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Alert | Health Care & FDA Practice

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New Cosmetic Regulatory Requirements: What Cosmetic Manufacturers Need to Know

On December 29, 2022, President Biden signed into law the "Modernization of Cosmetic Regulation Act of 2022,"[1] which requires increased Food and Drug Administration (FDA) oversight of cosmetics and the ingredients in them. This GT Alert outlines the law's key provisions, including timelines for FDA actions and enforcement. The law creates new requirements that may generate increased consumer litigation. This GT Alert summarizes the Act's provisions and does not constitute legal advice. Many provisions are subject to regulatory implementation by a date provided for in the Act.

The new law also includes amendments modifying other FDA requirements. In particular, the law modifies the law as to issues such as improvements and innovations in drug manufacturing, reauthorization of key FDA programs such as the Humanitarian Device Exemption Incentive, the Best Pharmaceuticals for Children Program, and Reauthorization of Orphan Drug Grants. There are also modifications to biologics and drugs, as well as modifications of the Save Medical Device amendments.

Modernization of Cosmetic Regulation Act of 2022 (MoCRA)

MoCRA, the new cosmetic regulation law, establishes a process, similar to those for other FDA-regulated products, that ensures the cosmetic manufacturers provide assurances that the cosmetic products are safe. This GT Alert provides general information on these new requirements, with effective dates for

[1] This legislation was included in H.R. 2617, the "Consolidated Appropriations Act, 2023," as part of a year-end bill.

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certain regulatory and other requirements. The law establishes obligations on the "responsible person" that is, the manufacturer, packer, or distributor of a cosmetic and those whose name appears on the products label.

MoCRA is only applicable to importers and entities that manufacture or process cosmetic products. It **does not** apply to the following entities if they do not import, manufacturer, or process cosmetics: beauty salons; cosmetic product retailers; distribution facilities; pharmacies; hospitals; physicians offices; health care clinics; public health agencies and other nonprofit entities; entities that provide complimentary cosmetic products; trade shows and others giving free samples; entities that are only doing research; and entities that prepare labels, relabel, package, repackage, hold, and/or distribute cosmetic products.

Key Terms

Good Manufacturing Practices: The secretary of the Department of Health and Human Services (HHS) (through the FDA) will propose and finalize regulations to establish good manufacturing practices. The key is to ensure that products are not adulterated and will allow FDA to inspect records to ensure compliance. The proposed rulemaking shall be no later than two years **after date of enactment (December 29, 2022)** with final regulations no later than three years after date of enactment (December 29, 2022).

Adverse Events: Any health-related event associated with the use of a cosmetic product.

Serious Adverse Event: Any event that is a result of death, life-threatening experience; inpatient hospitalization; persistent or significant disability or incapacity; a congenital anomaly or birth defect; and infection or significant disfigurement **OR** requires, based on reasonable medical judgment, a medical or surgical intervention to prevent an outcome described in the first definition of serious adverse event.

Process for Reporting Adverse Events: In compliance with the HHS secretary's regulations, the responsible person shall file a report within 15 days and may supplement the report within one year. A serious adverse event report is similar to other safety reports and can include a statement released to the public (without any personal health information). The HHS secretary may exempt certain reports that do not involve a significant public health issue. Records must be kept by the responsible person for six years; three years for small businesses. There is a Rule of Construction that the submission of any report shall not be construed as an admission that the cosmetic product involved, caused, or contributed to the relevant adverse event.

- **Fragrance and Flavor Ingredients**: If an ingredient(s) has caused or contributed to a serious adverse event, the HHS secretary may request a list of such ingredients, and such list must be provided within 30 days of the request.
- **Safety Substantiation**: Records must be maintained that demonstrates adequate substantiation of the safety of the cosmetic product. Adequate substantiation means tests, studies, or other evidence to support a reasonable certainty that the product is safe.

Inspection: The responsible person shall permit an officer or HHS employee (with credentials) to have access to inspect records, manufacturing and other issues.

Registration and Product Listing: Cosmetic manufacturers must submit a registration no later than **ONE YEAR AFTER ENACTMENT** (December 29, 2022). New facilities must register within 60 days (or 60 days after deadline). Renewal is every two years. Updates or changes must be submitted within 60

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days of the change. The content of the information required for registration is outlined in the law. The registering company must also list all cosmetic products it imports, manufactures, or processes and include product category or categories, list of ingredients (fragrances, flavors, or colors), and product listing number (if previously assigned). Flexibility is given to the listing of multiple products with identical formulations or those that differ only to colors, fragrances, flavors, or quantity. Annual updates are to be submitted. FDA will withhold confidential information included in a listing when a request for information is filed.

The HHS secretary may suspend a cosmetic entity's registration if there is a reasonable probability that a product is causing serious adverse health or deaths, and the secretary has reasonable belief that other products made or processes may also be affected and for which health concerns are raised about the products manufactured. Notice of suspension is to be provided and an opportunity within five days to provide corrective action; or a hearing may be held. The secretary may conclude (a) the suspension remains necessary or (b) the registrant must submit a corrective action plan to demonstrate remediation of the problem conditions. The plan will be reviewed not later than 14 business days or such other time agreed upon by the parties. If the secretary vacates the suspension, FDA will then reinstate the registration. If the facility is suspended, no person shall introduce or deliver in the United States cosmetic products from such facility. The secretary can only delegate this authority to the FDA Commissioner.

Labeling: Each cosmetic product shall have a label that includes a domestic address, domestic phone number, or electronic contact information. In addition, the following applies to labeling.

- **Fragrance Allergens**: The responsible person shall identify on the label each fragrance allergen included. The secretary shall propose a rule on June 29, 2024 (18 months after date of enactment) and final rule 180 days after the public comment period closes. The secretary shall consider international, state, and local requirements for allergen disclosure and threshold amount levels.
- **Cosmetic Products for Professional Use**: A professional is an individual licensed by a state authority to practice in the field of cosmetology, nail care, barbering, or esthetics.
- **Professional Use Labeling**: A cosmetic product introduced into interstate commerce and intended to be used only by a professional shall bear a label that contains a clear and prominent statement that the product shall be administered for use only by a licensed professional; and is in conformity with the requirements for cosmetics labeling.

Records: Records are to be available to authorized personnel to examine products if there is reason to believe a cosmetic product is adulterated or an ingredient could cause harm or run afoul of other standards. The authorized personnel must provide written notice to have access to records at a reasonable time to determine whether the product poses a threat. The records to be reviewed do not include recipes or formulas for cosmetics, financial data, pricing data, personnel data (except qualifications) research data (other than safety substantiation) or sales data (other than shipment data regarding sales).

- **Rule of Construction**: Nothing in this section shall be construed to limit the secretary's ability to inspect records or require establishment and maintenance of records under any other provision of the law.

Mandatory Recall Authority: If the secretary determines there is a reasonable probability that a cosmetic is adulterated or misbranded and the use or exposure will cause serious adverse health consequences or death, the secretary shall provide the cosmetic manufacturer an opportunity to voluntarily cease distribution and recall such article. If the entity refuses or does not recall the cosmetic within the time and manner prescribed, the secretary may order that the product not be distributed.

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- **Hearing**: A hearing may be held, no later than 10 days after the date of issuance. A process for resolution is provided by the law to either recall the product and cease distribution based on evidence provided or permit the product to continue distribution. Notice to affected individuals may be required.
- **Public Notification**: If a recall is required, a press release is to be published, and alerts and public notices are to be issued, as appropriate. The materials must include the name of the cosmetic; a description of the risk; to the extent practicable, information for consumers about similar cosmetics that are not affected by the recall and ensure publication on the FDA website of the image of the cosmetic. The secretary can only delegate this authority to the Commissioner of the FDA.
- **Rule of Construction**: Nothing in this section shall affect the authority of the secretary to request or participate in a voluntary recall or to issue an order to cease distribution or to recall under any other provision of this chapter.

Small Businesses: Responsible persons and owners and operators of facilities whose gross annual sales in the United States of cosmetic products for the previous three-year period is less than $1,000,000 shall be considered small business and not subject to Good Manufacturing Practices, registration, and listing requirements.

- **Exemptions**: The small business exceptions do NOT apply to (1) cosmetic products that contact the mucus membrane of the eye under conditions of use that are customary or usual; (2) products that are injected; (3) products that are intended for internal use; or (4) products that are intended to alter appearance for more than 24 hours under conditions of use that are customary or usual, and removal by the consumer is not a part of such conditions of use that are customary or usual.

Preemption. No state or political subdivision of a state may establish any law, regulation, order, or other requirement for cosmetics that is different for registration and product listing, good manufacturing practice, records, recalls, adverse event reporting or safety substantiation. Nothing prevents any state from prohibiting the use of an ingredient in a cosmetic product, or continuing requirement of any state in effect at time of enactment.

- **Savings Clause**: Nothing in the amendments shall be construed to modify, preempt, or displace any action for damages or the liability of any person under the law of any state, whether statutory or based in common law.

Talc-containing cosmetics: The HHS secretary shall propose regulations one year after December 29, 2022 and finalize the rules 180 days after the comment period to establish testing for detecting asbestos in talc products.

(1) Not later than one year after date of enactment of this act, the secretary shall promulgate proposed regulations to establish and require standardized testing methods for detecting and identifying asbestos in talc-containing cometic products and

(2) Not later than 180 days after the date on which the public comment period on the proposed regulations closes, the secretary shall issue such final regulations.

PFAS in Cosmetic. The HHS secretary shall assess the use of perfluoroalkyl and polyfluoroalkyl substances (PFAS) in cosmetic products and the scientific evidence regarding the safety in cosmetic products, including risks. The secretary may consult with the National Center for Toxicological Research.

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Report must be issued not later than **three years after enactment** summarizing the results of the assessment conducted.

Sense of the Congress on animal testing: It is the sense of the Congress that animal testing should not be used for the purposes of safety testing on cosmetic products and should be phased out except for appropriate allowances.

Funding: $14,200,000 for 2023, 25,960,000 for 2024, and $41,890,000 for 2025-2027 have been identified for these activities. The new law provides no industry user fees.

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