

Cosmetics – Moving From Voluntary Compliance to Mandatory Regulation



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Compared to drugs and even food, cosmetics have been the regulatory stepchild in the Federal Food, Drug, and Cosmetic Act (FFDCA) since its adoption in 1938 – until now. At the end of 2022, Congress enacted legislation to mandate that cosmetic product manufacturers and processors take certain actions that the Food and Drug

Administration (FDA) has encouraged them to take for years but for which it had no enforcement authority. Cosmetic producers beware: Increased regulation is coming by the end of 2023. Get ready now.

The Basics

The Modernization of Cosmetics Regulation Act of 2022 (MoCRA) was tucked into the omnibus appropriations bill passed at the end of December. MoCRA appears as Subtitle E of Title II of Division H of the 1,653-page Consolidated Appropriations Act, 2023, [Public Law 117-328](#) (Dec. 29, 2022), beginning at section 3501.

The passage of MoCRA as part of the omnibus illustrates how difficult it has been to enact legislation to strengthen FDA’s authority over cosmetics. Since at least 2010, multiple Congresses have considered, but not enacted, cosmetic regulation bills. Legislation similar to MoCRA was introduced in [2017](#), [2019](#), and [2021](#). None passed, partly because of disputes between large and small cosmetic producers, and between the industry and NGOs.

Now, however, Congress has enacted MoCRA, legislation that reflects numerous compromises. Most provisions take effect one year from enactment, or by December 29, 2023. The new labeling requirement becomes effective one year later on December 29, 2024. (MoCRA § 3503(b))

MoCRA is mainly concerned with cosmetic products, a term defined to mean “a preparation of cosmetic ingredients with a qualitatively and quantitatively set composition for use in a finished product.” (FFDCA § 604(2)) In other words, a “cosmetic product” has been formulated but not necessarily packaged for retail sale. The term does not include chemicals intended for use in a cosmetic product. However, cosmetic ingredient suppliers can expect their customers to ask for help in compliance with some provisions.

Some MoCRA provisions apply to cosmetic product facilities. “Facility” refers to an establishment that manufactures or processes cosmetic products distributed in the U.S., including foreign establishments. (FFDCA § 604(3))

In brief, MoCRA amends the FFDCRA to add several new provisions:

- ◆ **Serious adverse event reporting** – It requires the person whose name appears on the label to submit a “serious adverse event report” within 15 business days after receiving the report. (FFDCA § 605)
- ◆ **Good manufacturing practices** – It directs FDA to adopt good manufacturing practice regulations by December 29, 2025. (FFDCA § 606)
- ◆ **Facility registration and product listing** – It requires manufacturers and processors to register their facilities with FDA and submit product lists to FDA. (FFDCA § 607)
- ◆ **Safety substantiation** – It requires the person whose name appears on a cosmetic product’s label to maintain records establishing that there is “an adequate substantiation of safety” for the product. (FFDCA § 608)
- ◆ **Labeling** – It mandates that certain information appears on the label. (FFDCA § 609)
- ◆ **Records inspection** – It authorizes FDA to inspect certain records. (FFDCA §§ 610 and 704)
- ◆ **Mandatory recall authority** – FDA is now authorized to order cosmetic product recalls in appropriate circumstances. (FFDCA § 611)
- ◆ **Exemptions** – Small businesses and certain facilities and products have limited exemptions. (FFDCA §§ 612 and 613)
- ◆ **Preemption** – MoCRA can preempt some state laws affecting cosmetics. (FFDCA § 614)
- ◆ **Talc and PFAS in Cosmetics** – It directs FDA to adopt standardized test methods for asbestos in talc-containing cosmetics, and to study PFAS in cosmetics. (MoCRA §§ 3505 and 3506)
- ◆ **Animal testing** – It provides the “sense of Congress” that animal testing of cosmetics should be phased out with “appropriate allowances.” (MoCRA § 3507)

In short, both FDA and cosmetic product manufacturers and processors have a lot of work to do. We understand that FDA is working on MoCRA implementation, but it has not yet commented on MoCRA on its website.

Serious Adverse Event Reporting

Adverse event reporting (AER) is an early warning system for potential public health issues associated with using FDA-regulated products. It also serves as a mechanism to track patterns of adulteration in FDA-regulated products that supports FDA efforts to target limited inspection resources to protect public health. Until now, FDA’s authority to require AER has been limited to prescription and non-prescription drugs, medical devices, biologics, dietary supplements, and food. With MoCRA, add cosmetics to that list.

FDA has a voluntary AER system for cosmetics. [MedWatch](#) allows health care professionals and consumers to submit reports to FDA regarding problems with FDA-regulated products, including cosmetics. It also allows cosmetic user facilities, importers, and manufacturers to report using [Form FDA 3500A](#).

FFDCA § 605 only mandates reporting of a serious adverse event. That term is defined to mean an adverse event (i.e., any adverse health-related event associated with use of a cosmetic) that results in death, life-threatening experience, in-patient hospitalization, persistent or significant disability or incapacity, congenital anomaly or birth defect, an infection, serious disfigurement, or requires a medical or surgical intervention to prevent such an outcome. (FFDCA § 604(1), (5)) The reporting obligation would

apply to any “responsible party,” including the manufacturer, packer, or distributor whose name appears on the cosmetic product’s label. (FFDCA §§ 604(4), 605(a))

Cosmetic product manufacturers and distributors may want to familiarize themselves with the MedWatch system, as the new system may be similar.

Good Manufacturing Practice Regulations

FDA has good manufacturing practice (GMP) regulations for other products it regulates. Without statutory authority to require GMPs for cosmetics, FDA has instead provided [voluntary cosmetic product GMP guidance](#) (2013, although still a draft).

FFDCA § 606 directs FDA to adopt mandatory GMP regulations for cosmetic products, with simplified requirements for smaller businesses. The regulations are to be generally consistent with national and international standards. Since the FDA voluntary GMP guidance is brief, cosmetic product manufacturers, processors, and distributors may want to review [ISO 22715:2006, Cosmetics – Packaging and labelling](#) (last reviewed and confirmed in 2022). This international standard has provisions on personnel, premises, raw materials, packaging materials, production, finished products, quality control laboratory, dealing with out-of-specification results, complaints, recalls, change control, internal audits, and documentation.

FDA must publish its proposed regulations by December 29, 2024, and its final regulations by December 29, 2025.

Facility Registration and Product Listing

FFDCA § 607(a) requires the owners and operators of existing cosmetic product facilities in the U.S. or that distribute to the U.S. to register with FDA by December 29, 2023. New facilities must be registered within 60 days of startup. Registrations will need to be renewed every two years, with changes to registration information to be reported within 60 days of the change. Registration will have significance since FDA can suspend a registration if it determines that the cosmetic products manufactured or processed at the facility may cause serious health consequences or death. A suspension would preclude the distribution of cosmetic products from that facility. (FFDCA § 607(f))

Since 1974, FDA has promoted a [Voluntary Cosmetic Registration Program](#). (21 C.F.R. Part 710) As the mandatory registration program is likely to be similar to the voluntary one, owners and operators of cosmetic product facilities in the U.S. or that distribute into the U.S. may want to review Part 710 and consider submitting [Form FDA 2511](#) to register their facilities, if they have not already done so.

FFDCA § 607(c) requires the responsible person for each cosmetic product currently marketed in the U.S. to list that product with FDA by December 29, 2023. New cosmetic products must be listed within 120 days of being marketed. Updated information must be submitted annually. Among other information, a product listing must include a list of ingredients, including fragrances, flavors, or colors, as provided in 21 C.F.R. § 701.3.

FDA’s Voluntary Cosmetic Registration Program includes voluntary product listing, referred to as voluntary filing of cosmetic product ingredient composition statements. (21 C.F.R. Part 720) As the mandatory product listing program is likely to be similar to the voluntary one, responsible persons may want to review Part 720 and consider submitting [Form FDA 2512](#) for their cosmetic products if they have not already done so.

Safety Substantiation

FDA regulations currently require safety substantiation:

Each ingredient used in a cosmetic product and each finished cosmetic product shall be adequately substantiated for safety prior to marketing. Any such ingredient or product whose safety is not adequately substantiated prior to marketing is misbranded unless it contains the following conspicuous statement on the principal display panel: "Warning – The safety of this product has not been determined."

21 C.F.R. § 740.10(a). FFDCRA § 608 will bolster that requirement.

It requires the responsible person for a cosmetic product to ensure adequate substantiation of the product's safety, and to maintain records supporting that substantiation. "Adequate substantiation of safety" refers to tests, studies, research, or other information that is considered, among qualified experts, to be sufficient to support a reasonable certainty that a cosmetic product is safe. (FFDCRA § 606(c)(1)) "Safe" means that the cosmetic product, including its ingredients, is not injurious to users under label conditions or customary or usual conditions. (FFDCRA § 606(c)(2)) Cosmetic ingredient suppliers may expect requests from cosmetic product manufacturers for substantiation of the safety of their ingredients.

The FFDCRA § 608 safety substantiation requirement takes effect on December 29, 2023. (MoCRA § 3503(b)(1)) Before that date, responsible persons should confirm that they have documentation to support that their cosmetic products have adequate substantiations of safety.

Labeling

FDA already has some labeling requirements for cosmetic products, 21 C.F.R. Part 701, and [cosmetics labeling guidance](#). FFDCRA § 609 supplements those requirements and that guidance. Labels meeting the new requirements are required for cosmetic products marketed on or after December 29, 2024. (MoCRA § 3503(b)(2))

The new label must:

- ◆ Include a domestic address and domestic phone number, or electronic contact information (which could be a website), through which the responsible person can receive adverse event reports for its cosmetic product. (FFDCRA § 609(a))
- ◆ Identify each fragrance allergen included in the cosmetic product, as determined by FDA by regulation. (FFDCRA § 609(b))
 - ◆ FDA must propose a regulation by June 29, 2024 and finalize it 180 days later (i.e., just before the labeling requirement's compliance date).
 - ◆ FDA currently identifies a number of fragrance allergens on its [website](#), which are taken from the EU's [Cosmetic Products Regulation](#).
 - ◆ In promulgating its regulation, FDA must consider international, state, and local allergen disclosure requirements, specifically including the EU requirements. Presumably, these also include California's Cosmetic Fragrance and Flavor Ingredient Right to Know Act of 2020, Cal. Health & Safety Code § 111792.6(b)(1), which refers to the EU list and requires disclosure to the California Department of Public Health. For information on this California requirement, see the [California Safe Cosmetics Program website](#).

- ◆ FDA may establish thresholds subject to disclosure. The California program requires disclosure of fragrance allergens if they are present in a rinse-off cosmetic product at a concentration at or above 0.01% (100 ppm) or in a leave-on cosmetic product at a concentration at or above 0.001% (10 ppm).
- ◆ MoCRA § 3503(c) directs FDA to take appropriate measures to prevent the unauthorized disclosure of trade secrets and confidential business information. It is unclear how this provision relates to the fragrance ingredient labeling requirement.
- ◆ Say that the product is for professional use only if it is intended only for use by licensed cosmetologists, nail care technicians, barbers, and/or estheticians. (FFDCA § 609(c))

Records

The Factory Inspection authority of FFDCA § 704 extends to cosmetic product facilities. MoCRA § 3504 amended FFDCA § 704 to specify that inspections “shall” cover records and other information related to serious adverse event reporting, GMPs, and records covered by FFDCA § 610.

FFDCA § 610 authorizes FDA to have access to all records related to cosmetic products and their ingredients which it reasonably believes may be adulterated to present a threat of serious adverse consequences or death.

This records access provision does not extend to recipes or formulas for cosmetics, financial data, pricing data, or personnel data (other than with respect to their qualifications), research data (other than safety substantiation data), or sales data (other than shipment data).

Mandatory Recall Authority

With FFDCA § 611, FDA now has recall authority for cosmetic products which it reasonably determines may be adulterated (including due to noncompliance with the new GMP or safety substantiation requirements) or misbranded (including due to noncompliance with the new labeling requirements). (MoCRA § 3503(a)(2), (3))

The provision lays out several procedural protections, including the requirement that FDA provide an opportunity for a voluntary recall.

Small Businesses and Other Exemptions

Under FFDCA § 612, with some exceptions, small businesses (those with gross annual sales less than \$1 million (adjusted for inflation)) are not subject to the GMP or facility registration and product listing requirements.

Under FFDCA § 613, cosmetic products that are also drugs are exempt from most MoCRA requirements. Facilities that manufacture or process cosmetic products subject to drug requirements are also exempt.

Preemption

MoCRA adds a new express preemption provision, FFDCA § 614(a). In general, no state or locality may impose any requirement for cosmetics regarding registration and product listing, GMPs, records, recalls, adverse event reporting, or safety substantiation that is not identical to the federal requirement.

Important exclusions from this preemption provision in FFDCA § 614(b) include state requirements:

- ◆ Addressing other aspects of cosmetic regulation

- ◆ Prohibiting or limiting the use or amount of an ingredient in a cosmetic product
- ◆ Mandating the reporting of an ingredient in a cosmetic product under a requirement in effect on December 29, 2022 (presumably this is aimed at the California Safe Cosmetics Program)
- ◆ Providing for damages under statutory or common law (i.e., tort suits)

This preemption provision does not affect the provision on preemption of requirements for labeling or packaging cosmetics in FFDCRA § 752.

Talc-Containing Cosmetics

Some cosmetics contain talc, and talc may potentially contain asbestos. FDA [reports](#) annual results from testing cosmetic products containing talc to see if they also contain asbestos.

MoCRA § 3505 directs FDA to adopt regulations on standardized testing methods for detecting and identifying asbestos in talc-containing cosmetic products. The proposed rule is due by December 29, 2023. The final rule is due 180 days later.

PFAS in Cosmetics

The FDA [website](#) confirms that, “PFAS are used as ingredients in certain cosmetics, such as lotions, cleansers, nail polish, shaving cream, and some types of makeup, such as lipstick, eyeliner, eyeshadow, and mascara.”

MoCRA § 3507 directs FDA to issue a report assessing the safety of using PFAS in cosmetic products. The report is due by December 29, 2025.

Animal Testing

An FDA [policy statement on animal testing](#) says that “animal testing by manufacturers seeking to market new products may be used to establish product safety” after consideration of alternatives.

MoCRA § 3507 conveys 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.

This provision does not bind FDA or manufacturers or processors of cosmetic products.

For questions, please contact [Mark Duvall](#).

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