



# FDA Regulation Rescue

**ESSENTIAL STRATEGIES AND TIPS TO MEET FD&C  
ACT AND M<sub>o</sub>CRA**

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# FD&C Act and MoCRA

- ▶ The FD&C Act (Federal Food, Drug, and Cosmetic Act) is a comprehensive law that regulates the safety, manufacturing, and marketing of food, drugs, and cosmetics in the United States.
- ▶ FDA is an authorized agency that enforces the FD&C Act.
- ▶ MoCRA (Modernization of Cosmetics Regulation Act) is an amendment to this framework, specifically focusing on strengthening the regulation of cosmetic products to ensure their safety and transparency for consumers.

FDA  
requirements  
under MoCRA  
legislation

- ▶ Product Safety Substantiation
- ▶ Facility Registration
- ▶ Product Listing – must list each marketed cosmetic product with FDA
- ▶ Adverse Event Reporting

# MoCRA Requirement: Product Safety Substantiation

- ▶ Raw Material
- ▶ Finished Product

# MoCRA Requirement: Product Safety Raw Material Impurities

- ▶ **EG (ethylene glycol) and DEG (diethylene glycol):**

Glycerin, Propylene Glycol, Ethylene Glycol, Maltitol,  
Sorbitol, Polysorbates, Hydrogenated starch hydrolysate, PEG's

- ▶ **1,4 Dioxane and Ethylene Oxide**

Ethoxylated ingredients: PEG's or ingredients that end in "eth" or "oxynol"

- ▶ **Heavy Metals (Lead, Arsenic, Cadmium, Mercury, Antimony)**

# MoCRA Requirement: Product Safety Finished Product Testing

- ▶ Analytical testing

pH, Viscosity, Color, Odor, Physical Form, etc...

- Microbial testing

Total Plate Count, Total Yeast and Mold, Pathogens  
specifically: ***Burkholderia Cepacia complex (Bcc)***

# MoCRA Requirements: Facility Registration and Product Listing

Tutorial and User Guide

**<https://www.fda.gov/cosmetics/registration-listing-cosmetic-product-facilities-and-products/cosmetics-direct>**

NOTE: Exemptions and more detailed information:

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

# Adverse Event Reporting

<https://www.fda.gov/cosmetics/cosmetics-news-events/fda-issues-updated-instructions-serious-adverse-event-reporting-cosmetic-products>

# Audit Tips

- ▶ Sign in sheet (Have an auditor sign and out each day)
- ▶ Allocate a room for the audit (conference room works best)
- ▶ Current list of products
- ▶ Organizational Chart (make sure it's updated)
- ▶ List of SOP's (Standard Operational Procedures)

# Audit Tips

- ▶ Water source for production and cleaning
- ▶ Water specification and testing
- ▶ Raw material used in product
- ▶ Customer Complaint log

Audit tip:  
Water  
Specification  
(cosmetics)

Monograph driven (Distilled,  
Purified, DI, WFI etc.)

- ▶ At minimum water specification shall address:
  - Microbial limits
  - Chemical purity
  - Testing Frequency

# Audit Tip: Water – Microbial Testing

- ▶ TPC (Total Plate Count)
- ▶ TYM (Total Yeast and Mold): Absent
- ▶ ***Burkholderia cepacia complex (Bcc): Absent***

# Audit Tip: Water –Chemistry

- ▶ pH: 5.0 – 7.0
- ▶ TOC (Total Organic Carbon): Usually less than **0.5 mg/L**.
- ▶ Conductivity: Typically less than **1.3  $\mu\text{S/cm}$**  at 25°C)
- ▶ Appearance: Clear, colorless, odorless and free from visible particles.

Audit Tip:  
Water System  
Validation

- ▶ Water testing frequency

# Audit Tip: Water testing frequency

Daily

Weekly

Monthly

# Audit tip: Water System Maintenance

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Binder or a logbook includes dates and part numbers

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Filter changes

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Backflow flush

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Any Repairs

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Alarm Systems Test (if applicable)

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In-line readers recordings

# Summary

## MoCRA requirements for Cosmetic Industry

- ▶ Facility Registration
- ▶ Product Listing with FDA
- ▶ ***Burkholderia Cepacia complex (Bcc)***
- ▶ Impurity testing raw material: DEG, EG, 1,4 Dioxane
- ▶ Heavy metal limits in Finished Product:
  - \**antimony shall not exceed 5 ppm*
  - \**arsenic shall not exceed 3 ppm*
  - \**cadmium shall not exceed 3 ppm*
  - \**lead shall not exceed 10 ppm*
  - \**mercury shall not exceed 1 ppm*

\*NSF Certification Guideline  
527 –Personal Care Products

Thank you



Questions/Comments



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