



Regulatory News Alerts & Updates

Regulatory Alert: FDA MoCRA Overview

July 18, 2024

BACKGROUND

The Modernization of Cosmetics Regulation Act of 2022 (MoCRA) is the largest expansion of the FDA authority in regulating cosmetics in over 80 years. The stated purpose of MoCRA is to better ensure consumer safety in their use of cosmetic products.

WHAT ARE THE CORE REGULATORY REQUIREMENTS AND DETAILS FOR MoCRA?

MoCRA includes several new authorizations for the FDA. A summary of the primary changes is listed below:

Records access - FDA can access and copy certain records related to a cosmetic product, including safety records if certain conditions are met.

- Mandatory recall authority - If the FDA determines that there is a reasonable probability that a cosmetic is adulterated or misbranded and the use of or exposure to the cosmetic will cause serious adverse health consequences, FDA can order a mandatory recall if the responsible person refuses to do so voluntarily.

Facility registration - Manufacturers and processors must register their facilities with FDA and renew their registration every two years.

Safety substantiation - Companies and individuals who manufacture or market cosmetics have a responsibility to ensure the safety of their products. This includes maintaining records supporting adequate safety substantiation of their cosmetic products.

Adverse event reporting - A responsible person is required to report serious adverse events associated with the use of cosmetic products in the United States to FDA within 15 business days.

MoCRA allows exemptions for certain small businesses from good manufacturing practices (GMP), registration, and product listing requirements. Exemptions exist also for certain products and facilities that are subject to requirements for drugs and devices. However, these exemptions do NOT apply to manufacturers or businesses that process these cosmetics products:

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- Products that regularly come into contact with mucus membrane of the eye under usual conditions of use.
- Products that are injected.
- Products that are intended for internal use.
- Products that are intended to alter appearance for more than 24 hours under usual conditions of use and removal by the consumer is not part of such conditions of use.

While MoCRA implements these new regulatory requirements for cosmetics, there are no new data elements required for U.S. import clearance at this time.

Q & A

Q 1 - If a customer in the business of importing cosmetics has a question re MoCRA, is there a MoCRA FDA site available for support?

A 1 -The FDA MoCRA website is listed in the REFERENCES section below. Any customer that has an issue or question regarding MOCRA should direct their specific issue to QuestionsAboutMoCRA@fda.hhs.gov .

Q 2 - Has the FDA announced a specific start date for MoCRA requirements and enforcement?

A 2 – While the FDA has announced that it will begin enforcing the MoCRA legislation effective July 1, 2024, the core takeaway for our customers is that there are no new import data element or declaration requirements at this time.

Q 3 – Where can cosmetics businesses find details on GMP (Good Manufacturing Practices)?

A 3 – The FDA provides this link as guidance to the cosmetics industry:
<https://www.fda.gov/regulatory-information/search-fda-guidance-documents/draft-guidance-industry-cosmetic-good-manufacturing-practices>

Q 4 – How do I know what is defined by the FDA as a “cosmetic”?

A 4 – An area of confusion can be determining if an item is a cosmetic or a drug. A cosmetic product is one that is designed to “cleanse or beautify.” A drug product is one that is intended to treat or prevent disease or affect the structure or function of the body.

The FDA provides a resource to help the trade understand the statutory definition of cosmetics, and when products move from being regulated as cosmetics to being regulated as pharmaceuticals, on its webpage entitled “Is it a Cosmetic, a Drug, or Both? (Or Is It Soap?).” A link to this webpage is listed in the References section below.

REFERENCES

FDA MoCRA website

<https://www.fda.gov/cosmetics/cosmetics-laws-regulations/modernization-cosmetics-regulation-act-2022-mocra>

FDA Webpage “Is it a Cosmetic, a Drug, or Both? (Or Is It Soap?)”

<https://www.fda.gov/cosmetics/cosmetics-laws-regulations/it-cosmetic-drug-or-both-or-it-soap>

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