MoCRA Update:

Complete Guide for Cosmetic Suppliers

ALS | BEAUTY & PERSONAL CARE

Understand the new regulations to maintain business as the USA and the importance of clinical tests

Summary

A message from Barry Reece.

"Regulatory compliance is essential to guarantee the quality and safety of cosmetic products. The recent updates in legislation, especially with the introduction of the MoCRA (Modernization of Cosmetics Regulation Act), present new challenges and opportunities for suppliers of the cosmetics chain. This handbook was created to provide a comprehensive overview of these changes and how they impact small and medium-sized suppliers. Additionally, we highlight the laboratory tests offered by ALS, which can add value to your compliance process."

Barry Reece
General Manager, Beauty and Personal Care, The Americas

The purpose of this handbook is to guide cosmetics suppliers on the new regulations imposed by MoCRA and how they can prepare to comply with these requirements. By the end of this material, you will have a clear understanding of regulatory changes, the role of the FDA, and how ALS laboratory testing can support your company.

About ALS

ALS is a global analytical services company that offers a broad range of solutions to ensure product quality, safety, and compliance across diverse industries. Our Beauty and Personal Care business unit specializes in providing laboratory testing services for the cosmetic and personal care industries, such as clinical efficacy and safety, analytical chemistry, microbiology, stability studies and toxicology. With laboratories equipped with cutting-edge technology and a team of highly qualified experts, ALS helps companies ensure that their products meet the highest standards of safety and effectiveness, complying with all current regulations.

What is **MoCRA?**

Definition

The Modernization of Cosmetics Regulation Act of 2022 (MoCRA) is a recent and significant piece of legislation that updates and modernizes regulations for the cosmetics industry in the United States.

Passed in December 2022 as part of the Consolidated Appropriations Act, MoCRA aims to ensure that cosmetic products are safe for consumers and that companies are transparent about ingredients and manufacturing processes. This law represents the most comprehensive update to cosmetics regulations in the U.S. since 1938.

Importance

This legislation introduces new regulatory requirements for the cosmetics industry, aiming to enhance consumer safety and streamline oversight.

MoCRA is crucial for the cosmetics industry as it establishes stricter safety and quality standards. These changes are critical for protecting consumers and ensuring products are manufactured according to best practices.

For suppliers and manufacturers this means the need to adapt their processes and ensure compliance with new requirements.

Key Provisions of MoCRA

1. Mandatory Registration:
Cosmetic manufacturers and processing facilities, both domestic and foreign, are required to register with the FDA. They must renew this registration biennially. This allows the FDA to keep an updated database of all facilities involved in the production of cosmetics sold in the U.S.

2. Adverse Event Reporting:
Manufacturers must report serious adverse events related to their products to the FDA within 15 days of becoming aware of them. This includes incidents like hospitalizations, significant disfigurements, or death. The company is also required to keep records of all adverse events, both serious and non-serious for up to 6 years.

3. Labeling Requirements:
MoCRA mandates more detailed labeling, including the disclosure of fragrance allergens. It also requires clear instructions on product usage and warnings if a product could pose risks when misused.

4. Good Manufacturing Practices:
The FDA is now authorized to establish good manufacturing practices for cosmetics. These standards will help ensure that products are consistently produced in a safe and clean environment, reducing the risk of contamination or other safety issues.

5. Identification of a Responsible Person (RP):
Is the natural or legal person whose name will appear on the label of a cosmetic product. This could be the manufacturer, packer, or distributor.

6. Product List:
It is mandatory to register each cosmetic product sold in the USA with the FDA. Products launched after 2023 must be registered within 120 days. Updates may be sent annually.

7. Recall authority:
The FDA can directly access all records relating to the manufacturing and safety data of cosmetic products. The FDA also has the authority to order recalls if a responsible party does not voluntarily stop selling or distributing a product.

8. Safety of Ingredients:
The RP must ensure and maintain records that support adequate proof of the safety of cosmetic products.

FDA: Who is the FDA and what is their role?

History and Role

The FDA, or Food and Drug Administration, is a United States federal agency responsible for regulating foods, drugs, cosmetics and other health-related products. Founded in 1906, the FDA's mission is to protect public health by ensuring the safety, effectiveness and security of products.

FDA Requirements

For the cosmetics industry, the FDA sets guidelines that must be followed to ensure that products are safe to use and do not contain harmful ingredients. Requirements include:

- **Registration of Establishments and Products:** Companies must register their establishments and cosmetic products with the FDA.
- **Product Safety:** Ensure cosmetic products are safe to use as directed.
- **Proper Labeling:** Product labels must be clear and informative, including all ingredients and any safety warnings.
- **Post-Market Monitoring:** Companies must monitor and report any adverse events associated with their products

MoCRA Timeline

2022

December 29: Modernization of Cosmetics Regulation Act (MoCRA) signed into law.

2023

January: FDA begins implementation of MoCRA.

April 12: FDA announces the creation of the Office of Cosmetics, Skin, and Allergenic Products (OCSAP) within the Center for Drug Evaluation and Research (CDER).

June 27: FDA announces the formation of the Cosmetics Advisory Committee.

July 17: FDA announces the transition of cosmetics regulation from the Center for Food Safety and Applied Nutrition (CFSAN) to OCSAP.

December 29: Mandatory reporting of serious adverse events, adverse event recordkeeping, safety substantiation documentation, and professional use product labeling requirements go into effect.

2024

January: FDA issues guidance on serious adverse event reporting.

February 27: FDA releases a public update on MoCRA implementation progress.

July 1: Deadline for cosmetic facility registration and product listing.

Ongoing: FDA continues to develop regulations for Good Manufacturing Practices (GMPs), fragrance allergens, and other provisions of MoCRA.

Upcoming Deadlines and Future Implementations

GMP Regulations: FDA is required to issue regulations establishing GMPs for cosmetic products. No specific deadline has been set, but the industry anticipates these regulations to be issued within the next few years.

Fragrance Allergen Labeling: MoCRA requires the FDA to issue regulations for fragrance allergen labeling. A timeline for this has not yet been established.

Other Provisions:

- FDA will continue to implement other provisions of MoCRA, such as facility registration and product listing, through rulemaking and guidance documents.
- FDA is required to issue guidance on testing for per- and polyfluoroalkyl substances (PFAS) in cosmetic products. The guidance should provide insight as to the FDA's position on the presence ot PFAS in cosmetic products and may outline procedures and standards for ensuring that products are safe for consumer use and compliant with regulatory standards by December, 2025.

Important Considerations

Industry Compliance:
Cosmetic companies must stay updated on FDA regulations and guidance to ensure compliance with MoCRA requirements. Follow ALS to stay up to date.

Consumer Protection:
MoCRA is expected to enhance consumer safety by improving the oversight of the cosmetics industry.

Regulatory Flexibility:
FDA will likely provide opportunities for industry input through public comment periods during the rulemaking process.

Facility **Registration**

The Modernization of Cosmetics Regulation Act of 2022 (MoCRA) represents a significant shift in the regulatory landscape for cosmetic product manufacturers. To ensure compliance, facilities that manufacture or process cosmetic products must adhere to specific registration and product listing requirements with the U.S. Food and Drug Administration (FDA). Below, we will thoroughly explore these requirements and outline the step-by-step process to register a facility.

1 Understanding the MoCRA Facility Registration Requirement

Under MoCRA, any facility that manufactures or processes cosmetic products intended for use in the United States must be registered with the FDA. This includes both domestic and foreign facilities. Failure to register can result in products being deemed misbranded, which can lead to enforcement actions, including potential recalls or import refusals.

Key Points:

Who Must Register:
All facilities involved in the manufacturing or processing of cosmetic products distributed in the U.S., regardless of whether the products are made domestically or abroad.

The FDA also has the authority to suspend a facility's registration if it determines that a cosmetic product from the facility poses a significant risk to health. This suspension can occur if:

- The product has a reasonable probability of causing serious adverse health consequences or death.
- There is a reasonable belief that other products from the same facility might be similarly affected due to pervasive issues that cannot be isolated to a single product.

If a facility's registration is suspended, it becomes illegal to distribute, sell, or introduce cosmetic products from that facility into the U.S. market.

Exemptions: Facilities that only perform labeling, relabeling, packaging, repackaging, or distribution of cosmetic products do not need to register under MoCRA.

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The initial registration deadline was July 1, 2024. For new facilities, registration must occur within 60 days of beginning operations or by July 1, 2024, whichever is later. Registrations must be renewed biennially.

Steps for Facility Registration

Obtain an FDA Establishment Identifier (FEI):

- Before submitting a facility registration, you must obtain an FDA Establishment Identifier (FEI) number. The FEI number is crucial for the registration process.
- To determine if your facility already has an FEI, you can use the FEI Search Portal. If your facility does not have an FEI, you can request one through the same portal.

Establish a FURLS Account:

- The FDA uses the FDA Unified Registration and Listing System (FURLS) to manage cosmetic facility registrations. Facilities must first create an account within this system if they do not already have one.

Submit Registration Information:

- Once the FURLS account is established, facilities can log in and submit the required registration information, including the facility's details and product categories. This can be done electronically using the FDA's preferred method, Cosmetics Direct, which is a Structured Product Labeling (SPL) authoring tool. This tool simplifies the submission process by providing user-friendly data entry forms and initial validations.

- Alternatively, you can use the Electronic Submissions Gateway (ESG) or other SPL-compliant software, such as SPL Xforms. The ESG system requires a free account, which can take one to three weeks to set up, so early registration is advised.

Obtain a Registration Number:

- After the registration is submitted and reviewed, the FDA will assign a unique registration number to the facility. This number must be maintained as it is required for future communications and renewals.

Biennial Renewal:

- Facilities must renew their registration every two years by updating their information in FURLS and confirming the accuracy of the data provided.

Information Required for Registration

When registering a facility, the following information must be provided to the FDA:

- **Facility Name and Address:** The legal name, physical address, and contact information of the facility.
- **Facility Type:** Indicate whether the facility is a manufacturer or processor of cosmetics.
- **Facility Operator Information:** The name and contact information of the facility's operator.
- **Product Category Information:** A list of cosmetic product categories that the facility manufactures or processes.
- **Responsible Person:** The name, title, and contact information of the individual responsible for the facility's registration and communication with the FDA.

The information provided must be accurate and up to date. Any changes to the registration details must be reported to the FDA within 60 days.

Product Listing Requirements
In addition to facility registration, MoCRA mandates that a responsible person - defined as the manufacturer, packer, or distributor whose name appears on the product label - must list each cosmetic product marketed in the U.S. with the FDA. This listing must include all product ingredients and be updated annually.

Product Information
The listing includes the product name, category, ingredients (in descending order of predominance), and a copy of the product's label, including any variations. This product listing must be kept up to date, and any changes to the product formulation or labeling must be reported to the FDA.

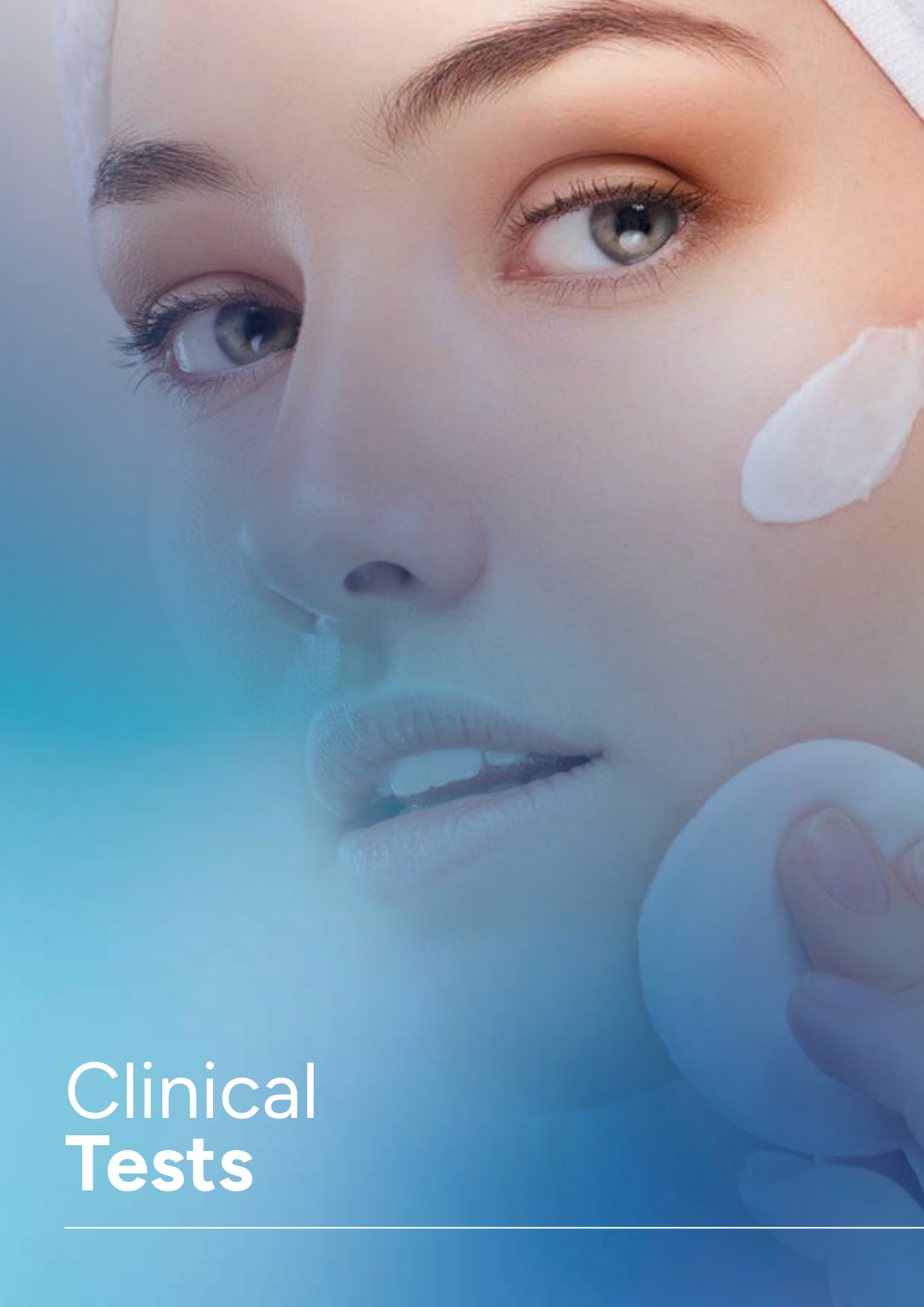
Compliance and Enforcement

Failure to comply with the facility registration and product listing requirements under MoCRA can result in serious consequences, including:

- Product Detention: Products from unregistered facilities may be detained at the U.S. border.
- Civil Penalties: Financial penalties may be imposed for non-compliance.
- Injunctions: The FDA may seek court orders to prevent the distribution of non-compliant products.
- To avoid these issues, it is crucial for facilities to ensure they meet all MoCRA requirements and maintain accurate and timely records.

Key Hyperlinks:

FDA Establishment Identifier (FEI) Search Portal
Cosmetics Direct Registration and Listing Tool
Electronic Submissions Gateway (ESG)
Guidance for Industry: Registration and Listing of Cosmetic Product Facilities and Products



Clinical **Tests**

MoCRA has introduced a paradigm shift in cosmetic regulation by requiring more rigorous scientific evidence to support product safety and claims. Clinical testing is now a critical component of demonstrating compliance with the law. A laboratory testing partner like ALS can perform clinical testing to help companies stay compliant.

Key areas where clinical testing is essential include:

1. Laboratory Testing for Quality Control

Laboratory testing is fundamental for ensuring that cosmetic products meet stringent safety and effectiveness standards. The following quality control tests are essential for MoCRA compliance:

- **Microbiological Tests:** These tests are crucial for checking the presence of microorganisms that can cause contamination and affect the safety of the product. They include:
  - Total Viable Count (TVC): Measures the total number of viable microorganisms present in a product.
  - Pathogen Screening: Detects specific harmful microorganisms like Staphylococcus aureus and Pseudomonas aeruginosa.
  - Preservative Efficacy Testing (PET): Assesses the effectiveness of preservatives in inhibiting microbial growth over time.
- **Physical-Chemical Tests:** These tests evaluate the physical and chemical properties of the product to ensure its stability and effectiveness. Key aspects include:
  - pH Testing: Ensures that the product's pH is within a safe and effective range for human skin.
  - Viscosity Testing: Measures the thickness of the product, which impacts application and user experience.
  - Stability Testing: Assesses how the product's formulation holds up under various environmental conditions like temperature and humidity.

2. Efficacy Tests

Cosmetic products must not only be safe but also effective. Efficacy tests are designed to scientifically validate product claims:

- **Clinical Studies:** These studies evaluate the effectiveness of products under controlled conditions with human volunteers. Clinical studies are can be designed as randomized, double-blind, and placebo-controlled to minimize bias. They focus on specific claims such as anti-aging effects or moisturization, using endpoints like skin hydration levels measured with instruments such as corneometer.

Information Required for Registration

- **Consumer Perception Studies:** These studies collect feedback from consumers about product performance and acceptance. This subjective data provides insights into how well the product meets consumer expectations in real-world settings.

3. Safety Tests

Ensuring the safety of cosmetic products is a critical aspect of MoCRA compliance. Safety tests are designed to identify any potential risks associated with product use:

- **Irritation and Sensitization Tests:** These tests evaluate the potential of products to cause skin irritation or allergic reactions. They include:
  - Primary Irritation Test (PIT): Applies the product to the skin of volunteers and monitors for signs of irritation, such as redness or swelling.
  - Human Repeat Insult Patch Test (HRIPT): Involves repeated application of the product to assess cumulative irritation or sensitization.

- **Phototoxicity Tests:** These tests evaluate how the product reacts when exposed to light, particularly UV radiation. They ensure that the product does not cause harm when used during the day. Types of phototoxicity tests include:
  - **In Vitro Phototoxicity Test:** Uses cell cultures to assess potential phototoxic reactions without human volunteers.
  - **In Vivo Phototoxicity Test:** Applies the product to human skin and exposes it to controlled UV light to observe any adverse reactions.

- **Safety in Use Tests:** These tests check the skin acceptance of the cosmetic product for topical use by observing the non-occurrence of adverse events such as allergic reactions, irritation, and other tolerability endpoints.. They also verify effectiveness through subjective self-assessments by study volunteers using the product under the conditions that it is intended to be used.

4. Regulatory Compliance and Reporting

Following the completion of laboratory and clinical tests, companies must compile and submit their findings to the FDA as part of their compliance documentation. This includes:

- **Record Keeping:** Companies must maintain detailed records of all adverse event data for at least six years (three years for small businesses). These records must be available for FDA inspection upon request.

Adverse **Event Reporting**

Adverse Event Reporting Under MoCRA

Introduction to Adverse Event Reporting

Introduction to Adverse Event Reporting

Adverse event reporting is a critical component of the Modernization of Cosmetics Regulation Act of 2022 (MoCRA), which mandates that cosmetic product manufacturers must retain information on adverse events and report serious adverse events to the FDA. The purpose of this reporting is to ensure consumer safety and to enable the FDA to take appropriate regulatory actions when necessary.

Definition of an Adverse Event

Under MoCRA, an "adverse event" is defined as any negative health-related incident associated with the use of a cosmetic product. This includes:

- **Persistant burning, stinging, itching,**
- **Allergic reactions**

What Constitutes a Serious Adverse Event?

MoCRA specifically emphasizes the reporting of "serious adverse events." A serious adverse event is one that results in:

- Death or life-threatening experience
- In-patient hospitalization
- A persistent or significant disability or incapacity
- Congenital anomaly or birth defect
- An infection or
- Significant disfigurement other than as intended, under conditions of use that are customary or usual, such as:
    - Serious, persistent rashes or infections;
    - Second- or third-degree burns;
    - Significant hair loss;
    - or Persistent or significant alteration of appearance

Reporting Requirements

Who Must Report?

The "responsible person," typically the manufacturer, packer, or distributor whose name appears on the product label, is obligated to report serious adverse events to the FDA. This is a crucial aspect of MoCRA as it assigns clear accountability for the safety of cosmetic products.

Timeline for Reporting

MoCRA mandates that serious adverse events be reported within 15 business days of receiving the information. The report must include any new and material medical information related to the adverse event that becomes available within one year of the initial report.

Information Required for Registration

Information to Include in the Report

When reporting an adverse event, the responsible person must include the following information:

- **Product Information:** Name of the product involved and its labeling.
- **Description of the Adverse Event:** Detailed account of the adverse event, including the outcome.
- **Information on the Affected Individual:** Demographics, medical history, and any relevant information about the individual's exposure to the product.
- **Contact Information:** For follow-up questions, the FDA may need the contact details of the person who can provide further information.

Reporting Process

Submitting an Adverse Event Report

Reports must be submitted to the FDA using the MedWatch system, which is the FDA's adverse event reporting program for medical products, including cosmetics. This system allows for electronic submission, ensuring that the information is promptly received and processed.

FDA MedWatch System

What Happens After Reporting?

Once an adverse event report is submitted, the FDA may take various actions depending on the severity and nature of the reported event. Actions can include:

- **Requesting additional information or samples from the manufacturer**
- **Conducting an investigation**
- **Issuing safety alerts or recalls if necessary**

For more detailed guidance on how to report adverse events, including access to the reporting forms and additional resources, you can visit the FDA's Adverse Event Reporting System (FAERS) Public Dashboard.

Regulatory Implications

Failure to report serious adverse events as required under MoCRA can lead to significant consequences, including:

- Product recalls
- Legal action
- Fines and penalties

It is crucial for cosmetic product companies to have robust systems in place to monitor adverse events and ensure timely and accurate reporting to the FDA.

Conclusion

Adverse event reporting under MoCRA is essential for maintaining consumer safety and regulatory compliance. By understanding the requirements and establishing effective reporting processes, cosmetic manufacturers can minimize risks and protect both their consumers and their business.

Key Resources

FDA Adverse Event Reporting System (FAERS) Public Dashboard

FDA MedWatch System

Reporting Adverse Events to the FDA

Consequences and business implications for noncompliance with MoCRA

The Modernization of Cosmetics Regulation Act of 2022 (MoCRA) introduces stringent requirements for the cosmetics industry in the United States. Noncompliance with these regulations can result in serious and far-reaching consequences for businesses. This section outlines these consequences in detail, highlighting the legal, financial, and operational impacts of failingto adhere to MoCRA.

Information Required for Registration

Legal Actions

Overview: Failure to comply with MoCRA can lead to legal actions against a company. The FDA has the authority to enforce compliance through various legal mechanisms.

- **Enforcement Actions:** The FDA may initiate enforcement actions, including warning letters, seizures, or injunctions. A warning letter is typically the first step, detailing the violations and providing a timeline for corrective action. If a company fails to address the issues, the FDA may escalate to more severe measures.

- **Court Cases:** Persistent noncompliance can lead to legal proceedings in federal court. Companies may face lawsuits filed by the government seeking injunctions or penalties.

Example: If a company fails to register its facility or products, the FDA could issue a warning letter followed by legal action if the company does not rectify the situation.

Fines and Penalties

Overview: The FDA has the authority to impose substantial fines and penalties for noncompliance with MoCRA.

- **Financial Penalties:** Companies may face significant fines for violations such as failure to report adverse events or non-adherence to good manufacturing practices (GMP). The exact amount of fines can vary depending on the severity and nature of the violation.

- **Criminal Charges:** In cases of egregious noncompliance or fraudulent activities, criminal charges may be brought against responsible individuals within the company. This could result in additional fines and potential imprisonment.

Source: FDA Compliance Policy

Damage to Reputation

Overview: Noncompliance with MoCRA can severely impact a company's reputation.

- **Consumer Trust:** When a company faces legal actions or recalls due to non-compliance, consumer trust can be eroded. Consumers may perceive the company as irresponsible or negligent.

- **Market Position:** Damage to reputation can lead to a decline in sales and loss of market position. Rebuilding trust can be challenging and costly.

Example: A company that repeatedly fails to report adverse events may be perceived as putting profits over consumer safety, leading to negative publicity and decreased consumer loyalty.

Suspension of Operations

Overview: The FDA has the authority to suspend operations of facilities that fail to comply with MoCRA.

- **Operational Impact:** Suspension of operations can halt production and distribution, leading to significant disruptions in the company's ability to deliver products to the market.

- **Financial Losses:** Facility suspension can result in loss of revenue, increased costs related to regulatory compliance, and potential layoffs of employees.

Source: FDA Guidance on Cosmetic Facility Registration

Product Withdrawal

Overview: Non-compliant products may be withdrawn from the market, leading to substantial financial repercussions.

- **Market Withdrawal:** The FDA can mandate the withdrawal of products that do not meet safety standards or labeling requirements. This process involves removing the products from store shelves and stopping their distribution.

- **Financial Impact:** The withdrawal of products can lead to loss of revenue, reimbursement costs, and logistical expenses associated with retrieving and disposing of non-compliant products.

Example: A company may be required to withdraw a product if it fails to include mandatory safety warnings or if adverse events are reported and not properly addressed.

Detailing the Integration between Clinical Tests and FDA Registration

Clinical Trials and Product Registration

Clinical trials play a crucial role in the FDA registration process for cosmetic products. To ensure compliance with MoCRA. This includes demonstrating the efficacy and safety of cosmetic products.

Integration Steps

1. Planning and Carrying Out Clinical Tests:

- Identify the efficacy and safety parameters to be tested.
- Select a representative sample of volunteers.
- Conduct testing under controlled conditions and document results.

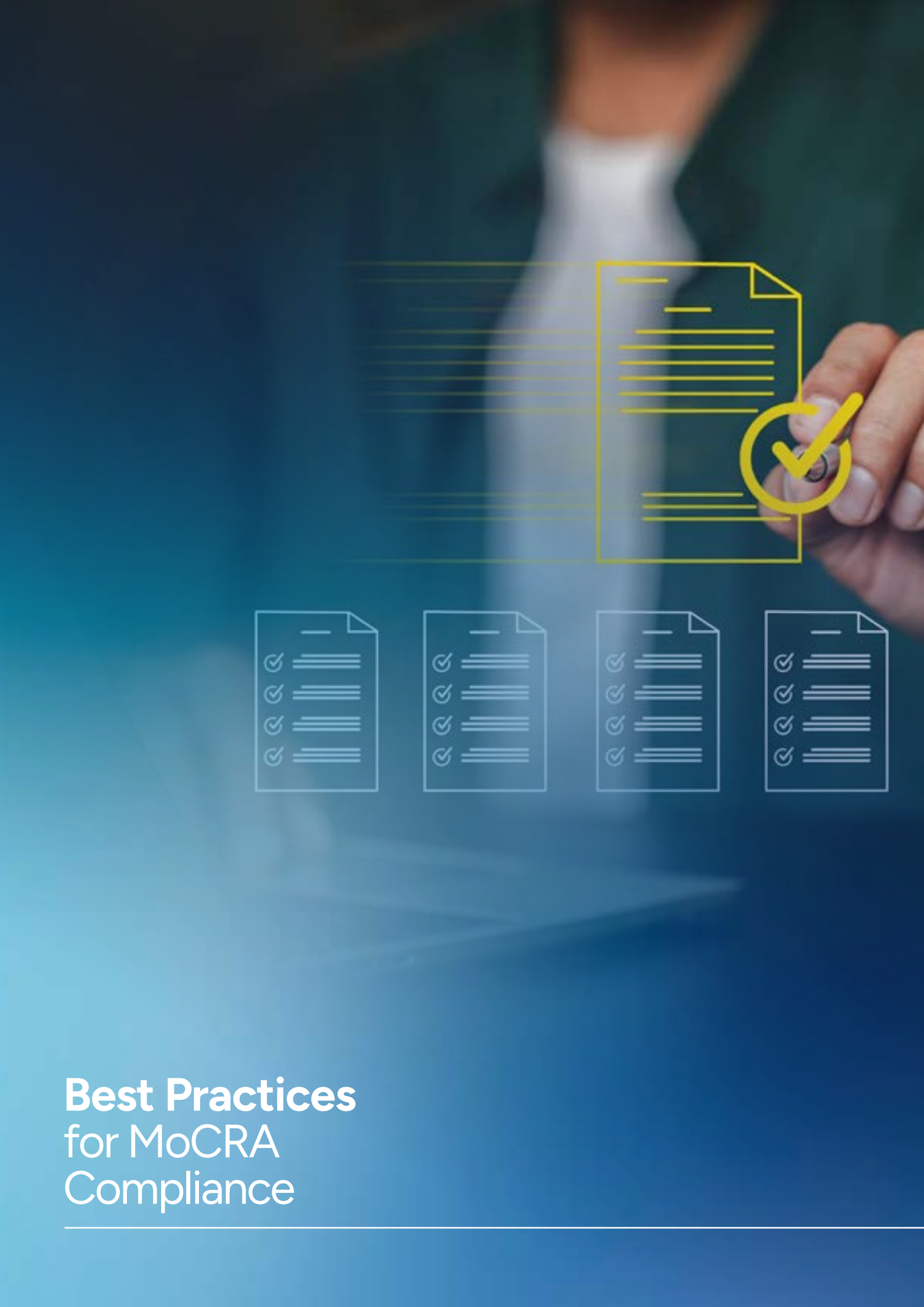
2. Security Documentation and Substantiation:

- Compile clinical trial data, including results, methods used and data analysis.
- Prepare detailed reports that prove the effectiveness and safety of the product.

3. Post-Market Monitoring:

- Continue to monitor the safety of the product after its commercialization.
- Report any adverse events to the FDA as required by MoCRA.

By integrating clinical efficacy and safety testing into the FDA registration process, companies can ensure that their cosmetic products meet the highest standards of quality and regulatory compliance.



Best Practices for MoCRA Compliance

Adherence to MoCRA guidelines ensures that your products meet the safety and regulatory standards set forth by the FDA, protecting both your consumers and your business. Below is a step-by-step guide to implementing best practices for MoCRA compliance.

Initial Assessment

Identify All Products and Processes Requiring Compliance

The first step in achieving MoCRA compliance is conducting a comprehensive assessment of all cosmetic products and related processes within your organization. This includes not only the finished products but also all ingredients, formulations, and manufacturing methods used. Each of these elements must be evaluated to determine which are subject to MoCRA and other applicable FDA regulations.

- **Review MoCRA Requirements:** Familiarize yourself with the specific provisions of MoCRA that apply to your business. This involves understanding both the broad requirements of the act and how they translate into actionable steps within your operations. A thorough review of MoCRA's provisions will be essential to guide this process.

- **Evaluate FDA Requirements:** MoCRA does not exist in isolation but as part of the broader framework of FDA regulations. It's crucial to cross-reference MoCRA requirements with other relevant FDA guidelines to ensure comprehensive compliance. Key resources include FDA guidelines for cosmetic labeling and safety testing.

Registration of Establishments

Register All Establishments with the FDA

MoCRA requires that all establishments involved in the manufacturing, packaging, and distribution of cosmetic products register with the FDA. This registration is crucial as it allows the FDA to maintain an updated inventory of all players in the cosmetics market, facilitating oversight and regulatory enforcement.

- **Steps for Registration:** Registering with the FDA involves submitting detailed information about each establishment, including its location, operations, and the types of products handled. The FDA's online registration portal provides a user-friendly interface for this process.

- **Compliance Documentation:** Ensure that all documentation related to the registration is maintained accurately and updated regularly. This documentation serves as proof of compliance in case of FDA inspections or audits.

Product Documentation

Compile Detailed Information on Ingredients, Formulations, and Manufacturing Processes

Maintaining accurate and comprehensive documentation is at the heart of MoCRA compliance. Every aspect of your products, from ingredient sourcing to the final formulation, must be meticulously recorded.

- **Ingredient and Formulation Records:** Detailed records should include the source of each ingredient, its concentration in the product, and any relevant safety data. This information must be readily accessible for regulatory review and consumer inquiries.

- **Manufacturing Process Documentation:** Documenting the manufacturing process includes detailing the procedures used, equipment involved, and any quality control measures in place. This level of detail ensures that products are manufactured consistently and safely, meeting MoCRA standards.

Safety and Efficacy Tests

Conduct Necessary Laboratory Tests to Ensure Safety and Effectiveness

One of the core requirements under MoCRA is that all cosmetics must be safe for use. This mandates rigorous safety testing of both individual ingredients and final products.

Laboratory Testing: Conduct tests to assess potential risks, such as allergic reactions, toxicity, and long-term health effects. The FDA outlines acceptable testing methodologies in its Cosmetic Product Testing guidelines.

Efficacy Testing: In addition to safety, your products must perform as advertised. Conduct efficacy testing to verify that products deliver on their claims, whether it be moisturizing, anti-aging, or other benefits.

Documentation of Test Results: Keep detailed records of all tests conducted, including methodologies, results, and interpretations. This data not only supports MoCRA compliance but also serves as a foundation for marketing claims.

Labeling

Ensure All Product Packaging Complies with New Labeling Requirements

Product labeling is a significant focus under MoCRA, as labels must convey essential information clearly and accurately to consumers.

- **Labeling Requirements:** Labels must include ingredient lists, usage instructions, warnings, and any other information required by MoCRA and FDA regulations. Review the FDA's Labeling Guide to ensure all elements are covered.

- **Compliance Checks:** Regularly review and update labels to ensure ongoing compliance. This is particularly important when formulations change or when new regulatory guidelines are issued.

Adverse Event Reports

Implement an adverse event monitoring system

Under MoCRA, cosmetic companies are required to monitor adverse events associated with their products and report them to the FDA.

- **Adverse Event Reporting System:** Develop a robust system for tracking, documenting, and reporting adverse events. This includes setting up channels for consumers to report issues and ensuring that these reports are promptly and accurately conveyed to the FDA. The FDA's MedWatch program offers a framework for adverse event reporting.

- **Continuous Monitoring:** Implement ongoing monitoring processes to identify potential issues before they escalate. This proactive approach not only aids in compliance but also helps protect consumers and your brand's reputation.

Training and Education

Train Employees on New Regulatory Requirements and Good Manufacturing Practices

Employee training is essential for ensuring that everyone involved in the production and distribution of cosmetics understands MoCRA requirements and how to implement them.

- **Regulatory Training:** Develop a training program that covers all aspects of MoCRA compliance, from documentation to adverse event reporting. Make sure this training is accessible to all relevant employees and updated regularly to reflect any changes in regulations.

- **Good Manufacturing Practices (GMP):** Emphasize the importance of Good Manufacturing Practices (GMP) in training programs. GMP are critical to maintaining the quality and safety of cosmetic products. The FDA provides GMP guidelines that can be integrated into your training materials.

- **Record of Training:** Maintain records of all training sessions, including attendees, materials covered, and assessments. This documentation can be invaluable during FDA inspections or in the event of compliance issues.

Compliance Checklist

- Evaluate all products and processes.
- Register establishments with the FDA.
- Compile complete product documentation.
- Carry out safety and effectiveness tests.
- Update product labeling.
- Implement an adverse event monitoring system.
- **Train Employees on New Regulatory Requirements and Good Manufacturing Practice**

Common Challenges in Implementing New Regulations

Implement an adverse event monitoring system

Challenges	Solutions
1. Complexity of Requirements: Understanding and implementing all regulatory changes can be complex and time-consuming.	**1. Specialized Consulting:** Hire specialized consultants to help interpret and implement new regulations.
2. High Costs: Investment in laboratory tests and process updates can be significant.	**2. Financial Planning:** Plan and allocate adequate budget to cover compliance costs.
3. Resistance to Change: Employees and stakeholders may resist changes necessary for compliance.	**3. Employee Engagement:** Clearly communicate the benefits of changes and involve all levels of the organization.
4. Data Management: Collecting and maintaining detailed and accurate records can be challenging.	**4. Data Management Systems:** Invest in robust data management systems to ensure the accuracy and integrity of records.
5. Systems Integration: Integrating new monitoring and reporting systems with existing ones can be difficult.	**5. Training and Support:** Provide ongoing training and support to facilitate adaptation to new processes.

Glossary **of Key Terms**

- **Adverse Event:** A health-related incident caused by a cosmetic product.
- **Clinical Testing:** Tests conducted to ensure the safety and efficacy of cosmetic products.
- **Compliance Documentation:** Documentation required to demonstrate that products meet regulatory requirements.
- **Efficacy Testing:** Tests conducted to verify that a product performs as advertised.
- **Efficacy Tests:** Tests carried out to ensure that products work as promised.
- **Facility Registration:** Mandatory registration of cosmetic manufacturing facilities with the FDA.
- **FDA:** Food and Drug Administration, the agency responsible for regulating foods, medicines and cosmetics in the USA.
- **Fragrance Allergens:** Substances in fragrances that can cause allergic reactions and must be listed on labels.
- **GMP (Good Manufacturing Practices):** A set of guidelines that create consistent procedures for manufacturing goods according to a set of quality standards
- **Human Repeat Insult Patch Test (HRIPT):** A test used to evaluate a product's potential to cause skin irritation or sensitization.
- **In Vitro Testing:** Tests conducted on cells or tissues outside of a living organism to assess product safety.
- **In Vivo Testing:** Tests conducted on living organisms to assess product safety and efficacy.
- **Labeling Requirements:** Regulations that require detailed information to be included on product labels.
- **MedWatch:** The FDA's system for reporting adverse events and problems related to health products, including cosmetics.
- **Microbiological Testing:** Tests to detect the presence of microorganisms that could contaminate the product.
- **MoCRA:** Modernization of Cosmetics Regulation Act of 2022, legislation that updates regulations for the cosmetics industry.
- **pH Testing:** Testing that measures the acidity or alkalinity level of a product.
- **Phototoxicity Testing:** A test that assesses how a product reacts when exposed to light, particularly UV light.
- **Post-Market Surveillance:** Ongoing monitoring of product safety and efficacy after it has been released to the market.
- **Preservative Efficacy Testing:** Testing to ensure that preservatives in the product effectively prevent microbial growth.
- **Product Listing:** The process of listing all cosmetic products manufactured, processed, or distributed in the U.S.
- **Product Registration:** The mandatory process of listing cosmetic products with the FDA.
- **Product Safety:** Ensuring that a product is safe to use as directed.
- **Quality Control:** Set of processes used to ensure that products meet quality and safety standards
- **Recall:** The removal of a product from the market due to safety issues or non-compliance with regulations.
- **Responsible Person (RP):** The individual or entity identified on the product label as responsible for MoCRA compliance.
- **Safety Substantiation:** Documentation proving that a product is safe for use.
- **Safety Tests:** Tests conducted to ensure that products do not cause harm to consumers' health.
- **Stability Testing:** Tests that evaluate how a product holds up under various storage conditions.
- **Viscosity Testing:** Testing that measures the thickness or fluidity of a product.

FAQ

1. What are the main requirements of MoCRA?
Registration of establishments and products, adverse event reporting, labeling requirements and implementation of good manufacturing practices.

2. How does MoCRA affect small and medium cosmetics suppliers?
Suppliers need to adapt their processes to comply with new regulatory requirements, which may involve investments in testing and compliance.

3. What tests are mandatory under MoCRA?
Quality control testing and safety testing are essential to ensure compliance. Additionally, efficacy testing will be necessary if claims associated with the product are being made, especially any safety based claims.

4. How can ALS help with the compliance process?
ALS offers a full range of laboratory tests that ensure products meet MoCRA and FDA requirements.

5. What are the consequences of not complying with MoCRA regulations?
Companies can face legal action, fines and the withdrawal of products from the market, as well as damage to their reputation.

6. Who needs to register under MoCRA?
All facilities that manufacture or process cosmetics for the U.S. market, whether domestic or international, must register with the FDA.

7. What are the key requirements of MoCRA?
The key requirements include facility and product registration, adverse event reporting, detailed labeling, and adherence to Good Manufacturing Practices (GMP).

8. What are adverse events?
Adverse events are health-related issues associated with the use of a cosmetic product. Serious events, such as hospitalizations, must be reported to the FDA within 15 days.

9. What happens if a company does not comply with MoCRA?
Non-compliance can result in legal action, fines, product recalls, and damage to the company's reputation.

10. How can ALS help with the compliance process?
ALS offers a full range of laboratory tests to ensure products meet MoCRA and FDA requirements.

11. What are the legal consequences of not registering a facility?
Failure to register a facility can lead to operational suspension, product recalls, and potential legal actions against the company.

12. What is required to register a cosmetic product with the FDA?
It is necessary to provide detailed information about the product, including ingredients, labels, and the identification of a Responsible Person (RP).

13. How do clinical tests integrate with the FDA registration process?
Clinical tests are essential to demonstrate the safety and efficacy of products. Lack of sufficient safety substantiation could lead the FDA to consider the product unsafe, which could result in the product being recalled.

14. What does the term "Responsible Person" Mean?
A "responsible person" refers to the company (manufacturer, packer, importer, or distributor) whose contact details must be on product labels, as per the bill. While it suggests an individual, it legally means the company registered with the FDA. Assigning a staff member or team to lead MoCRA compliance and act as the FDA contact can be beneficial due to increased communication requirements.

15. How should we handle products that are both cosmetics and drugs?
MoCRA generally does not apply to products that are both cosmetics and drugs, nor to the businesses that produce them, because drugs are subject to stricter regulations due to their potential health impacts. These regulations are based on the FD&C Act and other acts like the Food and Drug Administration Modernization Act of 1997. However, if a facility produces cosmetics that are also drugs and cosmetics that are only cosmetics, the facility and the purely cosmetic products must comply with all MoCRA requirements.

16. Why is this new law important?
This law is significant because it updates outdated regulations from over 80 years ago, addressing long-recognized needs for reform in cosmetics regulation. It replaces the FDA's voluntary registration program with mandatory requirements, ensuring better safety and transparency in the cosmetics industry.

17. What are the new labeling requirements?
MoCRA mandates that all cosmetic products must have a label with the responsible person's address (likely the manufacturing facility), contact phone number, and electronic contact information for adverse event reports. Professional use products must also have this label. Additional guidance on allergen labeling in fragrances is also provided with MoCRA approval.

Cosmetic Product **Categories and Codes**

From the Guidance for Industry: Registration and Listing of Cosmetic Product Facilities and Products

(01) Baby products.
(a) Baby shampoos.
(b) Lotions, oils, powders, and creams.
(c) Baby wipes.
(d) Other baby products.
    1. Leave-on.
    2. Rinse-off.

(02) Bath preparations.
(a) Bath oils, tablets, and salts.
(b) Bubble baths.
(c) Bath capsules.
(d) Other bath preparations.

(03) Eye makeup preparations (other than children's eye makeup preparations).
(a) Eyebrow pencils.
(b) Eyeliners.
(c) Eye shadows.
(d) Eye lotions.
(e) Eye makeup removers.
(f) False eyelashes.
(g) Mascaras.
(h) Eyelash and eyebrow adhesives, glues, and sealants.
(i) Eyelash and eyebrow preparations (primers, conditioners, serums, fortifiers).
(j) Eyelash cleansers.
(k) Other eye makeup preparations.

(04) Children's eye makeup preparations.
(a) Children's eyeshadows.
(b) Other children's eye makeup.

(05) Fragrance preparations.
(a) Colognes and toilet waters.
(b) Perfumes.
(c) Powders (dusting and talcum) (excluding aftershave talc).
(d) Other fragrance preparations.

(06) Hair preparations (non-coloring).
(a) Hair conditioners.
    1. Leave-on.
    2. Rinse-off.
(b) Hair sprays (aerosol fixatives).
(c) Hair straighteners.
(d) Permanent waves.
(e) Rinses (non-coloring).
(f) Shampoos (non-coloring).
    1. Leave-on.
    2. Rinse-off.
(g) Tonics, dressings, and other hair grooming aids.
(h) Wave sets.
(i) Other hair preparations.
    1. Leave-on.
    2. Rinse-off.

(07) Hair coloring preparations.
(a) Hair dyes and colors (all types requiring caution statement and patch test).
(b) Hair tints.
(c) Hair rinses (coloring).
    1. Leave-on.
    2. Rinse-off.
(d) Hair shampoos (coloring).
    1. Leave-on.
    2. Rinse-off.
(e) Hair color sprays (aerosol).
(f) Hair lighteners with color.
(g) Hair bleaches.
(h) Eyelash and eyebrow dyes.
(i) Other hair coloring preparations.
    1. Leave-on.
    2. Rinse-off.

(08) Makeup preparations (not eye) (other than makeup preparations for children).
(a) Blushers and rouges (all types).
(b) Face powders.
(c) Foundations.
    1. Traditional applications.
    2. Airbrush applications.
(d) Leg and body paints.
    1. Traditional applications.
    2. Airbrush applications.
(e) Lipsticks and lip glosses.
(f) Makeup bases.
    1. Traditional applications.

2. Airbrush applications.

(g) Makeup fixatives.

(h) Other makeup preparations.

1. Traditional applications.
2. Airbrush applications.

(09) Makeup preparations for children (not eye).

(a) Children's blushers and rouges (all types).

(b) Children's face paints.

(c) Children's face powders.

(d) Children's foundations.

(e) Children's lipsticks and lip glosses.

(f) Children's color hairsprays.

(g) Other children's makeup.

(10) Manicuring preparations.

(a) Basecoats and undercoats.

(b) Cuticle softeners.

(c) Nail creams and lotions.

(d) Nail extenders.

(e) Nail polishes and enamels.

(f) Nail polish and enamel removers.

(g) Other manicuring preparations.

(11) Oral products.

(a) Dentifrices (aerosols, liquids, pastes, and powders).

(b) Mouthwashes and breath fresheners (liquids and sprays).

(c) Other oral products.

(12) Personal cleanliness.

(a) Bath soaps and body washes.

(b) Deodorants (underarm).

1. Sticks, roll-ons, gels, creams, and wipes.
2. Sprays.

(c) Douches.

(d) Feminine deodorants.

1. Leave-on.
2. Rinse-off.

(e) Disposable wipes.

(f) Other personal cleanliness products.

1. Leave-on.
2. Rinse-off.

(13) Shaving preparations.

(a) Aftershave lotions.

(b) Beard softeners.

(c) Men's talcum.

(d) Pre-shave lotions (all types).

(e) Shaving creams (aerosol, brushless, and lather).

(f) Shaving soaps (cakes, sticks, etc.).

(g) Other shaving preparation products.

(14) Skin care preparations, (creams, lotions, powder, and sprays).

(a) Cleansing (cold creams, cleansing lotions, liquids, and pads).

(b) Depilatories.

(c) Face and neck (excluding shaving preparations).

1. Leave-on.
2. Rinse-off.

(d) Body and hand (excluding shaving preparations).

1. Leave-on.
2. Rinse-off.

(e) Foot powders and sprays.

(f) Moisturizing.

(g) Night.

(h) Paste masks (mud packs).

(i) Skin fresheners.

(j) Other skin care preparations.

1. Leave-on.
2. Rinse-off.

(15) Suntan preparations.

(a) Suntan gels, creams, and liquids.

(b) Indoor tanning preparations.

Traditional applications (creams, lotions, etc.).

1. Airbrush applications.
2. Spray applications.
3. Professional airbrush tanning applications.
4. Professional spray tanning applications.

(c) Other suntan preparations.

(16) Tattoo preparations.

(a) Permanent tattoo inks.

(b) Temporary tattoo inks.

(c) Other tattoo preparations.

(17) Other preparations (i.e., those preparations that do not fit another category)

Contact us

ALS can assist you in understanding MoCRA regulations and creating a comprehensive compliance plan.

Connect with us: 310 214-0043
or send an inquiry to
mocra.info@alsglobal.com