Bureau Veritas Bulletin

United States Cosmetic Regulations Get Major Updates

After years of effort from the cosmetic industry, the Modernization of Cosmetics Regulations Act of 2022 (MoCRA) was signed into law on December 29, 2022 as part of the Consolidated Appropriations Act. MoCRA is the first major update to cosmetic regulations in the United States since the Federal Food, Drug, and Cosmetic Act became law in 1938.

The Modernization of Cosmetics Regulations Act of 2022 (MoCRA) includes a few new important definitions:

- **Facility**
  - "The term 'facility' includes any establishment (including an establishment of an importer) that manufacturers or processes cosmetic products distributed in the United States."
  - Exemptions include, but are not limited to:
    - Cosmetic product retailers, including individual sales representatives, direct sellers (as defined in section 3508(b)(2) of the IRS 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
    - Entities (such as hotels and airlines) that provide complementary cosmetic products to customers incidental to other services
    - Trade shows and other venues where cosmetic product samples are provided free of charge
    - An establishment that solely performs one or more of the following with respect to cosmetic products: Labeling, Relabeling, Packaging, Repackaging, Holding, Distributing (note: 'packaging' and 'repackaging' do not include filling a product container with a cosmetic product)

- **Responsible Person**
  - "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) [adverse event report labeling requirement] of this Act or section 4(a) of the Fair Packaging and Labeling Act."

As part of the overhaul of the Cosmetic Regulations, MoCRA includes the following new requirements for cosmetic products:

1) Mandatory serious adverse event reporting (Sec. 605 Adverse Events)

The responsible person shall submit to the FDA any report received of a serious adverse event associated with the use, in the United States, of a cosmetic product manufactured, packed, or distributed by such person within 15 business days of receipt.

The responsible person shall receive reports of adverse events through the domestic address, domestic telephone number, or electronic contact information on the label (see new labeling requirements information below).

Additionally, the responsible person shall maintain records relating to each adverse event report received for a period of 6 years, except small businesses shall maintain records for 3 years.

If the FDA suspects that the serious adverse event was due to a fragrance or flavor ingredient, they may request a list of substances in the fragrance or flavor ingredient.

2) Cosmetic Good Manufacturing Practices (GMPs) (Sec. 606 Good Manufacturing Practice)

The FDA shall propose for rulemaking Good Manufacturing Practices (GMPs) for cosmetic facilities within 2 years of the enactment of MoCRA (December 29, 2024) and finalize the requirements no later than December 29, 2025. The GMPs shall be as consistent as practicable with existing national and international standards. Also, when developing the GMP requirements, the FDA shall also take into consideration the size and scope of manufacturers and the potential risk to public health.

Once effective, cosmetic products manufactured at a facility that does not meet the GMP requirements will be deemed adulterated.

3) Facility registration (Sec. 607 Registration and Product Listing)

Existing Facilities: Every person that owns or operates a facility that manufactures or processes a cosmetic product for distribution in the US shall register each facility with the FDA by December 29, 2023.

New Facilities: Every person that owns or operates a facility that first engages in manufacturing or processing of a cosmetic product for distribution in the US after December 29, 2022, shall register with the FDA within 60 days of first engaging in such activity or 60 days after December 29, 2023, whichever is later.

It should be noted foreign facilities must have contact information for a US agent and, if available, electronic contact information. Registration is required biennially. However, the facility may need to notify the FDA within 60 days if information changes. When facility registration is complete, the FDA will issue a facility registration number.

The FDA can suspend registration of a facility if it is determined that a cosmetic product manufactured or processed by the facility and distributed in the US has reasonable probability of a serious adverse health consequence. Facilities that have their registration suspended are not permitted to introduce or deliver for introduction cosmetic products in the US.

4) Cosmetic product listing (Sec. 607 Registration and Product Listing)

The responsible person shall submit a list of cosmetic products on the market as of December 29, 2022 to the FDA by December 29, 2023. Cosmetic products first marketed after December 29, 2022 shall have 120 days to notify the FDA.

The cosmetic product listing shall include information such as identifying 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 cosmetic category or categories for the cosmetic product, and a list of ingredients in the cosmetic product. The FDA will assign a product listing number to each cosmetic product. Although, a single listing submission may be used for multiple cosmetic products with identical formulations or formulations that differ only by color, fragrance, flavors, or net quantity. Updates to cosmetic product listings shall be submitted annually.

5) Safety Substantiation (Sec. 608 Safety Substantiation)

“A responsible person for a cosmetic product shall ensure, and maintain records supporting, that there is adequate substantiation of safety of such cosmetic product.”

“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.”

It should be noted that a product is not considered unsafe “solely because it can cause minor and transient reactions or minor and transient skin irritations in some users.”

The safety substantiation requirements do not apply to coal-tar hair dyes that are compliant with the requirements in section 601(a) of the cosmetic requirements. However, “a responsible person for a coal-tar hair dye shall maintain records related to the safety of such product.”

6) New labeling requirements (Sec. 609 Labeling)

(a) “Each cosmetic product shall bear on the 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) The label of a cosmetic product shall identify the fragrance allergens included in the product. The FDA shall propose rulemaking identifying substances considered fragrance allergens within 18 months (June 29, 2024) and shall finalize the rulemaking 180 days after the comment period closes.

(c) Cosmetics for professional use only shall have a clear and prominent statement that the product is intended for use only by licensed professionals. Also, professional use cosmetics shall include all the labeling information that is required on consumer use cosmetic products. This means that professional use cosmetics will require an ingredient list required under the Fair Packaging and Labeling Act (FPLA), among other requirements.

If a cosmetic does not meet these new labeling requirements, the product would be considered misbranded.

7) Record Access (Sec. 610 Records)

If the FDA has a reasonable belief that a cosmetic product, including an ingredient in a cosmetic product, is likely to be adulterated and could cause a serious adverse health consequence, they may request records from the facility and responsible person.

8) Mandatory recall authority (Sec. 611 Mandatory Recall Authority)

If the FDA determines that a cosmetic is adulterated or misbranded and the use of the product will cause serious adverse health consequences, the FDA shall request that the responsible person voluntarily cease distribution and recall the product. However, if the responsible person does not voluntarily cease distribution or recall the product within a timely manner, the FDA can mandate that the person immediately cease distribution and recall the product.

Small Business Exemptions (Sec. 612 Small Businesses)

Small businesses with less than $1,000,000 average gross sales for the previous 3-year period are exempt from the GMP, facility registration, and cosmetic product listing requirements. However, small businesses that manufacture cosmetics that come into contact with the mucous membrane of the eye under customary use, cosmetics that are injected, cosmetics intended for internal use, or cosmetics that alter the appearance for more than 24 hours under customary conditions of use do not fall under the exemption.

Cosmetic / Drug Exemptions (Sec. 613 Exemption for Certain Products and Facilities)

Facilities that only manufacture products that are classified as both a cosmetic and a drug are exempt from many of the requirements, except for the fragrance allergen and professional use labeling. However, if a facility manufactures products that are only classified as a cosmetic and products that are cosmetic / drugs, the cosmetic products need to meet the applicable cosmetic requirements.

Preemption (Sec. 614 Preemption)

MoCRA includes a preemption clause for registration and product listing, GMPs, records, recall, adverse event reporting, and safety substantiation. However, it should be noted that the preemption clause does not prohibit states from prohibiting or restricting the use of certain ingredients in cosmetic products and states can still require the reporting of cosmetic ingredients.

Effective Dates (Sec. 3503(b) Enforcement and Conforming Amendments)

- Unless otherwise stated, the new requirements take effect in one year (December 29, 2023)
- The requirement under Section 609(a) described above, requiring the label to bear the responsible persons contact information for adverse event reporting shall take effect in 2 years (December 29, 2024).

Additional Provisions (Sec. 3505 – Sec. 3507)

MoCRA also included provisions requiring the FDA to develop and propose a standardized test for detecting asbestos in talc-based cosmetics within one year (December 29, 2023) and finalize the rule within 180 days of closing the comment period.

The FDA shall also conduct a safety assessment of PFAS in cosmetics and issue a report no later than three years after the enactment of this Act (December 29, 2025).

Lastly, the Act states, “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.” It should be noted that multiple states have banned the use of animal testing for cosmetic safety substantiation and several states have proposed bills banning cosmetic animal testing.

Link to Consolidated Appropriations Act: https://www.congress.gov/bill/117th-congress/house-bill/2617

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