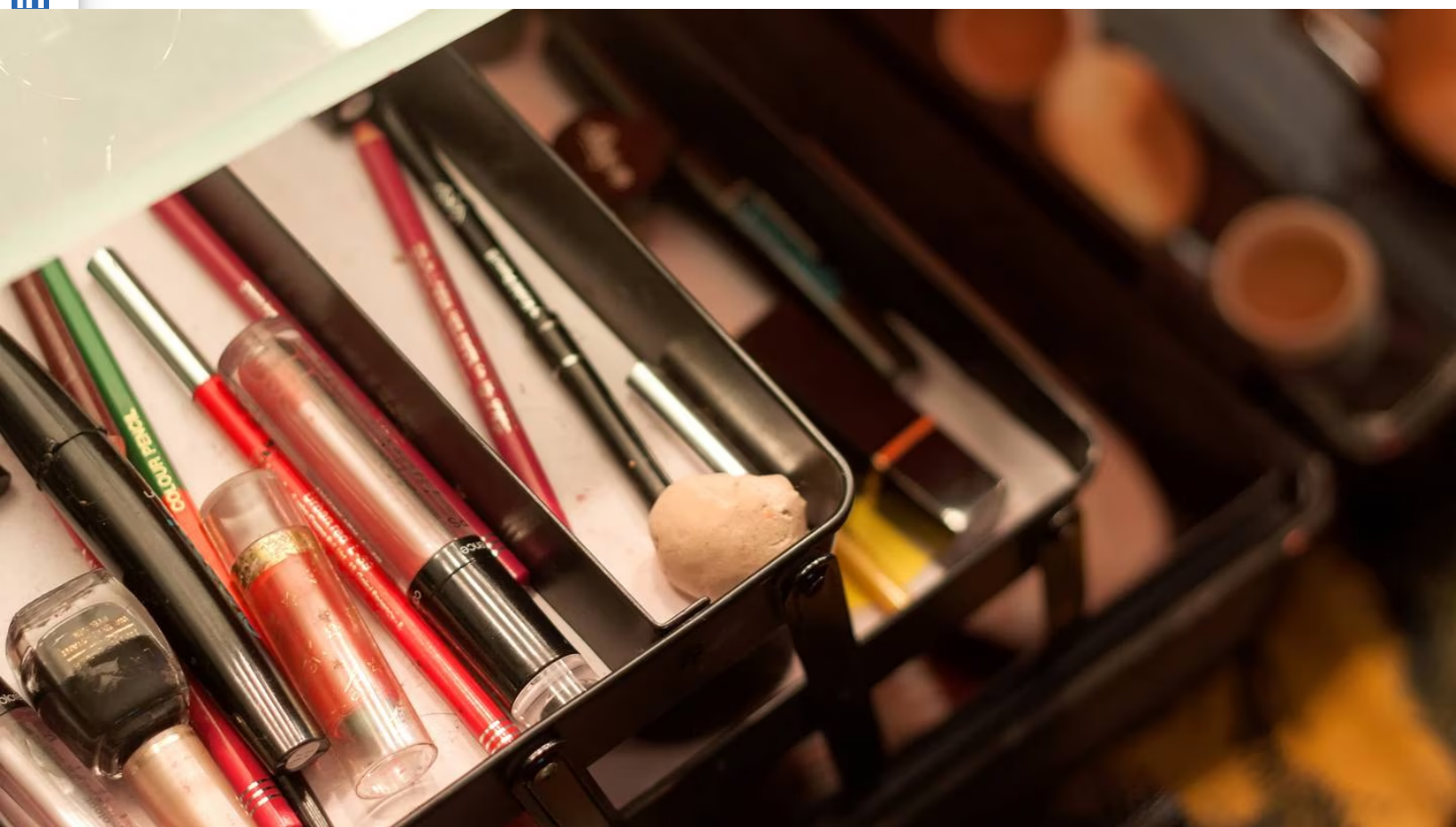


BEAUTY

What Beauty Needs to Know About the Biggest New Regulations in 80 Years

The Modernization of Cosmetics Regulations Act (MoCRA) transforms the US cosmetics landscape from a self-governing body to a federally regulated industry. And with the first deadline just months away, brands need to take heed of new FDA guidelines.



The Modernization of Cosmetics Regulations Act (MoCRA) transforms the US cosmetics landscape from a self-governing body to a federally regulated industry (Getty Images)

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BoF PROFESSIONAL

Compared to the food and drug businesses, the safety of cosmetics has historically been a low priority for the US Food and Drug Administration (FDA). But with the cosmetics industry growing in size and influence, the organisation is exerting newfound authority over lipsticks and moisturisers the same way it does for pain meds.

On December 29, 2022, President Joe Biden signed into law the Modernization of Cosmetics Regulations Act (MoCRA), making it the first major piece of US cosmetics legislation since the 1938 Federal Food, Drug, Cosmetic Act. MoCRA grants the FDA increased oversight on beauty products sold in the US. And for much of the beauty industry, that's a good thing.

“[MoCRA] is obviously imperfect, but it's a movement in the right direction,” said Dieux co-founder and head of product Joyce de Lemos. “I'm happy that it's happening. It'll just be interesting to see how brands rise to the occasion.”

The US has been an outlier when it comes to global cosmetics regulations, according to Geoff Waby, board director of Obelis USA, the American branch of the Brussels-based regulatory advisor Obelis Group. MoCRA is set to change that. “It's bringing [the US] more in line with the other major markets around the world,” said Waby.

Starting on December 29, 2023, MoCRA will enforce its first set of provisions, including requiring beauty brands sold in the US to register their facilities with the FDA, with more requirements to be enacted in 2024.

With that first deadline less than six months away, beauty brands and manufacturers need to be well on their way to adhering to the new law. But with specific MoCRA provisions still to be determined, the future of US cosmetics regulations is uncertain.

What Are MoCRA's Key Provisions?

The threat of litigation or tarnished reputations from hazardous products has kept the US cosmetics industry in check, notes attorney Kelly A. Bonner, an associate at Philadelphia law firm Duane Morris. But as the industry becomes more lucrative, companies would prefer federal regulations to standardise safety. With MoCRA, brands must answer to an authority greater than their consumers. Whereas cosmetic recalls were previously voluntary, MoCRA grants the FDA mandatory recall authority in the event a product may be adulterated or unsafe.

By December, brands and manufacturers creating cosmetics for sale in the US will need to register their facilities, including third-party logistics firms that process cosmetics, with the FDA, along with a list of products on the market and their corresponding ingredients. Companies also need to establish a contact for consumers to report adverse events associated with a product, as MoCRA will require a responsible party to report such events to the FDA within 15 business days.

While cosmetics brands will not need FDA approval to bring a product to market, they will need to maintain records that substantiate the safety of their products by the end of the year. Cosmetics manufacturers should already be maintaining such records, said Harold Chase, regulatory affairs manager of global certification at non-profit consulting and third-party certification agency NSF. But now they need to document it in a way the FDA can access.

“The FDA is very strict, if it’s not documented, it didn’t happen,” said Katherine Fillinger, senior manager of global certification at NSF.

But MoCRA has yet to define some guidelines. MoCRA requires that cosmetics facilities meet FDA standards for Good Manufacturing Practice (GMP), but the FDA has until December 29, 2024, to propose GMP guidelines and will finalise them the following year.

Fillinger advises brands to begin preparing for GMP standards by looking at existing global standards, such as the **International Organization for Standardization (ISO)**. She compares the rollout of MoCRA to standards the FDA enacted on dietary supplements in 2007, where some brands struggled to follow evolving guidelines.

Beginning December 29, 2024, MoCRA will put fragrances under the microscope, as it will require product labelling to include US contact information where consumers can report adverse effects and list fragrance allergens. But the FDA needs to determine whether it will follow the EU’s guidelines on fragrance allergens or develop its own.

To prepare for the upcoming change, New York-based men’s grooming brand Hawthorne has already begun listing fragrance allergens on its packaging in accordance with EU guidelines.

“We just always try to make sure that we’re future-proofed,” said Hawthorne co-founder Brian Jeong.

Waby notes that cosmetics companies should think ahead to meet upcoming labelling requirements, as the FDA has historically been proactive in enforcing its authority over sectors like OTC drugs.

“The bottom line is that people have to take it seriously,” said Waby.

Who Does MoCRA Impact?

MoCRA’s requirements extend to international companies that wish to sell cosmetics in the US. Global manufacturers making products for the US will need to register with the FDA and establish a US-based representative to field safety concerns.

“Part of our advice to our clients is you now have to think about your supply chain,” said Waby.

“The regulation clearly covers your responsibility as a brand owner, but also the responsibility of the manufacturer to register and to provide safe products for the US market.”

MoCRA's mandates are global, but not universal. The act exempts companies with under \$1 million USD in gross annual sales from facility registration, GMP and product listing requirements.

What Doesn't MoCRA Cover?

MoCRA mostly aligns the US with global regulations, but it still differs from certain EU guidelines: it does not restrict ingredients like borates and coal tars, which are banned in Europe. MoCRA also does not preempt state bans on cosmetics ingredients, like New York's ban on mercury or California's ban on PFAs, which goes into effect in 2025. That can force brands to comply with patchwork ingredient regulations, Chase said.

Nor does MoCRA provide definitions for contentious terms like "**clean**" or "natural." The meaning of those labels is at the heart of a recent **class action lawsuit filed against Sephora** over allegedly misleading information in its Clean at Sephora program.

Though MoCRA offers guidelines on safety compliance, Bonner notes that it doesn't regulate marketing claims companies can make about safety. And that grey area may open the door to more lawsuits.

"MoCRA creates ambiguity, and litigation thrives in ambiguity," said Bonner. "As MoCRA continues to unpack, hopefully, the FDA will step in and provide some guidance."

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