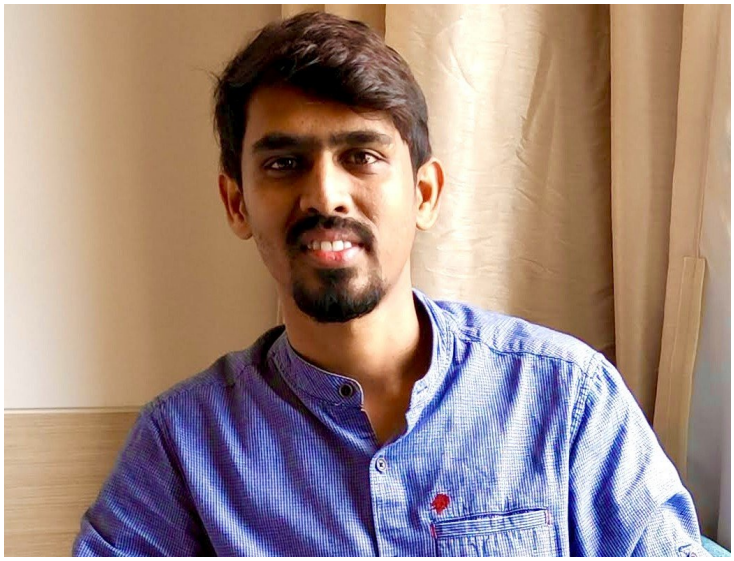
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Era of global transformation for cosmetics industry

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A comprehensive analysis of the Regulatory aspects of Modernization of Cosmetics Regulation Act, highlighting its key provisions and its impact on the industry



The beauty and cosmetics industry has witnessed exponential growth in recent years, with increasing demand for innovative products. Governments worldwide have been implementing regulations to ensure the safety and efficacy of cosmetic products to keep pace with this rapidly evolving industry. A significant development is the Modernization of Cosmetics Regulation Act (MoCRA), 2022, which aims to enhance the Regulatory framework governing cosmetics in the United States.

MoCRA was signed into law on December 29, 2022, marking a significant milestone in the cosmetics industry. This legislation significantly enhances the jurisdiction of the United States Food and Drug Administration (US FDA) over the cosmetics industry, representing the most substantial revision to cosmetic regulations since the inception of the Federal Food, Drug, and Cosmetic (FD&C) Act that was enforced back in 1938. The implications of MoCRA are profound and far-reaching, impacting both domestic and international cosmetics manufacturers, who market their products within the US. This editorial provides a comprehensive analysis of the Regulatory aspects of MoCRA, highlighting its key provisions and its impact on the industry at large.

MoCRA Objectives

- **Enhancing Consumer Safety:** MoCRA aims to ensure that cosmetic products meet the highest safety standards by strengthening ingredient safety assessments, enhancing post-market surveillance, and promoting transparency.
- **Streamlining the Regulatory Process:** MoCRA streamlines the Regulatory process by facilitating efficient communication among regulators, manufacturers, and consumers.
- **Encouraging Innovation:** MoCRA recognises the importance of innovation in the cosmetics industry and aims to strike a balance between enhancing safety and innovation.

MoCRA: Key Requirements

Mandatory Facility Registration

All cosmetic manufacturing facilities that manufacture or process cosmetic products for distribution in the US, regardless of their location, must register with the US FDA. While the statutory deadline for receiving facility registration information was December 29, 2023, the US FDA intends not to enforce the requirements under section 607 of the FD&C Act related to cosmetic product facility registration until **July 01, 2024**. Furthermore, the US FDA will not enforce the registration requirement for owners or operators of facilities that commenced manufacturing or processing cosmetic products after December 29, 2022, until **July 01, 2024**.

To register a facility, the following information must be submitted to the US FDA:

- Name of the owner and/or operator of the facility.
- Name and address of the facility.
- Contact information of the US agent for the foreign facility (Name and phone number/email address).
- Previously assigned facility registration number (if any).
- List of all brand names of the cosmetic products manufactured/processed at the facility that are sold.
- Product category/categories and RP for each cosmetic product manufactured or processed at the facility.
- Type of submission (initial, amended, biennial, renewal, or abbreviated renewal).

Product Listing

RPs for cosmetic products must submit a product listing to the US FDA that includes information such as the product name, ingredients, and contact information of the RP. While the statutory deadline for listing information for cosmetic products was December 29, 2023, the US FDA does not intend to enforce the requirements under section 607 of the FD&C Act related to cosmetic product listing until **July 01, 2024**. This extension aims to offer the regulated industry extra time to ensure compliance with these listing requirements. Additionally, the US FDA won't enforce the listing requirement for cosmetic products first marketed after December 29, 2022, until **July 01, 2024**.

To submit a product listing, the RP must create an account in the US FDA's Cosmetic Direct Portal. After that, they can submit a product listing for each cosmetic product that they manufacture/distribute.

The product listing must include the following information:

- Facility registration numbers for each facility where the cosmetic product is manufactured/ processed.
- Name and contact number of the RP.
- Product name.
- List of ingredients.
- Cosmetic category.
- Submission type.

The US FDA intends to make relevant information from cosmetic product listings available to the public to the extent permitted by law.

Adverse Event Reporting

Adverse Event Reporting (AER), effective since December 29, 2023, means that cosmetic companies will have an obligation to report any serious adverse events linked to the domestic use of a cosmetic product that they manufacture, package, or distribute. The term "serious adverse event" means an adverse event that results in death, a life-threatening experience, inpatient hospitalization, a persistent or significant disability or incapacity, a congenital anomaly or birth defect, an infection, or significant disfigurement.

Companies must promptly report serious adverse events within fifteen (15) business days from the receipt of the report; they also need to keep the US FDA informed as and when new information becomes available. Moreover, cosmetic companies are mandated to maintain records of health-related adverse events for a minimum of six years following the reporting of the incident. For small businesses, the retention period is three years. Under MoCRA, registered facilities may be subject to inspection by the US FDA, during which the agency can request copies of all adverse event reports. Failing to provide such records would result in non-compliance by the product or facility. Thus, companies should establish a comprehensive AER program and ensure that they adhere to the record-keeping stipulations laid out under MoCRA.

Safety Substantiation

Since December 29, 2023, cosmetic companies have been mandated to ensure that they can adequately prove the safety of each cosmetic product they sell. They must also maintain records that support the adequate substantiation of product safety. Section 608 of the FD&C Act defines “adequate substantiation of safety” as the process of obtaining evidence that qualified experts find reasonably convincing. This evidence should demonstrate that cosmetic products, when used as directed, do not pose harm to users in any way.

Moreover, the US FDA has the authority to examine any relevant documentation pertaining to a cosmetic product if they have a “reasonable belief” that the product might potentially result in serious adverse health effects or even fatality. To meet these new requirements, companies should establish a safety substantiation policy and consider enlisting the services of a certified toxicologist who can perform a risk assessment on their products.

Mandatory Recall Authority

Effective December 29, 2023, the US FDA is expected to wield a new authority with respect to mandatory recalls. When the US FDA concludes that there exists a credible likelihood that a cosmetic product is either adulterated or misbranded and that its usage or exposure may result in severe adverse health consequences or even fatality, it will offer the RP an opportunity to voluntarily halt distribution and recall the respective product. If the RP declines the opportunity or fails to voluntarily discontinue distribution of the product or is unable to initiate the recall within the timeframe and manner specified by the US FDA (if such instructions are given), the US FDA may issue an order for an immediate cessation of the product’s distribution.

Labeling

By December 29, 2024, cosmetic labels must include the domestic address, domestic telephone number, or electronic contact information of the cosmetic company. This information is provided to facilitate the reporting of adverse events related to the use of the product. Professional cosmetic products must state that the products are intended for use only by licensed professionals. After public comments on the potential health risks of fragrance allergens, the US FDA will issue a rule requiring cosmetic labels to identify each fragrance allergen in a product.

MoCRA necessitates the disclosure of every fragrance allergen present in a product on its label, with specific guidelines to be established by the US FDA. This directive is set to take effect within eighteen (18) months following MoCRA's enactment, precisely on **June 29, 2024**, and within 180 days after the closure of the public comment period.

PFAS in Cosmetics

The US FDA must conduct a safety assessment and offer scientific evidence regarding the utilization of Perfluoroalkyl and Polyfluoroalkyl Substances (PFAS) in cosmetic products within three (03) years from the enactment of the Act, that is, by December 29, 2025.

GMPs

MoCRA mandates industry compliance with forthcoming US FDA regulations governing Good Manufacturing Practice (GMP) requirements for facilities engaged in cosmetic product manufacturing. The US FDA intends to withdraw, revise, and reissue the current draft guidance as necessary, aligning with the GMP rulemaking mandated by the MoCRA.

Additionally, the US FDA held a public listening session on June 01, 2023, engaging cosmetics manufacturers, smaller businesses, contract manufacturers, consumer organizations, and industry experts. During this session, the US FDA addressed the following topics related to GMPs:

- Identification of national or international standards and their potential alignment with GMP regulations for cosmetics. Stakeholders were encouraged to highlight burdensome aspects and propose less onerous alternatives to maintain public health standards and prevent product adulteration.

- Determination of necessary flexibility within GMP requirements to ensure practicable regulations for diverse-sized facilities engaged in cosmetic production, considering associated public health risks.
- Description of simplified GMP requirements suitable for smaller cosmetic businesses to prevent undue economic hardship and promote compliance.
- Discussion on appropriate compliance timelines with GMP regulations.

Per MoCRA guidelines, the US FDA must draft cosmetic GMP regulations by **December 29, 2024**, and issue the final rule by **December 29, 2025**. These regulations must align with the existing US FDA standards and international benchmarks, including ISO 22716, a recognized GMP standard for cosmetics.

Exemptions for Small Businesses

The MoCRA provides exemptions from GMPs, registration, and product listing requirements for certain small businesses within the cosmetic industry. Businesses with an average gross annual sale of cosmetic products in the US, adjusted for inflation, less than $1 Million over the previous three (03) years. However, it's important to note that these exemptions do not cover manufacturers/facilities involved in the production or processing of specific types of cosmetic products. These include:

- Products designed for regular contact with the mucus membrane of the eye under customary or usual conditions of use.
- Injected cosmetic products.
- Products intended for internal use.
- Products meant to alter appearance for more than 24 hours under customary or usual conditions of use, where consumer removal is not considered part of these conditions.

Impact on Cosmetic Brands

Here are some of the specific ways in which MoCRA will impact cosmetic brands:

- **Increased Costs of Compliance:** Cosmetic brands will have to invest in software, and training procedures, as well as hire new staff to comply with MoCRA's new requirements.
- **Increased Regulatory Scrutiny:** The US FDA will now have more authority to inspect cosmetic manufacturing facilities and will require cosmetic companies to substantiate the safety of their products.
- **Need for More Transparency:** Cosmetic brands will have to be more transparent about their products under MoCRA's new labeling requirements.

How Can Cosmetic Manufacturers Overcome Challenges?

Here are some thoughts on how cosmetic brands can overcome the challenges of MoCRA and rather, capitalize on the opportunities it presents:

- **Start Planning Now:** Cosmetic brands should start planning now to comply with MoCRA's new requirements. This will help them minimize costs and prevent disruption of compliance.
- **Invest in New Technology:** Cosmetic brands should invest in new technology to improve their safety testing and quality control procedures.
- **Be Transparent with Consumers:** Cosmetic brands should be transparent with consumers about their products and their commitment to safety. They can do this through marketing materials, social media, and customer service.
- **Get Help from Experts:** Cosmetic brands should get help from Regulatory experts to understand and comply with MoCRA's requirements.

Conclusion

In the wake of MoCRA's implementation, the cosmetics industry faces an era of transformation, requiring substantial adjustments in operations, investments, and compliance efforts. This regulatory paradigm shift is not solely about meeting requirements; it's an opportunity for visionary brands to set new benchmarks, driving the industry towards safer, more innovative, and consumer-centric horizons.

Navigating MoCRA's demands will not be facile, yet those proficient in its nuances will capitalise on the opportunity to excel and stand out in a growingly competitive market. As the cosmetics industry moves forward under MoCRA's purview, the onus lies on manufacturers to not merely comply but to lead – to champion safety, transparency, and consumer trust.

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