Modernization of Cosmetic Regulations Act 2022

A Review and Practical Advice

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President

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On December 29, 2022, President Biden signed into law the omnibus “Consolidated Appropriations Act, 2023

Which included

"Modernization of Cosmetics Regulation Act of 2022".

Definitions

- ADVERSE EVENT.

The term 'adverse event' means any health-related event associated with the use of a cosmetic product that is adverse.

- COSMETIC PRODUCT

The term 'cosmetic product' means a preparation of cosmetic ingredients with a qualitatively and quantitatively set composition for use in a finished product.

- SAFE.-The term 'safe' means that the cosmetic product, including any ingredient thereof, is not injurious to users under the conditions of use prescribed in the labeling thereof,
  or under such conditions of use as are customary or usual. The Secretary shall not consider a cosmetic ingredient or cosmetic product injurious to users solely because it can cause minor and transient reactions or minor and transient skin irritations in some users. In determining for purposes of this section whether a cosmetic product is safe, the secretary may consider, as appropriate and available, the cumulative or other relevant exposure to the cosmetic product, including any ingredient thereof.

FACILITY.

"(A) IN GENERAL.-The term 'facility' includes any establishment (including an establishment of an importer) that manufactures or processes cosmetic products distributed in the United States.

"(B) Such term does not include any of the following:

"(i) Beauty shops and salons, unless such establishment manufactures or processes cosmetic products at that location.

"(ii) Cosmetic product retailers, in- eluding individual sales representatives, direct sellers (as defined m section) 3508(b)(2) of the Internal Revenue Code of 1986), retail distribution facilities, and pharmacies, unless such establishment manufactures or processes cosmetic products that are not sold directly to consumers at that location.

"(iii) Hospitals, physicians' offices, and health care clinics.

"(iv) Public health agencies and other nonprofit entities that provide cosmetic products directly to the consumer.

"(v) Entities (such as hotels and air lines) that provide complimentary cosmetic products to customers incidental to other schemes.

"(vi) Trade shows and other venues where cosmetic product samples are provided free of charge.

"(vii) An establishment that manufactures or processes cosmetic products that are solely for use in research or evaluation, including for production testing and not offered for retail sale.

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

"(I) Labeling. "(II) Relabeling. "(III) Packaging.

An establishment that manufactures or processes cosmetic products that are solely for use in research or evaluation, including for production testing and not offered for retail

sale.

An establishment that solely performs one or more of the following with respect to cosmetic products:

"(I) Labeling. "(II) Relabeling. "(III) Packaging.

"(IV) Repackaging. "(V) Holding.

"(VI) Distributing.

CLARIFICATION.-For the purposes of subparagraph (B)(viii), the terms 'packaging' and 'repackaging' do not include filling a product container with a cosmetic product.

RESPONSIBLE PERSON.-The term 'responsible person' means the manufacturer, packer, or distributor of a cosmetic product whose name appears on the label of such cosmetic product in accordance with section 609(a) of this Act or section of the Fair Packaging and Labeling Act.

- SERIOUS ADVERSE EVENT. The term 'serious adverse event' means an adverse event
  That results in
    (i) death;
    (ii) a life-threatening experience; “
    (iii) inpatient hospitalization;
    (iv) a persistent or significant dis- ability or incapacity;
    (v) a congenital anomaly or birth defect;
    (vi) an infection
    (vii) significant disfigurement (including serious and persistent rashes, second- or third-degree burns, significant hair loss, or persistent or significant alteration of appearance), other than as in tended, under conditions of use that are customary or usual;
    "(B) requires, based on reasonable medical judgment, a medical or surgical intervention to prevent an outcome described in subparagraph (A).

- Must be reported within 15 days
  - Through the FDA MedWatch site MedWatch Online Voluntary Reporting Form (fda.gov)
  - Followed for 1 year with all new medical information
  - Exemptions are possible
  - Reported through the responsible person (domestic address, phone number, website)

MAINTENANCE AND INSPECTION OF ADVERSE EVENT RECORDS

- Maintenance of **all** adverse events
  - Six years
- Small business (under $1M average revenue over three years)
  - Three years
- Consider a SOP on complaints and AE's

- lNSPECTION

The responsible person shall permit an authorized person to have access to records required to be maintained under this section during an inspection

- FRAGRANCE AND FLAVOR INGREDIENTS.-If the Secretary has reasonable grounds to believe that an ingredient or combination of ingredients in a fragrance or flavor has caused or contributed to a serious adverse event required to be reported under this section, the Secretary may request in writing a list of such ingredients or categories of ingredients in the specific fragrances or flavors in the cosmetic product, from the responsible person. The responsible person shall ensure that the requested information is submitted to the Secretary within 30 days of such request. fu response to a request under section 552 of title 5, United States Code, information submitted to the Secretary under this subsection shall be withheld under section 552(b)(3) of title 5, United States Code.

- IN GENERAL.-Nothing in this section shall affect the authority of the Secretary to provide adverse event reports and information to any health, food, or drug officer or employee of any State, territory, or political subdivision of a State or territory, under a memorandum of understanding between the Secretary and such State, territory, or political sub-division.

  - Possible starting point for state bans of chemicals
  - Passible starting point for class actions

- The Secretary shall by regulation establish good manufacturing practices for facilities

- ANPR within two years of enactment of MoCRA

- Consistent, to the extent practicable, and appropriate, with national and international standards, in accordance with section 601. .Any such regulations shall be intended to protect the public health and ensure that cosmetic products are not adulterated. Such regulations may allow for the Secretary to inspect records necessary to demonstrate compliance with good manufacturing practices prescribed by the Secretary under this paragraph during an inspection conducted under section 704.
    - May be ISO 22716
    - May be an adaptation of GMP's for
        - Drug
        - Foods
        - Dietary supplement
- Such regulations shall include simplified good manufacturing practice requirements for smaller businesses, as appropriate, to ensure that such regulations do not impose undue economic hardship for smaller businesses, and may include longer compliance times for smaller business

REGISTRATION AND PRODUCT LISTING.

SUBMISSION OF REGISTRATION.- " INITIAL REGISTRATION.-

- "EXISTING FACILITIES.-Every person that, on the date of enactment of the Modernization of Cosmetics Regulation Act of 2022, owns or operates a facility that engages in the manufacturing or processing of a cosmetic product for distribution in the United States shall register each facility with the Secretary not later than 1 year after date of enactment of such Act.
- "NEW FACILITIES.-Every person that owns or operates a facility that first engages, after the date of enactment of the Modernization of Cosmetics Regulation Act of 2022, in manufacturing or processing of a cosmetic product for distribution in the United States, shall register with the Secretary such facility within 60 days of first engaging in such activity

- Biannual registration renewal
- Contract manufacturers single registration
- Updates to registrations within 60 days of any changes

- ~~VCRP~~
  - Closed 3/27/2023
    - Creating a new system

CONTENTS OF REGISTRATION

Registration information under this section may be submitted at such time and in such manner as the Secretary may prescribe. “

CONTENTS

- The facility's name, physical address, email address, and telephone number;
- Foreign facility, the contact for the United States agent of the facility, and, if available, the electronic contact information
- Facility registration number, if any, previously assigned by the Secretary
- All brand names under which cosmetic products manufactured or processed in
- the facility are sold; and
- The product category or categories and responsible person for each cosmetic product manufactured or processed at the facility.

COSMETIC PRODUCT LISTING

- For each cosmetic product, the responsible person shall submit to the cosmetic product listing, or ensure that such submission is made

- The responsible person of a cosmetic product that is marketed on the date of enactment of the Modernization of Cosmetics Regulation Act of 2022 shall submit to the Secretary a cosmetic product listing not later than 1 year after the of enactment of the Modernization of Cosmetics Regulation Act of 2022,

- A cosmetic product that is first marketed after the date of enactment of such Act, within 120 days of marketing such product in interstate commerce.

- Updates to listing shall be made annually
- An abbreviated process for the renewal of any cosmetic product listing to which there has been no change since the responsible person submitted the previous listing.

CONTENTS OF LISTING

- Each cosmetic product listing shall include

The facility registration number of each facility where the cosmetic product is manufactured or processed;

- The name and contact number of the responsible person and the name for the cosmetic product, as such name appears on the label
- The applicable cosmetic category or categories for the cosmetic product;
- A list of ingredients in the cosmetic product, including any fragrances, flavors, or colors, with each ingredient identified by the name, as required under section 701.3 (INCI) or by the common or usual name of the ingredient
- The product listing number, if any previously assigned by the Secretary under

FLEXIBLE LISTINGS

- A single listing submission for a cosmetic product may include multiple cosmetic products with identical formulations, or formulations that differ only with respect to colors, fragrances or flavors, or quantity of contents.

- Annual updates to listing

- "(1) SUSPENSION OF REGISTRATION OF A FACILITY.-The Secretary may suspend the registration of a facility if the Secretary determines that a cosmetic product manufactured or processed by a registered facility and distributed in the United States has a reasonable probability of causing serious adverse health consequences or death to humans and the Secretary has a reasonable belief that other products manufactured or processed by the facility may be similarly affected because of a failure that cannot be isolated to a product or products, or is sufficiently pervasive to raise concerns about other products manufactured in the facility.

- RP has 5 days to submit corrections
  - Informal hearing
- 14 Days to submit CAPA

- GMP's could indite all products at a manufacturer
- Ingredient concern could spark audits at multiple manufacturers

SAFETY SUBSTANTIATION.

(a) SUBSTANTIATION OF SAFETY.-A responsible person for a cosmetic product shall ensure, and maintain records supporting, that there is adequate substantiation of safety of such cosmetic product.
(b) COAL-TAR HAIR DYE.-Subsection (a) shall not apply to coal-tar hair dye that otherwise complies with the requirements of section 601(a). A responsible person for a coal-tar hair dye shall maintain records related to the safety of such product.

(c) DEFINITIONS.-For purposes of this section:
(1) ADEQUATE SUBSTANTIATION OF SAFETY.-The term 'adequate substantiation of safety' means tests or studies, research, analyses, or other evidence or information that is considered, among experts qualified by scientific training and experience to evaluate the safety of cosmetic products and their ingredients, sufficient to support a **reasonable certainty** that a cosmetic product is safe.

- TRA
  - No official serial review of ingredients
- Testing
  - HRIPT
  - PET
  - Safety in-USE

"SEC. 609. LABELING.

"(a) GENERAL REQUIREMENT.-Each cosmetic product shall bear a label that includes a domestic address, domestic phone number, or electronic contact information, which may include a website, through which the responsible person can receive adverse event reports with respect to such cosmetic product.

"(b) FRAGRANCE ALLERGENS.-The responsible person shall identify on the label of a cosmetic product each fragrance allergen included in such cosmetic product. Substances that are fragrance allergens for purposes of this subsection shall be determined by the Secretary by regulation. The Secretary shall issue a notice of proposed rule- making promulgating the regulation implementing this requirement not later than 18 months after the date of enactment of the Modernization of Cosmetics Regulation Act of 2022, and not later than 180 days after the date on which the public comment period on the proposed rulemaking closes, shall issue a final rulemaking. In promulgating regulations implementing this subsection, the Secretary shall consider international, State, and local requirements for allergen disclosure, including the substance and format of requirements in the European Union and may establish threshold levels of amounts of substances subject to disclosure pursuant to such regulations.

"(c) COSMETIC PRODUCTS FOR PROFESSIONAL USE.-

"(1) DEFINITION OF PROFESSIONAL.-For purposes of this subsection, the term 'professional' means an individual who is licensed by an official State authority to practice in the field of cosmetology, nail care, barbering, or esthetics.

"(2) PROFESSIONAL USE LABELING.-A cosmetic product introduced into interstate commerce and intended to be used only by a professional shall bear a label that-

"(A) contains a clear and prominent statement that the product shall be administered or used only by licensed professionals; and

"(B) is in conformity with the requirements of the Secretary for cosmetics labeling under this Act and section 4(a) of the Fair Packaging and Labeling Act.

- Professional product will now need all labeling requirements

"SEC. 610. RECORDS.

"(a) IN GENERAL.-If the Secretary has a reasonable belief that a cosmetic product, including an ingredient in such cosmetic product, and any other cosmetic product that the Secretary reasonably believes is likely to be affected in a similar manner, is likely to be adulterated such that the use or exposure to such product presents a threat of serious adverse health consequences or death to humans, each responsible person and facility shall, at the re- quest of an officer or employee duly designated by the Secretary, permit such officer or employee, upon presentation of appropriate credentials and a written notice to such person, at reasonable times and within reasonable limits and in a reasonable manner, to have access to and copy all records relating to such cosmetic product, and to any other cosmetic product that the Secretary reasonably believes is likely to be affected in a similar manner, that are needed to assist the Secretary in determining whether the cosmetic product is adulterated and presents a threat of serious adverse health consequences or death to hu- mans. This subsection shall not be construed to extend to recipes or formulas for cosmetics, financial data, pricing data, personnel data (other than data as to qualification of technical and professional personnel performing functions subject to this Act), research data (other than safety substantiation data for cosmetic products and their ingredients), or sales data (other than shipment data regarding sales).

- Inspection right to conceivably everything!
  - GMP
  - Ingredient issues

"SEC. 611. MANDATORY RECALL AUTHORITY.

"(a) IN GENERAL.-If the Secretary determines that there is a reasonable probability that a cosmetic is adulterated under section 601 or misbranded under section 602 and the use of or exposure to such cosmetic will cause serious adverse health consequences or death, the Secretary shall provide the responsible person with an opportunity to voluntarily cease distribution and recall such article. If the responsible person refuses to or does not voluntarily cease distribution or recall such cosmetic within the time and manner prescribed by the Secretary (if so prescribed), the Secretary may, by order, require, as the Secretary determines necessary, such person to immediately cease distribution of such article.

"(b) HEARING.-The Secretary shall provide the responsible person who is subject to an order under subsection (a) with an opportunity for an informal hearing, to be held not later than 10 days after the date of issuance of the order, on whether adequate evidence exists to justify the order.

- Depending on circumstances
  - Revocation of listing
  - Revocation of registration
    - GMP

"(f) PUBLIC NOTIFICATION.-ln conducting a recall under this section, the Secretary shall-
"(1) ensure that a press release is published regarding the recall, and that alerts and public notices are issued, as appropriate, in order to provide notification“

(A) of the recall to consumers and retailers to whom such cosmetic was, or may have been, distributed; and
(B) that includes, at a minimum the name of the cosmetic subject to the recall;
a description of the risk associated with such article; and to the extent practicable, information for consumers about similar cosmetics that are not affected by the recall; and ensure publication, as appropriate, on the website of the Food and Drug Administration of an image of the cosmetic that is the subject of the press release described in paragraph (1), if available.

- Brand damage
- Food for the class action lawyers

"SEC. 612. SMALL BUSINESSES.

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

- 606
  - GMP

- 607
  - Registration
  - Listing

The exemptions shall not apply to any responsible person or facility engaged in the manufacturing or processing of any of the following products:

(1) Cosmetic products that regularly come into contact with mucus membrane of the eye under conditions of use that are customary or usual.

(2) Cosmetic products that are injected.

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

(4) Cosmetic products that are intended to alter appearance for more than 24 hours under conditions of use that are customary or usual and removal by the consumer is not part of such conditions of use that are customary or usual.

"SEC. 614. PREEMPTION.

"(a) IN GENERAL.-No State or political subdivision of a State may establish or continue in effect any law, regulation, order, or other requirement for cosmetics that is different from or in addition to, or otherwise not identical with, any requirement applicable under this chapter with respect to registration and product listing, good manufacturing practice, records, recalls, adverse event reporting, or safety substantiation.

"(b) LIMITATION.-Nothing in the amendments to this Act made by the Modernization of Cosmetics Regulation Act of 2022 shall be construed to preempt any State statute, public initiative, referendum, regulation, or other State action, except as expressly provided in subsection

(a). Notwithstanding subsection (a), nothing in this section shall be construed to prevent any State from prohibiting the use or limiting the amount of an ingredient in a cosmetic product, or from continuing in effect a requirement of any State that is in effect at the time of enactment of the Modernization of Cosmetics Regulation Act of 2022 for the reporting to the State of an ingredient in a cosmetic product.

- State laws already in place are here to stay!!!!!!
- State ingredient bans and limitations will continue
  - Over 11 states have bills limiting chemicals
  - NY&CA lead the list

For the Class action lawyers:

Nothing in the amendments to this Act made by the Modernization of Cosmetics Regulation Act of 2022, nor any standard, rule, requirement, regulation, or adverse event report shall be construed to modify, preempt, or displace any action for damages or the liability of any person under the law of any State, whether statutory or based in common law.

(c) CONFIDENTIALITY.-

(1) IN GENERAL.-The Secretary shall take appropriate measures to ensure that there are in effect effective procedures to prevent the unauthorized disclosure of any trade secret or confidential commercial information that is obtained by the Secretary of Health and Human Services pursuant to this subtitle, including the amendments made by this subtitle.

SEC.3504. RECORDS INSPECTION.

Section 704(a)(1) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 374(a)(1)) is amended by inserting after the second sentence the following: "In the case of a facility (as defined in section 604) that manufactures or processes cosmetic products, the inspection shall extend to all records and other information described in sections 605, 606, and 610, when the standard for records inspection under such section applies."

- 605
  - Adverse events
- 606
  - GMP
- 610
  - Records
    - A bit redundant

SEC.3505. TALC-CONTAINING COSMETICS.
The Secretary of Health and Human Services-
(1) not later than one year after the date of enactment of this Act, shall promulgate proposed regulations to establish and require standardized testing methods for detecting and identifying asbestos in talc-containing cosmetic products; and
(2) not later than 180 days after the date on which the public comment period on the proposed regulations closes, shall issue such final regulations.

SEC.3506. PFAS IN COSMETICS.
(a) IN GENERAL.-The Secretary of Health and Human Services (referred to in this section as the "Secretary'') shall assess the use of perfluoroalkyl and polyfluoroalkyl substances in cosmetic products and the scientific evidence regarding the safety of such use in cosmetic products, including any risks associated with such use. In conducting such assessment, the Secretary may, as appropriate, consult with the National Center for Toxicological Research.
(b) REPORT .-Not later than 3 years after enactment of this .Act, the Secretary shall publish on the website of the Food and Drug .Administration a report summarizing the results of the assessment conducted under subsection (a).

SEC. 3507. SENSE OF THE CONGRESS ON ANIMAL TESTING.
It is the sense of the Congress that animal testing should not be used for the purposes of safety testing on cosmetic products and should be phased out with the exception of appropriate allowances.

Timeline

MoCRA	Timeline
Enactment	December 29, 2022
Active	December 29, 2023
Proposed fragrance allergen list	June 29, 2024
Labelling requirements	December 29, 2024
Cosmetic GMP's proposed	December 29, 2024
GMP final rule publication	December 29, 2025
Release of PFAS report	December 29, 2025

FDA announced a proposal that will include moving cosmetics regulation and color certification functions out of CFSAN and into the Office of the Chief Scientist. This proposed move will better align the expertise of the agency's cosmetics subject matter experts with the Chief Scientist who is focused on research, science, and innovation that underpins the agency's regulatory mission, and recognize the evolution and innovation in this product space. Further, this shift will leverage the FDA's areas of expertise across the agency as it works to implement MoCRA

Questions ?

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