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New Year, New Federal Cosmetics Reform

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In the final days of 2022, the long-awaited Modernization of Cosmetics Regulation Act of 2022 ("**MoCRA**")[1] was signed into law, marking the first major amendment to the federal framework governing cosmetics since 1938.

What are the most significant changes that the new law will bring to the cosmetics industry?

MoCRA significantly expands FDA oversight of the cosmetics industry. Once fully implemented, MoCRA will require:

- Facility registration;
- Product listing;
- Adherence to current Good Manufacturing Practices ("**CGMPs"**);
- Maintenance of records of adverse events;
- Reporting of serious adverse event reports to FDA;
- Records supporting substantiation of safety for each cosmetic product;
- Potential, minor label modifications to include contact information for adverse event reporting; and
- Labeling of fragrance allergens.

The law also grants FDA the authority to initiate mandatory recalls and to suspend facility registration if warranted.

Who must comply with the new law?

Both manufacturers and distributors (*i.e.*, brands). Most of the obligations set forth under MoCRA apply to "responsible persons," while some are limited to cosmetics "facilities":

- "**Responsible person**" refers to the manufacturer, packer, or distributor of a cosmetic product whose name appears on such product's label in accordance with the "name and place of business" requirement set forth in 21 CFR § 701.12 and 16 CFR § 500.5.[2]

- "**Facility**" includes any establishment, including that of an importer, that manufactures or processes cosmetic products distributed in the U.S. and expressly *excludes* (among others):
  - retailers (unless they manufacture/process cosmetics distributed or sold elsewhere);
  - beauty shops and salons (unless also engaged in manufacturing); and
  - establishments solely engaged in labeling, relabeling, packaging, repackaging, holding, and/or distributing of cosmetics.[3]

What should cosmetics manufacturers, brands, retailers, and others in the industry do in 2023?

Those involved in the manufacture, distribution, sale, and/or marketing of cosmetics in the U.S. should determine whether they meet the definition of an RP and/or facility and identify the corresponding MoCRA requirements to which they are subject as such. RPs that do not manufacture the cosmetic products distributed under their respective brand(s), but instead, outsource manufacturing to contract manufacturers, should discuss the new law

with such contract manufacturers and consider amending their manufacturing and/or quality agreement(s) to allocate responsibility for applicable MoCRA requirements accordingly. In addition, the following four action items must be accomplished in 2023:

1. Facility registration	**2.** Product listing	**3.** Safety Substantiation	**4.** Procedures to support adverse event recordkeeping and reporting

What does the new law require?

Requirement	Who?	When?	Description
Adverse Event Recordkeeping and Reporting (§ 605)	Responsible Person	December 2023	Every RP must maintain records of all adverse events associated with any of its cosmetic products for six years. Serious adverse event reports must be submitted to FDA (along with retail packaging of the product at-issue) within 15 business days after receipt of same. "Serious adverse events" include death, life-threatening experiences, hospitalization, significant disabilities, major disfigurement, congenital anomalies or birth defects, as well as infections.[4]
CGMPs (§ 606)	Facilities	Likely within 3-6 years	Like their applicable drug, device, and food counterparts, once FDA issues the requisite rulemaking, cosmetic manufacturers/importers (that meet the above definition of a "facility") will be required to comply with cosmetics-specific CGMPs designed to protect consumers and ensure that cosmetics marketed in the U.S. are not adulterated. Such CGMPs will be consistent with applicable national and international quality standards, to the extent practicable.
Establishment Registration (§ 607)	Facilities	December 2023*	After initial registration, renewal is required every two years. For a contract manufacturer making/processing cosmetics on behalf of one or more RPs, only one registration is needed, which may be submitted by the contract manufacturer or by any such RP. Each registration must include certain information, including (among other things) the name of each RP for which the registered facility makes/processes cosmetics and all brand names under which such products are sold.
Product Listing (§ 607)	Responsible Person	December 2023	RPs must submit, or ensure submission of, a complete product listing for each cosmetic marketed in the U.S. as of the compliance date shown here (and for new products entering the market thereafter, within 120 days after commencing marketing). Among various other required items, each listing must include a full ingredient list (with each ingredient identified by its established or customary name). Product listings may be submitted as part of a facility registration or separately.
Safety Substantiation (§ 608)	Responsible Person	December 2023	RPs must ensure, and maintain documentation of, "adequate substantiation of safety" for each cosmetic product it distributes/manufactures. "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 [the] product is safe," i.e., "not injurious to users under the conditions of use prescribed in the labeling thereof or [] as are customary or usual."

Requirement	Who?	When?	Description
Updated Contact Info. on Label (§ 609)	Responsible Person	December 2024[1+]	Each cosmetic-product label must be updated to include a domestic address, a domestic phone number, or electronic contact information (e.g., website or e-mail) through which the RP can receive AE reports.
Fragrance Allergen Disclosure (§ 609)	Responsible Person	Likely Q4 of 2024 – Q1 of 2025	Each fragrance allergen included in a given cosmetic product must be identified on such product's label in accordance with FDA's Fragrance Allergen Disclosure Rule, which will set forth the substances that constitute fragrance allergens for purposes of this requirement, along with other related specifics.

When can FDA initiate a mandatory recall of a cosmetic?

MoCRA expressly authorizes FDA to initiate a mandatory recall when:

- FDA determines that there is "a reasonable probability" that a cosmetic product is adulterated or misbranded under the FDCA and the use of, or exposure to, the cosmetic product "will cause serious adverse health consequences or death;" and
- The responsible entity has refused to voluntarily cease distribution and/or recall the product.

Presumably, such authority takes effect immediately.

What should industry expect from FDA in connection with MoCRA?

Three New Rules:

- **CGMP Rule** – As noted above, MoCRA directs FDA to establish CGMP regulations based on applicable national/international cosmetic-quality standards, taking into account the size and scope of the facilities that will be subject to the rule.
  - ⏳ Deadline for Proposed Rule: December 2024
  - ⏳ Deadline for Final Rule: December 2025
- **Fragrance Allergen Disclosure Rule** – Also noted above, MoCRA includes an updated labeling requirement under which RPs must disclose "fragrance allergens" on cosmetic labels. To implement this requirement, FDA must promulgate regulations identifying the substances that will be deemed fragrance allergens under MoCRA and, in doing so, must consider international, State, and local allergen-disclosure requirements, "including the substance and format of requirements in the European Union."[5]

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[*] The compliance date for new establishments (i.e., those first-engaging in cosmetic manufacturing/processing after MoCRA's enactment) is the later of 60 days after (i) first-engaging in such activities and (ii) one year after the enactment of MoCRA.

[+] The listed compliance date applies to the general (RP-contact-info.) labeling updates for retail cosmetics. There are also updated labeling requirements for professional cosmetics, which must be met by 12/29/2023.

- Deadline for Proposed Rule: June 2024
- Deadline for Final Rule: Within 180 days after the Proposed Rule's public comment period ends

- **Talc Rule** – The first MoCRA-mandated rulemaking cosmetics RPs and facilities can expect to see at the end of this year will establish standardized testing methods for detecting and identifying asbestos in talc-containing cosmetic products. Though MoCRA does not dictate whether RPs or facilities will be responsible for complying with such testing requirements, all manufacturers, importers, and distributors of talc-containing cosmetics should carefully review the forthcoming Proposed Rule and be prepared to take the necessary steps to comply (as applicable) thereafter.
  - Deadline for Proposed Rule: December 2023
  - Deadline for Final Rule: Within 180 days after the Proposed Rule's public comment period ends

Not so PFAS(t):

Finally, MoCRA would not be complete without addressing one of the hottest topics for industry in 2022 – Per- and polyfluoroalkyl substances ("**PFAS**"). At the close of 2022, 17 states had enacted or proposed legislation restricting the intentional addition of these "forever chemicals" in certain products. MoCRA does not mandate an FDA regulation regarding PFAS in cosmetics or their packaging, but rather, requires FDA to assess the use of PFAS in cosmetics and any associated safety risks and to publish a report summarizing the results thereof by December, 2025.

We will continue watching for any relevant action from FDA, as well as the plaintiffs' bar, and will provide further insight as to new or increased areas of enforcement and/or liability risk for cosmetics companies as the post-MoCRA era continues to unfold. For any questions that may arise in the meantime, contact Suzie Trigg or Kayla Cristales.

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[1] H.R. 2617 (2022).
[2] 21 U.S.C. § 604(4).
[3] The "facility" definition also excludes (i) hospitals, physicians' offices, and healthcare clinics; (ii) certain public health agencies/nonprofits; (iii) entities providing complimentary cosmetics incident to other services (e.g., hotels and airlines); (iv) trade shows and other venues where cosmetics are offered for free; and (iv) establishments that make cosmetics solely for use in research/evaluation. 21 U.S.C. § 604(3).
[4] 21 U.S.C. § 604(5).
[5] *See* Regulation (EC) No. 1223/2009. The EU's current list of fragrance allergens contains 26 substances that must be disclosed on labels when present at or above 0.01% in a "rinse-off" cosmetic and 0.001% in a "leave-on" cosmetic. EU regulators are currently in the process of increasing the current list to include 56 additional substances. *See* SCCS/1459/11, *Opinion on Fragrance Allergens in Cosmetic Products*.