Client Alert

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FDA COSMETICS REFORM IS JUST AROUND THE CORNER – GMPS, FACILITY REGISTRATION, PRODUCT LISTING, RECALL AUTHORITY, AND MORE: MEET THE MODERNIZATION OF COSMETICS REGULATION ACT OF 2022

By Angela Diesch

Just before the Christmas holiday, in a scramble to avoid a partial government shutdown, both houses of Congress approved a $1.7 trillion government spending bill. Earlier that week, the Senate had amended the Consolidated Appropriations Act of 2023 (the "Appropriations Bill") to, among other things, reintroduce the Modernization of Cosmetics Regulations Act of 2022 ("MOCRA"). Once signed into law by President Biden, MOCRA will add significant new authorities to chapter VI of the Federal Food, Drug, and Cosmetic Act ("FDCA").

This came as a surprise to some since earlier this year, although MOCRA passed the Senate HELP Committee with bipartisan support, as part of broader Committee efforts to reauthorize FDA's medical product user fee programs, it did not advance when Congress enacted the user fee package in late September.

MOCRA represents over a decade of significant efforts by Congress and many stakeholders, including the FDA, consumer and environmental groups, and the beauty and personal care industry including, among others, the Personal Care Products Council and the Independent Beauty Association. Importantly, none of the new requirements will require immediate compliance. Instead, as described below, MOCRA provides specific compliance dates for certain of the requirements and directs FDA to undertake rulemaking or issue guidance to implement other requirements. Over the next year, we will provide updates to keep you apprised of FDA's efforts in implementing these new authorities.

New Requirements of Cosmetics

The following is a summary of the new requirements that will be codified within Chapter VI of the Food, Drug, and Cosmetic Act ("FDCA"). These requirements are generally imposed on a "Responsible Person," which MOCRA defines as "the manufacturer, packers, or distributor of a cosmetic product whose name appears on the label of such cosmetic product in accordance with section 609(a) [the FDCA] or section 4(a) of the Fair Packaging and Labeling Act." In other words, the Responsible Person is typically the entity listed on the label of a cosmetic product. Unless otherwise noted, the requirements described below become effective one year after enactment of MOCRA.

Are you a small or very small business? MOCRA defines a small business as a Responsible Person, and owners and operators of facilities, whose average gross sales in the U.S. of cosmetics for the previous three year period less than $1,000,000, adjusted for inflation, and those small businesses who do not engage in the manufacturing or processing of cosmetics that come into contact with mucus membrane of the eye under conditions of customary or usual use, cosmetics that are injected, intended for internal use, or intended to alter the appearance for more than 24 hours (referred to hereafter as the "612(b) products"). Such small businesses are not subject to sections 606 or 607, described below. Otherwise, MOCRA provides for a number of accommodations for small businesses. For your convenience, they are highlighted where applicable below.

FDCA Section 605: Adverse Events

MOCRA imposes new adverse event record keeping and serious adverse event reporting. Similar to the FDA's existing authorities for dietary supplements and OTC drugs, MOCRA requires a Responsible Person to (i) maintain records of *any health-related adverse events* associated with the use of its product for **six years** (**three years for some small businesses not engaged in manufacturing 612(b) products**) and, (ii) report to FDA any *serious adverse events* no later than 15 days after learning about the issue. The submission of the serious adverse event must include a copy of the label on or within the retail packaging of the cosmetic. In addition, for serious adverse events, a Responsible Person must provide any new and material medical information it learns of related to the serious adverse event for one year following the initial submission.

Given the particular context of the cosmetics sector, MOCRA broadens the scope of what constitutes a serious adverse event from the existing meaning prescribed to adverse events involving dietary supplements and OTC drugs. Specifically, under MOCRA a serious adverse event is an adverse event that results in:

- death;
- a life-threatening experience;
- inpatient hospitalization;
- a persistent or significant disability or incapacity;
- a congenital anomaly or birth defect;
- 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; or
- an adverse event that requires, based on reasonable medical judgment, a medical or surgical intervention to prevent one of the above outcomes.

Notably, MOCRA also expressly provides that a Responsible Person shall receive reports of adverse events through the domestic address, domestic telephone number, **or** electronic contact information included on the label.

In addition, if the FDA has reasonable grounds to believe a flavor or fragrance ingredient caused or contributed to the serious adverse event, it may request a list of the ingredients or

categories of ingredients in the specific fragrances or flavors and the Responsible Person must then submit the information within 30 days of the request.

FDCA Section 606: Good Manufacturing Practice

Section 606 provides FDA authority to establish good manufacturing practices for facilities that are consistent, to the extent practicable and appropriate, with national and international standards. The FDA must publish a notice of proposed rulemaking within two years of MOCRA's enactment and must publish a final rule within three years.

Small businesses: The regulations are to include simplified good manufacturing practice requirements for smaller businesses, as appropriate, to ensure that such regulations do not impose undue economic hardship for smaller businesses and may include longer compliance times for smaller businesses.

FDCA Section 607: Registration and Product Listing

Section 607 requires existing cosmetic facility registration and cosmetic product and ingredient listing with FDA within one year of MOCRA's enactment. New facilities must register within 60 days of first engaging in activities or 60 days after the one-year deadline describe above, whichever is later. For cosmetics first marketed after the date of enactment, registration must occur within 120 days of first marketing the product. Updates to facility registrations or products are to be submitted annually and all registrations must be renewed biennially. Notably, each facility that manufactures or processes cosmetics for U.S. distribution, whether the facility is located in the U.S. or abroad, must register.

Exceptions: MOCRA excludes from the definition of facility requiring registration an establishment that solely performs labeling, relabeling, packaging, repackaging, holding, and/or distributing of cosmetic products, as well as 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.

Also, a notable new authority for the FDA is its ability to suspend the registration of a facility if it determines 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. Before suspension, the FDA must provide notice and the manufacturer has five days to provide a plan of corrective action. In addition, the FDA must provide the manufacturer with an informal hearing to be held within five days after issuance of the suspension order. Once suspended, a facility may not introduce any cosmetic products into commerce until its registration is reinstated.

FDCA Section 608: Safety Substantiation

Section 608 requires Responsible Persons to ensure, and maintain records supporting, "adequate substantiation" showing a cosmetic product is "safe," and establishes a safety standard that products must meet in order to be marketed in the U.S. MOCRA defines "adequate substantiation of safety" as meaning "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 a cosmetic product is safe." Notably, a cosmetic or ingredient is not considered unsafe solely because it can "cause minor and transient reactions or minor and transient skin irritations in some users."

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 Disclosures

Section 609 adds onto existing cosmetic labeling requirements in three ways:

1. Within one year of enactment, labels for professional cosmetics will now have to include the same information that is required of cosmetic products intended for sale to consumers and must include a statement that only licensed professionals may use the product.
2. Within 18 months of enactment, cosmetic labels must identify each fragrance allergen in a product once FDA issues the fragrance allergen rule (discussed in detail below).
3. Within two years of enactment, cosmetic labels must include contact information through which the Responsible Person can receive adverse event reports via domestic address, domestic phone number, or electronic contact information, which may include a website.

FDCA Section 610: Records

If FDA reasonably believes that a product or its ingredients are adulterated and present a threat of serious adverse health consequences, newly added section 610 gives FDA the authority to access and copy records relating to the product and any other product FDA reasonably believes is similarly affected. The authority does not extend to cosmetic recipes or formulas, or to financial, pricing, personnel, sales, or research data (other than safety substantiation data). (This is in addition to FDA's new authority under Section 605 to seek the 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: Mandatory Recall Authority

Section 611 provides FDA with the authority to order a person to immediately cease distribution of any cosmetic FDA determines, with reasonable probability, is adulterated under section 601 or misbranded under section 602, and the use of or exposure to such cosmetic will cause serious adverse health consequences or death. Before issuing the order, FDA must provide a Responsible Person with an opportunity to voluntarily cease distribution and recall the product. FDA must provide the Responsible Person with an informal hearing within 10 days after the date of issuance of the order, on whether adequate evidence exists to justify the order. In addition, MOCRA provides for specific notification requirements to consumers for recalled articles.

FDCA Section 613: Exemption for Certain Products and Facilities – OTC/Cosmetic Products

For products that are both a drug and a cosmetic under the FDCA and related operations, MOCRA makes clear that the drug requirements of chapter V of the FDCA apply instead of the

cosmetic requirements of chapter VI, except as to the fragrance allergen disclosure and professional use labeling requirements.

FDCA Section 614: Preemption

New 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. Section 614 also includes a limitation clause to clarify nothing in MOCRA prevents any State from prohibiting the use or limiting the amount of an ingredient in a cosmetic, or from continuing requirements in effect at the time of MOCRA's enactment for the reporting to the State of an ingredient in a cosmetic product. In addition, there is a savings clause, which clarifies that neither MOCRA nor any standard, rule, requirement, regulation, or adverse event report modifies, preempts, or displaces any action for damages or the liability of any person under the law of any State, whether based on statute or common law.

A Few Other Notable Mentions and Future FDA Activity

- *User Fees*: There are no imposed user fees.
- *Animal Testing*: Although there is no explicit prohibition of animal testing, under section 3507, MOCRA instead simply clarifies that it is Congress's sense "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."
- *Talc*: FDA is to promulgate regulations that establish and require standardized testing methods for detecting asbestos in talc-containing cosmetics (section 3505). The proposed rule is to be issued within one year of the enactment of the Appropriations Bill, and a final rule no later than 180 days after the close of the public comment period of the proposed rule.
- *Allergen Rule*: Within 18 months of enactment, FDA must issue a proposed rule identifying the fragrance allergens that must be listed on cosmetics product labels, and a final rule no later than 180 days after the close of the public comment period of the proposed rule.
- *PFAS*: Within three years of the enactment of the Appropriations Bill, section 3506 requires FDA to publish an assessment of the use of per- and polyfluoralkyl substances ("PFAS") in cosmetic products and the scientific evidence regarding the safety of their use in cosmetics products.

Amin Talati Wasserman, LLP is here to help! If you have questions, need assistance with facility registration or product listings, need help with putting together your safety substantiation or with putting together operating procedures for maintaining records of adverse events, or have any other questions, we are here for you.