Crowell

Modernization of Cosmetics Regulation Act White Paper

Robbie Jost, Helen Ogunyanwo, Julia Carbonetti, Moriah Denton

TABLE OF CONTENTS

INTRODUCTION

Every day, consumers in the United States use a wide variety of cosmetic products, including makeup and facial cleansers, shampoos and conditioners, and moisturizers and other skin care products. Yet the U.S. cosmetics industry has remained largely unregulated. On December 29, 2022, the Modernization of Cosmetics Regulation Act of 2022 (MoCRA) became law. MoCRA, which is part of the Consolidated Appropriations Act of 2023, is the most significant expansion of the U.S. Food and Drug Administration's (FDA) authority to regulate cosmetics in nearly 85 years.

Under this new law, FDA has the power to:

- Require manufacturing and processing facilities to register with the agency;
- Require cosmetics manufacturers, distributors, and packers to submit lists of products and ingredient information;
- Impose recordkeeping obligations with respect to product safety;
- Require manufacturers, distributors, and packers to report and maintain records of adverse events;
- Recall cosmetic products in certain situations;
- Demand access to safety substantiation records and records for cosmetic products that FDA reasonably believes pose a serious health risk;
- Require additional information on cosmetic product labels, such as contact information for adverse event reporting;
- Establish Good Manufacturing Practices (GMPs) and labeling requirements for fragrance allergens; and
- Suspend facility registration if FDA reasonably believes that the facility manufactures or processes a cosmetic product that poses a serious health risk.

In addition to giving FDA increased regulatory authority, MoCRA instructs FDA to enact regulations that provide for standardized testing for asbestos in cosmetic products with talc and report on the use and safety of per- and polyfluorinated substances (PFAS) in cosmetic products.

For many companies who manufacture, package, import, distribute, and/or sell cosmetic products in the United States, MoCRA is likely to mean big changes in the ways they validate products prior to sale, substantiate the safety and efficacy of those products, track products through the

distribution chain, and/or monitor consumer feedback. And with the majority of MoCRA's provisions already in effect as of July 2024, it is important for all cosmetics companies to be aware of the new regulatory requirements and the steps they should take now to put themselves in the best possible position to deal with all that is to come. This paper provides a detailed roadmap of the new regulatory requirements and enforcement powers, analyzes the potential litigation impacts, and offers a series of priority actions for cosmetics companies.

HISTORY OF COSMETICS REGULATION IN THE UNITED STATES

The origins of FDA as a federal consumer protection agency began with the Pure Food and Drug Act of 1906—an expansive set of regulations for food and drug products, which at that point lacked any formal oversight by the U.S. government. Although the Pure Food and Drugs Act marked a historic shift in the use of government powers to enhance consumer protections, it did not include cosmetic products within its scope. And despite the significance of the new law, FDA's authority was highly circumscribed.

It was not until 32 years later, in 1938, that Congress passed the Food, Drug, and Cosmetics Act (FDCA), 21 U.S.C. § 301 *et seq.*, to address the various shortcomings of the existing regulatory landscape. For the first time, FDA obtained authority to regulate cosmetics as well as medical devices and to establish safety standards for food products. Yet even under the FDCA, cosmetics did not need pre-sale FDA review or approval, there was no legally required safety testing, and FDA was not granted authority to recall cosmetics.

In its own words, FDA historically has had "limited tools" to regulate cosmetics, and it relied in large part on voluntary registration and self-regulation.[1] Between 1972 and 1973, FDA implemented three voluntary programs for cosmetics companies. These programs provided for registration of cosmetic manufacturers, filing of cosmetic product ingredients, and reporting of adverse events[2], and eventually became the Voluntary Cosmetic Registration Program (VCRP), a reporting system for manufacturers, packers, and distributors of cosmetics in the U.S.[3]

Despite various attempts to reform U.S. cosmetics regulation over the last several decades, FDA's

---

[1] Press Release, Scott Gottlieb, M.D , FDA Commissioner, and Susan Mayne, Ph.D., Director of the Center for Food Safety and Applied Nutrition, Statement on Tests Confirming a 2017 Finding of Asbestos Contamination in Certain Cosmetic Products and New Steps that FDA is Pursuing to Improve Cosmetic Safety(Mar. 5, 2019), https://www.fda.gov/news-events/press-announcements/statement-fda-commissioner-scott-gottlieb-md-and-susan-mayne-phd-director-center-food-safety-and.

[2] Elmer B. Staats, Lack of Authority Hampers Attempts to Increase Cosmetic Safety, H.R. Doc. No. 78-139, at 3-4 (1978).

[3] FDA, Voluntary Cosmetic Registration Program (March 27, 2023), https://www.fda.gov/cosmetics/voluntary-cosmetic-registration-program.

authority over cosmetics remained unchanged. Expansion and innovation in the cosmetics industry spurred a renewed push for change over the last few years. In 2017, Senator Orrin Hatch (R-Utah) introduced the FDA Cosmetic Safety and Modernization Act and Senator Dianne Feinstein (D-Calif.) introduced the Personal Care Products Safety Act—efforts to enhance oversight, require adverse event reporting, and establish mandatory registration for cosmetics.[4] During this same time, FDA has also increased cosmetics-related enforcement activity, started to survey the cosmetics industry to evaluate manufacturing practices[5], and issued draft guidance for the cosmetics industry on good manufacturing practices.[6] MoCRA is a culmination of these efforts and is the first legislation in 84 years modifying—and in this case, greatly expanding—FDA's regulatory oversight and authority over the cosmetics industry.

NEW REQUIREMENTS AND FDA ENFORCEMENT POWERS

The primary regulatory changes under MoCRA fall into seven categories: (1) facility registration, (2) product listing, (3) adverse event reporting and record keeping, (4) labeling requirements, (5) safety substantiation, (6) recall authority, and (7) records access.

FACILITY REGISTRATION

Under MoCRA, the "responsible person" (i.e., the manufacturer, packer, or distributor of a cosmetic product whose name appears on the label of the product [except to the extent the small business exception applies[7]]) must register their facilities with FDA and update that registration every two years.[8] This requirement applies regardless of whether the owner or operator is a U.S. company or whether the facility is located in the United States.[9] FDA began enforcing the requirement that all owners and operators register their facilities through a new FDA system (even

---

[4] Cosponsors, S.1113 - Personal Care Products Safety Act, 115th Cong., Congress.gov, https://www.congress.gov/bill/115th-congress/senate-bill/1113/cosponsors (last visited June 15, 2023); S. 1113, 115th Cong., (as introduced in Senate May 11, 2017). , https://www.congress.gov/bill/115th-congress/senate-bill/2003/text?format=txt.

[5] Constituent Update, FDA To Survey Cosmetics Industry on Current Manufacturing Practices, FDA, (Apr. 24, 2019), https://www.fda.gov/food/cfsan-constituent-updates/fda-survey-cosmetics-industry-current-manufacturing-practices.

[6] Hassan Z. Sheikh and Agata Bodie, FDA Regulation of Cosmetics and Personal Care Products, Cong. Rsch. Serv. (Mar. 9, 2022), https://sgp.fas.org/crs/misc/R42594.pdf.

[7] Food, Drug, and Cosmetic Act, 21 U.S.C. § 612 (2022).

[8] *Id*. at § 607(a).

[9] *Id.* at § 604. The term "facilities" does not include (1) beauty salons that use cosmetics for consumer services; (2) retailers that only sell finished products; (3) health care facilities; (4) public health and non-profit organizations that only provide cosmetic products directly to consumers; (5) venues that provide free samples; (6) establishments that manufacture or process cosmetics only for research or evaluation purposes (not for sale); (7) establishments that only label/re-label finished cosmetic products, package/repackage pre-filled finished cosmetic products, or store and/or distribute cosmetic products. *Id.* at § 604 (3)(B).

if they previously registered voluntarily through the VCRP) on July 1, 2024.[10] FDA launched Cosmetics Direct, an electronic submission portal for facility registration and product listing submissions. FDA strongly recommends electronic submissions through this platform.

Companies are required to notify FDA within 60 days of any changes to information that is required to be submitted as part of the registration process. Facilities that manufacture or process products on behalf of multiple companies (*i.e.*, contract manufacturers) would only need to register once—either on their own or through a company whose cosmetic products are manufactured or processed at the facility.[11]

Under MoCRA, FDA also has the authority to suspend facility registration if it determines there is a reasonable probability that a facility's product could cause serious adverse health consequences or death, and that the issue is pervasive (*i.e.*, affecting other products at the facility).[12] While a facility's registration is suspended, it may not distribute or sell cosmetics in the United States. Before FDA can suspend registration, however, it must notify the facility of the reason(s) for the suspension. Within five business days of that notice, FDA will grant the facility an opportunity to be heard, and the facility must provide a plan for addressing the reasons identified by FDA. The facility will also be entitled to an informal hearing to determine the actions required to have registration reinstated. If FDA determines adequate grounds do not exist to continue the suspension after the hearing, it will promptly reinstate registration. Alternatively, if FDA determines the suspension is still necessary, the facility will need to submit a corrective action plan.[13]

FDA published final guidance concerning the registration and product listing submission requirements on December 11, 2024. In this guidance, FDA made clear that responsibilities of U.S. agents for foreign establishments or facilities include: (1) assisting FDA in communications with the foreign establishment; (2) responding to questions concerning the foreign establishment's products that are imported or offered in the U.S.; (3) assisting FDA in scheduling inspections of the foreign establishment; and (4) receiving information or documents from FDA on behalf of the foreign establishment. In addition, FDA clarified that a cosmetic facility that includes multiple buildings with different physical addresses but within three miles of each other are considered to be one facility with one FDA Establishment Identifier (FEI) number if the following conditions are

---

[10] *Id.* at § 607(a). As of March 27, 2023, FDA stopped accepting and processing submissions through the VRCP. Voluntary Cosmetic Registration Program, supra note 3.

[11] 21 U.S.C. § 607(a). For any new facilities that begin operating after December 29, 2022, MoCRA provides they will need to register with FDA within 60 days of manufacturing or processing activities or 60 days after December 29, 2023, whichever is later. *Id.*

[12] *Id.* at § 607(f).

[13] *Id.*

met: (1) the activities of the buildings are all closely related to the same business enterprise; (2) the buildings are under the supervision of the same local management; and (3) the buildings can all be inspected by FDA during a single inspection. Registering for an FEI number must be completed before starting the facility registration submission.

PRODUCT LISTING

MoCRA further provides that the "responsible person" (the manufacturer, packer, or distributor of a cosmetic product whose name appears on the label of the product) must submit a list of each cosmetic product (including ingredients) to FDA, which began enforcing this requirement on July 1, 2024.[14] Similar to facility registration, all companies must submit product listings through a new system regardless of whether they previously provided this information through the VCRP. Also, like facility registration, FDA strongly recommends that responsible persons use its Cosmetics Direct electronic submission portal for product listing submissions. In its December 11, 2024, final guidance concerning the registration and product listing submission requirements, FDA clarified that a responsible person must submit a product listing for each cosmetic product, even those that are provided as free samples or gifts, unless another exemption applies. However, FDA does not require a product listing for a cosmetic sample that is provided within the industry for research and product development where the product is not intended for consumer consumption—*e.g.*, free finished product samples for industry participants.

Small businesses will be exempt from the product listing requirement,[15] which includes: (i) the facility registration number for each facility where the product is manufactured or processed; (ii) the name and contact number for the responsible person and the name of the cosmetic product as it appears on the label; (iii) a list of ingredients in the cosmetic products, including fragrances, flavors, or colors; (iv) the applicable cosmetic category; and (v) listing number if previously assigned. Products that differ only in flavor, fragrance, color, or quantity may be covered by a single listing.[16]

Under MoCRA, the responsible person will also have to review and update their product listings annually; when there are no changes to report, there will be an abbreviated process for renewing cosmetic product listings.[17]

---

[14] *Id.* at § 604. For cosmetic products first marketed after December 29, 2022, MoCRA states that product listings will be due to FDA within 120 days from that date. *Id.* at §607.

[15] 21 U.S.C. at § 612.

[16] *Id.* at § 607(c).

[17] *Id.*

ADVERSE EVENT REPORTING AND RECORD KEEPING

Responsible persons will also need to maintain records of, and report, adverse health-related events associated with the use of their cosmetic products.[18] Companies will need to report via MedWatch[19] any serious adverse events related to the use of cosmetics they manufactured, distributed, or packed in the United States within 15 business days of receipt.[20] Serious adverse events include those that result in death, threat to life, inpatient hospitalization, persistent or significant disability or incapacity, congenital anomaly or birth defect, infection, or serious disfigurement (*e.g.*, serious rashes, significant hair loss, or significant alteration of appearance) other than as intended when used in a customary or usual manner. Events that require medical or surgical intervention to prevent a serious adverse event from occurring also trigger an adverse report.[21] Along with a report, cosmetics manufacturers, distributors, and packers also will need to send a copy of the product label or packaging to FDA and submit any new or material medical information received within one year of a reported event within 15 business days of receipt.[22]

Additionally, if FDA reasonably believes that an ingredient or combination of ingredients in a fragrance or flavor has caused or contributed to the serious adverse event, FDA may request a list of ingredients or categories of ingredients in those specific fragrances or flavors. Cosmetics companies will have 30 days to comply with FDA's request.[23]

Although by law, the fragrance and flavor list cannot be requested by the public, [24] other information submitted by a company to FDA may be released to the public.[25] Per the Freedom of Information Act (FOIA), any member of the public is entitled to request to obtain documents submitted under MoCRA so long as all personally identifiable information is redacted. This includes adverse reports and any other information submitted to FDA, except for the list of cosmetics ingredients and fragrances, which is prohibited by law from disclosure.[26] FDA clarified in its December 11, 2024, final guidance concerning the facility registration and product listing submission requirements that in response to a request under FOIA, FDA will not disclose the

---

[18] *Id.* at § 605. Although FDA is authorized to create exemptions to the adverse event reporting requirement, it has yet to do so.

[19] MedWatch reporting forms can be found at FDA, The FDA Safety Information and Adverse Event Reporting Program, FDA (Jul. 7, 2023), https://www.fda.gov/safety/medwatch-fda-safety-information-and-adverse-event-reporting-program.

[20] 21 U.S.C. § 605.

[21] *Id.* at 604(5).

[22] *Id.* at § 605(a)-(e)(1).

[23] *Id.* at § 605(f).

[24] *Id.*

[25] *Id.* at § 605 (g).

[26] *Id.* at § 605(f)-(g).

product listing number (a number FDA will generate for each unique product) or information from a facility on the brand names of products manufactured or processed at the facility. However, all other information from the facility registration and product listings will be available for public disclosure under FOIA.

Although MoCRA does not require companies to submit reports related to non-serious adverse events associated with the use of U.S. cosmetics, they must maintain records of those events for six years. Small businesses not engaged in the manufacturing or processing of certain cosmetic products must maintain these records for three years. Notably too, FDA will not construe a serious adverse event report as an admission that the cosmetic product in fact caused or contributed to the injuries described. But companies may also choose to attach a statement expressly denying that a cosmetic product caused or contributed to such an event, and if they do so, this statement will become part of any report released publicly.[27]

LABELING REQUIREMENTS

MoCRA also provides that, beginning December 29, 2024, all cosmetic products sold in the U.S. will need to contain labels with a domestic address/phone number or electronic contact information, which may include a website that a consumer can visit, to submit complaints of adverse events.[28] In addition, cosmetic products introduced solely for professional use will need to have clear and prominent statements that the products are to be used only by licensed professionals (*i.e.*, those licensed by an official state authority in cosmetics, nail care, barbering, or esthetics).[29]

SAFETY SUBSTANTIATION

Prior to sale, responsible persons must determine that their products (and ingredients) are safe for use (*i.e.*, not harmful when used as directed). Companies also will need to maintain records supporting that safety determination, such as tests, studies, research, analyses, and other evidence considered among qualified experts sufficient to support a reasonable certainty that a cosmetic product is safe. When ensuring the safety of a cosmetic product, companies must also document the effect of cumulative exposure, which FDA may consider in its own determination.[30] However, cosmetic products (or ingredients) that cause transient or minor reactions or irritations are not considered unsafe.[31]

---

[27] *Id.* at § 605.

[28] *Id.* at § 609; How MoCRA Affects the Cosmetics Regulation in the USA, Cosmeservice, (May 3, 2023), https://www.cosmeservice.com/en/modernization-of-cosmetic-regulation-act-mocra/.

[29] *Id.* at § 609(c).

[30] *Id.* at § 608.

[31] *Id.*

RECALL AUTHORITY

FDA has the authority to request a voluntary recall of any cosmetic product that the agency determines is adulterated, misbranded, or the cause of death or serious adverse health consequences. If a company refuses to or otherwise fails to voluntarily recall the product in the time requested, the agency may issue a mandatory recall order.[32] In the event that FDA chooses to do so, it must provide an opportunity for an informal hearing within 10 days to determine whether there is adequate evidence to justify FDA's recall order. Following the hearing, FDA has the authority to extend, amend, or vacate its order.[33]

RECORDS ACCESS

FDA is also entitled to access and copy a company's records relating to cosmetics if it reasonably believes a product or its ingredient is tainted and creates a threat of death or serious adverse health consequences. FDA may also access records relating to any other cosmetic product that it believes to be similarly affected. Additionally, during a facility inspection, FDA may access the company's adverse event records.[34] FDA, however, may not access recipes, formulas, financial/pricing data, personnel information, or irrelevant research data.[35]

OTHER MOCRA REQUIREMENTS

Beyond these seven primary categories, MoCRA contains several other changes. More specifically, FDA must propose rules on GMPs, labeling requirements for fragrance allergens, testing methods for detecting asbestos in talc-containing cosmetics, and a report assessing the use and safety of PFAS in cosmetic products.

REGULATION ON GOOD MANUFACTURING PRACTICES (GMPs)

FDA must establish GMPs—a system for ensuring that cosmetics products are consistently produced and controlled according to quality standards—that may include FDA's authority to conduct records inspections to assess compliance.[36] In establishing GMPs, FDA must consider: (i) business size and scope; (ii) public health risk, and (iii) whether there is sufficient flexibility in the GMPs to be practicable. Smaller businesses may be afforded longer compliance times or be exempt from complying with certain GMPs to avoid economic hardship.[37]

---

[32] *Id.* at § 611.

[33] *Id.*

[34] *Id.* at 610.

[35] *Id.*

[36] *Id.* at § 606.

[37] *Id.*

FDA was required to publish a notice of proposed rulemaking on GMPs by December 29, 2024, and a final rule by December 29, 2025. In its fall 2024 regulatory agenda, FDA indicated that it expects the proposed rule establishing GMPs will be delayed until October 2025, likely delaying the final rule as well. Additional delays may result from the recent change in Administration. Although it has yet to indicate what this forthcoming guidance will entail, FDA's 2022 GMP Guidelines and Inspection Checklist for Cosmetics[38] offers a potential roadmap:

Building & Facilities

- ✓ Unobstructed equipment, orderly storage, sanitary operation, proper maintenance
- ✓ Easily cleanable walls and ceilings
- ✓ Properly installed fixtures, ducts, and pipes that do not drip or cause condensation
- ✓ Lighting and ventilation are sufficient
- ✓ Washing and toilet facilities, sewage system, and floor drainage are sanitary

Equipment

- ✓ Appropriate design, material/workmanship to prevent corrosion, buildup, and adulteration
- ✓ Utensils, transfer piping, and cosmetic contact surfaces are sanitized
- ✓ Portable equipment/utensils are cleaned and stored, and contact surfaces are covered to prevent contamination or dust

Personnel

- ✓ Employees have the necessary education, training, and experience
- ✓ Those in direct contact with materials wear appropriate garments, gloves, and hair restraint
- ✓ No consumption of food or drink, or use of tobacco in appropriately designated areas

Raw Materials

- ✓ Raw/primary packaging materials are stored/handled to prevent mix-up, contamination, or decomposition
- ✓ Containers of materials are closed, and bagged or boxed materials are stored off the floor
- ✓ Containers of materials are labeled with their identity, lot identification, and control status
- ✓ Materials are sampled, tested, and/or examined to assure no contamination
- ✓ Materials not meeting acceptance specifications are identified/controlled to prevent use

Production

- ✓ Create and maintain written instructions for formulations, processing, transfer, filling, etc.
- ✓ Equipment for processing, transfer, and filling utensils/containers are clean and in good repair
- ✓ Using only approved materials
- ✓ Samples are taken as appropriate during and after processing, transfer, or filling
- ✓ Weighing and measuring of raw materials is checked by a second person, and containers holding raw materials are properly identified
- ✓ Major equipment, transfer lines, containers, and tanks used for processing, filling, or holding cosmetics are identified with contents, batch designation, and control status
- ✓ Labels are examined to avoid mix-up
- ✓ Equipment is labeled with identity, batch identification, and control status
- ✓ Packages of finished products have permanent code marks; returned cosmetics are examined for contamination/deterioration

Lab

- ✓ Raw materials, in-process samples, and finished products are tested/examined to verify identity and determine compliance
- ✓ Reserve samples of approved batches of raw materials and finished products are retained for specified time, stored in appropriate conditions, and retested
- ✓ Water supply (especially if used as an ingredient) is tested regularly
- ✓ Fresh and retained samples of finished product are tested

PROPOSED RULE ON LABELING REQUIREMENTS FOR FRAGRANCE ALLERGENS

Under MoCRA, FDA was required to issue a proposed rule on fragrance allergen labeling requirements for cosmetic products by June 29, 2024. FDA was then obligated to issue the final rule on fragrance allergen labeling within 180 days after the comment period closed. The regulation was to determine what constitutes a "fragrance allergen" and what is required for such allergens on cosmetic labels, considering international, state, and local requirements for allergen disclosure, including E.U. requirements that demand disclosure of any recognized allergens.[39]

As of February 2025, this rule has not yet been released. However, it is shown as pending for release at the Office of Management and Budget (OMB), and FDA's regulatory agenda indicates it should be released soon. The rule on labeling requirements for fragrance allergens may be further delayed by the change in Administration.

REGULATIONS TO ESTABLISH TESTING METHODS FOR TALC

By December 29, 2023, MoCRA required FDA to propose regulations establishing mandatory standardized testing methods for detecting asbestos in talc-containing products. Final rules and regulations must follow a public comment period.[40] Talc is a naturally occurring mineral ingredient used in many popular cosmetics, ranging from eye shadow to baby powder. Because talc is mined from the earth, there is the potential for contamination with asbestos deposits. FDA had started testing for asbestos contamination in talc-containing products but had not previously assessed how best to regulate talc products that contain asbestos.

On December 27, 2024, FDA published a proposed rule requiring standardized testing methods to detect and identify asbestos in talc-containing cosmetic products. FDA's proposed rule would require manufacturers to test a representative sample of each batch or lot of a talc-containing cosmetic product or test the talc ingredient for the presence of asbestos. This testing would need to be done using both Polarized Light Microscopy (PLM) (with dispersion staining) and Transmission Electron Microscopy (TEM)/Energy Dispersive Spectroscopy (EDS)/Selected Area Electron Diffraction (SAED). Under the rule, any amount of asbestos detected by either approach would render the sample positive for asbestos.

In lieu of testing the product batch or talc ingredient, the proposed rule would also allow manufacturers to rely on a certificate of analysis from a talc supplier prior to using the talc ingredient in manufacturing a cosmetic product. If a manufacturer relies on a certificate of analysis, they will also need to verify that the supplier's asbestos testing includes both PLM and

[39] 21 U.S.C. § 609.

[40] *Id.* at § 3505.

TEM/EDS/SAED approaches and that the testing is performed on the specific talc purchased by the manufacturer on an annual basis.

Under the proposed rule, a cosmetic product will be considered adulterated if (1) any asbestos is present in any finished cosmetic product or the talc used in the product, or (2) if the manufacturer fails to comply with either the testing or recordkeeping requirements. The significance of deeming a cosmetic product adulterated would be at least twofold. First, both the FD&C Act and MoCRA prohibit the sale or delivery of an adulterated cosmetic product. In addition, under MoCRA, FDA has authority to recall any cosmetic product the agency determines is adulterated.

FDA is seeking comments on the proposed rule by March 27, 2025.

REPORT ON PFAS IN COSMETICS

MoCRA also requires FDA to assess the use and safety of PFAS (perfluoroalkyl and polyfluoroalkyl) in cosmetic products, and by December 29, 2025, publish a report summarizing its findings.[41] PFAS are a group of human-made so-called "forever" chemicals used in many cosmetic products, including cleansers, lotions, and makeup. Often, PFAS are intentionally added to products to adjust the texture or to add conditioning properties. But PFAS also form in products because of raw material impurities or the breakdown of other ingredients. There are not many studies on the impact of PFAS in cosmetic products, making FDA's forthcoming report significant.[42]

POTENTIAL LITIGATION IMPACTS

MoCRA's various requirements, such as recordkeeping and reporting of adverse events, means added benefits and new challenges for cosmetics companies when it comes to litigation.

- **Discovery of Adverse Event Reports, Safety Substantiation, and Voluntary Recalls.** Although plaintiffs are prohibited from relying on adverse events or serious adverse event reports as evidence of an admission that a cosmetic product caused or contributed to an adverse event,[43] it does not prevent discovery of this information. The recordkeeping, reporting, and testing now required by MoCRA are now fair game. With access to this information, plaintiffs, potential plaintiffs, and their counsel may be better positioned to scrutinize (and criticize) a company's safety substantiation data and risk assessment processes and allege with more specificity the potential risks posed by a company's products. Plaintiffs may also attempt to use the information in an adverse report to show

[41] *Id.* at § 3506.

[42] Per and Polyfluoroalkyl Substances (PFAS) in Cosmetics, FDA (Feb. 25, 2022), https://www.fda.gov/cosmetics/cosmetic-ingredients/and-polyfluoroalkyl-substances-pfas-cosmetics.

[43] 21 U.S.C. § 605(h)(4).

that a company knew of a problem with its product or had a habit of dilatory reporting. Companies should expect to see broad discovery requests seeking not only information found in the adverse reports, but the company's testing and compliance practices, which prior to MoCRA, a company might have had a better chance of shielding as privileged or proprietary.

- **Violations of Good Manufacturing Practices and *Per Se* Liability**. Once FDA issues GMPs for cosmetic manufacturers and processing facilities, there will be clearer guidance for companies on the standard of care in the cosmetics industry. A manufacturer or a facility's failure to comply with these GMPs could face not just scrutiny from FDA but from discerning plaintiffs who can argue that the violation is sufficient evidence to show the company was negligent. Under the law, this would be described as negligence *per se*—the company is presumed to have breached the duty of care. Rather than the plaintiff having the burden of proof, the company must demonstrate it was not negligent in its conduct.

- **Unclear Guidance as a Defense**. Although MoCRA's requirements provide guidance to cosmetics companies, much of this guidance is relatively vague and open-ended. Given the ambiguity, companies might consider arguing that MoCRA and its requirements are not specific enough to put companies on notice as to what is prohibited and what is acceptable.

- **Primary Jurisdiction as a Defense.** Companies may also be able to rely on the primary jurisdiction doctrine as a defense in product liability litigation. Under the primary jurisdiction doctrine, a court may dismiss or stay a case pending agency review when the case presents a novel or complex issue that implicates the specialized or technical expertise of a regulatory agency. Pursuant to MoCRA, FDA now has the authority to, among other things, investigate and propose rules regarding the use and safety of PFAS, cosmetics labels, and the disclosure of fragrance allergens. Once FDA issues this guidance, cosmetics companies will be able to potentially defeat lawsuits early in the proceedings on the grounds that FDA has made pronouncements on the same issues.

- **Prudential Mootness as a Defense.** Another defense that may be available to cosmetics companies in litigation is prudential mootness. Under this doctrine, courts may dismiss a case as moot where the alleged product defect has been properly remedied by the defendant while the litigation is pending (or even before it has started). Particularly in recent months, federal district courts have increasingly exercised their discretion to dismiss cases where a government agency is overseeing the remedial actions (*e.g.*, product recalls) that address and alleviate any potential injuries arising from the alleged product defect. As a result of FDA's newfound ability to mandate recalls of cosmetic products and suspend facility registration (and therefore, operation) of companies that manufacture and process

those products, cosmetics companies who recall products or carry out other remedial actions in coordination with FDA may have a strong defense against certain lawsuits involving their products.

- **Compliance as a Defense.** Any ambiguity aside, MoCRA provides cosmetics manufacturers, packers, and distributors a better road map for how to, among other things, substantiate product safety, track customer feedback, respond to adverse events, and guarantee the quality of their products. Cosmetics companies that invest in educating their employees and creating internal systems aimed at achieving compliance with MoCRA's new requirements will be in the most defensible position in the event of a lawsuit involving one of their products. Evidence of compliance may lead to inferences that the company acts diligently or even that its products are safe and effective. And industry members who are making every effort to comply with MoCRA's various requirements may help set a baseline standard of care (*i.e.*, what is considered sufficient compliance).

CONCLUSION AND RECOMMENDED NEXT STEPS

MoCRA may mean big changes (and big undertakings) for many companies that currently manufacture, distribute, and sell cosmetics in the United States. And there is still time for the public to comment on many of the new cosmetics regulations and new or forthcoming guidance. Affected companies may submit their own feedback, recommendations, or concerns, or solicit trade groups to advocate on their behalf. Among other things, companies might want to consider which aspects of the 2024 proposed rule requiring standardized testing methods to detect and identify asbestos in talc-containing cosmetic products might create unforeseen costs or other problems.

These public comment periods are opportunities to be heard and to potentially influence the scope of forthcoming rules and regulations. Regardless, with the proper planning and the steps outlined below, companies will have the time and the tools to put together policies and procedures to ensure compliance with MoCRA and everything that is to follow.

PRELIMINARY: CONDUCT A GAP ANALYSIS.

Before taking any action to comply with MoCRA's requirements, companies should engage in gap analysis to determine what systems, records, and processes they already have in place and how this differs from what is now required. For example, companies may already have a way for consumers to provide product feedback and report a negative reaction. If so, those companies

need to determine whether and how this process might be updated to enable reporting of serious adverse events within 15 days of receipt. This outcome of a gap analysis is a list of items that may already comply with MoCRA and a list of items that do not, allowing companies to direct their resources to tasks with the most imminent deadlines.

STEP #1: CREATE A SYSTEM FOR TRACKING, REPORTING, AND MAINTAINING RECORDS OF ADVERSE EVENTS.[44]

Following a gap analysis, the next best step is to create an online portal, system, or telephone line to efficiently and effectively collect and store consumer feedback, particularly complaints involving adverse health-related events. At the same time, companies should also create a corresponding system for maintaining all records related to adverse events and train employees on how to use these systems.

STEP #2: PREPARE FOR INSPECTIONS AND CREATE A SYSTEM FOR MAINTAINING SAFETY SUBSTANTIATION RECORDS.[45]

Companies will also need to ensure that they have sufficient records demonstrating that all products and their ingredients are safe. For some companies, this may be as simple as ensuring that all safety substantiation records are saved and maintained and creating a system that enables FDA to view these records upon inspection or request. For other companies, sufficient safety substantiation may require new or additional testing, studies, research, and analysis. Given FDA's new record inspection authority, companies should implement the same processes for all future products.

While FDA works to establish new guidelines and regulations for safety substantiation, companies should familiarize themselves with existing FDA requirements for pre-market food additives and tobacco product petitions, which offer insight into what FDA will likely expect from the cosmetics industry.

For pre-market food additives, FDA requires:

(1) a detailed description of the additive;

(2) information on the method of manufacture and alternative methods of manufacture;

(3) specifications for identity and purity of the additive, including published specifications, and special attention to the proposed specification for lead;

---

[44] *See id.* at § 605.

[45] *See id.* at § 608, 704.

(4) data demonstrating the stability of the additive, considering whether it is sensitive to environmental conditions;

(5) an analysis of the intended use of the additive, including data that shows the amount required to achieve the intended effect;

(6) method of quantifying how much of the additive is in food if the assurance of safe use depends on a limitation; and

(7) an analysis of the estimated daily intake.[46]

For pre-market tobacco product applications, FDA requires:

(1) full reports of all information published or known to the applicant concerning investigations that have been made to show health risks of the product;

(2) a full statement of the components, ingredients, additives, and properties of the product;

(3) a full description of the methods used in the manufacture, processing, packing, and installation;

(4) information demonstrating the product complies with applicable tobacco product standards.

As to health risk investigations, applicants must include toxicological and pharmacological profiles of the product, a health risks comparison between products, and studies on the impacts of using the products.[47]

STEP #3: PLAN FOR AND SUBMIT FACILITY REGISTRATION AND PRODUCT LISTING.

MoCRA requires facility registration and product listing, and these requirements are being enforced as of July 2024. To best prepare for accurate and timely filing during a tight turnaround, companies should compile current facility registration information and prepare their product listing information, including the place of manufacture, category of product, and a full list of ingredients. Companies should also review the new Cosmetics Direct electronic submission portal and FDA's recent and future guidance on completing the registration and listing.

[46] Guidance for Industry: Recommendations for Submission of Chemical and Technological Data for Direct Food Additive Petitions, FDA (Sep. 20, 2018), https://www.fda.gov/regulatory-information/search-fda-guidance-documents/guidance-industry-recommendations-submission-chemical-and-technological-data-direct-food-additive.

[47] Premarket Tobacco Product Applications, FDA (Apr. 11, 2023), https://www.fda.gov/tobacco-products/market-and-distribute-tobacco-product/premarket-tobacco-product-applications.

ABOUT US

Robbie Rogart Jost, Partner

rjost@crowell.com

Robbie Rogart Jost has over a decade of experience managing complex consumer litigation. She employs a multi-faceted approach—understanding the product, as well as the client's goals, business model, industry, and the regulatory framework in which it operates. Robbie forged her litigation skills by defending clients in dozens of high-stakes class actions and mass actions and several of the largest multidistrict ligations (MDLs) in the U.S.

Helen Ogunyanwo, Counsel

hogunyanwo@crowell.com

Helen Ogunyanwo provides clients with practical, creative, and individualized approaches in navigating advertising, unfair competition, brand disparagement, reputation, and intellectual property matters. She has extensive litigation experience in defending companies in protecting their technology and brands from their competitors, regulators, state attorneys, and private consumer class action claimants.

Julia Carbonetti, Counsel

jcarbonetti@crowell.com

Julia Carbonetti represents clients in complex tort and product liability matters. She handles all aspects of litigation, including dispositive motions, mediations, and/or arbitrations. She also has experience defending clients in breach of warranty and negligence cases.

Moriah Denton, Associate

mdenton@crowell.com

Moriah Denton focuses on complex litigation matters, including class actions. She assists corporations from the consumer products, technology, transportation, and chemicals industries with risk assessment and litigation needs. Moriah's pro bono practice includes adoption cases and helping refugees seek asylum.

Crowell & Moring LLP is an international law firm with offices in the United States, Europe, MENA, and Asia. Drawing on significant government, business, industry, and legal experience, the firm helps clients capitalize on opportunities and provides creative solutions to complex litigation and arbitration, regulatory and policy, and corporate and transactional issues. The firm is consistently recognized for its commitment to pro bono service as well as its programs and initiatives to advance diversity, equity and inclusion.