Registrar Corp

COSMETICS
EXECUTIVE BRIEF

Minimizing Business & Legal Risks of FDA's New Adverse Events Reporting

Executive Summary:

Growing concerns over cosmetic product safety led the U.S. Congress to pass the Modernization of Cosmetics Regulation Act (MoCRA) in 2022. MoCRA includes mandatory requirements for Adverse Events and grants the FDA significant new regulatory authority.

These requirements require companies to change labels, intake sensitive medical data, and coordinate investigations to determine if it is a "Serious Adverse Event." The investigation must be completed within 15 business days and can involve 6-8 departments and external experts. There is also a requirement to maintain all records for up to 6 years.

The new regulations create business and legal risks that cosmetics companies need to mitigate. The business risk is from FDA enforcement actions (e.g., product recall) impacting retailer and consumer confidence. And the legal risk is from product liability lawsuits if an Adverse Event is not sufficiently investigated and resolved. This brief covers:

Key MoCRA Roles and Adverse Event Definitions

MoCRA includes updates to FDA terminology for cosmetic Adverse Events and introduced new roles for regulatory compliance. Knowing these terms will help you better understand how MoCRA affects your organization and how to comply efficiently and effectively.

Who is a “Responsible Person”?

A new role for cosmetics regulation, the Responsible Person is the entity in charge of complying with all Adverse Event-related requirements for cosmetics facilities. It is the manufacturer, packer, or distributor of a cosmetic product whose name appears on the label of such cosmetic product in accordance with section 609(a) of (FD&C) or section 4(a) of the Fair Packaging and Labeling Act (FPLA).

What is an “Adverse Event”?

"Any health-related event associated with the use of a cosmetic product that is adverse." Examples: irritation, rash, burn, allergic reaction, hair loss

What is a “Serious Adverse Event”?

A health-related event that results in:

(A)

- Death or a life-threatening experience
- Inpatient hospitalization or an infection
- A persistent or significant disability or incapacity
- A congenital anomaly or birth defect
- ***Significant disfigurement including serious and persistent rashes, second or third-degree burns, significant hair loss, or persistent or significant alteration of appearance not intended under conditions of use***

OR,
(B) Requires, based on reasonable medical judgment, a medical or surgical intervention to prevent an outcome described above
The highlighted text was added in MoCRA specifically for cosmetics.

Recommendations on Meeting the Five Key Adverse Events Requirements

1. Adding Adverse Event contact information on labels

To facilitate consumer reporting, Adverse Event contact information must be on both primary (product) and secondary (packaging) labels. MoCRA allows for any of the following three options:

- **Physical mail** – must be a domestic U.S. address where paper mail can be delivered, or
- **Phone** - must be a domestic U.S. phone number, or
- **Electronic** – can be weblink or QR code that leads to a dedicated intake form

While adding contact information on the label may seem like a straightforward matter, there are major implications that must be considered. For example, as soon as a consumer reports an Adverse Event, the Responsible Person only has 15 business days to investigate if it is "serious" and needs to be reported to the FDA. Therefore, getting all the personal and medical data to conduct the investigation upfront is critical. Paper and phone-based intakes are likely to be incomplete and/or delayed (Exhibit A) which increases business and legal risk.
Recommendation: Use electronic means to collect Adverse Event information.

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Exhibit A: Advantages of Electronic Consumer Reporting

Physical Mail Challenges:	Phone Challenges:
• Consumers unlikely to write a letter with detailed data (up to 43 fields) needed to conduct the investigation • If lab reports, medical bills, photos needed, additional steps take time • Responsible Person may not in office when mail arrives • Limited space for addresses on smaller products (e.g., lipstick) • No physical location for Non-U.S. companies • Label updates if location changes	• Customer support agent ability to ask/get the up to 43 data fields of personal and medical information • If lab reports, medical bills, or photos needed, additional steps take time • Consumers may not want to share sensitive and private medical information • As soon as the call is made, the 15-business day deadline starts. If all the required data is not collected, investigation at risk • Call center may not be live 24x7

Electronic Contact Advantages:
• Smart form can require a consumer to enter all data required for an investigation • Data can be instantly transmitted to multiple relevant staff inside the company • Consumers more likely fill out a form than talk to a person about a sensitive topic • Additional documents, photos, medical information can be attached for faster investigation • 24x7 availability and easier for consumers to report

2. Collecting up to 43 medical/personal data fields from consumers

To determine if it is a "Serious" Adverse Event, up to 43 data fields of personal and medical data may be required. The data fields include Personal Identifiable Information (PII) such as name, date of birth, and address. They also include medical information like what happened, where on the body it happened, what lab reports and medical exams indicated, photos of the affected area(s), and more.

Given the sensitive nature of the consumer data, it is critical that data access is limited to authorized personnel.

Recommendation: Conduct a data security review to ensure that the consumer PII/medical data is safeguarded and restricted to authorized personnel only. For example, if a call center system is used, is the data resident in that system? How long? How many staff will have access?

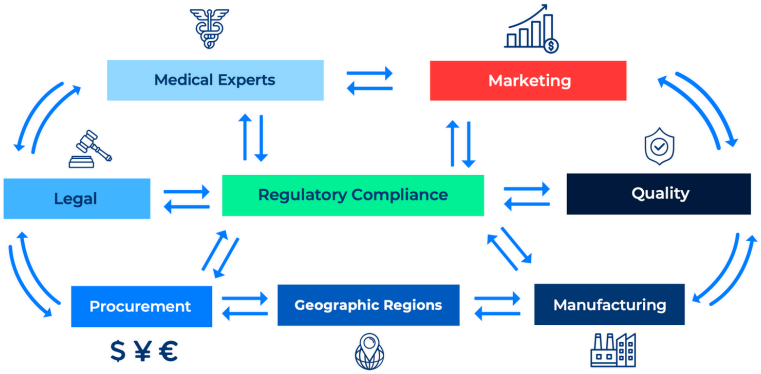
3. Investigating if it is a "Serious" Adverse Event

As soon as the consumer submits an Adverse Event, the 15-business day "Serious" Adverse Event reporting clock starts ticking. In those critical 15-days, the company needs to analyze the personal and medical data to determine severity and root cause. There could be several issues/areas to investigate including:

- Quality issue
- Manufacturing issue
- Formulation issue
- Usage issue
- Dosage issue

It may also require consulting with external medical experts, supply chain/procurement, manufacturing, distribution, legal, quality, R&D, and regional sales/marketing teams (Exhibit B). Most cosmetics companies do not have prior experience or expertise in conducting these types of investigations.

Recommendation: Conduct a "mock investigation" drill from the initial consumer contact all the way through the investigation to ensure all the processes are in place and staff are ready. The practice drill will identify process, data, skills, and timing gaps.



4. Reporting "Serious" Adverse Events to FDA within 15 business days

If the investigation concludes that it is a "Serious" Adverse Event, then the Responsible Person must report it to the FDA along with a copy of the label within 15 business days of receiving the consumer complaint. Any new material information related to the Serious Adverse Event report received within a year of the initial report must also be submitted within 15 business days of receipt.

FDA recommends that Serious Adverse Events be reported using the MedWatch Form 3500A. This form is the same one used for Drug Adverse Event reporting and will be new to cosmetic companies.
Recommendation: Familiarize the regulatory/legal team with the MedWatch form and "mock fill" several scenarios to understand the process and required fields.

Case Study: Only 4 Days to Investigate

Situation: A global cosmetic company based in Europe received a U.S. consumer Adverse Event via the customer complaints phone line. The agent was only able to get limited information and emailed it to the Regulatory department (based in Europe).

Crisis: Due to email delays, language barriers, and limited experience in Adverse Event management, by the time the Regulatory department responded, 10 business days had passed. The company had only 5 days left and had to go into "crisis response mode" to coordinate legal, medical, quality, and manufacturing across multiple regions.

5. Keeping all records for up to 6 years

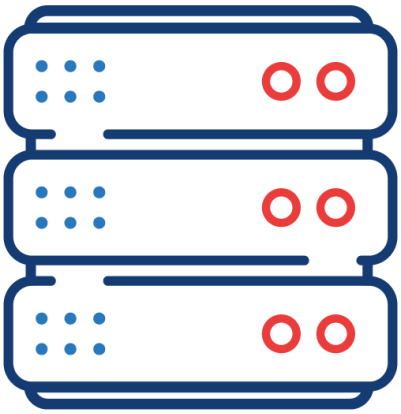
Responsible Persons must maintain records related to each Adverse Event associated with the use of a cosmetic product for 6 years. If a cosmetic company is **a small business** that does not manufacture or process the cosmetic product related to the Adverse Event, it must maintain records for 3 years.

Companies must store all related records and reports for Adverse Events upon request from FDA or during an inspection. This may include, but is not limited to:

- Records of communication with Adverse Event reporter (consumer)
- Records of brand(s) involved
- Assessments of the report received
- Relevant hospital, doctor, or laboratory data
- Safety testing and clinical data

Most companies do not have a centralized recordkeeping system for Adverse Events. Records are scattered among multiple staff members in their emails and storage drives. If the staff member leaves the company, the email/storage is typically wiped within a year. And even if it is kept for 6 years, it would be hard to locate and retrieve.
Finally, the sensitive consumer and investigative records need to be securely stored, preferably in ISO27001 (standard for data security) certified systems.

Recommendation: Conduct a "6-years back" review to determine if current recordkeeping storage and retrieval practices will work. If in 2030 the FDA requests all consumer and investigation records from an Adverse Event in 2024, would they be available in a centralized place for quick retrieval?



Business and Legal Risks of Adverse Events

MoCRA grants the U.S. FDA strong new regulatory authority over cosmetics to ensure safety, including inspections, suspensions and recalls (Exhibit C). Prior to MoCRA, the FDA received over 5,000 Adverse Events reports from consumers a year with about 25% meeting the "Serious" Adverse Event definition according to Dr. Linda Katz, Director of the FDA Office of Cosmetics and Colors.[2] It is widely believed in the industry that only a small fraction of Adverse Events were reported in the past.

MoCRA shifts the responsibility for receiving and investigating Adverse Events to the Responsible Person (the company on the label) to manage post-market safety issues.

Exhibit C: FDA's Regulatory Authority for Cosmetics Products

Suspensions: FDA can suspend a facility if there is a reasonable probability that a cosmetic product may cause a serious adverse health consequence or public health concern.

Inspections: FDA can inspect facilities and request access to records relating to a cosmetic product.

Mandatory Recalls: FDA may issue a mandatory recall if they determine that a cosmetic product is adulterated or misbranded, or the use and exposure will cause serious adverse health consequences or death.

Import Alerts: FDA has the ability to prevent potentially violative products from being distributed in the U.S. and places regulatory responsibility back on the importer. An Import Alert indicates that a country, company, and/or products are in potential violation and may be detained without a physical examination (DWPE).

Warning Letters: FDA can issue Warning Letters to the responsible persons and manufacturers that violate FDA regulations around MoCRA requirements. Warning Letters notify the appropriate parties of potential concerns and require corrective action or an appeal of FDA's decision within a specific timeframe.

Import Detentions: FDA may detain an imported product if FDA finds that the product appears to violate the Food, Drug, and Cosmetics Act (FD&C Act) during an import.

Business Risks of Non-Compliance

FDA enforcement actions impact consumer confidence in the product and the company. With the addition of Adverse Event contact information on labels, the quantity of “Serious” Adverse Event reported to the FDA will increase dramatically. And as the FDA makes enforcement decisions (e.g., product recalls), consumers could lose confidence in both the affected product and the company’s overall product line.

U.S. retailers have tremendous power in the industry value chain. They do not want to risk their own reputation by selling non-compliant products. Nor do they want to manage product returns, destroy/return inventory, field negative media coverage, or face potential lawsuits. That is why many retailers are requiring suppliers to be MoCRA compliant. If a brand is not MoCRA compliant or recalled, it can face serious business consequences including:

- Penalties paid to retailer for missed sales
- Jeopardized contracts
- Returned or destroyed products
- Reduced shelf space or brand removed from shelves entirely

For brands that use co-manufacturers or packers, ensuring the entire supply chain is MoCRA compliant is critical. For example, if the FDA inspects a facility and forces a suspension, it can lead to products made at that facility facing a recall, impacting the entire supply chain.

Legal Risks of Non-Compliance

The legal risk arises from product liability lawsuits if an Adverse Event is not sufficiently investigated, documented, reported, and resolved. With more transparency and 6-year recordkeeping requirements, there will be more legal scrutiny for the Responsible Person. Individual or class-action lawsuits could be filed with probes on how quickly the company reacted, how thoroughly it investigated the Adverse Event, was the “Serious” criteria met, and how complete the records were. Since the regulatory language (e.g., "reasonable medical judgement”) is not defined, there may be room for interpretation by the U.S. legal system.

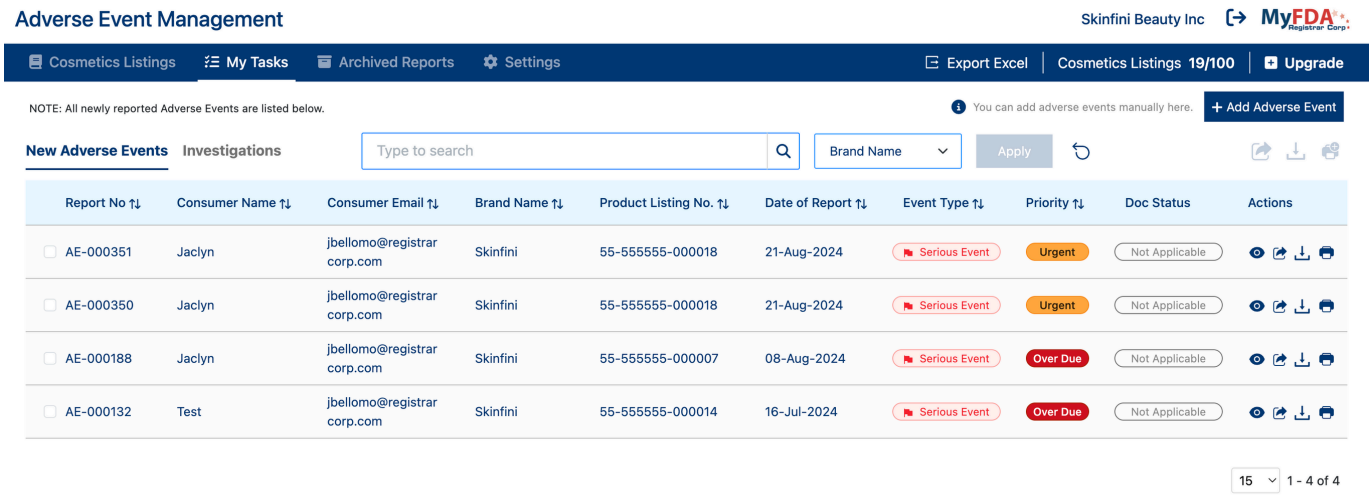
Recommendation: Conduct a complete risk assessment

The Adverse Events requirements are new, and most companies are still learning their way. We recommend all cosmetics companies selling into the U.S.A. conduct a thorough risk assessment to ensure that the organization understands the business and legal risks of non-compliance.

Introducing Registrar's Turnkey Adverse Events Management Software

Registrar Corp is the world's largest FDA compliance company with over 30,000 clients around the world. Registrar's Adverse Events Management (AEM) software is a turnkey solution to manage the entire Adverse Event process from consumer intake to investigation management to FDA reporting to records storage (Exhibit D).

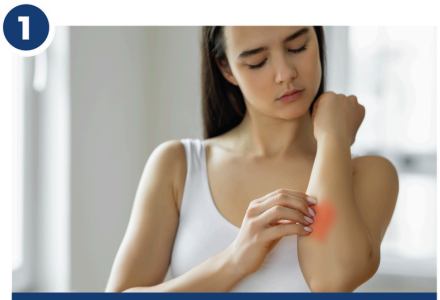
- Helps manage business and legal risk
- Covers the entire Adverse Event process from consumer intake to FDA reporting
- Supports electronic consumer intake with custom weblinks or QR codes
- Captures up to 43 personal and medical data fields with a mobile-friendly smart form
- Enables consumers to upload photos, documents, and medical records
- Alerts and shares the consumer intake data in real-time with all internal and external staff for immediate review/investigation
- Manages the entire investigation in a single portal with real-time access across to all authorized users
- Enables internal staff and external experts to coordinate investigations
- Stores sensitive consumer and investigative data in a secure, ISO27001 certified platform
- Auto-fills the Serious Adverse Events report in the FDA MedWatch format
- Keeps all records for 6 years or longer
- Reports on the status of all Adverse Events in one convenient dashboard
- Replaces emails, spreadsheets, and paper records



Introducing Registrar's Turnkey Adverse Events Management Software

Exhibit D. Registrar AEM Software Manages Entire Workflow

1



Consumer has an adverse event to your product

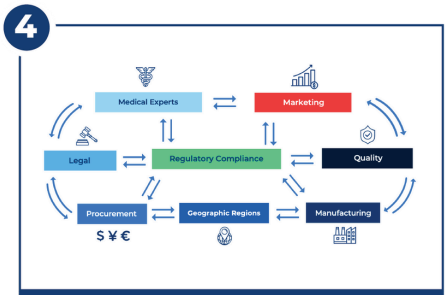
2

Consumer uses QR code/URL to confidentially fill intake form with all required fields

3

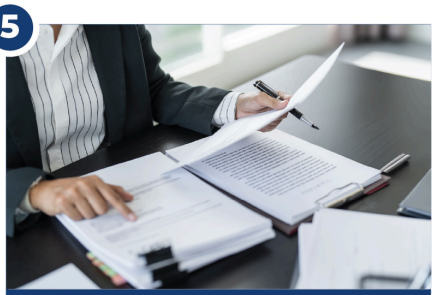
Data instantly in the AEM platform and all authorized staff alerted

4



Investigation conducted in a centralized platform with alerts

5



If a serious event, FDA MedWatch formatted report for quick submission

6

All consumer & investigation records kept in secure, central storage for easy retrieval

MoCRA is complicated. Registrar gets and keeps you compliant.

Complete MoCRA Solutions

- Product Listings
- Facility Registration & U.S. Agent
- LabelComply and LabelCheck
- Product Lifecycle Management (PLM) software
- Custom Consulting

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