment fails to up-
15 date such information promptly when there is a
16 change in such information.

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

18 “(a) IN GENERAL.—The Secretary shall require the
19 label on each package of cosmetics, including cosmetics
20 distributed for retail sale and professional use, to bear a
21 declaration of the name of each ingredient in such cos-
22 metic in descending order of predominance. The Secretary
23 may allow that the declaration of an ingredient present
24 as a contaminant is not required if the contaminant is
25 present at levels below technically feasible detection limits.

1 “(b) LABELING OF INGREDIENTS IN COSMETICS
2 SOLD THROUGH INTERNET COMMERCE.—Subject to sub-
3 section (d), the Secretary shall require—

4 “(1) in the case of a cosmetic sold on the Web
5 site of an Internet vendor, that the manufacturers
6 and distributors of such cosmetic provide to such
7 Internet vendor a list of the ingredients of the cos-
8 metic; and

9 “(2) each Internet vendor to display the list of
10 ingredients of each cosmetic sold by such vendor on
11 the Web site of the vendor.

12 “(c) TRADE SECRETS.—Notwithstanding any other
13 provision of law, an ingredient required to be listed or la-
14 beled under this section shall not have protection as a
15 trade secret.

16 “(d) DEADLINE.—Not later than one year after the
17 date of the enactment of the Safe Cosmetics Act of
18 2010—

19 “(1) all cosmetics that are available for retail
20 sale shall be labeled in a manner that complies with
21 the requirements under subsection (a); and

22 “(2) manufacturers, distributors, and Internet
23 venders shall comply with the applicable require-
24 ments of subsection (b).

1 **“SEC. 614. COSMETIC AND INGREDIENT TESTING AND SAFE-**
2 **TY.**

3 “(a) PUBLICLY AVAILABLE COSMETIC AND INGRE-
4 DIENT TEST DATA.—

5 “(1) SUBMISSION OF INFORMATION.—

6 “(A) INITIAL SUBMISSION.—Not later than
7 1 year after the date of the enactment of the
8 Safe Cosmetics Act of 2010, manufacturers and
9 distributors of cosmetics and ingredients shall
10 submit to the Secretary (in an electronic format
11 that the Secretary shall determine) all reason-
12 ably available information in the possession or
13 control of the manufacturer or distributor that
14 has not previously been submitted to the Sec-
15 retary regarding the physical, chemical, and
16 toxicological properties of single or multiple
17 chemicals listed on the cosmetic labels under
18 section 613, including—

19 “(i) functions and uses;

20 “(ii) exposure and fate information;

21 “(iii) tests of finished cosmetics; and

22 “(iv) any other information used to
23 substantiate the safety of such cosmetics
24 or ingredients.

25 “(B) NEW OR UPDATED INFORMATION.—

26 Not later than 60 days after the date on which

1 new or updated information that is required
2 under subparagraph (A) becomes available to a
3 manufacturer or distributor, such manufacturer
4 or distributor shall submit such information to
5 the Secretary in the same form and manner as
6 information submitted under subparagraph (A).

7 “(2) AVAILABILITY OF INFORMATION.—The
8 Secretary shall require that any manufacturer, dis-
9 tributor, or marketer of a cosmetic or ingredient (in-
10 cluding a fragrance or preservative) make available
11 to any entity purchasing the cosmetic or ingredient
12 (excluding an individual who is a consumer and who
13 is purchasing the cosmetic or ingredient for personal
14 use) all available information in the possession or
15 control of the manufacturer, distributor, or marketer
16 described in paragraph (1), within 90 days of receipt
17 of the request from such entity.

18 “(3) DATABASE.—

19 “(A) INITIAL PUBLICATION.—Not later
20 than 12 months after the date of the enactment
21 of the Safe Cosmetics Act of 2010, the Sec-
22 retary shall publish a comprehensive, publicly
23 accessible database containing all non-confiden-
24 tial information submitted under paragraph (1).

1 “(B) UPDATES.—Not later than 90 days
2 after the Secretary receives new or updated in-
3 formation under paragraph (1)(B), the Sec-
4 retary shall update the database described in
5 subparagraph (A) with such information.

6 “(b) LISTS OF INGREDIENTS.—

7 “(1) PROHIBITED AND RESTRICTED INGREDI-
8 ENTS.—

9 “(A) LIST OF INGREDIENTS THAT ARE
10 PROHIBITED OR RESTRICTED.—Not later than
11 2 years after the date of the enactment of the
12 Safe Cosmetics Act of 2010, the Secretary shall
13 issue, by regulation, a list of ingredients that
14 are identified by the Secretary as—

15 “(i) prohibited ingredients; or

16 “(ii) restricted ingredients.

17 “(B) UPDATES.—The Secretary shall con-
18 tinually update the list under subparagraph
19 (A), including when—

20 “(i) determinations under paragraph
21 (3)(D) are made; or

22 “(ii) new information becomes avail-
23 able demonstrating that an ingredient fails
24 to meet the safety standard.

25 “(C) INFORMATION SOURCES.—

1 “(i) USE OF AUTHORITATIVE INFOR-
2 MATION.—The list under subparagraph
3 (A) shall contain ingredients that are
4 known to be carcinogenic, mutagenic, or
5 have reproductive and developmental tox-
6 icity, based on information from the Envi-
7 ronmental Protection Agency, the Inter-
8 national Agency for Research on Cancer,
9 the National Toxicity Program through the
10 National Institutes of Health, the Cali-
11 fornia Environmental Protection Agency,
12 and other authoritative international, Fed-
13 eral, and State entities (as determined by
14 the Secretary).

15 “(ii) USE OF OTHER INFORMATION
16 SOURCES.—In identifying ingredients for
17 purposes of the list under subparagraph
18 (A), the Secretary shall use all reasonably
19 available information, including new sci-
20 entific information and submissions from
21 manufacturers and distributors of cos-
22 metics.

23 “(D) PROHIBITED INGREDIENTS.—Ingre-
24 dients that are listed as prohibited under sub-
25 paragraph (A) shall include all ingredients that

1 the Secretary determines are unsafe for use in
2 cosmetics in any amount because such ingredi-
3 ents fail to meet the safety standard defined in
4 section 611(5).

5 “(E) RESTRICTED INGREDIENTS.—Ingre-
6 dients that are listed as restricted under sub-
7 paragraph (A) shall include all ingredients for
8 which the Secretary determines that limits on
9 use or concentration are necessary to satisfy the
10 safety standard defined in section 611(5).

11 “(F) INGREDIENTS AND COSMETICS
12 FOUND TO INDUCE CANCER OR BIRTH DEFECTS
13 OR HAVE REPRODUCTIVE OR DEVELOPMENTAL
14 TOXICITY.—

15 “(i) PRESUMPTION.—The Secretary
16 shall presume that any ingredient or cos-
17 metic that induces cancer or birth defects
18 or has reproductive or developmental tox-
19 icity when ingested by, inhaled by, or
20 dermally applied to a human or an animal
21 has failed to meet the safety standard (as
22 defined in section 611(5)).

23 “(ii) REBUTTAL.—The presumption
24 under clause (i) may be rebutted only if
25 the Secretary determines that the ingre-

1 dient or cosmetic meets such safety stand-
2 ard.

3 “(iii) PUBLIC COMMENT.—The Sec-
4 retary shall solicit public comment before
5 making a determination under clause (ii).

6 “(2) SAFE WITHOUT LIMITS.—

7 “(A) IN GENERAL.—Not later than 2 years
8 after the date of the enactment of the Safe Cos-
9 metics Act of 2010, the Secretary shall issue,
10 by regulation, a list of ingredients that the Sec-
11 retary has determined are safe without limits
12 for use in cosmetics.

13 “(B) STANDARD FOR INCLUSION IN
14 LIST.—The Secretary may only include an in-
15 gredient on the list under subparagraph (A) if
16 the Secretary determines that such ingredient
17 meets the safety standard (as defined in section
18 611(5)) regardless of—

19 “(i) the type and form of cosmetic the
20 ingredient is used in; or

21 “(ii) the concentration of the ingre-
22 dient that is used in a cosmetic.

23 “(C) UPDATE.—The Secretary shall up-
24 date the list under subparagraph (A) when new
25 information becomes available.

1 “(D) CONSULTATIONS.—In determining
2 whether a cosmetic or ingredient is safe, the
3 Secretary shall consult hazard listings and as-
4 sessments from authoritative international,
5 Federal, and State entities, including the enti-
6 ties listed in paragraph (1)(C)(i).

7 “(E) REDETERMINATIONS.—The Secretary
8 may redetermine whether a cosmetic or ingre-
9 dient distributed in commerce meets the safety
10 standard if, in the judgment of the Secretary,
11 new information raises a credible question as to
12 whether the cosmetic or ingredient continues to
13 meet the safety standard.

14 “(3) PRIORITY ASSESSMENT LIST.—

15 “(A) IN GENERAL.—Not later than 18
16 months after the date of the enactment of the
17 Safe Cosmetics Act of 2010, the Secretary shall
18 develop a priority assessment list of not less
19 than 300 ingredients—

20 “(i) which cannot be included on the
21 restricted and prohibited list under para-
22 graph (1) or the safe without limits list
23 under paragraph (2) because of a lack of
24 authoritative information on the safety of
25 the ingredient; and

1 “(ii) for which safety determinations
2 under subparagraph (D) shall be made.

3 “(B) ADDITIONAL INGREDIENTS.—The
4 Secretary shall add not less than 100 ingredi-
5 ents to the priority assessment list under sub-
6 paragraph (A) annually until all ingredients
7 that are used in the formulation or manufac-
8 ture of cosmetics have been added to the pri-
9 ority assessment list, the safe without limits
10 list, or the prohibited and restricted list.

11 “(C) CONSIDERATIONS.—In developing or
12 updating the priority assessment list under this
13 paragraph, the Secretary shall take into ac-
14 count all relevant data with respect to ingredi-
15 ents including whether the ingredients—

16 “(i) react to form harmful byproducts;

17 “(ii) are found to be present in the
18 body through biomonitoring;

19 “(iii) are found in drinking water or
20 indoor or outdoor air;

21 “(iv) are a known or suspected neuro-
22 logical or immunological toxicant, res-
23 piratory asthmagens, or endocrine
24 disruptor, or have other toxicological con-
25 cerns; or

1 “(v) persist in the environment or bio-
2 accumulate.

3 “(D) DETERMINATION OF WHETHER IN-
4 GREDIENT MEETS SAFETY STANDARD.—

5 “(i) IN GENERAL.—Not later than 24
6 months after the date on which an ingre-
7 dient is placed on the priority assessment
8 list under subparagraph (A), the Secretary
9 shall issue, by rule, a determination of—

10 “(I) whether the ingredient meets
11 the safety standard (as defined in sec-
12 tion 611(5)) and can be placed on the
13 safe without limits list under para-
14 graph (2); or

15 “(II) whether to include the in-
16 gredient in the prohibited and re-
17 stricted ingredients list under para-
18 graph (1), to ensure that the safety
19 standard is not violated.

20 “(ii) RULEMAKING.—Before issuing
21 final regulations under clause (ii), the Sec-
22 retary shall issue a notice of proposed rule-
23 making and provide a period of not less
24 than 60 days for public comment on the
25 proposed regulation, except that a shorter

1 period for comment may be provided if the
2 Secretary—

3 “(I) finds that it would be in the
4 public interest to have a shorter pe-
5 riod; and

6 “(II) states the reasons for such
7 finding in the notice of proposed rule-
8 making.

9 “(c) MANUFACTURER INFORMATION AND SAFETY
10 TESTING.—

11 “(1) PROVISION OF INFORMATION.—A manu-
12 facturer of an ingredient or cosmetic shall provide to
13 the Secretary, through a statement under paragraph
14 (3), all information required to determine if an in-
15 gredient or cosmetic meets the safety standard.

16 “(2) MINIMUM DATA REQUIREMENTS AND TEST
17 PROTOCOLS.—Not later than 1 year after the date
18 of the enactment of the Safe Cosmetics Act of 2010,
19 the Secretary shall establish minimum data require-
20 ments and test protocols to be used by manufactur-
21 ers to assess the safety of cosmetic ingredients that
22 would ensure that statements under paragraph
23 (3)(A) regarding compliance with the safety stand-
24 ard are based on sufficient and reliable data.

25 “(3) STATEMENTS.—

1 “(A) IN GENERAL.—Not later than 18
2 months after the date of the enactment of the
3 Safe Cosmetics Act of 2010, each manufacturer
4 or marketer of a cosmetic shall submit to the
5 Secretary a statement signed by the chief execu-
6 tive officer of such manufacturer or marketer,
7 based on available information after a good
8 faith inquiry, that—

9 “(i) the cosmetic and its ingredients
10 meet the safety standard; or

11 “(ii) there is insufficient data to de-
12 termine whether the cosmetic and its in-
13 gredients meet the safety standard.

14 “(B) UPDATES.—Each manufacturer or
15 marketer of a cosmetic shall update the state-
16 ment under subparagraph (A) when there be-
17 comes available significant new information re-
18 garding the safety, or lack thereof, of a cos-
19 metic or its ingredients.

20 “(4) AUDIT.—The Secretary shall perform an
21 annual comprehensive data audit on a statistically
22 significant number of the statements submitted by
23 manufacturers or marketers under paragraph (3).

24 “(d) NANOMATERIALS IN COSMETICS.—The Sec-
25 retary shall—

1 “(1) monitor developments in the scientific un-
2 derstanding of any adverse health effects related to
3 the use of nanotechnology in the formulation of cos-
4 metics; and

5 “(2) consider scale specific hazard properties of
6 ingredients when conducting or reviewing safety sub-
7 stantiation of cosmetic ingredients.

8 “(e) **PRODUCT TESTING AND REVIEW AUDIT.**—The
9 Secretary shall conduct annual audits of random samples
10 of cosmetic products to assess or test for acute negative
11 reactions, pathogen hazards, contaminants, or leaching of
12 packaging additives, mislabeling, or other relevant issues
13 of concern (as determined by the Secretary).

14 **“SEC. 615. MARKET RESTRICTIONS.**

15 “(a) **FAILURE TO PROVIDE DATA OR MEET SAFETY**
16 **STANDARD.**—No person shall manufacture, import, dis-
17 tribute, or market in commerce a cosmetic or an ingre-
18 dient for use in a cosmetic if the Secretary determines
19 that—

20 “(1) the person failed to provide information to
21 the Secretary as required under this subchapter; or

22 “(2) beginning 180 days after the date on
23 which the Secretary places an ingredient on a list
24 under section 614(b)(1)—

25 “(A) the ingredient—

1 “(i) is on the list under section
2 614(b)(1)(A)(i); or

3 “(ii) is a cosmetic containing an in-
4 gredient on such list;

5 “(B) the ingredient is on the list under
6 section 614(b)(1)(A)(ii) and is being used in a
7 cosmetic in a manner that violates the limit on
8 use or concentration of such ingredient under
9 section 614(b)(1)(E).

10 “(b) FAILURE OF SECRETARY TO ACT.—

11 “(1) ISSUANCE OF PENDING NOTIFICATION.—If
12 the Secretary fails to act by an applicable deadline
13 under section 614, a manufacturer or marketer of
14 an ingredient affected by the failure to act shall
15 issue to the Secretary, the public, and each known
16 customer of the ingredient a written notice that a
17 determination by the Secretary of the safety of the
18 ingredient for use in cosmetics is pending.

19 “(2) PROHIBITED USE.—If, by the last day of
20 the 5 year period beginning on the date on which an
21 ingredient is placed on the priority assessment list
22 under section 614(b)(3), the Secretary has not made
23 a determination under such section concerning
24 whether such ingredient meets the safety standard,
25 the ingredient may not be—

1 “(A) used in cosmetics; or

2 “(B) manufactured, imported, distributed,
3 or marketed for use in cosmetics.

4 **“SEC. 616. NOTIFICATION, NONDISTRIBUTION, AND RECALL**
5 **OF ADULTERATED OR MISBRANDED COS-**
6 **METICS.**

7 “(a) NOTIFICATION, NONDISTRIBUTION, AND RE-
8 CALL OF ADULTERATED OR MISBRANDED COSMETICS.—

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

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

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

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

9 “(1) recall such cosmetic; and

10 “(2) provide for notice, including to individuals
11 as appropriate, to persons who may be affected by
12 the recall.

13 “(c) ORDER TO CEASE DISTRIBUTION.—

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

16 “(A) the use of, or exposure to, a cosmetic
17 may cause serious adverse health consequences
18 or death to humans;

19 “(B) the cosmetic is misbranded; or

20 “(C) the cosmetic is manufactured, pack-
21 aged, or distributed by an unregistered facility;
22 the Secretary shall have the authority to issue an
23 order requiring any person who distributes such cos-
24 metic to immediately cease distribution of such cos-
25 metic.

1 “(2) ACTION FOLLOWING ORDER.—Any person
2 who is subject to an order under paragraph (1) shall
3 immediately cease distribution of such cosmetic and
4 provide notification as required by such order, and
5 may appeal such order to the Secretary within 24
6 hours of the issuance of such order. Such appeal
7 may include a request for an informal hearing and
8 a description of any efforts to recall such cosmetic
9 undertaken voluntarily by the person, including after
10 a request under subsection (b). Except as provided
11 in subsection (e), an informal hearing shall be held
12 as soon as practicable, but not later than 5 calendar
13 days, or less as determined by the Secretary, after
14 such an appeal is filed, unless the parties jointly
15 agree to an extension. After affording an oppor-
16 tunity for an informal hearing, the Secretary shall
17 determine whether the order should be amended to
18 require a recall of such cosmetic. If, after providing
19 an opportunity for such a hearing, the Secretary de-
20 termines that inadequate grounds exist to support
21 the actions required by the order, the Secretary shall
22 vacate the order.

23 “(d) ORDER TO RECALL.—

24 “(1) AMENDMENT.—Except as provided under
25 subsection (e), if after providing an opportunity for

1 an informal hearing under subsection (c)(2), the
2 Secretary determines that the order should be
3 amended to include a recall of the cosmetic with re-
4 spect to which the order was issued, the Secretary
5 shall amend the order to require a recall.

6 “(2) CONTENTS.—An amended order under
7 paragraph (1) shall—

8 “(A) specify a timetable in which the recall
9 will occur;

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

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

15 In providing for such notice, the Secretary may
16 allow for the assistance of health professionals, State
17 or local officials, or other individuals designated by
18 the Secretary.

19 “(3) NONDELEGATION.—An amended order
20 under this subsection shall be ordered by the Sec-
21 retary or an official designated by the Secretary. An
22 official may not be so designated unless the official
23 is the director of the district under this Act in which
24 the cosmetic involved is located, or is an official sen-
25 ior to such director.

1 “(e) EMERGENCY RECALL ORDER.—

2 “(1) IN GENERAL.—If the Secretary has cred-
3 ible evidence or information that a cosmetic subject
4 to an order under subsection (c) presents an immi-
5 nent threat of serious adverse health consequences
6 or death to humans, the Secretary may issue an
7 order requiring any person who distributes such cos-
8 metic—

9 “(A) to immediately recall such cosmetic;
10 and

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

14 “(2) ACTION FOLLOWING ORDER.—Any person
15 who is subject to an emergency recall order under
16 this subsection shall immediately recall such cos-
17 metic and provide notification as required by such
18 order, and may appeal within 24 hours after
19 issuance such order to the Secretary. An informal
20 hearing shall be held as soon as practicable but not
21 later than 5 calendar days, or less as determined by
22 the Secretary, after such an appeal is filed, unless
23 the parties jointly agree to an extension. After af-
24 fording an opportunity for an informal hearing, the
25 Secretary shall determine whether the order should

1 be amended pursuant to subsection (d)(1). If, after
2 providing an opportunity for such a hearing, the
3 Secretary determines that inadequate grounds exist
4 to support the actions required by the order, the
5 Secretary shall vacate the order.

6 “(3) NONDELEGATION.—An order under this
7 subsection shall be issued by the Commissioner of
8 Food and Drugs, the Principal Deputy Commis-
9 sioner, or the Associate Commissioner for Regu-
10 latory Affairs of the Food and Drug Administration.

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

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

21 **“SEC. 617. PETITIONS.**

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

1 or cosmetic safety determinations, not later than 180 days
2 after the date on which the Secretary receives from any
3 individual or entity a reasonable petition—

4 “(1) to prohibit or restrict an ingredient for use
5 in cosmetics and list such ingredient on the list
6 under section 614(b)(1);

7 “(2) to remove an ingredient from the list of in-
8 gredients that are safe without limits under section
9 614(b)(2); or

10 “(3) to add an ingredient to the priority assess-
11 ment list under section 614(b)(3).

12 “(b) REASONABLE PETITION.—Not later than one
13 year after the date of the enactment of this Act, the Sec-
14 retary shall issue rules specifying the criteria which the
15 Secretary will use to determine if a petition submitted
16 under this section is a reasonable petition.

17 **“SEC. 618. COSMETIC AND INGREDIENT STATEMENTS.**

18 “(a) IN GENERAL.—Each establishment engaged in
19 the manufacture of a cosmetic intended to be marketed
20 in the United States shall submit electronically to the Sec-
21 retary for each cosmetic manufactured in the establish-
22 ment that is intended to be marketed in the United States
23 a statement containing—

24 “(1) the registration number of the manufac-
25 turing establishment where the cosmetic is manufac-

1 tured or, if the same cosmetic is manufactured in
2 more than 1 establishment, the registration number
3 of each establishment where it is manufactured;

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

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

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

9 “(5) the ingredient list as it appears on the cos-
10 metic label or insert, including the particle size of
11 any nanoscale cosmetic ingredients;

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

14 “(7) the title and full contact information for
15 the individual responsible for submitting and main-
16 taining such statement.

17 “(b) NOTIFICATION OF CHANGES.—The establish-
18 ment shall notify the Secretary in a timely manner of any
19 change to the information required under subsection (a).

20 “(c) PROCEDURE.—Upon receipt of a completed
21 statement described under subsection (a), the Secretary
22 shall notify the establishment of the receipt of such state-
23 ment and assign a cosmetic statement number.

1 “(d) LIST.—The Secretary shall compile and main-
2 tain an up-to-date list of cosmetics for which statements
3 are submitted under this section.

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

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

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

15 “(f) ACCESS TO SAFETY INFORMATION.—The cos-
16 metic and ingredient statements collected under this sec-
17 tion shall be added to the publicly accessible database cre-
18 ated by the Secretary under section 614(a)(3).

19 “(g) EFFECTIVE DATES.—

20 “(1) IN GENERAL.—The provisions of this sec-
21 tion shall take effect 1 year after the date of the en-
22 actment of the Safe Cosmetics Act of 2010.

23 “(2) APPLICATION TO NEW COSMETICS.—An
24 establishment that begins to manufacture a cosmetic
25 after the date of the enactment of the Safe Cos-

1 “(3) A suspect cosmetic.

2 “(4) A serious and unexpected adverse event.

3 “(d) PUBLIC AVAILABILITY AND PRIVACY.—

4 “(1) PUBLIC AVAILABILITY.—Subject to para-
5 graph (2), the adverse health effects reports col-
6 lected by the Secretary under this section shall be
7 submitted electronically and shall be made accessible
8 to the public.

9 “(2) PRIVACY.—

10 “(A) PERSONALLY IDENTIFIABLE INFOR-
11 MATION.—Notwithstanding any other provision
12 of law, personally identifiable information in ad-
13 verse event reports provided to the Secretary
14 under this section, shall not—

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

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

22 “(B) TREATMENT OF INFORMATION
23 UNDER PRIVACY ACT AND FOIA.—An adverse
24 event report submitted to the Secretary under
25 this section, shall be considered to be a record

1 about an individual under section 552a of title
2 5, United States Code (commonly referred to as
3 the “Privacy Act of 1974”) and a medical or
4 similar file the disclosure of which would con-
5 stitute a violation of section 552 of such title 5
6 (commonly referred to as the “Freedom of In-
7 formation Act”), and shall not be publicly dis-
8 closed unless all personally identifiable informa-
9 tion is redacted.

10 **“SEC. 620. NONCONFIDENTIAL INFORMATION.**

11 “(a) IN GENERAL.—Subject to subsection (b) and
12 section 619(d)(2), all nonconfidential information sub-
13 mitted pursuant to this subchapter shall be made available
14 to the public. The name, identity, and structure of a chem-
15 ical substance, contaminant, or impurity that is an ingre-
16 dient and all information concerning function, exposure,
17 health hazards, and environmental hazards, and the func-
18 tions of ingredients in cosmetics shall not be considered
19 to be confidential business information under this sub-
20 chapter. Fragrance, flavor, and colorants shall not be con-
21 sidered confidential business information under this sub-
22 chapter. The concentration of cosmetic ingredients used
23 in a finished cosmetic shall be considered confidential busi-
24 ness information except as otherwise required in section
25 613.

1 “(b) PETITION FOR INFORMATION TO REMAIN CON-
2 FIDENTIAL.—

3 “(1) IN GENERAL.—The Secretary shall create
4 a process for an entity to petition for nonconfidential
5 information described in subsection (a) to remain
6 confidential if the entity shows that there would be
7 serious commercial harm to such entity if such infor-
8 mation were disclosed publicly.

9 “(2) LIMITATION.—The Secretary may not ap-
10 prove a petition under paragraph (1) to the extent
11 that such petition would prevent the public disclo-
12 sure of—

13 “(A) the name, identity, and structure of
14 any substance referred to in subsection (a);

15 “(B) all health and safety data related to
16 that substance; or

17 “(C) any data used to substantiate the
18 safety of that substance.

19 **“SEC. 621. SAVINGS CLAUSE.**

20 “Nothing in this subchapter shall affect the right of
21 a State, political subdivision of a State, or tribe to adopt
22 or enforce any regulation, requirement, liability, or stand-
23 ard of performance that is more stringent than a regula-
24 tion, requirement, liability, or standard of performance es-

1 tablished by this subchapter, including requiring the provi-
2 sion of a warning of risk, illness, or injury.

3 **“SEC. 622. ANIMAL TESTING ALTERNATIVES.**

4 “(a) IN GENERAL.—To minimize the use of animal
5 testing of ingredients, the Secretary shall—

6 “(1) require, where practicable, alternative test-
7 ing methods that—

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

10 “(B) provide information that is equivalent
11 or superior in scientific quality to the animal
12 testing method; and

13 “(C) use fewer animals than conventional
14 animal-based tests when non-animal methods
15 are impracticable, including the use of tests
16 that combine multiple endpoints; and

17 “(2) encourage, where practicable—

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

23 “(B) the formation of industry consortia to
24 conduct testing to avoid duplication of tests;
25 and

1 “(C) funding for research and validation of
2 alternative test methods, in accordance with
3 this subsection.

4 “(b) LIST OF ALTERNATIVE TESTING METHODS.—
5 Not later than 1 year after the date of the enactment of
6 the Safe Cosmetics Act of 2010, and triennially thereafter,
7 the Secretary shall publish a list of the alternative testing
8 methods described in subsection (a).

9 **“SEC. 623. INTERAGENCY COOPERATION AND FUNDING.**

10 “‘There is established an Interagency Council on Cos-
11 metic Safety for the purpose of sharing data and pro-
12 moting collaboration on cosmetic safety among and be-
13 tween the Food and Drug Administration, the National
14 Institute of Environmental Health Sciences, the Centers
15 for Disease Control and Prevention, the Occupational
16 Safety and Health Administration, and the Environmental
17 Protection Agency.

18 **“SEC. 624. AUTHORIZATION OF APPROPRIATIONS.**

19 “‘There are authorized to be appropriated such sums
20 as may be necessary to carry out this subchapter for each
21 of the fiscal years 2011 through 2015.’”.

22 (b) ADULTERATED AND MISBRANDED COSMETICS.—

23 (1) ADULTERATED COSMETICS.—Section 601 of
24 the Federal Food, Drug, and Cosmetic Act (21
25 U.S.C. 361) is amended—

1 (A) in subsection (a), by striking “, except
2 that this provision shall not apply to coal-tar
3 hair dye” and all that follows through “or eye-
4 brow dyes”; and

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

6 “(f) If it—

7 “(1) was manufactured, packaged, or distrib-
8 uted by an entity that failed to register as required
9 under section 612;

10 “(2) was sold by an Internet vendor that failed
11 to comply with the requirements of section 613(b);

12 “(3) the person who manufactures, imports,
13 distributes, or markets the cosmetic, or an ingre-
14 dient in the cosmetic, fails to comply with the appli-
15 cable requirements of section 615 (including failure
16 to issue a notice required under section 615(b)(1));

17 “(4) is manufactured, packaged, distributed, or
18 sold in retail by a manufacturer, packager, dis-
19 tributor, or retailer, respectively, who fails to notify
20 the Secretary as required under section 616(a);

21 “(5) is distributed in violation of an order
22 under section 616(c);

23 “(6) is not recalled as required by an order
24 under subsection (d) or (e) of section 616;

1 “(7) is manufactured in a manner that fails to
2 comply with good manufacturing practices for cos-
3 metics, as determined (and periodically updated), by
4 the Secretary; or

5 “(8) is manufactured by a manufacturer who
6 fails to submit the statement required under section
7 618 or notify the Secretary of changes to informa-
8 tion contained in such statement as required by such
9 section.”.

10 (2) MISBRANDED COSMETICS.—Section 602 of
11 the Federal Food, Drug, and Cosmetic Act (21
12 U.S.C. 362) is amended in subsection (a), by insert-
13 ing “, fails to meet the requirements of section
14 613(a), or fails to meet any requirements under sec-
15 tion 618(e)” before the period.

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

17 (a) IN GENERAL.—The Secretary of Labor shall pro-
18 mulgate an occupational safety and health standard under
19 section 6 of the Occupational Safety and Health Act of
20 1970 (29 U.S.C. 655) that requires the following:

21 (1) MANUFACTURERS AND IMPORTERS.—

22 (A) IN GENERAL.—Each manufacturer or
23 importer selling any cosmetic for professional
24 use shall—

1 (i) obtain or develop an expanded ma-
2 terial safety data sheet described in sub-
3 section (b) for each such cosmetic or per-
4 sonal care product that—

5 (I) the manufacturer or importer
6 produces or imports; and

7 (II) includes a hazardous chem-
8 ical, or product ingredient associated
9 with any chemical hazard, that has
10 been indicated by authoritative bodies
11 or scientific studies to be linked to
12 health hazards including mutation, re-
13 productive or developmental toxicity,
14 neurotoxicity, endocrine disruption,
15 asthma, or other immunological tox-
16 icity; and

17 (ii) make the expanded material safety
18 data sheet available to distributors and
19 employers, including salon owners, in
20 English and, upon request, in other lan-
21 guages, including Spanish and Vietnamese.

22 (B) PROFESSIONAL USE DEFINED.—In
23 this paragraph, the term “professional use” has
24 the meaning given such term in section 611 of
25 the Federal Food, Drug, and Cosmetic Act.

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

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

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

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

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

1 data sheet in other languages, including Span-
2 ish and Vietnamese.

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

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

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

18 **SEC. 4. FDA SAFETY STANDARD AS IT RELATES TO OTHER**
19 **ADMINISTRATIVE AGENCIES.**

20 (a) USE OF DATA FROM FEDERAL SOURCES.—The
21 Secretary shall request and utilize ingredient toxicity, use,
22 and exposure data from other Federal agencies as appro-
23 priate, to assist with developing the priority assessment
24 list under section 614(b)(3) of the Federal Food, Drug,

1 and Cosmetic Act, and for reaching safety determinations
2 under section 614(b)(3)(E) of such Act.

3 (b) USE OF OTHER FEDERAL STANDARDS.—If any
4 Federal agency has promulgated a standard for an ingre-
5 dient that satisfies the safety standard under section 611
6 of the Federal Food, Drug, and Cosmetic Act, the Sec-
7 retary may adopt it for purposes of this Act or an amend-
8 ment made by this Act.

○