Exponent®

Upcoming Changes for Cosmetic/Personal Care Companies Selling in the United States

The Modernization of Cosmetics Regulation Act of 2022

Last December, the Food and Drug Administration announced major upcoming changes to current U.S. cosmetics regulations that have been in place since 1938. Many of the changes outlined are comparable to the European Cosmetic Regulation 1223/2009, which is considered the gold standard for cosmetic product safety in most parts of the world.

The new law is called the Modernization of Cosmetics Regulation Act of 2022 (MoCRA), and all manufacturers, distributors, and packers that make cosmetic products available in the U.S. will have to comply with each new requirement from FDA to help ensure consumer safety.

These updates will require significant attention from companies that sell any cosmetic products in the U.S. market, and this year will determine whether these new rules will impact product development or even affect product sales in the future.

Although FDA still needs to provide overall clarity to the industry on various provisions, understanding these regulatory changes now and how they will impact products and overall business plans is critical in preparing for the future. Being proactive and assessing all risks that these new rules may create will also help companies implement the necessary measures to continue selling cosmetic products in the U.S. beyond December 2023.

Key MoCRA Provisions

1. Mandatory Site Registration & Product Listing

Within one year of enactment (by December 31, 2023), all facilities that manufacture or process cosmetic products for U.S. distribution must register with FDA. FDA registration will require contact information and the brand names of any cosmetic products manufactured or processed in a company's facility.

A responsible person (RP) will also be required to list each product with FDA. This notification will include details on the cosmetic category, the manufacturing site, product ingredients (including the ingredients of any fragrances or flavors), and a product listing number. Each listing is required to be updated annually, and new products must be listed within 120 days of being marketed in the U.S.

As of March 27, 2023, FDA has ceased accepting submissions to the Voluntary Cosmetic Registration Program (VCRP) and will no longer use this system. A new system for submitting facility registrations and cosmetic product listings will be implemented, and FDA will provide more information in the coming months.

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2. Current Good Manufacturing Practice Requirements

FDA will be introducing Good Manufacturing Practice (GMP) requirements in line with national and international standards within approximately 2-3 years. Once enacted, any product processed or manufactured outside the applicable GMP standards will be considered non-compliant or adulterated.

3. Mandatory Reporting of Adverse Health Events

The U.S. RP must manage all adverse event reports for all cosmetic products. The RP must also submit any report of a "serious adverse event" to FDA within 15 business days of receiving one. This essentially will require companies to implement a very clear internal standard procedure for reporting and managing all desirable and serious undesirable reported events or outsource this expertise. This requirement is expected to take effect 1 year after MoCRA is enacted.

4. Enforcement of Mandatory Recall & Cessation of Product Distribution

The law now allows FDA to suspend a facility's registration, preventing it from operating, if it is determined that a cosmetic product manufactured by the facility poses a risk of serious harm to consumers.

FDA is also permitted to request and access information on a cosmetic product if it suspects a product has been adulterated and presents a serious risk to consumers.

Lastly, FDA can order a mandatory product recall or cease sale of a product if the RP fails to comply with the necessary requirements in the case of a safety concern or an adulterated or misbranded product. These enforcement action initiatives will take effect 1 year after MoCRA is enacted.

5. Safety Substantiation for Cosmetic Products

From December 29, 2023, RPs must ensure that there is adequate substantiation of the safety of each cosmetic product they represent. Cosmetic products without sufficient safety information on file would effectively be considered non-compliant or adulterated.

The adequate substantiation of safety is defined in Section 608(c)(1) as "tests or studies, research, analyses, or other evidence or information that is considered, among experts qualified by scientific training and experience to evaluate the safety of cosmetic products and their ingredients, sufficient to support a reasonable certainty that a cosmetic product is safe.''

Failure to provide adequate substantiation of safety will render the cosmetic adulterated and subject to FDA enforcement action.

6. Mandatory Product Labeling Information

All cosmetic product labels must include an RP U.S. domestic address, telephone number, or electronic contact information so that a consumer can report any adverse events. Cosmetic labels must also now include each fragrance allergen present in the product.

Lastly, all "professional" products must include the text "Only licensed professionals may use this product" and must also follow the new cosmetic requirements. These labeling requirements are expected to take effect at the end of 2024.

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Frequently Asked Questions

Is it too early for companies to start preparing for MoCRA?

Certainly not! When legislation as major as this is signed into law and specific new industry requirements are outlined, it's important to be as proactive and informed as possible.

How can my business start preparing for these upcoming changes?

Strategic business considerations and preparation will be crucial in the successful implementation of the new MoCRA rules, especially this year!

It's best to begin preparation for MoCRA with consumer safety, especially given the amount of effort required and the increased risk of litigation. For companies that do not routinely have their products assessed and tested for safety, these new requirements will likely require new hires (regulatory and toxicology) or using external regulatory/test labs/toxicology services to help ensure compliance.

Increased demand for safety assessments in 2023 will likely result in higher costs and lead times for this work. The sooner companies set about getting their products assessed, the lower their risk of non-compliance.

Additionally, we recommend working closely with your contract manufacturers so they are aware of all the new requirements and have plans in place for these upcoming changes.

It is also imperative that companies begin reviewing internal processes and current products on the market as soon as possible to avoid critical challenges in the near future.

My company sells products in the EU in line with the required regulatory rules; if we apply the same rigorous review approach and internal processes to our U.S. products, will we comply?

Since the EU Cosmetic Regulation 1223/2009 is quite prescriptive in its Cosmetic Product Safety Report (CPSR) requirements, we believe that applying a similar approach may be of great advantage for companies. It is currently unclear, however, whether additional test data such as patch testing may also be required; this may be a likely scenario.

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What can we help you solve?

Exponent is one of the world's largest engineering and scientific consulting firms, with offices in North America, Europe, and Asia. Our cosmetic regulations team has over 35 years of experience working in international product compliance across all areas of the personal care/cosmetics industry, including product development, regulatory compliance, product safety/toxicology, auditing, and manufacturing.

Exponent is pleased to offer the personal care/ cosmetics industry the following services:

- Cosmetic Product Safety Reports (CPSRs)/toxicological risk assessments
- Management of adverse events and serious adverse events support
- Global registration/notification/listing
- Product information file creation/review/audit
- Cosmetic compliance labeling review and advice/claim substantiation
- Support in product withdrawal or recall
- Personalized regulatory training and compliance audits