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Fact Sheet on Modernization of Cosmetics Regulation Act

Prepared for Israel's Foreign Trade Administration by Steptoe LLP

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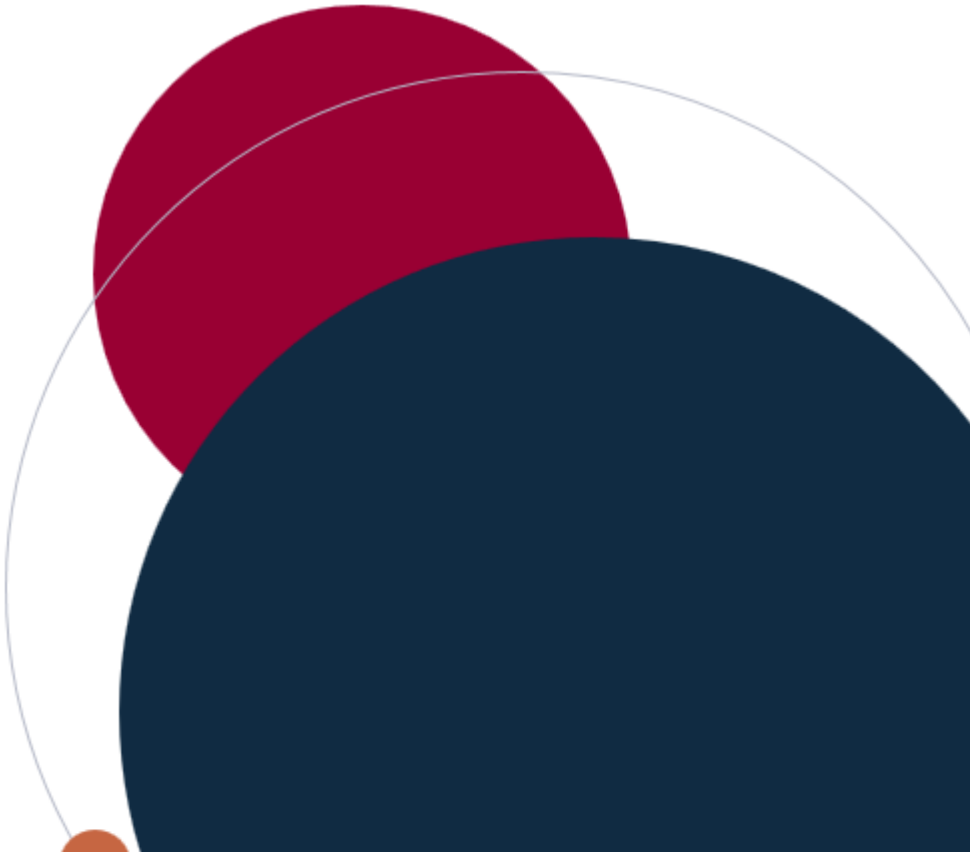
Intended to accompany the "MoCRA from A to Z – New US Legal Requirements for Cosmetics" webinar, recorded on May 7th, 2024



Fact Sheet: Modernization of Cosmetics Regulation Act

This document summarizes key federal compliance requirements for the cosmetics industry under the Modernization of Cosmetics Regulation Act (MoCRA) of 2022—the biggest expansion of the US Food and Drug Administration's (FDA) authority to regulate cosmetics in the US since 1938.

While this document focuses on federal requirements, companies should take care to monitor and comply with applicable laws in any state they are selling or distributing (including online). A growing number of states have regulations targeting cosmetics products, including disclosure requirements and often strict limits and prohibitions on chemical ingredients. Additional compliance requirements often apply to cosmetics advertising and labeling including under regulations or rules issued by the Federal Trade Commission and state and local laws. Cosmetics are also popular targets for consumer litigation, usually brought under one or more of the consumer protection laws that are in effect in all 50 states.

Cosmetics products must comply with all applicable laws and regulations—federal, state, and local. Companies should pay close attention and when appropriate, engage counsel to assist.

Key Definitions

Cosmetics vs. Drugs (21 USC 321) – Cosmetics and drugs are regulated differently in the U.S.

- "Cosmetics" means articles "intended to be…applied to the human body or any part thereof for cleansing, beautifying, promoting attractiveness, or altering the appearance" and any component thereof except soap.[1] Examples include basic lotion, lipstick, and nail polish.
- "Drugs" means articles "intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease...and articles…intended to affect the structure or any function of the body." Examples include prescription pills, over-the-counter medications, and sunscreens. Drugs typically have stricter regulatory requirements than cosmetics.
- Some products are both cosmetics and drugs, like makeup and skincare with SPF. The distinction often depends on how the product is marketed. Exercise caution with products targeting aging, acne, and other "longer-term" concerns.

Cosmetic Product (21 USC 364) – This term means "a preparation of cosmetic ingredients with a qualitatively and quantitatively set composition for use in a finished product."

Responsible Person (21 USC 364) – This term means "manufacturer, packer, or distributor of a cosmetic product whose name appears on the label." This includes natural persons and corporate entities. If the label identifies more than one person/entity (*e.g.,* the label identifies the distributor and the manufacturer), the parties should decide who assumes this role.

Small Businesses (21 USC 364h) – "Responsible Persons" and owners/operators of facilities that manufacture cosmetics products qualify as small businesses that are exempt from *some* MoCRA requirements, if they meet *both* of the following requirements:

- Their average gross annual sales in the U.S. of cosmetics products for the previous 3-years is less than $1,000,000; *and*

[1] Soap is a very strictly defined term and subject to additional unique requirements.

- They do not manufacture, process, or distribute any cosmetics that (1) do or would likely contact the eye area; (2) are injected; (3) are for internal use; or (4) are intended to alter appearances for more than 24 hours.
    - Businesses that make, process, or distribute these products are *NOT* exempt even if they meet the revenue requirement.

MoCRA: New Requirements for the Cosmetics Industry

New Reporting and Records Keeping Requirements:

Facility Registration (21 USC 364c) – By July 1, 2024, any person that owns or operates a facility, including a foreign facility, that manufactures a cosmetic product must register with FDA. Registration must be updated biannually thereafter.

- Qualifying small businesses and facilities that make only ingredients are exempt, and contract manufacturers who make products for multiple brands need only register once.

Product Listing (21 USC 364c) – By July 1, 2024, the "Responsible Person" must list with FDA any cosmetic products marketed in the US, which includes providing ingredient lists, facilities registration, and contact information to FDA. New products must be listed within 120 days of the first marketing, and listings must be updated annually thereafter.

- Qualifying small businesses and facilities that make only ingredients are exempt.

Adverse Events and Serious Adverse Events (21 USC 364a) – The "Responsible Person" must accept reports of any *adverse events* associated with the use of a cosmetic product and maintain records for at least 6 years (3 years for qualifying small businesses). The responsible person must report *serious adverse events* to FDA within 15 days of learning about the issue and for the year following the report, update FDA with new material information within 15 days.

- A serious adverse event is one that results in: (1) death, a life-threatening experience or hospitalization; (2) a persistent or significant disability or incapacity; (3) a congenital anomaly or birth defect; (4) an infection or significant disfigurement, including serious and persistent rashes, burns, hair-loss, or appearance change (other than intended); or (5) requires "based on reasonable medical judgment" a medical/surgical intervention to prevent these outcomes.

New Product Labeling Requirements:

Responsible Person Contact (21 USC 364e) – Labels for every cosmetic product shall include contact information for the "Responsible Person" to receive adverse event reports. This can be satisfied with either a domestic address, domestic phone number, *or* electronic contact information (including a website).

Fragrance Allergens (21 USC 364e) – Labels for every cosmetic product must disclose all fragrance allergens, with the list of allergens to be determined by FDA in forthcoming regulation.

Cosmetic Products for Professional Use (21 USC 364e) – Cosmetic products for use by licensed professionals (*e.g.,* cosmetologists, hair stylists, estheticians, etc.) must be labeled accordingly.

Additional labelling laws – Cosmetics products are subject to additional labeling requirements pursuant to other federal laws and regulations, and potentially state laws as well.

- For example, the Fair Packaging and Labeling Act (FPLA)[2], enacted in 1967, requires cosmetics products labels to disclose net contents, the product's identity, and the name and business of the product's manufacturer, packer, or distributor.
  - If the product is manufactured by a person/entity other than whose name appears on the label, the label needs to explain the relationship using a phrase like "Manufactured by ____" or "Distributed by ____."
  - Note that MoCRA allows the "responsible person" to be either the manufacturer *or* distributer, so compliance with both laws may require additional labelling information.
- Compliance with MoCRA, FPLA, and any other applicable laws (including state laws) must be evaluated on a case by case basis and depends on each product's supply chain, distribution, business structure, and markets where it is sold.

New Safety Substantiation Requirements:

Adequate Safety Substantiation (21 USC 364d) – A "Responsible Person" for a cosmetic product must ensure there is, and maintain records of, adequate safety substantiation for that product.

- 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.
- Substantiation can take the form of tests, studies, research analyses, or other evidence considered by qualified experts (in science training and experience) to evaluate cosmetics products and ingredients. The substantiation must exist by the time of marketing (*i.e.,* can't sell first, substantiate later).

MoCRA: New FDA Authorities

Mandatory Recalls (21 USC 364g) – FDA can require a recall if the Agency determines that a cosmetic is adulterated or misbranded such that a reasonable probability exists that use and/or exposure to the product will cause serious adverse consequences or death. This includes notifying persons affected, potentially through public alerts or press releases.

Records Access (21 USC 364f) – FDA can access the records of a "Responsible Person" if the Agency reasonably believes that the product and/or ingredients present a risk of serious adverse consequences or death *or* as needed to enforce other business compliance requirements. Financial and personnel records, or data unrelated to safety are excluded.

Facility Suspension (21 USC 364c) – FDA may suspend a facility if the Agency determines that a cosmetic product from that facility has a reasonable probability of causing serious adverse consequences or death to humans and FDA has a reasonable belief that other cosmetic products manufactured or processed by the facility may be similarly affected.

MoCRA: New FDA Rulemakings and Forthcoming Guidance

Good Manufacturing Practices (21 USC 364b) – By approximately January 1, 2025, FDA must come out with proposed rule on GMPs and with final rule by January 1, 2026. FDA is required

[2] FPLA (15 U.S.C. 1451 *et seq.*) directs the Federal Trade Commission and FDA to issue labeling regulations for all "consumer commodities" including cosmetics products.

to consider existing national and international standards, as well as size of business, in developing GMP regulations.

- Qualifying small businesses are exempt.

Fragrance Allergens (21 USC 364e) – The list of allergens that need to be on label will be determined by FDA through regulation by approximately July 2024, but this may be delayed.

Talc in Cosmetics (21 USC 364d) – FDA must propose regulations to establish and require standardized testing methods for detecting and identifying asbestos in talc-containing cosmetic products. The original Jan. 1, 2024 deadline has passed and it is unclear when FDA will issue this.

PFAS (MoCRA Section 3506) – FDA must, by end of 2025, publish a report assessing the use and safety of per- and polyfluoroalkyl substances (PFAS) in cosmetics.

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Surya Kundu focuses her practice on products liability, false advertising, consumer protection, and other complex disputes before state and federal courts, proceedings involving the Federal Trade Commission (FTC), in arbitrations, and negotiating pre-suit resolutions. She also provides compliance and risk reduction counselling on a variety of issues, including ESG and "green" marketing, cosmetics and product safety, labelling, social media, pricing practices, and consumer facing advertising. She writes and speaks frequently on emerging developments and serves on the Food & Drug Law Institute's inaugural Cosmetics Task Force.

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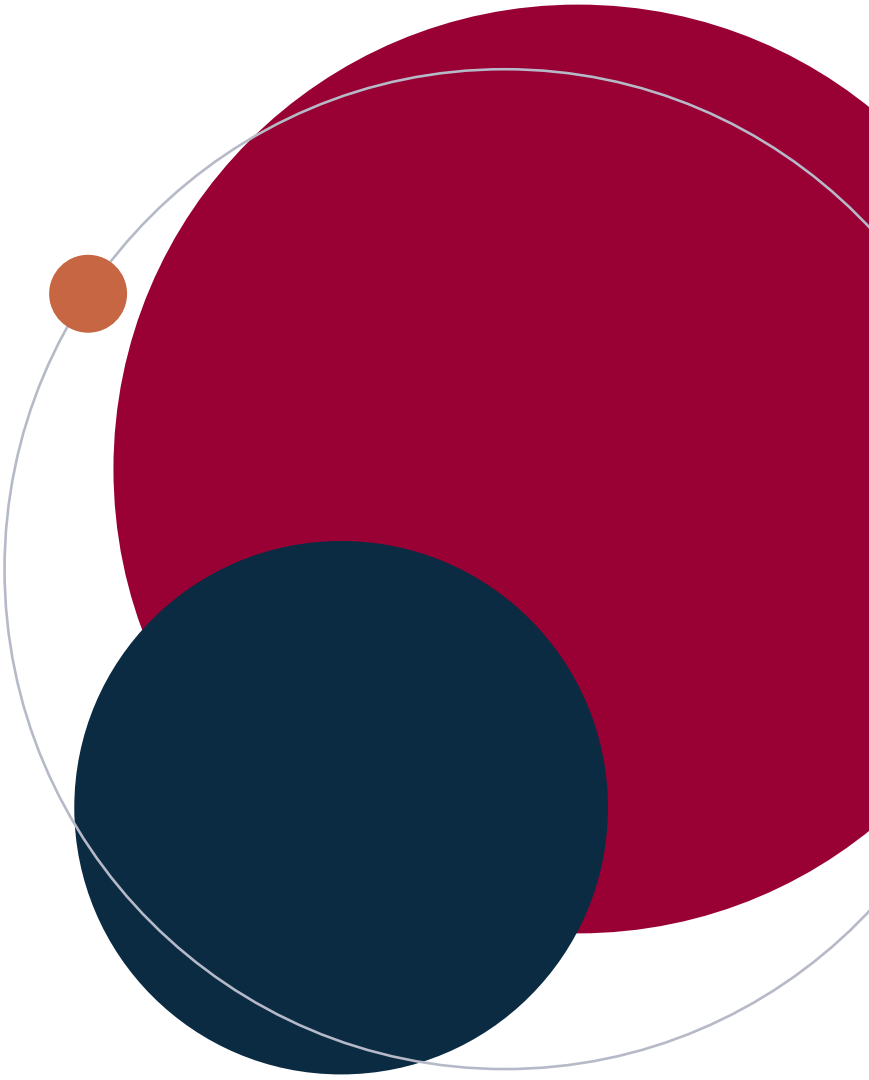

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