

1
2
3
4
5
6
7
8
9
10
11
12
13
14
15
16
17
18
19
20
21
22
23

**Extracted from the
Full Omnibus Spending Bill**

Subtitle E—Cosmetics

SEC. 3501. SHORT TITLE.

This subtitle may be cited as the “Modernization of
Cosmetics Regulation Act of 2022”.

SEC. 3502. AMENDMENTS TO COSMETIC REQUIREMENTS.

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

“SEC. 604. DEFINITIONS.

“In this chapter:

3577

1 “(1) ADVERSE EVENT.—The term ‘adverse
2 event’ means any health-related event associated
3 with the use of a cosmetic product that is adverse.

4 “(2) COSMETIC PRODUCT.—The term ‘cosmetic
5 product’ means a preparation of cosmetic ingredi-
6 ents with a qualitatively and quantitatively set com-
7 position for use in a finished product.

8 “(3) FACILITY.—

9 “(A) IN GENERAL.—The term ‘facility’ in-
10 cludes any establishment (including an estab-
11 lishment of an importer) that manufactures or
12 processes cosmetic products distributed in the
13 United States.

14 “(B) Such term does not include any of
15 the following:

16 “(i) Beauty shops and salons, unless
17 such establishment manufactures or proc-
18 esses cosmetic products at that location.

19 “(ii) Cosmetic product retailers, in-
20 cluding individual sales representatives, di-
21 rect sellers (as defined in section
22 3508(b)(2) of the Internal Revenue Code
23 of 1986), retail distribution facilities, and
24 pharmacies, unless such establishment
25 manufactures or processes cosmetic prod-

3578

1 ucts that are not sold directly to con-
2 sumers at that location.

3 “(iii) Hospitals, physicians’ offices,
4 and health care clinics.

5 “(iv) Public health agencies and other
6 nonprofit entities that provide cosmetic
7 products directly to the consumer.

8 “(v) Entities (such as hotels and air-
9 lines) that provide complimentary cosmetic
10 products to customers incidental to other
11 services.

12 “(vi) Trade shows and other venues
13 where cosmetic product samples are pro-
14 vided free of charge.

15 “(vii) An establishment that manufac-
16 tures or processes cosmetic products that
17 are solely for use in research or evaluation,
18 including for production testing and not of-
19 fered for retail sale.

20 “(viii) An establishment that solely
21 performs one or more of the following with
22 respect to cosmetic products:

23 “(I) Labeling.

24 “(II) Relabeling.

25 “(III) Packaging.

3579

1 “(IV) Repackaging.

2 “(V) Holding.

3 “(VI) Distributing.

4 “(C) CLARIFICATION.—For the purposes
5 of subparagraph (B)(viii), the terms ‘packaging’
6 and ‘repackaging’ do not include filling a prod-
7 uct container with a cosmetic product.

8 “(4) RESPONSIBLE PERSON.—The term ‘re-
9 sponsible person’ means the manufacturer, packer,
10 or distributor of a cosmetic product whose name ap-
11 pears on the label of such cosmetic product in ac-
12 cordance with section 609(a) of this Act or section
13 4(a) of the Fair Packaging and Labeling Act.

14 “(5) SERIOUS ADVERSE EVENT.—The term ‘se-
15 rious adverse event’ means an adverse event that—

16 “(A) results in—

17 “(i) death;

18 “(ii) a life-threatening experience;

19 “(iii) inpatient hospitalization;

20 “(iv) a persistent or significant dis-
21 ability or incapacity;

22 “(v) a congenital anomaly or birth de-
23 fect;

24 “(vi) an infection; or

1 “(vii) significant disfigurement (in-
2 cluding serious and persistent rashes,
3 second- or third-degree burns, significant
4 hair loss, or persistent or significant alter-
5 ation of appearance), other than as in-
6 tended, under conditions of use that are
7 customary or usual; or

8 “(B) requires, based on reasonable medical
9 judgment, a medical or surgical intervention to
10 prevent an outcome described in subparagraph
11 (A).

12 **“SEC. 605. ADVERSE EVENTS.**

13 “(a) **SERIOUS ADVERSE EVENT REPORTING RE-**
14 **QUIREMENTS.**—The responsible person shall submit to the
15 Secretary any report received of a serious adverse event
16 associated with the use, in the United States, of a cosmetic
17 product manufactured, packed, or distributed by such per-
18 son.

19 “(b) **SUBMISSION OF REPORTS.**—

20 “(1) **SERIOUS ADVERSE EVENT REPORT.**—The
21 responsible person shall submit to the Secretary a
22 serious adverse event report accompanied by a copy
23 of the label on or within the retail packaging of such
24 cosmetic product no later than 15 business days

1 after the report is received by the responsible per-
2 son.

3 “(2) NEW MEDICAL INFORMATION.—The re-
4 sponsible person shall submit to the Secretary any
5 new and material medical information, related to a
6 serious adverse event report submitted to the Sec-
7 retary in accordance with paragraph (1), that is re-
8 ceived by the responsible person within 1 year of the
9 initial report to the Secretary, no later than 15 busi-
10 ness days after such information is received by such
11 responsible person.

12 “(3) CONSOLIDATION OF REPORTS.—The Sec-
13 retary shall develop systems to enable responsible
14 persons to submit a single report that includes du-
15 plicate reports of, or new medical information re-
16 lated to, a serious adverse event.

17 “(c) EXEMPTIONS.—The Secretary may establish by
18 regulation an exemption to any of the requirements of this
19 section if the Secretary determines that such exemption
20 would have no significant adverse effect on public health.

21 “(d) CONTACT INFORMATION.—The responsible per-
22 son shall receive reports of adverse events through the do-
23 mestic address, domestic telephone number, or electronic
24 contact information included on the label in accordance
25 with section 609(a).

1 “(e) MAINTENANCE AND INSPECTION OF ADVERSE
2 EVENT RECORDS.—

3 “(1) MAINTENANCE.—The responsible person
4 shall maintain records related to each report of an
5 adverse event associated with the use, in the United
6 States, of a cosmetic product manufactured or dis-
7 tributed by such person received by such person, for
8 a period of 6 years, except that a responsible person
9 that is considered a small business for the purposes
10 of section 612, who does not engage in the manufac-
11 turing or processing of the cosmetic products de-
12 scribed in subsection 612(b), shall maintain such
13 records for a period of 3 years.

14 “(2) INSPECTION.—

15 “(A) IN GENERAL.— The responsible per-
16 son shall permit an authorized person to have
17 access to records required to be maintained
18 under this section during an inspection pursu-
19 ant to section 704.

20 “(B) AUTHORIZED PERSON.—For pur-
21 poses of this paragraph, the term ‘authorized
22 person’ means an officer or employee of the De-
23 partment of Health and Human Services who
24 has—

3583

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

3 “(ii) been duly designated by the Sec-
4 retary to have access to the records re-
5 quired under this section.

6 “(f) FRAGRANCE AND FLAVOR INGREDIENTS.—If
7 the Secretary has reasonable grounds to believe that an
8 ingredient or combination of ingredients in a fragrance or
9 flavor has caused or contributed to a serious adverse event
10 required to be reported under this section, the Secretary
11 may request in writing a list of such ingredients or cat-
12 egories of ingredients in the specific fragrances or flavors
13 in the cosmetic product, from the responsible person. The
14 responsible person shall ensure that the requested infor-
15 mation is submitted to the Secretary within 30 days of
16 such request. In response to a request under section 552
17 of title 5, United States Code, information submitted to
18 the Secretary under this subsection shall be withheld
19 under section 552(b)(3) of title 5, United States Code.

20 “(g) PROTECTED INFORMATION.—A serious adverse
21 event report submitted to the Secretary under this section,
22 including any new medical information submitted under
23 subsection (b)(2), or an adverse event report, or any new
24 information, voluntarily submitted to the Secretary shall
25 be considered to be—

1 “(1) a safety report under section 756 and may
2 be accompanied by a statement, which shall be a
3 part of any report that is released for public disclo-
4 sure, that denies that the report or the records con-
5 stitute an admission that the product involved
6 caused or contributed to the adverse event; and

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

15 “(h) EFFECT OF SECTION.—

16 “(1) IN GENERAL.—Nothing in this section
17 shall affect the authority of the Secretary to provide
18 adverse event reports and information to any health,
19 food, or drug officer or employee of any State, terri-
20 tory, or political subdivision of a State or territory,
21 under a memorandum of understanding between the
22 Secretary and such State, territory, or political sub-
23 division.

24 “(2) PERSONALLY IDENTIFIABLE INFORMA-
25 TION.—Notwithstanding any other provision of law,

1 personally-identifiable information in adverse event
2 reports provided by the Secretary to any health,
3 food, or drug officer or employee of any State, terri-
4 tory, or political subdivision of a State or territory,
5 shall not—

6 “(A) be made publicly available pursuant
7 to any State or other law requiring disclosure
8 of information or records; or

9 “(B) otherwise be disclosed or distributed
10 to any party without the written consent of the
11 Secretary and the person submitting such infor-
12 mation to the Secretary.

13 “(3) USE OF REPORTS.—Nothing in this sec-
14 tion shall permit a State, territory, or political sub-
15 division of a State or territory, to use any safety re-
16 port received from the Secretary in a manner incon-
17 sistent with this section.

18 “(4) RULE OF CONSTRUCTION.—The submis-
19 sion of any report in compliance with this section
20 shall not be construed as an admission that the cos-
21 metic product involved caused or contributed to the
22 relevant adverse event.

23 **“SEC. 606. GOOD MANUFACTURING PRACTICE.**

24 “(a) IN GENERAL.—The Secretary shall by regula-
25 tion establish good manufacturing practices for facilities

1 that are consistent, to the extent practicable, and appro-
2 priate, with national and international standards, in ac-
3 cordance with section 601. Any such regulations shall be
4 intended to protect the public health and ensure that cos-
5 metic products are not adulterated. Such regulations may
6 allow for the Secretary to inspect records necessary to
7 demonstrate compliance with good manufacturing prac-
8 tices prescribed by the Secretary under this paragraph
9 during an inspection conducted under section 704.

10 “(b) CONSIDERATIONS.—In establishing regulations
11 for good manufacturing practices under this section, the
12 Secretary shall take into account the size and scope of the
13 businesses engaged in the manufacture of cosmetics, and
14 the risks to public health posed by such cosmetics, and
15 provide sufficient flexibility to be practicable for all sizes
16 and types of facilities to which such regulations will apply.
17 Such regulations shall include simplified good manufac-
18 turing practice requirements for smaller businesses, as ap-
19 propriate, to ensure that such regulations do not impose
20 undue economic hardship for smaller businesses, and may
21 include longer compliance times for smaller businesses.
22 Before issuing regulations to implement subsection (a),
23 the Secretary shall consult with cosmetics manufacturers,
24 including smaller businesses, consumer organizations, and
25 other experts selected by the Secretary.

1 “(c) TIMEFRAME.—The Secretary shall publish a no-
2 tice of proposed rulemaking not later than 2 years after
3 the date of enactment of the Modernization of Cosmetics
4 Regulation Act of 2022 and shall publish a final such rule
5 not later than 3 years after such date of enactment.

6 **“SEC. 607. REGISTRATION AND PRODUCT LISTING.**

7 “(a) SUBMISSION OF REGISTRATION.—

8 “(1) INITIAL REGISTRATION.—

9 “(A) EXISTING FACILITIES.—Every person
10 that, on the date of enactment of the Mod-
11 ernization of Cosmetics Regulation Act of 2022,
12 owns or operates a facility that engages in the
13 manufacturing or processing of a cosmetic
14 product for distribution in the United States
15 shall register each facility with the Secretary
16 not later than 1 year after date of enactment
17 of such Act.

18 “(B) NEW FACILITIES.—Every person that
19 owns or operates a facility that first engages,
20 after the date of enactment of the Moderniza-
21 tion of Cosmetics Regulation Act of 2022, in
22 manufacturing or processing of a cosmetic
23 product for distribution in the United States,
24 shall register with the Secretary such facility
25 within 60 days of first engaging in such activity

1 or 60 days after the deadline for registration
2 under subparagraph (A), whichever is later.

3 “(2) BIENNIAL RENEWAL OF REGISTRATION.—

4 A person required to register a facility under para-
5 graph (1) shall renew such registrations with the
6 Secretary biennially.

7 “(3) CONTRACT MANUFACTURERS.—If a facility
8 manufactures or processes cosmetic products on be-
9 half of a responsible person, the Secretary shall re-
10 quire only a single registration for such facility even
11 if such facility is manufacturing or processing its
12 own cosmetic products or cosmetic products on be-
13 half of more than one responsible person. Such sin-
14 gle registration may be submitted to the Secretary
15 by such facility or any responsible person whose
16 products are manufactured or processed at such fa-
17 cility.

18 “(4) UPDATES TO CONTENT.—A person that is
19 required to register under subsection (a)(1) shall no-
20 tify the Secretary within 60 days of any changes to
21 information required under subsection (b)(2).

22 “(5) ABBREVIATED RENEWAL REGISTRA-
23 TIONS.—The Secretary shall provide for an abbrevi-
24 ated registration renewal process for any person
25 that owns or operates a facility that has not been re-

1 quired to submit updates under paragraph (4) for a
2 registered facility since submission of the most re-
3 cent registration of such facility under paragraph
4 (1) or (2).

5 “(b) FORMAT; CONTENTS OF REGISTRATION.—

6 “(1) IN GENERAL.—Registration information
7 under this section may be submitted at such time
8 and in such manner as the Secretary may prescribe.

9 “(2) CONTENTS.—The registration under sub-
10 section (a) shall contain—

11 “(A) the facility’s name, physical address,
12 email address, and telephone number;

13 “(B) with respect to any foreign facility,
14 the contact for the United States agent of the
15 facility, and, if available, the electronic contact
16 information;

17 “(C) the facility registration number, if
18 any, previously assigned by the Secretary under
19 subsection (d);

20 “(D) all brand names under which cos-
21 metic products manufactured or processed in
22 the facility are sold; and

23 “(E) the product category or categories
24 and responsible person for each cosmetic prod-
25 uct manufactured or processed at the facility.

3590

1 “(c) COSMETIC PRODUCT LISTING.—

2 “(1) IN GENERAL.—For each cosmetic product,
3 the responsible person shall submit to the Secretary
4 a cosmetic product listing, or ensure that such sub-
5 mission is made, at such time and in such manner
6 as the Secretary may prescribe.

7 “(2) COSMETIC PRODUCT LISTING.—The re-
8 sponsible person of a cosmetic product that is mar-
9 keted on the date of enactment of the Modernization
10 of Cosmetics Regulation Act of 2022 shall submit to
11 the Secretary a cosmetic product listing not later
12 than 1 year after the date of enactment of the Mod-
13 ernization of Cosmetics Regulation Act of 2022, or
14 for a cosmetic product that is first marketed after
15 the date of enactment of such Act, within 120 days
16 of marketing such product in interstate commerce.
17 Thereafter, any updates to such listing shall be
18 made annually, consistent with paragraphs (4) and
19 (5).

20 “(3) ABBREVIATED RENEWAL.—The Secretary
21 shall provide for an abbreviated process for the re-
22 newal of any cosmetic product listing under this sub-
23 section with respect to which there has been no
24 change since the responsible person submitted the
25 previous listing.

3591

1 “(4) CONTENTS OF LISTING.—

2 “(A) IN GENERAL.—Each such cosmetic
3 product listing shall include—

4 “(i) the facility registration number of
5 each facility where the cosmetic product is
6 manufactured or processed;

7 “(ii) the name and contact number of
8 the responsible person and the name for
9 the cosmetic product, as such name ap-
10 pears on the label;

11 “(iii) the applicable cosmetic category
12 or categories for the cosmetic product;

13 “(iv) a list of ingredients in the cos-
14 metic product, including any fragrances,
15 flavors, or colors, with each ingredient
16 identified by the name, as required under
17 section 701.3 of title 21, Code of Federal
18 Regulations (or any successor regulations),
19 or by the common or usual name of the in-
20 gredient; and

21 “(v) the product listing number, if
22 any previously assigned by the Secretary
23 under subsection (d).

24 “(B) FLEXIBLE LISTINGS.—A single list-
25 ing submission for a cosmetic product may in-

1 clude multiple cosmetic products with identical
2 formulations, or formulations that differ only
3 with respect to colors, fragrances or flavors, or
4 quantity of contents.

5 “(5) UPDATES TO CONTENT.—A responsible
6 person that is required to submit a cosmetic product
7 listing shall submit any updates to such cosmetic
8 product listing annually.

9 “(6) SUBMISSION.—A responsible person may
10 submit product listing information as part of a facil-
11 ity registration or separately.

12 “(d) FACILITY REGISTRATION AND PRODUCT LIST-
13 ING NUMBERS.—At the time of the initial registration of
14 any facility under subsection (a)(1) or initial listing of any
15 cosmetic product under (c)(1), the Secretary shall assign
16 a facility registration number to the facility and a product
17 listing number to each cosmetic product. The Secretary
18 shall not make such product listing number publicly avail-
19 able.

20 “(e) CONFIDENTIALITY.—In response to a request
21 under section 552 of title 5, United States Code, informa-
22 tion described in subsection (b)(2)(D) or (c)(4)(A)(i) that
23 is derived from a registration or listing under this section
24 shall be withheld under section 552(b)(3) of title 5, United
25 States Code.

1 “(f) SUSPENSIONS.—

2 “(1) SUSPENSION OF REGISTRATION OF A FA-
3 CILITY.—The Secretary may suspend the registra-
4 tion of a facility if the Secretary determines that a
5 cosmetic product manufactured or processed by a
6 registered facility and distributed in the United
7 States has a reasonable probability of causing seri-
8 ous adverse health consequences or death to humans
9 and the Secretary has a reasonable belief that other
10 products manufactured or processed by the facility
11 may be similarly affected because of a failure that
12 cannot be isolated to a product or products, or is
13 sufficiently pervasive to raise concerns about other
14 products manufactured in the facility.

15 “(2) NOTICE OF SUSPENSION.—Before sus-
16 pending a facility registration under this section, the
17 Secretary shall provide—

18 “(A) notice to the facility registrant of the
19 cosmetic product or other responsible person, as
20 appropriate, of the intent to suspend the facility
21 registration, which shall specify the basis of the
22 determination by the Secretary that the facility
23 registration should be suspended; and

24 “(B) an opportunity, within 5 business
25 days of the notice provided under subparagraph

1 (A), for the responsible person to provide a plan
2 for addressing the reasons for possible suspen-
3 sion of the facility registration.

4 “(3) HEARING ON SUSPENSION.—The Secretary
5 shall provide the registrant subject to an order
6 under paragraph (1) or (2) with an opportunity for
7 an informal hearing, to be held as soon as possible
8 but not later than 5 business days after the issuance
9 of the order, or such other time period agreed upon
10 by the Secretary and the registrant, on the actions
11 required for reinstatement of registration and why
12 the registration that is subject to the suspension
13 should be reinstated. The Secretary shall reinstate a
14 registration if the Secretary determines, based on
15 evidence presented, that adequate grounds do not
16 exist to continue the suspension of the registration.

17 “(4) POST-HEARING CORRECTIVE ACTION
18 PLAN.—If, after providing opportunity for an infor-
19 mal hearing under paragraph (3), the Secretary de-
20 termines that the suspension of registration remains
21 necessary, the Secretary shall require the registrant
22 to submit a corrective action plan to demonstrate
23 how the registrant plans to correct the conditions
24 found by the Secretary. The Secretary shall review
25 such plan not later than 14 business days after the

1 submission of the corrective action plan or such
2 other time period as determined by the Secretary, in
3 consultation with the registrant.

4 “(5) VACATING OF ORDER; REINSTATEMENT.—
5 Upon a determination by the Secretary that ade-
6 quate grounds do not exist to continue the suspen-
7 sion actions, the Secretary shall promptly vacate the
8 suspension and reinstate the registration of the facil-
9 ity.

10 “(6) EFFECT OF SUSPENSION.—If the registra-
11 tion of the facility is suspended under this section,
12 no person shall introduce or deliver for introduction
13 into commerce in the United States cosmetic prod-
14 ucts from such facility.

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

20 **“SEC. 608. SAFETY SUBSTANTIATION.**

21 “(a) SUBSTANTIATION OF SAFETY.—A responsible
22 person for a cosmetic product shall ensure, and maintain
23 records supporting, that there is adequate substantiation
24 of safety of such cosmetic product.

1 “(b) COAL-TAR HAIR DYE.—Subsection (a) shall not
2 apply to coal-tar hair dye that otherwise complies with the
3 requirements of section 601(a). A responsible person for
4 a coal-tar hair dye shall maintain records related to the
5 safety of such product.

6 “(c) DEFINITIONS.—For purposes of this section:

7 “(1) ADEQUATE SUBSTANTIATION OF SAFE-
8 TY.—The term ‘adequate substantiation of safety’
9 means tests or studies, research, analyses, or other
10 evidence or information that is considered, among
11 experts qualified by scientific training and experi-
12 ence to evaluate the safety of cosmetic products and
13 their ingredients, sufficient to support a reasonable
14 certainty that a cosmetic product is safe.

15 “(2) SAFE.—The term ‘safe’ means that the
16 cosmetic product, including any ingredient thereof,
17 is not injurious to users under the conditions of use
18 prescribed in the labeling thereof, or under such con-
19 ditions of use as are customary or usual. The Sec-
20 retary shall not consider a cosmetic ingredient or
21 cosmetic product injurious to users solely because it
22 can cause minor and transient reactions or minor
23 and transient skin irritations in some users. In de-
24 termining for purposes of this section whether a cos-
25 metic product is safe, the Secretary may consider, as

1 appropriate and available, the cumulative or other
2 relevant exposure to the cosmetic product, including
3 any ingredient thereof.

4 **“SEC. 609. LABELING.**

5 “(a) GENERAL REQUIREMENT.—Each cosmetic prod-
6 uct shall bear a label that includes a domestic address,
7 domestic phone number, or electronic contact information,
8 which may include a website, through which the respon-
9 sible person can receive adverse event reports with respect
10 to such cosmetic product.

11 “(b) FRAGRANCE ALLERGENS.—The responsible per-
12 son shall identify on the label of a cosmetic product each
13 fragrance allergen included in such cosmetic product. Sub-
14 stances that are fragrance allergens for purposes of this
15 subsection shall be determined by the Secretary by regula-
16 tion. The Secretary shall issue a notice of proposed rule-
17 making promulgating the regulation implementing this re-
18 quirement not later than 18 months after the date of en-
19 actment of the Modernization of Cosmetics Regulation Act
20 of 2022, and not later than 180 days after the date on
21 which the public comment period on the proposed rule-
22 making closes, shall issue a final rulemaking. In promul-
23 gating regulations implementing this subsection, the Sec-
24 retary shall consider international, State, and local re-
25 quirements for allergen disclosure, including the substance

1 and format of requirements in the European Union, and
2 may establish threshold levels of amounts of substances
3 subject to disclosure pursuant to such regulations.

4 “(c) COSMETIC PRODUCTS FOR PROFESSIONAL
5 USE.—

6 “(1) DEFINITION OF PROFESSIONAL.—For pur-
7 poses of this subsection, the term ‘professional’
8 means an individual who is licensed by an official
9 State authority to practice in the field of cosme-
10 tology, nail care, barbering, or esthetics.

11 “(2) PROFESSIONAL USE LABELING.—A cos-
12 metic product introduced into interstate commerce
13 and intended to be used only by a professional shall
14 bear a label that—

15 “(A) contains a clear and prominent state-
16 ment that the product shall be administered or
17 used only by licensed professionals; and

18 “(B) is in conformity with the require-
19 ments of the Secretary for cosmetics labeling
20 under this Act and section 4(a) of the Fair
21 Packaging and Labeling Act.

22 **“SEC. 610. RECORDS.**

23 “(a) IN GENERAL.—If the Secretary has a reasonable
24 belief that a cosmetic product, including an ingredient in
25 such cosmetic product, and any other cosmetic product

3599

1 that the Secretary reasonably believes is likely to be af-
2 fected in a similar manner, is likely to be adulterated such
3 that the use or exposure to such product presents a threat
4 of serious adverse health consequences or death to hu-
5 mans, each responsible person and facility shall, at the re-
6 quest of an officer or employee duly designated by the Sec-
7 retary, permit such officer or employee, upon presentation
8 of appropriate credentials and a written notice to such
9 person, at reasonable times and within reasonable limits
10 and in a reasonable manner, to have access to and copy
11 all records relating to such cosmetic product, and to any
12 other cosmetic product that the Secretary reasonably be-
13 lieves is likely to be affected in a similar manner, that
14 are needed to assist the Secretary in determining whether
15 the cosmetic product is adulterated and presents a threat
16 of serious adverse health consequences or death to hu-
17 mans. This subsection shall not be construed to extend
18 to recipes or formulas for cosmetics, financial data, pricing
19 data, personnel data (other than data as to qualification
20 of technical and professional personnel performing func-
21 tions subject to this Act), research data (other than safety
22 substantiation data for cosmetic products and their ingre-
23 dients), or sales data (other than shipment data regarding
24 sales).

1 “(b) **RULE OF CONSTRUCTION.**—Nothing in this sec-
2 tion shall be construed to limit the authority of the Sec-
3 retary to inspect records or require establishment and
4 maintenance of records under any other provision of this
5 Act, including section 605 or 606.

6 **“SEC. 611. MANDATORY RECALL AUTHORITY.**

7 “(a) **IN GENERAL.**—If the Secretary determines that
8 there is a reasonable probability that a cosmetic is adulter-
9 ated under section 601 or misbranded under section 602
10 and the use of or exposure to such cosmetic will cause
11 serious adverse health consequences or death, the Sec-
12 retary shall provide the responsible person with an oppor-
13 tunity to voluntarily cease distribution and recall such ar-
14 ticle. If the responsible person refuses to or does not vol-
15 untarily cease distribution or recall such cosmetic within
16 the time and manner prescribed by the Secretary (if so
17 prescribed), the Secretary may, by order, require, as the
18 Secretary determines necessary, such person to imme-
19 diately cease distribution of such article.

20 “(b) **HEARING.**—The Secretary shall provide the re-
21 sponsible person who is subject to an order under sub-
22 section (a) with an opportunity for an informal hearing,
23 to be held not later than 10 days after the date of issuance
24 of the order, on whether adequate evidence exists to justify
25 the order.

3601

1 “(c) ORDER RESOLUTION.—After an order is issued
2 according to the process under subsections (a) and (b),
3 the Secretary shall, except as provided in subsection (d)—

4 “(1) vacate the order, if the Secretary deter-
5 mines that inadequate grounds exist to support the
6 actions required by the order;

7 “(2) continue the order ceasing distribution of
8 the cosmetic until a date specified in such order; or

9 “(3) amend the order to require a recall of the
10 cosmetic, including any requirements to notify ap-
11 propriate persons, a timetable for the recall to occur,
12 and a schedule for updates to be provided to the
13 Secretary regarding such recall.

14 “(d) ACTION FOLLOWING ORDER.—Any person who
15 is subject to an order pursuant to paragraph (2) or (3)
16 of subsection (c) shall immediately cease distribution of
17 or recall, as applicable, the cosmetic and provide notifica-
18 tion as required by such order.

19 “(e) NOTICE TO PERSONS AFFECTED.—If the Sec-
20 retary determines necessary, the Secretary may require
21 the person subject to an order pursuant to subsection (a)
22 or an amended order pursuant to paragraph (2) or (3)
23 of subsection (c) to provide either a notice of a recall order
24 for, or an order to cease distribution of, such cosmetic,
25 as applicable, under this section to appropriate persons,

1 including persons who manufacture, distribute, import, or
2 offer for sale such product that is the subject of an order
3 and to the public.

4 “(f) PUBLIC NOTIFICATION.—In conducting a recall
5 under this section, the Secretary shall—

6 “(1) ensure that a press release is published re-
7 garding the recall, and that alerts and public notices
8 are issued, as appropriate, in order to provide notifi-
9 cation—

10 “(A) of the recall to consumers and retail-
11 ers to whom such cosmetic was, or may have
12 been, distributed; and

13 “(B) that includes, at a minimum—

14 “(i) the name of the cosmetic subject
15 to the recall;

16 “(ii) a description of the risk associ-
17 ated with such article; and

18 “(iii) to the extent practicable, infor-
19 mation for consumers about similar cos-
20 metics that are not affected by the recall;
21 and

22 “(2) ensure publication, as appropriate, on the
23 website of the Food and Drug Administration of an
24 image of the cosmetic that is the subject of the press
25 release described in paragraph (1), if available.

1 “(g) NO DELEGATION.—The authority conferred by
2 this section to order a recall or vacate a recall order shall
3 not be delegated to any officer or employee other than the
4 Commissioner.

5 “(h) EFFECT.—Nothing in this section shall affect
6 the authority of the Secretary to request or participate
7 in a voluntary recall, or to issue an order to cease distribu-
8 tion or to recall under any other provision of this chapter.

9 **“SEC. 612. SMALL BUSINESSES.**

10 “(a) IN GENERAL.—Responsible persons, and owners
11 and operators of facilities, whose average gross annual
12 sales in the United States of cosmetic products for the
13 previous 3-year period is less than \$1,000,000, adjusted
14 for inflation, and who do not engage in the manufacturing
15 or processing of the cosmetic products described in sub-
16 section (b), shall be considered small businesses and not
17 subject to the requirements of section 606 or 607.

18 “(b) REQUIREMENTS APPLICABLE TO ALL MANU-
19 FACTURERS AND PROCESSORS OF COSMETICS.—The ex-
20 emptions under subsection (a) shall not apply to any re-
21 sponsible person or facility engaged in the manufacturing
22 or processing of any of the following products:

23 “(1) Cosmetic products that regularly come into
24 contact with mucus membrane of the eye under con-
25 ditions of use that are customary or usual.

1 “(2) Cosmetic products that are injected.

2 “(3) Cosmetic products that are intended for
3 internal use.

4 “(4) Cosmetic products that are intended to
5 alter appearance for more than 24 hours under con-
6 ditions of use that are customary or usual and re-
7 moval by the consumer is not part of such conditions
8 of use that are customary or usual.

9 **“SEC. 613. EXEMPTION FOR CERTAIN PRODUCTS AND FA-**
10 **CILITIES.**

11 “(a) IN GENERAL.—Notwithstanding any other pro-
12 vision of law, except as provided in subsection (b), a cos-
13 metic product or facility that is also subject to the require-
14 ments of chapter V shall be exempt from the requirements
15 of sections 605, 606, 607, 608, 609(a), 610, and 611.

16 “(b) EXCEPTION.—A facility described in subsection
17 (a) that also manufactures or processes cosmetic products
18 that are not subject to the requirements of chapter V shall
19 not be exempt from the requirements of sections 605, 606,
20 607, 608, 609(a), 610, and 611, with respect to such cos-
21 metic products.

22 **“SEC. 614. PREEMPTION.**

23 “(a) IN GENERAL.—No State or political subdivision
24 of a State may establish or continue in effect any law,
25 regulation, order, or other requirement for cosmetics that

1 is different from or in addition to, or otherwise not iden-
2 tical with, any requirement applicable under this chapter
3 with respect to registration and product listing, good man-
4 ufacturing practice, records, recalls, adverse event report-
5 ing, or safety substantiation.

6 “(b) LIMITATION.—Nothing in the amendments to
7 this Act made by the Modernization of Cosmetics Regula-
8 tion Act of 2022 shall be construed to preempt any State
9 statute, public initiative, referendum, regulation, or other
10 State action, except as expressly provided in subsection
11 (a). Notwithstanding subsection (a), nothing in this sec-
12 tion shall be construed to prevent any State from prohib-
13 iting the use or limiting the amount of an ingredient in
14 a cosmetic product, or from continuing in effect a require-
15 ment of any State that is in effect at the time of enact-
16 ment of the Modernization of Cosmetics Regulation Act
17 of 2022 for the reporting to the State of an ingredient
18 in a cosmetic product.

19 “(c) SAVINGS.—Nothing in the amendments to this
20 Act made by the Modernization of Cosmetics Regulation
21 Act of 2022, nor any standard, rule, requirement, regula-
22 tion, or adverse event report shall be construed to modify,
23 preempt, or displace any action for damages or the liabil-
24 ity of any person under the law of any State, whether stat-
25 utory or based in common law.

1 “(d) **RULE OF CONSTRUCTION.**—Nothing in this sec-
2 tion shall be construed to amend, expand, or limit the pro-
3 visions under section 752.”.

4 **SEC. 3503. ENFORCEMENT AND CONFORMING AMEND-**
5 **MENTS.**

6 (a) **IN GENERAL.**—

7 (1) **PROHIBITED ACTS.**—Section 301 of the
8 Federal Food, Drug, and Cosmetic Act (21 U.S.C.
9 331), as amended by section 3210, is further
10 amended—

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

12 “(hhh) The failure to register or submit listing infor-
13 mation in accordance with section 607.

14 “(iii) The refusal or failure to follow an order under
15 section 611.”; and

16 (B) in paragraph (d), by striking “or 564”
17 and inserting “, 564, or 607”.

18 (2) **ADULTERATED PRODUCTS.**—Section 601 of
19 the Federal Food, Drug, and Cosmetic Act (21
20 U.S.C. 361) is amended by adding at the end the
21 following:

22 “(f) If it has been manufactured or processed under
23 conditions that do not meet the good manufacturing prac-
24 tice requirements of section 606.

3607

1 “(g) If it is a cosmetic product, and the cosmetic
2 product, including each ingredient in the cosmetic product,
3 does not have adequate substantiation for safety, as de-
4 fined in section 608(c).”.

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

8 (A) by striking “and (2)” and inserting
9 “(2)”; and

10 (B) by inserting after “numerical count”
11 the following: “; and (3) the information re-
12 quired under section 609”.

13 (4) ADVERSE EVENT REPORTING.—The Federal
14 Food, Drug, and Cosmetic Act (21 U.S.C. 301 et
15 seq.) is amended—

16 (A) in section 301(e) (21 U.S.C. 331(e))—

17 (i) by striking “564, 703” and insert-
18 ing “564, 605, 703”; and

19 (ii) by striking “564, 760” and insert-
20 ing “564, 605, 611, 760”;

21 (B) in section 301(ii) (21 U.S.C.
22 331(ii))—

23 (i) by striking “760 or 761) or” and
24 inserting “604, 760, or 761) or”; and

3608

1 (ii) by inserting “or required under
2 section 605(a)” after “report (as defined
3 under section 760 or 761”;

4 (C) in section 801(a) (21 U.S.C. 381(a))—

5 (i) by striking “under section 760 or
6 761” and inserting “under section 605,
7 760, or 761”;

8 (ii) by striking “defined in such sec-
9 tion 760 or 761” and inserting “defined in
10 section 604, 760, or 761”;

11 (iii) by striking “of such section 760
12 or 761” and inserting “of such section
13 605, 760, or 761”; and

14 (iv) by striking “described in such
15 section 760 or 761” and inserting “de-
16 scribed in such section 605, 760, or 761”;
17 and

18 (D) in section 801(b) (21 U.S.C.
19 381(b))—

20 (i) by striking “requirements of sec-
21 tions 760 or 761,” and inserting “require-
22 ments of section 605, 760, or 761”;

23 (ii) by striking “as defined in section
24 760 or 761” and inserting “as defined in
25 section 604, 760, or 761”; and

3609

1 (iii) by striking “with section 760 or
2 761” and inserting “with section 605, 760,
3 or 761”.

4 (b) EFFECTIVE DATES.—

5 (1) IN GENERAL.—The amendments made by
6 subsection (a) shall take effect on the date that is
7 1 year after the date of enactment of this Act.

8 (2) LABELING REQUIREMENT.—Section 609(a)
9 of the Federal Food, Drug, and Cosmetic Act, as
10 added by section 802, shall take effect on the date
11 that is 2 years after the date of enactment of this
12 Act.

13 (c) CONFIDENTIALITY.—

14 (1) IN GENERAL.—The Secretary shall take ap-
15 propriate measures to ensure that there are in effect
16 effective procedures to prevent the unauthorized dis-
17 closure of any trade secret or confidential commer-
18 cial information that is obtained by the Secretary of
19 Health and Human Services pursuant to this sub-
20 title, including the amendments made by this sub-
21 title.

22 (2) CLARIFICATION.—Nothing in this subtitle,
23 including the amendments made by this subtitle,
24 shall be construed to authorize the disclosure of in-
25 formation that is prohibited from disclosure under

3610

1 section 301(j) of the Federal Food, Drug, and Cos-
2 metic Act (21 U.S.C. 331(j)) or section 1905 of title
3 18, United States Code, or that is subject to with-
4 holding under section 552(b)(4) of title 5, United
5 States Code.

6 **SEC. 3504. RECORDS INSPECTION.**

7 Section 704(a)(1) of the Federal Food, Drug, and
8 Cosmetic Act (21 U.S.C. 374(a)(1)) is amended by insert-
9 ing after the second sentence the following: “In the case
10 of a facility (as defined in section 604) that manufactures
11 or processes cosmetic products, the inspection shall extend
12 to all records and other information described in sections
13 605, 606, and 610, when the standard for records inspec-
14 tion under such section applies.”.

15 **SEC. 3505. TALC-CONTAINING COSMETICS.**

16 The Secretary of Health and Human Services—

17 (1) not later than one year after the date of en-
18 actment of this Act, shall promulgate proposed regu-
19 lations to establish and require standardized testing
20 methods for detecting and identifying asbestos in
21 talc-containing cosmetic products; and

22 (2) not later than 180 days after the date on
23 which the public comment period on the proposed
24 regulations closes, shall issue such final regulations.

3611

1 SEC. 3506. PFAS IN COSMETICS.

2 (a) IN GENERAL.—The Secretary of Health and
3 Human Services (referred to in this section as the “Sec-
4 retary”) shall assess the use of perfluoroalkyl and
5 polyfluoroalkyl substances in cosmetic products and the
6 scientific evidence regarding the safety of such use in cos-
7 metic products, including any risks associated with such
8 use. In conducting such assessment, the Secretary may,
9 as appropriate, consult with the National Center for Toxi-
10 cological Research.

11 (b) REPORT.—Not later than 3 years after enactment
12 of this Act, the Secretary shall publish on the website of
13 the Food and Drug Administration a report summarizing
14 the results of the assessment conducted under subsection
15 (a).

16 SEC. 3507. SENSE OF THE CONGRESS ON ANIMAL TESTING.

17 It is the sense of the Congress that animal testing
18 should not be used for the purposes of safety testing on
19 cosmetic products and should be phased out with the ex-
20 ception of appropriate allowances.

21 SEC. 3508. FUNDING.

22 There is authorized to be appropriated \$14,200,000
23 for fiscal year 2023, \$25,960,000 for fiscal year 2024, and
24 \$41,890,000 for each of fiscal years 2025 through 2027,
25 for purposes of conducting the activities under this sub-
26 title (including the amendments made by this subtitle) and

3612

- 1 hiring personnel required to carry out this subtitle (includ-
- 2 ing the amendments made by this subtitle).