genesis
FORMULAB



The Mordernization of Cosmetic Regulations Act (MoCRA)

And whati it means for you

FREE REPORT - NOT FOR SALE

www.genesisformulab.com

The Modernization of Cosmetic Regulations Act (MOCRA) Legislation and What It Means For You

In December 2022, the US passed a sweeping update to its cosmetic regulations, affecting cosmetics brands and manufacturers. Compliance must be reached by December 2023. This advice is from the viewpoint of a chemist, not a lawyer, as I am unqualified to give legal advice. FDA regulatory compliance firms such as www.registrarcorp.com exist for precise legal guidance. Below are what I consider some of the key elements of MOCRA

Facility and Product Registrations: Under MOCRA, it is now mandatory to register your facilities and product listings. Existing facilities must comply within a year, and new ones have 60 days. Every product you manufacture needs a listing on file with the FDA that details ingredients, the responsible party, and the manufacturing facility. If your products only differ by a small change in colour or aroma, you don’t need individual listings for all of them. Small businesses with gross sales below $1,000,000 over the past three years are exempt unless they produce specific types of cosmetics.

The Modernization of Cosmetic Regulations Act (MOCRA) Legislation and What It Means For You

Adverse Event Reporting: MOCRA requires reporting and record-keeping of adverse events (serious health complaints). Such reports must be submitted to the FDA within 15 days of receiving them. Companies should retain these reports for six years (three years for small businesses).

Product Safety Substantiation: MOCRA mandates stricter safety standards for cosmetics. Companies must prove their products are safe through scientific tests, studies, research, and analyses. This could involve laboratory tests and gathering safety information from suppliers.

This is sort of at the heart of the MOCRA legislation. Cosmetics are going to become safer. Basic to all the changes mandated, is a change in the safety standard of cosmetics. In the past, the standard for safety was simply an “adequate substantiation of safety” (21CFR§740.10) by people who didn’t have to be named. Usually, we would look back at the scientific literature and use resources such as

The Modernization of Cosmetic Regulations Act (MOCRA) Legislation and What It Means For You

the Cosmetics Ingredient Review Board (www.cir-safety.org) to become aware of any particular dangers of a particular ingredient. The CIR are dermatologists and toxicologists and publish safety reports on their website that talk about irritation, any carcinogenic properties, etc. While they haven't examined all cosmetic ingredients under the sun, they've done a lot of them, and the reports are all available for free on their website. For example, here is their report on vegetable glycerin, a common hydrating agent used in personal care products. https://www.cir-safety.org/sites/default/files/glycer_122014_FR.pdf

If the CIR report said it was safe, then we could carry that assurance over into the products we designed/sold. We could "stand on the shoulders" of previous statements by experts. Now, the law calls for "a reasonable certainty of no harm" as determined by "tests or studies, research, analyses or other evidence" [considered by] "experts qualified by scientific training and experience". The legislation is written a little loosely, which gives the FDA a lot of flexibility to interpret exactly what Congress meant when it wrote the legislation.

The Modernization of Cosmetic Regulations Act (MOCRA) Legislation and What It Means For You

Because of this, it's not yet clear what precise steps will be needed. However, the FDA is stressing safety. To prove safety determined by "tests or studies, research, analyses," you may need to proactively go the extra mile. You can start by downloading from www.cir-safety.org all of the CIR reports that are available for the ingredients in your products. Read through them all and focus on the safety issues. Keep digital and physical copies of these reports. On top of this (and especially for additives the CIR has not yet investigated), you may need to reach out to suppliers to see if they have safety information for their additives. Many will have done internal testing for skin irritation/eye irritation etc., and they can share those studies with you.

In some cases, this new legislation may require sending your finished product out to a testing lab that can assess the dangers. They can run a skin irritant test, skin sensitizer tests ("irritating after you use it for a while"), eye (ocular) irritation tests, and many more. You want to accumulate a mountain of authoritative data at your fingertips, attesting to the safety of your products.

The Modernization of Cosmetic Regulations Act (MOCRA) Legislation and What It Means For You

irritations and List of Allergens: Any fragrance allergens present in your fragrance/essential oils must be clearly identified on product labels.

Good Manufacturing Practices (GMP): GMP is now mandatory under MoCRA. The FDA will provide guidelines, including simplified requirements for smaller businesses, who may also have longer compliance times.

Labeling: Labels must now include contact information for the manufacturer and specify if products are for professional use only.

So, what does this all mean? Here is what I would start doing, just as soon as possible.

1) Consult with counsel before using any claims related to “safety” or “natural”.

2) Review all your labels / INCI lists to make sure they are compliant with the new fragrance allergens requirement.

The Modernization of Cosmetic Regulations Act (MOCRA) Legislation and What It Means For You

3) Review all your documentation on product composition, safety, toxicity and performance to make sure your claims are scientifically supported. Assume that someone is going to challenge every statement you make, possibly in court, including the use of third-party certifications or testing methods you've applied.

4) Carefully review and document processes and procedures for compliance with incoming regulations regarding GMP (Good Manufacturing Processes).

5) Take customer surveys asking questions about irritation, sensitivity - any criteria related to safety. Pounce on any claims and investigate them completely.

6) Include appropriate warning language on product labelling and packaging.

7) Test materials provided by third-party suppliers constantly for impurities, and/or obtain a signed

The Modernization of Cosmetic Regulations Act (MOCRA) Legislation and What It Means For You

certificate from the supplier attesting to the lack of impurities and contaminants.

8) Make sure your influencers have clear guidance about what can / cannot be said about your products on social media.

9) Finally, reconsider all your advertising and labelling claims. Even a reasonable person can sometimes misinterpret a claim. Especially if the claim involves “safety”, or the “natural” components of your product, I highly recommend that you involve an FDA-compliance firm such as www.registrarcorp.com in this process. Even the safest, simplest product can run afoul of this new legislation if your company says the wrong thing.

We have approximately half a year to get ready.Don’t wait! You don’t want to be in a time crunch in November. Any products not in compliance by the end of December may (at the FDAs discretion) get pulled from shelves. Gear up and get going now! You won’t regret it.

The Modernization of Cosmetic Regulations Act (MOCRA) Legislation and What It Means For You

Safety is one of the most essential aspects of designing formulas. That's one of the very first things you learn about when you take our Advanced Diploma in Cosmetic Science and Skin Lightening. We show you how to research the relevant sites in the industry, access raw material safety and use information, interpret the information you find and make the most educated choices in raw material selection and concentrations of use. If you are taking our advanced class, you're already equipped with this skill!

genesis FORMULAB

The Mordernization of Cosmetic Regulations Act (MoCRA) and What It Means For You

A simple Guide for the Cosmetic Formulator

NOT FOR SALE

copyright © www.genesisformulab.com. All rights resered