

MoCRA Readiness Checklist: FDA Compliance for Cosmetics Manufacturers and Beauty Brands

This checklist is designed to help beauty brands and manufacturers ensure compliance with the Modernization of Cosmetics Regulation Act (MoCRA). Use this as a guide to evaluate and enhance your compliance systems.

1. Facility Registration

- Confirm that your facility meets the FDA's definition of a cosmetic manufacturing or processing establishment.
- Register your facility with the FDA and provide:
 - Facility name and address.
 - Contact information for the responsible person.
 - A list of cosmetic products manufactured or processed at the facility.
- Update facility registration annually or whenever significant changes occur.

2. Product Listing

- Submit a complete product listing for each cosmetic product:
 - Product name and category.
 - List of ingredients in descending order of predominance.
 - An image of the product label.
- Update product listings within 60 days of any significant changes (e.g., reformulations or labeling updates).

3. Ingredient Safety Compliance

- Conduct a safety assessment for each cosmetic product, ensuring it is not adulterated or misbranded.
- Document the safety of each ingredient used, including toxicological profiles and scientific data.
- Avoid the use of banned or restricted substances.

4. Labeling and Marketing Compliance

- Ensure all product labels include:
 - A complete list of ingredients.
 - Correct allergen declarations.
 - Contact information for the responsible person.
- Avoid unsubstantiated claims (e.g., "FDA-approved," "clinically proven" without evidence).

- Clearly differentiate between cosmetic and drug claims.

5. Good Manufacturing Practices (GMPs)

- Implement and follow FDA-compliant GMPs to ensure product quality and safety.
- Develop and maintain up-to-date Standard Operating Procedures (SOPs).
- Train employees regularly on GMP requirements.
- Conduct routine internal audits to verify compliance.

6. Adverse Event Reporting System

- Establish a system to capture, investigate, and report adverse events.
- Notify the FDA of any serious adverse events within 15 business days.
- Maintain records of all adverse event reports for a minimum of six years.

7. Recordkeeping and Documentation

- Maintain detailed records for each product, including:
 - Formulations.
- Manufacturing processes.
- Safety substantiation files.
- Testing records.
- Ensure documentation is readily accessible during FDA inspections.

8. Inspection Readiness

- Prepare for unannounced FDA inspections by:
 - Assigning a compliance officer or team.
 - Conducting mock inspections.
 - Keeping records and SOPs well-organized.
 - Address any identified gaps immediately.

9. Compliance with MoCRA Deadlines

- Review and adhere to all MoCRA deadlines for:
 - Facility registration.
 - Product listing updates.
 - Reporting serious adverse events.
 - Stay informed about new FDA guidance or rulemaking under MoCRA.

Next Steps:

- ✓ Conduct a gap analysis using this checklist.
- ✓ Develop an action plan to address areas of non-compliance.
- ✓ Schedule regular reviews to maintain ongoing readiness.

Got questions or need a hand with any of the above? Reach out to Trailblazer Quality Excellence. We're here to provide a full range of services to help you achieve your goals.