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The Standard of Excellence

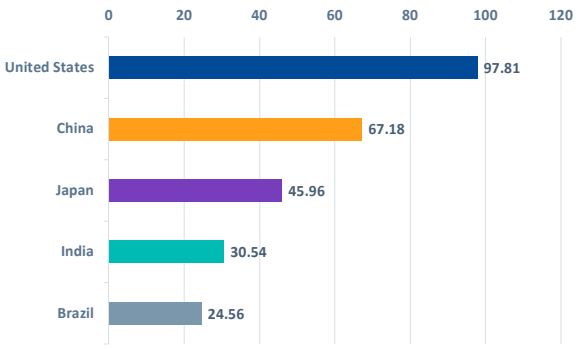
White Paper

MODERNIZATION OF COSMETICS REGULATION ACT

INTRODUCTION

The United States stands as one of the largest cosmetics markets globally, surpassing $87.7 billion in revenue in 2022 and expected to maintain a steady growth trajectory at a 5.6% CAGR over the next decade[1]. It is estimated that the average American uses between 6-12 cosmetic products, containing nearly 200 chemicals, daily[2]. Recent statistics predict that the average American woman spends more than $3,756 annually on beauty products and services[3]. While cosmetics do not necessitate approval from regulatory authorities in the USA, except for color additives, they are subject to regulation by the FDA under the Food, Drugs, & Cosmetics Act and the Fair Packaging and Labeling Act. In recent years, researchers have raised concerns regarding the presence of certain substances at dangerous levels and labeling discrepancies within major cosmetics brands. The enactment of the Modernization of Cosmetics Regulation Act (MoCRA) addresses these concerns by granting the FDA authority to access cosmetics product information, including safety records, and to initiate product recalls if safety concerns arise. This marks a significant shift in cosmetics oversight by the U.S. FDA, the first of its kind in over eight decades.

Revenue data for top 5 countries in 2023[4]



SAFETY SUBSTANTIATION & REPORTING REQUIREMENTS

While the law does not enforce specific tests to demonstrate the safety of individual products or ingredients for cosmetics, manufacturers or marketers of cosmetic products are mandated to maintain records substantiating safety through scientifically validated robust methods. There have been no significant modifications in safety substantiation and manufacturers still can perform toxicological assessments on ingredients using published databases such as the Cosmetic Ingredient Review, PubMed or TOXNET. Additional testing using scientifically validated methods is highly recommended for cases where the published databases are not sufficient to establish the safety of a product or ingredient.

Many cosmetics products are classified as drugs or medical devices, and implementing a flexible and cost-effective safety system can be a challenging task

1 Cosmetics market size estimated to reach USD 661.12 Bn by 2032 by Yahoo Finance; December 8, 2023

2 Everything You Need To Know to Choose Safe Cosmetic Products by Andrea Sun, MS, National Center for Health Research from https://www.center4research.org/cosmetics-safety-regulations-law-tips/

3 Haynes, C. (2018). True Cost of Beauty: Survey Reveals Where Americans Spend Most. Available online at: https://www.groupon.com/merchant/blog/true-cost-beauty-americans-spend-most-survey (accessed January 26, 2021)

4 https://www.statista.com/forecasts/758635/revenue-of-the-cosmetics-and-personal-care-market-worldwide-by-country

MoCRA has introduced significant changes in how safety records, including non-serious adverse events and adverse events, are managed by cosmetics companies. According to MoCRA, companies are required to maintain records of non-serious adverse events for a specified period and promptly report such events to the FDA via MedWatch. Furthermore, companies must designate a responsible person to report serious adverse events associated with the use of cosmetic products to the FDA within 15 business days. While these requirements align with common practices in the drug and device industry, cosmetics companies may encounter challenges in implementing cost-effective solutions to comply with these regulations. Existing solutions in the market are primarily designed for pharmaceutical and medical device companies and may turn out to be cost-prohibitive, complicated and need additional quality requirements for cosmetic companies.

LABELING AND LISTING

MoCRA mandates new labeling requirements for all cosmetics products in the United States. By December 29, 2024, all cosmetics labels must contain the contact information of a Responsible Person capable of receiving adverse event reports. The rule for professional cosmetics labels, mandating clear indication of use by licensed professionals, has already been implemented. Certain fragrances can cause allergies in consumers, prompting the FDA to issue a rulemaking for fragrance allergen identification by June 29, 2024. The final rulemaking is to be issued 180 days after the proposed rulemaking's public comment period providing additional time for companies to establish systems and policies to ensure compliance with this labeling requirement.

Furthermore, MoCRA includes additional provisions that may seem straightforward to implement but pose unique challenges. For instance, all manufacturers will be required to register facilities involved in the manufacturing and processing of cosmetics distributed in the United States. The FDA will have the authority to suspend registration due to suspected serious health risks, which may impact other products if they are also affected by the process. The issue cannot be isolated and will prohibit the distribution or sale of any cosmetics from the impacted facility in the US.

Raw material and product traceability will become increasingly important for companies, especially one with complex supply chain and third-party vendor network

Similarly, product listing is another provision under MoCRA wherein a responsible person will be required to submit detailed information such as product brand name, active ingredients, formulation, preparation, dose, and reference safety information, among others, for all products marketed in the United States. While this may seem like a simple exercise for companies with limited manufacturing sites, for a global cosmetics company with a complex supply chain network, these steps can easily evolve into a complex cross-functional project.

CONCLUSION

In conclusion, MoCRA signifies a new era for the cosmetics industry, emphasizing safety and transparency. Despite anticipated challenges in implementation, MoCRA promises long-term benefits of consumer confidence and fostering a secure marketplace, thereby ensuring safety beyond mere appearance.

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About ClinChoice

ClinChoice is a global full-service CRO specializing in clinical development and functional solutions for pharmaceutical, biotechnology, medical device, and consumer health companies. We have over 28 years of proven high-quality delivery and results across all our services. With over 4,000 professionals in more than 20 countries across the Americas, Europe, and Asia-Pacific, we are positioned to fulfill our clients' business requirements locally and globally. We offer high-quality, full-service clinical development and post-marketing solutions. For our clients, it means a reliable partner and quality results.

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