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Years in the Making—Congress Modernizes FDA's Cosmetics Authorities

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Food, Drugs, and Devices

In the final days of its last session, Congress overhauled FDA's regulatory framework for cosmetics as part of the year-end Consolidated Appropriations Act, 2023. Signed into law by President Biden on December 29, 2022, the Modernization of Cosmetics Regulation Act of 2022 ("MoCRA"), as it has been titled, added significant new authorities to chapter VI of the Federal Food, Drug, and Cosmetic Act ("FDCA")—the first major amendments to FDA's cosmetics authorities since President Franklin D. Roosevelt signed the FDCA into law in 1938. Earlier this year, MoCRA passed the Senate HELP Committee with bipartisan support, led by HELP Chair Patty Murray (D-WA) and Ranking Member Richard Burr (R-NC) as part of the broader committee efforts to reauthorize FDA's medical product user fee programs. MoCRA—considered a "super-rider" for the user fee reauthorization—did not advance when Congress enacted the user fee package in late September. But during the final weeks of the congressional session, Sens. Murray and Burr worked with E&C Chairman Frank Pallone (D-NJ) and Ranking Member Cathy McMorris Rodgers (R-WA) to settle on a suite of reforms to attach to the year-end omnibus appropriations package. Notably, while MoCRA will be included in that suite, certain other FDA-related "super-riders" did not advance, including: (i) the VALID Act, which would have established a regulatory framework specifically for diagnostics, and (ii) reforms to FDA's regulatory framework for dietary supplements.

MoCRA represents over a decade of significant efforts by Congress and many stakeholders, including FDA, consumer and environmental groups, and the beauty and personal care industry (on behalf of which Covington is proud to have been deeply involved in MoCRA's development).

This client alert summarizes the key provisions of MoCRA. Importantly, the new enforcement provisions of MoCRA do not require immediate compliance; instead, as outlined below, MoCRA includes specific compliance dates for certain of the requirements and directs FDA to undertake rulemaking or issue guidance to implement other of the requirements. We anticipate meaningful efforts by FDA this year to work towards implementing these new authorities.

Part I — New Requirements for Cosmetics

MoCRA adds several new authorities to chapter VI of the FDCA. In general, MoCRA imposes these requirements on a "responsible person," which is defined as "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) of [the FDCA] or section 4(a) of the Fair Packaging and Labeling Act." This is typically the entity listed in the name and place of business statement that currently appears on cosmetic labels.

FDCA Section 605: Adverse Event Recordkeeping and Serious Adverse Event Reporting

Newly-added section 605 requires—similar to the FDA's existing authorities for dietary supplements and OTC drugs—that a responsible person (i) maintain records of any health-related adverse events associated with the use of its product for six years (or three years for some small businesses) and, (ii) report to FDA any serious adverse events no later than 15 days after learning about the issue. A responsible person also must provide any new and material medical information it learns of related to the serious adverse event for one year following the initial submission. MoCRA broadens the scope of what constitutes a serious adverse event to account for particular considerations relevant to the cosmetics sector; in addition to the existing definition of serious adverse event for dietary supplements and OTC drugs, a reportable event for cosmetics also includes an infection or "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."

FDCA Section 607: Mandatory Facility Registration and Product and Ingredient Listing

Newly-added section 607 now requires cosmetic facility registration and cosmetic product and ingredient listing with FDA. Specifically, each facility that manufactures or processes cosmetic products for U.S. distribution, whether the facility is located in the U.S. or abroad, must register with FDA. The MoCRA definition of facility includes a number of carve outs; most notably, an establishment that solely performs labeling, relabeling, packaging, repackaging, holding, and/or distributing of cosmetic products is not a facility subject to the new requirements. Other carve outs include establishments that manufacture or process cosmetic products that are solely for use in research or evaluation, including for production testing, and not offered for retail sale, and establishments that manufacture cosmetic ingredients but not cosmetic products.

Existing facilities must register within one year after the date of enactment of MoCRA, whereas any new facilities must register within 60 days after beginning to manufacture cosmetics, or 60 days after the deadline for existing facilities, whichever is later. All registrations must be renewed biennially.

Responsible persons also must list each cosmetic product, including its ingredients and information about where the cosmetic product is manufactured, with FDA. For products marketed prior to enactment of MoCRA, a responsible person must submit product listings no later than one year after enactment; for products first marketed after enactment, a responsible person must submit product listings within 120 days of marketing. Responsible persons must update product listings annually. Importantly, a single listing submission for a cosmetic product may include multiple cosmetic products with identical formulations or formulations that differ only with respect to colors, fragrances, flavors, or quantity of contents.

FDCA Section 608: Cosmetic Safety Substantiation

Newly-added section 608 requires responsible persons to ensure, and maintain records supporting, "adequate substantiation" showing that a cosmetic product is "safe," and establishes a safety standard that products must meet in order to be marketed in the U.S. Cosmetic products that do not have adequate safety substantiation will be considered adulterated under section 601 of the FDCA.

FDCA Section 609: Cosmetic Labeling and Fragrance Allergen Transparency

Newly-added section 609 builds on FDA's current cosmetic labeling requirements in three ways. First, MoCRA requires cosmetic product labels to include contact information through which the responsible person can receive adverse event reports; this requirement takes effect two years after the date of enactment of MoCRA. Second, MoCRA requires labels for professional cosmetics products to include the same information that is required of cosmetic products intended for sale to consumers and to state that only licensed professionals may use the product; this requirement takes effect one year after the date of enactment of MoCRA. Third, MoCRA requires cosmetic labels to identify each fragrance allergen in a product once FDA issues the fragrance allergen rule discussed in Part IV below.

Part II — New FDA Enforcement Authorities

FDCA Section 607: Facility Suspension

Newly-added section 607 gives FDA the authority to suspend the registration of a facility if it determines that a cosmetic product manufactured by that facility has a reasonable probability of causing serious adverse health consequences and other products manufactured by the facility may be similarly affected. Once suspended, a facility may not introduce any cosmetic products into commerce until its registration is reinstated. This authority is very similar to FDA's authority to suspend a food facility's registration that was added to the FDCA in 2011.

FDCA Section 610: Records Access

Newly-added section 610 gives FDA the authority to access records relating to a cosmetic product if it reasonably believes that a product or its ingredients are adulterated and present a threat of serious adverse health consequences. This authority does not extend to cosmetic formulas/recipes, or to financial, pricing, sales, personnel, or research data (other than safety substantiation data). In addition, newly-added section 605 provides that FDA may request a list of ingredients in the fragrances or flavors in a product if it has reason to believe that a fragrance or flavor contributed to a serious adverse event.

FDCA Section 611: Recall Authority

Newly-added section 611 gives FDA mandatory recall authority if it determines that there is a reasonable probability that a cosmetic is adulterated or misbranded within the meaning of FDCA sections 601 and 602 and exposure to the product will cause serious adverse health consequences or death.

Part III — Other Notable Provisions

FDCA Section 614: Preemption

Newly-added section 614 preempts any state or local laws that differ from the federal framework on the topics of registration, product listing, good manufacturing practice, records, recalls, adverse event reporting, or safety substantiation. Newly-added section 614 also includes a limitation clause and savings clause, which may apply in certain circumstances.

FDCA Section 613: OTC Drug-Cosmetic Clarity

For products that are both a drug and a cosmetic under the FDCA and related operations, newly-added section 613 makes clear that the drug requirements of chapter V of the FDCA apply instead of the cosmetic requirements of chapter VI, except with regard to fragrance allergen disclosure and professional use labeling.

Animal Testing

MoCRA did not adopt any requirements specific to testing involving animals, but instead provided a sense of 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. Industry had advocated for inclusion of the Humane Cosmetics Act (S. 3357) in MoCRA.

Small Business Accommodations

MoCRA makes a number of accommodations for small businesses. First, the CGMP regulations issued by FDA under newly-added section 606 must offer flexibility, simplified requirements and a longer compliance period for small businesses. Second, very small businesses (as defined by MoCRA) are exempt from newly-added section 606 (for CGMP) and 607 (registration and listing) and, with regard to newly-added section 605, must maintain records of any health-related adverse events associated with the use of a product for three years, rather than six years.

Resources for FDA

The bill authorizes appropriations for FDA aimed at supporting activities related to MoCRA. The legislation does not impose industry user fees.

Part IV — Future FDA Implementation Actions

MoCRA requires FDA to issue three new rules and a report.

Current Good Manufacturing Practices Rule	• Newly-added section 606 directs FDA to establish good manufacturing practice regulations consistent with national and international standards. • FDA will issue a proposed rule within two years after enactment and a final rule no later than three years after enactment. • If a cosmetic product has been manufactured or processed under conditions that do not meet these regulations, it will be deemed adulterated under section 601 of the FDCA.
Fragrance Allergen Disclosure Rule	• Newly-added section 609 directs FDA to issue regulations to identify fragrance allergens that must be disclosed on cosmetics labels and the format for disclosure, considering EU requirements and other international requirements.

	• FDA will issue a proposed rule within 18 months after enactment and a final rule no later than 180 days after the close of the public comment period for the proposed rule. • If a cosmetic product label does not include required fragrance disclosures, it will be considered misbranded under section 602(b) of the FDCA.
Talc Rule	• Section 3505 of the omnibus bill directs FDA to issue regulations to establish and require standardized testing methods for detecting asbestos in talc-containing cosmetics. • FDA will issue a proposed rule within one year after enactment and a final rule no later than 180 days after the close of the public comment period for the proposed rule.
PFAS Report	• Section 3506 of the omnibus bill directs FDA to assess the use of per- and polyfluoralkyl substances ("PFAS") in cosmetic products and the scientific evidence regarding the safety of their use in cosmetics products. • FDA will publish the results of this assessment in a public report no later than three years after enactment.

What Comes Next?

We will co-host a webinar with the Personal Care Products Council (PCPC) in January 2023 to cover the key implications of MoCRA.

Webinar: Unpacking the Modernization of Cosmetics Regulation Act of 2022
Co-Hosted with the Personal Care Products Council (PCPC)

During this webinar, experts from the Personal Care Products Council (PCPC) and Covington's FDA regulatory team will discuss these reforms and assess key implications for cosmetics industry stakeholders.

Date: January 25, 2023
Time: 12 pm Eastern
Register Here

If you have any questions concerning the material discussed in this client alert, please contact the following members of our firm:

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