SQUIRE PATTON BOGGS

Revamping of Cosmetics Regulation and Safety

US – January 23, 2023

President Biden signed into law the "Consolidated Appropriations Act, 2023" on December 29, 2022 (the enactment date). The Act includes the Modernization of Cosmetics Regulation Act of 2022 ("**MOCRA**") which increases the authority of the United States Food and Drug Administration ("**FDA**") to regulate cosmetics and provide enhanced protections for consumers. The new law includes funding authorizations for implementation totaling $165-millon over federal fiscal years 2023 through 2027.

MOCRA requires compliance with several new FDA requirements, including adverse events reporting, Good Manufacturing Practices ("**GMPs**"), registration and product listing, safety substantiation, labeling, recordkeeping, access to records, and mandatory recall authority. Implementation of MOCRA will take several years with the general effective date beginning one year from enactment (December 29, 2023).

Background

The Federal Food, Drug, and Cosmetic Act ("**FD&C Act**") regulates cosmetics defined in 21 USC § 321(i) as:

> 1. articles intended to be rubbed, poured, sprinkled, or sprayed on, introduced into, or otherwise applied to the human body or any part thereof for cleansing, beautifying, promoting attractiveness, or altering the appearance, and
>
> 2. articles intended for use as a component of any such articles; except that such term shall not include soap.

Prior to MOCRA, cosmetics in the United States did not require manufacturer registration or product approval to go to market (except for color additives). Cosmetic companies had the option of participating in the Voluntary Cosmetic Registration Program ("**VCRP**") for products sold in domestic commerce. The purpose of VCRP was to help FDA gather information on cosmetics, including ingredients, frequency of use, etc. There are no GMPs under VCRP, but the agency may rely on its authority to enforce against misbranded, adulterated, mislabeled, and/or unsafe products.

MOCRA changes the regulatory landscape by providing FDA with specific regulatory tools to oversee the cosmetics industry. The changes will include mandatory facility registration, product listing, substantiation of product safety, establishment of good manufacturing practices, and more. MOCRA does not, however, go to the step of requiring pre-approval of cosmetics products prior to sale.

Applicability

Facilities regulated under MOCRA encompass any establishment that manufactures or processes cosmetics products. However, MOCRA exempts establishments downstream from the manufacturing and processing of cosmetics including beauty shops, product retailers, health care entities, public health agencies, hotels and airlines that provide complimentary cosmetics, and establishments that are only involved with tasks such as labeling, packaging, or distributing.

MOCRA also exempts small businesses from compliance with the GMPs and registration and listing requirements. Additionally, it provides for preemption of certain State laws with respect to registration and product listing, GMPs, records, recalls, adverse event reporting, and safety substantiation.

Registration and Listing Requirements

Facilities engaged in the manufacturing and processing of cosmetics will be required to complete biannual registration with FDA. The registration requirement applies to both existing and new facilities. Entities that are contract manufacturers will submit a single registration regardless of the number of customers it supports, which can be done either by the facility or a responsible person for whom it is manufacturing cosmetics. Note a responsible person under the MOCRA includes manufacturers, packers, or distributors of cosmetics whose name is on the product label.

Comparable to the registration for medical devices, establishments must provide a listing of their cosmetic products, including information such as the product name, cosmetic category, and a list of ingredients – including fragrances, flavors, or colors. MOCRA provides limited confidentiality protection, specifically for information provided on (i) all brand names under which cosmetics products are sold and (ii) the facility registration number of the facility where the cosmetic product is manufactured.

Certain facilities may already be assigned registration numbers with FDA under the VCRP, which should include any previously issued facility registration number and product listings. Under both the VCRP and the new registration requirements under MOCRA, industry should keep in mind that successful registration of an establishment is not an indication of FDA's approval of the cosmetic products.

Timing:

- Facility Registration:
  - Existing facilities must register within one year of the enactment date (on or before December 29, 2023).
  - Any new facilities, those established after the enactment date of MOCRA, must register within (a) 60 days of one year of the enactment date (February 27, 2023) or (b) 60 days of engaging in regulated activity, whichever is later.
- Cosmetic Product Listing
  - A listing for cosmetic products that existed on or before the enactment date must be submitted within one year of the enactment date (on or before December 29, 2023).
  - Listings for new cosmetic products on the market after the enactment date (after December 29, 2022) must be submitted within 120 days of marketing the product in interstate commerce.
  - Thereafter, listings must be updated annually.

Labeling

The cosmetics industry is currently subject to general labeling and warning statements requirements. *See* 21 CFR parts 701 and 740. MOCRA provides for additional requirements, including in three primary categories. First, cosmetic products must bear domestic contact information for the purposes of adverse event reporting. Second, fragrance allergens, to be identified in future rulemaking, must appear on labeling. Third, cosmetics intended for professional use (*i.e.*, licensed cosmetology professionals) shall contain a clear and prominent statement to that effect.

Timing:

Rulemaking shall be published within 18 months of the enactment date; final rulemaking within 180 days of the closing of the public comment period.

Good Manufacturing Practices

Section 606 requires FDA to issue regulations establishing good manufacturing practices for facilities "consistent, and to the extent practicable, and appropriate, with national and international standards." In implementing regulations, the agency will take into consideration public health risks, varying sizes of facilities, and potential economic hardship considerations for small businesses.

While there are no FDA-established GMPs, industry can look to previous guidance and reference materials for ideas of the direction the agency could take. The agency published guidance in June 2013 on GMPs that looked to ISO 22716 and involved coordination with the International Cooperation on Cosmetic Regulations ("**ICCR**"). The cosmetics industry should be prepared to review existing Statements of Procedure ("**SOPs**"), auditing practices, laboratory controls, and internal recordkeeping systems and be prepared to adapt them for upcoming regulatory requirements.

Timing:

NPRM to be published within two years of the enactment date and final rule within three years.

Adverse Event Reporting and Recalls

Currently, while adverse event reporting is required for medical devices, drugs, and therapeutic biologic products, such reporting for cosmetics is consumer-driven, with no expectation that cosmetics manufacturers or others in the distribution chain will report adverse events to FDA. Under MOCRA, responsible persons (*i.e.*, manufactures, packers, or distributors whose name is on the label) must report serious adverse events as defined specific to the cosmetic industry. The definition of serious adverse event includes seven categories ranging from death to significant disfigurement. Reports of serious adverse events will be due within 15 business days of receipt of information by the responsible person. Additionally, the responsible person will be required to maintain records of all adverse events for six years (small businesses for three). Industry should be prepared to provide additional information to the agency upon request – including details on fragrance and flavors.

The recordkeeping requirement applies to "Adverse Events" which means "any health-related event associated with the use of a cosmetic product that is adverse," and "Serious Adverse Events" which means "an adverse event that—(A) results in—(i) death; (ii) a life-threatening experience; (iii) inpatient hospitalization; (iv) a persistent or significant disability or incapacity; (v) a congenital anomaly or birth defect; (vi) an infection; or (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 intended, under conditions of use that are customary or usual; or (B) requires, based on reasonable medical judgment, a medical or surgical intervention to prevent an outcome described in subparagraph (A)."

The FD&C Act places no authority in FDA to enforce a mandatory recall of a cosmetic product though the regulatory framework for recalls in 21 CFR Part 7 provides the agency with the ability to monitor voluntary recalls performed by cosmetics manufacturers and to request that such occur. MOCRA fills this gap, and gives FDA this missing authority to order a mandatory recall if a cosmetics firm refuses to issue a voluntary recall when requested. This follows in the steps of the Food Safety Modernization Act ("**FSMA**"), which provided FDA comparable mandatory recall authority for food products in 2011.

Cosmetics firms should act now to review existing SOPs on adverse events and recalls and be prepared for the requirement to go into effect at the end of this year.

Timing:

December 29, 2023

Environmental, Health, and Safety Applications

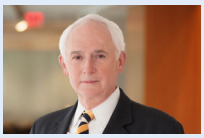
MOCRA places an elevated responsibility on responsible persons to have records available substantiating the safety of its products beyond existing prohibitions on adulterated or misbranded products. The single exception is for coal tar hair dye, due to existing limitations on FDA's ability to act on the substance. Color additives used in cosmetics must be approved under the FD&C Act prior to being used in regulated products. However, coal tar was excluded from this requirement in the FD&C Act in section 601(e) if required warnings are present on the labeling.

FDA is also paying increased attention to potentially unsafe ingredients in cosmetics, such as perfluoroalkyl and polyfluroalkyl substances ("**PFAS**") – commonly referred to in the media as the "forever chemicals." Specifically, in Section 3506, MOCRA directs the agency to assess use of PFAS in cosmetics and the "scientific evidence regarding the safety of such use." For talc, the law takes one step further and requires regulations for test methods for identifying and identifying asbestos in talc-containing cosmetics. This step likely sources from recent attention to and litigation regarding asbestos in talc-containing cosmetics.

Timing:

Regulations are expected within a year of the enactment date for asbestos. A report will also be due on the effects of PFAS within three years of the enactment date.

Contacts



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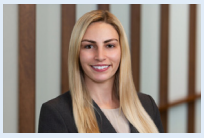

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