VII. Modernization of Cosmetics Regulations Act (MoCRA): The FDA's New Authority, Dialogue with the Public, and Implications for the Cosmetics Industry

A. Introduction

1. Sub-Topic Passage of Modernization of Cosmetics Regulations Act

The Modernization of Cosmetics Regulation Act (MoCRA)[1] was signed into law on December 29, 2022 as part of the Consolidated Appropriations Act 2023[2] and is included at Section 3501 of the Food and Drug Omnibus Reform Act of 2022.[3] MoCRA was crafted with support and input from a variety of stakeholders including the Food and Drug Administration (FDA), consumer groups, and the cosmetics industry.[4]

2. Before MoCRA

Regulations governing the cosmetics industry prior to MoCRA's recent enactment included the Federal Food, Drug, and Cosmetic Act (FDCA) and the Fair Packaging and Labeling Act

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[1] Modernization of Cosmetic Regulation Act of 2022, Pub. L. No. 117-328, sec. 2, § 3502, Stat. 1389 (codified at 21 USC 361).

[2] Consolidated Appropriations Act, 2023, H.R. 2617, 117th Cong. (2022).

[3] Kristen R. Klesh, *MoCRA Increases FDA Oversight of the Cosmetics Industry*, LOEB & LOEB LLP CLIENT ALERTS/REPORTS (March 2023), https://www.loeb.com/en/insights/publications/2023/03/mocra-increases-fda-oversight-of-the-cosmetics-industry (describing the passage of MoCRA).

[4] Wade Ackerman, Jessica O'Connell & James Holloway, *MoCRA: 6 Key Takeaways From The New Cosmetics Law*, COVINGTON & BURLING LLP NEWS AND INSIGHTS, 4 (Jan. 20, 2023), https://www.cov.com/-/media/files/corporate/publications/2023/01/mocra-6-key-takeaways-from-the-new-cosmetics-law.pdf (describing the support of MoCRA's creation and passage).

(FPLA).[5] The FDCA was enacted by Franklin Roosevelt in 1938.[6] The FDCA did not require cosmetic companies to register their cosmetic products, which meant that there was no way for the FDA to track which cosmetics were marketed to and used by American consumers.[7] This lenient framework led to abuses by cosmetic companies, who would develop and sell products that they marketed as "cosmetics" but were intended to treat conditions, essentially functioning as drugs.[8] This lack of regulation put cosmetics consumers at risk.[9] The FPLA was passed in 1966 and had some requirements for the ingredients included on cosmetics labels.[10]

3. A New Approach

MoCRA is the first major update to the FDA's regulatory authority over cosmetics since 1938.[11] MoCRA's new provisions represent shift in the FDA's regulation of cosmetics to a more rigorous standard.[12] For instance, the FDA did not previously require cosmetic companies to follow a set of good manufacturing practices, but rather offered voluntary guidelines and encouraged adherence.[13] However,

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[5] Frederick R. Ball, Alyson Walker Lotman & Kelly A. Bonner, *MoCRA[1] Is Here—Now What? Unpacking Litigation and Regulatory Risk for Cosmetics Brands Following MoCRA's Enactment*, FOOD AND DRUG LAW INSTITUTE (2023), https://www.fdli.org/2023/02/mocra-is-here-now-what-unpacking-litigation-and-regulatory-risk-for-cosmetics-brands-following-mocras-enactment/ (describing cosmetics regulations prior to MoCRA).

[6] Ackerman, O'Connell & Holloway, *supra* note 4, at 1 (describing history of FDA's cosmetics regulation).

[7] Megan Scime, *FIRST YOU BUY THE MOISTURIZER, THEN YOU PAY THE PRICE: AN OVERVIEW OF THE UNITED STATES' LACK OF COSMETIC MARKET REGULATION AND HOW IT HARMS THE CONSUMER*, 51 HOFSTRA L. REV. 349, 352-53 (2022) (criticizing the lack of cosmetic market regulation prior to MoCRA).

[8] *Id.* (describing the abuse of the unregulated pre-MoCRA cosmetics landscape).

[9] *Id.* (describing the resulting safety and health risks of the companies' behavior).

[10] Ball, Lotman & Bonner, *supra* note 5 (describing the previous federal regulations governing cosmetics).

[11] *Id.* (emphasizing the FDA's new expanded authority to regulate cosmetics).

[12] *Id.* (emphasizing the change to the FDA regulatory scheme for good manufacturing practices).

[13] *Id.* (describing the FDA previous lenient approach to good manufacturing practices).

MoCRA will mandate that companies implement good manufacturing practices that FDA sets forth.[14]

B. MoCRA's Provisions

1. Facility Registration Requirements

MoCRA requires cosmetic facilities that manufacture or process cosmetic products distributed in the U.S. to register with the FDA.[15] The registration must contain the facility's name, physical address, an email address, telephone number, the facility registration number, the brand names under which cosmetic products that are manufactured or processed in the facility are sold, the categories of products manufactured, and the person responsible for each product.[16] This requirement applies both to domestic facilities located in the U.S. and foreign facilities located outside of the country.[17] MoCRA provides exceptions for facilities that exclusively label, relabel, package, re-package, hold, or distribute cosmetic products.[18] Exceptions are also provided for facilities whose manufacturing or processing capabilities are only used for research or evaluation purposes and do not sell

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[14] *Id.* (describing the change the new mandatory good manufacturing practices will bring).

[15] Li X. Massie & Felicia Leborgne Nowels, *New FDA Regulatory Framework for Cosmetics: The Modernization of Cosmetics Regulation Act of 2022 (MoCRA)*, AKERMAN PRACTICE UPDATE (Jan. 31, 2023), https://www.akerman.com/print/v2/content/131481/New-FDA-Regulatory-Framework-for-Cosmetics-The-Modernization-of-Cosmetics-Regulation-Act-of-2022-MoCRA.pdf (outlining the cosmetic manufacturing facility registration requirement).

[16] Modernization of Cosmetic Regulation Act of 2022 § 607.

[17] Kristen R. Klesh, *MoCRA Increases FDA Oversight of the Cosmetics Industry*, LOEB & LOEB LLP CLIENT ALERTS/REPORTS (March 2023), https://www.loeb.com/en/insights/publications/2023/03/mocra-increases-fda-oversight-of-the-cosmetics-industry, *supra* note 3, at 1 (highlighting that cosmetic manufacturing facility registration requirement applies to both facilities in the U.S. and as well as foreign facilities, so long as their cosmetic products they manufacture or process are distributed in the U.S.).

[18] Cooley LLP, *FDA Regulatory Framework for Cosmetics Gets Major Overhaul,* COOLEY NEWS (Jan. 6, 2023), https://www.cooley.com/api/downloadpdf?contextItemId=%7B97F177A7-E836-4B5A-822B-312E02C3F73C%7D (describing the exception to the facility registration requirement).

products.[19] Additionally, "[r]etailers, salons and private label distributors . . . do not need to register their facility."[20] Cosmetic companies have one year from MoCRA's enactment date to register their existing facilities.[21] New facilities must be registered with the FDA within sixty days of the date in which they begin to manufacture or process products.[22] Facilities registrations must be renewed every two years.[23]

2. Product Listing Requirements

MoCRA stipulates that a "responsible person" (including manufacturers, packers, or distributors) must list "each cosmetic product offered for distribution in the U.S." with the FDA by December 29, 2023.[24] The following information must be included in the product listing: place of manufacture, the cosmetic category, the product's ingredients (including any fragrances, flavors, or colors), and the product listing number.[25] MoCRA has some flexibility by allowing

[19] Massie & Nowels, *supra* note 15, at 2 (describing the exceptions for mandatory facility registration for facilities devoted to research).
[20] Klesh, *supra* note 3, at 1.
[21] Li X. Massie & Felicia Leborgne Nowels, *New FDA Regulatory Framework for Cosmetics: The Modernization of Cosmetics Regulation Act of 2022 (MoCRA)*, AKERMAN PRACTICE UPDATE (Jan. 31, 2023), https://www.akerman.com/print/v2/content/131481/New-FDA-Regulatory-Framework-for-Cosmetics-The-Modernization-of-Cosmetics-Regulation-Act-of-2022-MoCRA.pdf, *supra* note 15, at 2 (describing the deadline for facility registration for existing facilities).
[22] David L. Rosen & Nathan A. Beaver, *Modernization of Cosmetics Regulation Act of 2022: What You Need to Know*, FOLEY & LARDNER LLP (Jan. 25, 2023), https://1npdf11.onenorth.com/pdfrenderer.svc/v1/abcpdf11/GetRenderedPdfByUrl/Modernization%20Cosmetics%20Regulation%20Act%202022.pdf/?url=https%3a%2f%2fwww.foley.com%2fen%2finsights%2fpublications%2f2023%2f01%2fmodernization-cosmetics-regulation-act-2022?format=pdf&attachment=false (describing the deadline for facility registration for new facilities).
[23] *Id.* at 1. ("facility registrations must be renewed biennially").
[24] Kristen R. Klesh, *MoCRA Increases FDA Oversight of the Cosmetics Industry*, LOEB & LOEB LLP CLIENT ALERTS/REPORTS (March 2023), https://www.loeb.com/en/insights/publications/2023/03/mocra-increases-fda-oversight-of-the-cosmetics-industry, *supra* note 3, at 1 (describing the deadline of the product listing requirement).
[25] Massie & Nowels, *supra* note 15, at 3 (detailing the required information required of the product listing).

cosmetic products that have identical formulation but different "colors, fragrances, flavors, or quantities of contents" to be included in the same product listing.[26] The deadline for listing existing products is one year after the date of MoCRA's enactment, and new products marketed in interstate commerce after the enactment must be listed within 120 days.[27] The responsible person must update the listing for each product annually.[28]

3. Adverse Event Reporting & Record Keeping

MoCRA requires a responsible person to report "serious adverse events" associated with the use of cosmetic products to the FDA within fifteen days of learning about such an event, and any new medical information regarding the adverse event must be reported within one year of the initial report.[29] MoCRA has expanded the definition of "serious adverse event" currently used by the FDA to include events resulting in "significant disfigurement, including serious and persistent rashes, second- or third-degree burns, significant hair loss, or persistent or significant alteration of appearance,"[30] other than as intended under

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[26] *Id.*

[27] *Id.* (outlining the deadlines for existing and new product listings with the FDA).

[28] David L. Rosen & Nathan A. Beaver, *Modernization of Cosmetics Regulation Act of 2022: What You Need to Know*, FOLEY & LARDNER LLP (Jan. 25, 2023), https://1npdf11.onenorth.com/pdfrenderer.svc/v1/abcpdf 11/GetRenderedPdfByUrl/Modernization%20Cosmetics%20Regulation%20Act%202022.pdf/?url=https%3a%2f%2fwww.foley.com%2fen%2finsights%2fpublications%2f2023%2f01%2fmodernization-cosmetics-regulation-act-2022?format=pdf&attachment=false, *supra* note 22, at 1 ("the responsible person must update product listing information annually").

[29] U.S. Food and Drug Administration, *Modernization of Cosmetics Regulation Act of 2022 – Key Terms and Provisions*, YOUTUBE (Apr. 12, 2023), https://www.youtube.com/watch?v=p4UsMzXKyck&t=282s (detailing adverse event reporting).

[30] Rosen & Beaver, *supra* note 22, at 2 (defining "serious adverse event"). *See also* Kristen R. Klesh, *MoCRA Increases FDA Oversight of the Cosmetics Industry*, LOEB & LOEB LLP CLIENT ALERTS/REPORTS (March 2023), https://www.loeb.com/en/insights/publications/2023/03/mocra-increases-fda-oversight-of-the-cosmetics-industry, *supra* note 3, at 2 (describing the expansion of FDA's definition of "serious adverse event").

customary usage of the product.[31] Cosmetic companies are required to maintain records of these "adverse events" for six years, but small businesses (defined as businesses with gross annual sales of cosmetic products for the previous three-year period is less than $1,000,000) will have to maintain records for only three years.[32] MoCRA also requires companies to include a point of contact within the U.S., including an address, phone number, or electronic contact information on product labels for reporting adverse events.[33] The FDA currently uses the program MedWatch to document voluntary cosmetic adverse event reporting and will most likely continue using it for its new mandatory reporting.[34]

4. Records Access

MoCRA has extended the FDA's inspection authority to allow the FDA inspect not only the cosmetics manufacturing or processing facilities themselves, but also their records and information.[35] For instance, if the FDA reasonably believes that a cosmetic product or ingredient (or even a combination of ingredients[36]) is likely adulterated and its use presents a threat (such as a serious adverse health consequence or even death), the FDA may request access to cosmetic

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[31] Cooley LLP, *FDA Regulatory Framework for Cosmetics Gets Major Overhaul,* COOLEY NEWS (Jan. 6, 2023), https://www.cooley.com/api/downloadpdf?contextItemId=%7B97F177A7-E836-4B5A-822B-312E02C3F73C%7D, *supra* note 18, at 1 (describing MoCRA's details on what constitutes a reportable event).

[32] Klesh, *supra* note 3, at 2 (outlining the record maintenance requirements for companies and small businesses).

[33] Rosen & Beaver, *supra* note 22, at 2 (describing the point of contact requirement for product labels for adverse event reporting).

[34] Cooley LLP, *supra* note 18, at 1 (describing FDA's current reporting system and likelihood of its continued use).

[35] U.S. Food and Drug Administration, *Modernization of Cosmetics Regulation Act of 2022 – Key Terms and Provisions*, YOUTUBE (Apr. 12, 2023), https://www.youtube.com/watch?v=p4UsMzXKyck&t=282s, *supra* note 29 (describing the FDA's new inspection of records authority).

[36] Li X. Massie & Felicia Leborgne Nowels, *New FDA Regulatory Framework for Cosmetics: The Modernization of Cosmetics Regulation Act of 2022 (MoCRA)*, AKERMAN PRACTICE UPDATE (Jan. 31, 2023), https://www.akerman.com/print/v2/content/131481/New-FDA-Regulatory-Framework-for-Cosmetics-The-Modernization-of-Cosmetics-Regulation-Act-of-2022-MoCRA.pdf, *supra* note 15, at 4 (describing particular instances when FDA may request records).

companies' records of the product or ingredient in question.[37] Cosmetic companies are required to comply with FDA record inspection requests within thirty days.[38]

5. Safety Substantiation

MoCRA requires the substantiation of the safety of products marketed and distributed in the U.S. through "tests or studies, research, analyses, or other information that supports a reasonable certainty that a cosmetic product is safe."[39] A responsible person must be tasked with ensuring and maintaining records that support the adequate substantiation of products' safety.[40] If a cosmetic company does not adequately substantiate the safety of its products, then those products will be deemed adulterated under a new adulteration provision.[41] However, FDA regulations do not require specific tests to demonstrate the safety substantiation.[42]

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[37] U.S. Food and Drug Administration, *supra* note 29 (describing the reasonable grounds upon which FDA may request access to records).

[38] Massie & Nowels, *supra* note 15, at 4 (describing cosmetic companies' required compliance with record requests).

[39] *Id.* (describing the safety substantiation requirement).

[40] David L. Rosen & Nathan A. Beaver, *Modernization of Cosmetics Regulation Act of 2022: What You Need to Know*, FOLEY & LARDNER LLP (Jan. 25, 2023), https://1npdf11.onenorth.com/pdfrenderer.svc/v1/abcpdf11/ GetRenderedPdfByUrl/Modernization%20Cosmetics%20Regulation%20Act%202022.pdf/?url=https%3a%2f%2fwww.foley.com%2fen%2finsights%2fpublications%2f2023%2f01%2fmodernization-cosmetics-regulation-act-2022?format=pdf&attachment=false, *supra* note 22, at 1 (describing the responsible person's required safety substantiation record maintenance).

[41] Cooley LLP, *FDA Regulatory Framework for Cosmetics Gets Major Overhaul,* COOLEY NEWS (Jan. 6, 2023), https://www.cooley.com/api/downloadpdf?contextItemId=%7B97F177A7-E836-4B5A-822B-312E02C3F73C%7D, *supra* note 18, at 1 (describing effect of new adulteration provision).

[42] Food and Drug Admin., *Modernization of Cosmetics Regulation Act of 2022*, COSMETICS LAWS & REGULATIONS (Sept. 18, 2023), https://www.fda.gov/cosmetics/cosmetics-laws-regulations/modernization-cosmetics-regulation-act-2022 ("Neither the law nor FDA regulations require specific tests to demonstrate the safety of individual products or ingredients.").

6. Labeling Requirements

In addition to the label requirements regarding the inclusion of point of contact information for adverse event reporting, MoCRA mandates that cosmetic products intended for licensed professionals must state this exclusive use on their labels.[43] These new labeling requirements will be effective at the end of 2024.[44]

7. Facility Suspension Authority

MoCRA provides the FDA with a new enforcement power to suspend a facility's registration and operation, if it determines that a manufactured product has "a reasonable probability of causing serious adverse health consequences and believes other products may be similarly affected."[45] If a facility's registration is suspended, it may not distribute or sell any cosmetic products until registration is reinstated.[46]

8. Mandatory Recall Authority

MoCRA also grants the FDA authority to request a voluntary recall of a product if it determines that there is a "reasonable probability that the product is adulterated or misbranded, and the use of or exposure to the product will cause serious adverse health consequences or death."[47] However, if the company refuses to comply with the request for a voluntary recall, the FDA now has the authority to order a mandatory recall and notify the public.[48]

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[43] Massie & Nowels, *supra* note 15, at 4-5 (describing MoCRA's labeling requirements).
[44] *Id.* at 5 (describing MoCRA's labeling requirements date of effectiveness).
[45] *Id.* (describing FDA's new facility suspension authority).
[46] U.S. Food and Drug Administration, *Modernization of Cosmetics Regulation Act of 2022 – Key Terms and Provisions*, YOUTUBE (Apr. 12, 2023), https://www.youtube.com/watch?v=p4UsMzXKyck&t=282s, *supra* note 29 (describing the prohibition of facility operation once registration is suspended).
[47] Massie & Nowels, *supra* note 15, at 5 (describing FDA's new recall authority).
[48] Kristen R. Klesh, *MoCRA Increases FDA Oversight of the Cosmetics Industry*, LOEB & LOEB LLP CLIENT ALERTS/REPORTS (March 2023), https://www.loeb.com/en/insights/publications/2023/03/mocra-increases-fda-oversight-of-the-cosmetics-industry, *supra* note 3, at 2 (describing FDA's mandatory recall authority).

9. Good Manufacturing Practices Requirements

MoCRA directs the FDA to set forth good manufacturing practice regulations for cosmetics manufacturing and processing that are consistent with existing national and international standards.[49] These regulations need to protect public health, be flexible enough to accommodate a variety of facilities, and include simplified requirements for small businesses to meet to ensure no undue economic hardship.[50] The FDA's proposed rule must be issued within two years of MoCRA's enactment, with a final rule coming within three years.[51]

10. Small Business Exemptions

MoCRA offers exemptions to the above requirements for small businesses.[52] Small businesses are exempt from complying with good manufacturing practices, facility registration, and product listing requirements.[53] The cosmetics industry is known for its many successful small businesses and these exemptions ensure that small businesses are not hampered by onerous compliance requirements.[54] However, these exemptions do not apply for facilities of small businesses that manufacture or produce products that: regularly come into contact with the mucus membrane of the eye, are injected or intended for internal use, or

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[49] David L. Rosen & Nathan A. Beaver, *Modernization of Cosmetics Regulation Act of 2022: What You Need to Know*, FOLEY & LARDNER LLP (Jan. 25, 2023), https://1npdf11.onenorth.com/pdfrenderer.svc/v1/abcpdf11/GetRenderedPdfByUrl/Modernization%20Cosmetics%20Regulation%20Act%202022.pdf/?url=https%3a%2f%2fwww.foley.com%2fen%2finsights%2fpublications%2f2023%2f01%2fmodernization-cosmetics-regulation-act-2022?format=pdf&attachment=false, *supra* note 22, at 2 (describing FDA's required action to create Good Manufacturing Practices).

[50] *Id.* (describing considerations for manufacturing regulations).

[51] Massie & Nowels, *supra* note 15, at 5 (describing deadline for FDA to issue good manufacturing practices rules).

[52] Klesh, *supra* note 3, at 3 (providing MoCRA's definition of small businesses).

[53] Wade Ackerman, Jessica O'Connell & James Holloway, *MoCRA: 6 Key Takeaways From The New Cosmetics Law*, COVINGTON & BURLING LLP NEWS AND INSIGHTS, 4 (Jan. 20, 2023), https://www.cov.com/-/media/files/corporate/publications/2023/01/mocra-6-key-takeaways-from-the-new-cosmetics-law.pdf, *supra* note 4, at 3-4 (describing what provisions small businesses are exempt from).

[54] *Id.* (explaining the rationale of the small business exemptions).

are intended to alter a user's appearance for more than twenty-four hours.[55]

11. Fragrance Allergens Disclosure

MoCRA instructs the FDA to promulgate regulations to identify fragrance allergens that must be disclosed on cosmetic product labels.[56] In crafting regulations, the FDA will take into consideration international and local requirements for allergen disclosure, such as the European Union's requirements for which fragrance allergens are included on product labels.[57]

12. Talc Regulation

The FDA must also develop regulations that establish and require standardized testing methods for identifying asbestos in talc-containing cosmetic products.[58] A proposed rule must be issued within a year after the enactment of MoCRA, with a final rule coming into effect after the period for public comments on the proposed rule closes.[59] The FDA has eighteen months after MoCRA's enactment to issue a proposed rule and a final rule 180 days after public comments close.[60]

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[55] U.S. Food and Drug Administration, *Modernization of Cosmetics Regulation Act of 2022 – Key Terms and Provisions*, YOUTUBE (Apr. 12, 2023), https://www.youtube.com/watch?v=p4UsMzXKyck&t=282s, *supra* note 29 (describing instances in which the small business exemptions do not apply if the cosmetics product falls into one of the described categories).

[56] David L. Rosen & Nathan A. Beaver, *Modernization of Cosmetics Regulation Act of 2022: What You Need to Know*, FOLEY & LARDNER LLP (Jan. 25, 2023), https://1npdf11.onenorth.com/pdfrenderer.svc/v1/abcpdf11/ GetRenderedPdfByUrl/Modernization%20Cosmetics%20Regulation%20Act%202022.pdf/?url=https%3a%2f%2fwww.foley.com%2fen%2finsights%2fpublications%2f2023%2f01%2fmodernization-cosmetics-regulation-act-2022?format=pdf&attachment=false, *supra* note 22, at 2 (describing FDA's required action to create Good Manufacturing Practices).

[57] Modernization of Cosmetic Regulation Act of 2022 § 609.

[58] Rosen & Beaver, *supra* note 22, at 2 (detailing the directive of the FDA to develop methods to test for asbestos in talc-containing products).

[59] Rosen & Beaver, *supra* note 22, at 3 (describing the FDA's fragrance allergen disclosure requirements).

[60] Modernization of Cosmetic Regulation Act of 2022 § 3505.

13. Perfluoralkyl and Polyfluoralky Substances (PFAS) Regulation

In addition, MoCRA also requires the FDA to assess the use of perfluoralkyl and polyfluoralky substances in cosmetic products.[61] The FDA must publish a report summarizing this assessment no later than three years after the enactment.[62]

14. MoCRA's Preemption

Once MoCRA becomes effective on December 29, 2023, it will immediately preempt all state and local laws regarding cosmetic product listing, facility registration, good manufacturing practices, adverse event reporting, recalls, and safety substantiation.[63] However this preemption provision does allow states to establish stricter requirements by prohibiting the use of a certain ingredient or limiting the amount of an ingredient present in cosmetic products.[64]

C. Public Engagement

The FDA has begun to issue draft guidance in accordance with MoCRA and engage the public in seeking comments and feedback.

1. Good Manufacturing Practices for Cosmetic Products Listening Session & Public Comments

On June 1, 2023, the FDA held a virtual public meeting to consult with the public about its efforts to develop good manufacturing practices for facilities.[65] The comments represent the concerns of

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[61] Modernization of Cosmetic Regulation Act of 2022 § 35056.
[62] *Id.*
[63] David L. Rosen & Nathan A. Beaver, *supra* note 22 (describing MoCRA's preemption provision).
[64] Kristen R. Klesh, *MoCRA Increases FDA Oversight of the Cosmetics Industry*, LOEB & LOEB LLP CLIENT ALERTS/REPORTS (March 2023), https://www.loeb.com/en/insights/publications/2023/03/mocra-increases-fda-oversight-of-the-cosmetics-industry, *supra* note 3, at 2 (describing the state's power to regulate certain cosmetic ingredients).
[65] Food and Drug Admin., *Public Meeting: Good Manufacturing Practices for Cosmetic Products*, COSMETICS NEWS & EVENTS (June 1, 2023),

stakeholders from a variety of large and small businesses and individuals within the U.S. and across the globe, shedding light on the global nature of the cosmetics industry and far-reaching implications MoCRA will have. For instance, Unilever USA voiced its support for MoCRA's passage and advises the FDA to allow for flexibility when developing its good manufacturing practices regulation.[66] Unilever USA also advised against adopting an entirely new framework, because this would require a longer period of time for companies to adopt and implement it.[67] Unilever USA therefore strongly urged the FDA base its rule upon existing standards that many companies already follow.[68] The European Federation for Cosmetic Ingredients, which represents 140 industry members, submitted its comment requesting that cosmetic "ingredient" manufacturers be exempted from having to register with the FDA in the same manner that cosmetic "product" manufacturers are.[69] A small business owner expressed their concerns about the adequacy of the exemptions for a small business with revenue of $1,000,000, because with the recent inflation $1,000,000 is no longer sufficient revenue to cover all small businesses and many small businesses make more than $1,000,000.[70] The small business owner suggested the FDA to change the definition of small business from one that has a revenue of $1,000,000 to one that has a revenue of $2,000,000 to $5,000,000.[71] If more small businesses were exempted from complying with strict regulations that impose costs, they could survive

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https://www.fda.gov/cosmetics/cosmetics-news-events/public-meeting-good-manufacturing-practices-cosmetic-products-06012023 (describing topics discussed at FD meeting on proposing manufacturing regulations).

[66] Patrizia Barone & Fred Soderstorm, *Food and Drug Administration Good Manufacturing Practices for Cosmetics Listening Session*, Unilever (June 30, 2023), https://downloads.regulations.gov/FDA-2023-N-1466-0065/attachment_1.pdf (Unilever's comments submitted on regulations.gov to the FDA).

[67] *Id.* at 5 (Unilever's recommendation against adopting an entirely new framework).

[68] *Id.* (Unilever's recommendation to keep the existing standards for good manufacturing practices).

[69] Iain Moore, EFfCI Submission to FDA Listening Session, THE EUROPEAN FEDERATION FOR COSMETIC INGREDIENTS (June 1, 2023), https://downloads.regulations.gov/FDA-2023-N-1466-0002/attachment_1.pdf (EFfCI's comment).

[70] Small Business Owner, *Comment*, REGULATIONS.GOV (Jun. 5, 2023) https://www.regulations.gov/comment/FDA-2023-N-1466-0028.

[71] *Id.* (describing the small business' suggestions).

and continue to function.[72] The industry association, Cosmetics New Zealand, which represents the majority of the New Zealand Cosmetics industry, advocated for the FDA to accept the existing best industry practices and standards.[73] This includes the International Organization for Standardization (ISO) 22716:2007 standard for cosmetics good manufacturing practices and the American National Standards (ANS) ANSI 455-3 standard.[74]

2. FDA's Draft Guidance on Cosmetic Product Facility Registrations and Product Listings

On August 8, 2023, the FDA announced the availability of draft guidance describing recommendations and instructions for compliance with requirements for facility registration and product listing.[75] A variety of businesses and associations contributed their comments and concerns. The American Herbal Products Association, the national trade organization for the herbal products industry, recommended that the FDA limit registration requirements to avoid duplication for facilities that process both foods and cosmetics and already are in compliance with the FDA's food facility registration regulations.[76] The Korean Cosmetic Association left a comment requesting a clear definition of the term "U.S. Agent", because many Korean companies confuse the term with "responsible person" and are unclear as to what the difference in

[72] *Id.* (describing the small business' suggestions).
[73] Cosmetics New Zealand, *Good manufacturing Practices for Cosmetic Products– request for comments*, COSMETICS NEW ZEALAND (June 30, 2023), https://downloads.regulations.gov/FDA-2023-N-1466-0069/attachment_1.pdf.
[74] *Id.* at 2. (suggesting the existing international and national standards be adopted by the FDA).
[75] Food and Drug Admin., *Draft Guidance for Industry: Registration and Listing of Cosmetic Product Facilities and Products*, FDA GUIDANCE DOCUMENTS (Aug. 7, 2023), https://www.fda.gov/regulatory-information/search-fda-guidance-documents/draft-guidance-industry-registration-and-listing-cosmetic-product-facilities-and-products (detailing compliance requirements).
[76] American Herbal Products Association, *Comments of the American Herbal Products Association* (Sept. 7, 2023), https://downloads.re gulations.gov/FDA-2023-D-1716-0037/attachment_1.pdf ("AHPA recommends that FDA further limit duplicative compliance requirements for facility registration for firms that manufacture or process both foods.").

responsibilities are between the two roles.[77] In their comment, the Japan Cosmetic Industry Association argued that the name of the owner or operator of the facility is unnecessary and should be optional.[78] They compare the requirement against the FDA's food facility registration regulations, which do not require the name of the facility's owner or operator.[79] A Foley & Lardner attorney submitted a comment on behalf of a tattoo ink manufacturer client requesting clarification on what types of products will be included in the category of "Other Tattoo Preparations."[80]

D. Advice of Legal Counsel

In anticipation of MoCRA's enactment in December 2023, lawyers have been advising cosmetic companies throughout the year to invest time and resources to collect information for facility registration and products listings.[81] They have also suggested a thorough review of all product composition, safety, and toxicity claims to ensure this information can be substantiated to meet the requirements of the safety

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[77] Korea Cosmetic Association, *KCA's Comments* (Sept. 7, 2023), https://downloads.regulations.gov/FDA-2023-D-1716-0034/attachment_1.pdf ("It would be helpful if you could provide a clear explanation of the definition and role of the 'U.S. Agent.'").

[78] Japan Cosmetic Industry Association, *JCIA comment on FDA Draft Guidance Registration and Listing - MoCRA* (Sept. 7, 2023), https://downloads.regulations.gov/FDA-2023-D-1716-0043/attachment_1.pdf ("Furthermore, 'the name of the owner and/or operator of the facility' is not required in the FDA's food facility registration. Therefore, the registration of the name of the owner and/or operator of the facility for cosmetics should be optional.").

[79] *Id.*

[80] David Rosen, *Request for Clarification on Cosmetic Categories and Codes; Specifically, What is Contemplated to be Included in Code 16 Tattoo Preparations: (c) Other Tattoo Preparations*, LAW360 (Oct. 11, 2023), https://downloads.regulations.gov/FDA-2023-D-1716-0045/attachment_1.pdf ("Specifically, it is not expressly clear on with respect to the Cosmetic Categories and Codes as to what FDA is contemplating to be included in Code 16 Tattoo Preparations; (c) Other Tattoo Preparations.").

[81] Li X. Massie & Felicia Leborgne Nowels, *New FDA Regulatory Framework for Cosmetics: The Modernization of Cosmetics Regulation Act of 2022 (MoCRA)*, AKERMAN PRACTICE UPDATE (Jan. 31, 2023), https://www.akerman.com/print/v2/content/131481/New-FDA-Regulatory-Framework-for-Cosmetics-The-Modernization-of-Cosmetics-Regulation-Act-of-2022-MoCRA.pdf, *supra* note 15, at 6 (providing next steps for cosmetic companies).

substantiation provision.[82] They advise saving and maintaining safety substantiation records in a manner that allows the FDA to easily inspect the records upon request.[83]

Lawyers have also advised companies to look at the systems they have in place and determine if they can be used or modified to capture information needed to comply with MoCRA provisions.[84] For instance, if companies already have a hotline in place, perhaps it could serve as the required point person for adverse event reporting.[85]

Regarding the preemption provision, lawyers are advising cosmetic companies to monitor how the FDA and courts interpret this provision, because preemption has been interpreted differently depending on the federal administration.[86] Since the FDA already uses similar tools in regulating other products (food and drugs), it may be helpful for cosmetic companies to consider how the FDA has used its authority in the past to extrapolate how it will proceed with bringing MoCRA to life through regulations.[87] For instance, for insight into the safety substantiation requirements, which the FDA is still in the process

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[82] Frederick R. Ball, Alyson Walker Lotman & Kelly A. Bonner, *MoCRA[1] Is Here—Now What? Unpacking Litigation and Regulatory Risk for Cosmetics Brands Following MoCRA's Enactment*, FOOD AND DRUG LAW INSTITUTE (2023), https://www.fdli.org/2023/02/mocra-is-here-now-what-unpacking-litigation-and-regulatory-risk-for-cosmetics-brands-following-mocras-enactment/, *supra* note 5 (advising cosmetic companies to take steps to protect themselves in the wake of MoCRA's enactment).

[83] Rachel Raphael, Julia Carbonetti & Moriah Denton, *MoCRA Will Give Cosmetics Litigation A Makeover*, LAW360 (Aug. 10, 2023), https://www.crowell.com/a/web/gssp2h3eavw3TVvMs3tzsK/mocra-will-give-cosmetics-litigation-a-makeover.pdf. ("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 the FDA to view these records upon inspection or request.").

[84] *Id.* at 4-5 (advising cosmetic companies to conduct a gap analysis).

[85] *Id.*

[86] Wade Ackerman, Jessica O'Connell & James Holloway, *MoCRA: 6 Key Takeaways From The New Cosmetics Law*, COVINGTON & BURLING LLP NEWS AND INSIGHTS, 4 (Jan. 20, 2023), https://www.cov.com/-/media/files/corporate/publications/2023/01/mocra-6-key-takeaways-from-the-new-cosmetics-law.pdf, *supra* note 4, at 2 (advising cosmetic companies to closely watch how the preemption provision is interpreted).

[87] *Id.* (advising cosmetic companies to "be mindful of how the FDA has implemented similar regulatory authorities in the past, as that will be instructive.")

of developing, companies may look at the existing premarket requirements for food additives.[88]

E. Impact on the Cosmetics Industry

1. Litigation

MoCRA has the potential to impact the cosmetics industry through the types of litigation that companies may be subject to.[89] Although plaintiffs are not allowed to use adverse event reports as evidence of an admission that a product caused the reported event, this information could be accessed at the discovery stage.[90] This would allow plaintiffs to criticize a company's safety substantiation and allege "with more specificity" the risks that the company's products pose to consumers.[91] Companies should look out for incoming discovery requests on their adverse event reporting data.[92] Once the FDA issues good manufacturing practices rules, companies could also face the threat of negligence allegations if they fail to comply.[93] Litigators are also already beginning to consider how MoCRA could be used to defend companies, such as by arguing MoCRA's guidance is unclear and thus companies were not put on sufficient notice of the requirements.[94]

2. Increased Costs

There are also concerns about the increased costs associated with compliance with the FDA's regulations, including creation and maintenance of adverse event reporting recording systems, employment of regulatory affairs and compliance employees, and annual product listing updates.[95] Small businesses are at a greater risk of facing

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[88] Raphael, Carbonetti & Denton, *supra* note 83, at 4 (advising cosmetic companies on how to look around the corner for incoming safety substantiation guidelines).
[89] *Id.* (discussing MoCRA's potential litigation impacts).
[90] *Id.* at 1 (discussing the discovery of adverse event reports).
[91] *Id.*
[92] *Id.*
[93] *Id.* at 2 (describing threat of negligence allegations for good manufacturing practices rules violations).
[94] *Id.* (describing potential defenses).
[95] Cristina Montemayor, *UNDERSTANDING MOCRA AND WHAT'S NEXT FOR THE BEAUTY INDUSTRY*, BEAUTYMATTER (Feb. 7, 2023)

financial burdens from these increased costs, whereas large cosmetic companies may already have compliance systems and officers in place which they can use to meet new FDA requirements.[96]

F. Conclusion

MoCRA is a significant expansion of the FDA's rulemaking and enforcement authority over the cosmetics industry.[97] As a result, MoCRA's provisions create "new substantial compliance obligations" for cosmetic companies.[98] The FDA is in the process of issuing draft guidance and requesting public comments, and businesses and trade associations from all over the world have been sharing suggestions, expressing concerns, and requesting clarification.[99] Companies should keep an eye on the FDA's website where the agency releases frequent updates to ensure they do not miss new draft guidance or the period for public comments. Although the full effect of MoCRA and the FDA's ensuing regulations is still unknown, lawyers have expressed concerns over the potential for increased litigation and costs to businesses in meeting the new requirements.[100] Although MoCRA introduces new compliance burdens on cosmetics companies, it was a long overdue

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https://beautymatter.com/articles/understanding-mocra (outlining the potential problems MoCRA poses for cosmetics companies).

[96] *Id.* (expressing concern for small businesses shouldering costs imposed by maintaining compliance with new regulations).

[97] Frederick R. Ball, Alyson Walker Lotman & Kelly A. Bonner, *MoCRA[1] Is Here—Now What? Unpacking Litigation and Regulatory Risk for Cosmetics Brands Following MoCRA's Enactment*, FOOD AND DRUG LAW INSTITUTE (2023), https://www.fdli.org/2023/02/mocra-is-here-now-what-unpacking-litigation-and-regulatory-risk-for-cosmetics-brands-following-mocras-enactment/, *supra* note 5 (commenting on MoCRA's effect on the FDA's authority).

[98] *Id.*

[99] Food and Drug Admin., *Public Meeting: Good Manufacturing Practices for Cosmetic Products*, COSMETICS NEWS & EVENTS (June 1, 2023), https://www.fda.gov/cosmetics/cosmetics-news-events/public-meeting-good-manufacturing-practices-cosmetic-products-06012023, *supra* note 65.

[100] Wade Ackerman, Jessica O'Connell & James Holloway, *MoCRA: 6 Key Takeaways From The New Cosmetics Law*, COVINGTON & BURLING LLP NEWS AND INSIGHTS, 4 (Jan. 20, 2023), https://www.cov.com/-/media/files/corporate/publications/2023/01/mocra-6-key-takeaways-from-the-new-cosmetics-law.pdf, *supra* note 4, at 4 (expressing the uncertainty of the effect of MoCRA).

overhaul of the FDA's authority over cosmetics[101] and brings cosmetics regulation more into line with the agency's authority over food, drugs, and devices.[102]

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[101] Cooley LLP, *FDA Regulatory Framework for Cosmetics Gets Major Overhaul,* COOLEY NEWS (Jan. 6, 2023), https://www.cooley.c om/api/down loadpdf?contextItemId=%7B97F177A7-E836-4B5A-822B-312E02C3F73C%7D, *supra* note 18, at 1 (describing MoCRA's overhaul of the pre-existing cosmetics regulatory regime).

[102] Kristen R. Klesh, *MoCRA Increases FDA Oversight of the Cosmetics Industry*, LOEB & LOEB LLP CLIENT ALERTS/REPORTS (March 2023), https://www.loeb.com/en/insights/publications/2023/03/mocra-increases-fda-oversight-of-the-cosmetics-industry, *supra* note 3, at 1 (comparing the FDA's authority over food, drugs, cosmetics to its newly expanded authority over cosmetics).

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