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Game-changing MoCRA regulations for cosmetics:

What to know and what the future holds

informa markets

Show Announcements:

- Download the Mobile App to view the Exhibitor List, Show Schedule, Floor Plan and our Sponsors.
  - Thank you to our Mobile App sponsor**: Epicor (Booth 4465)**
- Wi-Fi – Sponsored by **Cactus Botanicals (Booth 4237)**
  - Select network: SupplySideWest23
  - On the splash page, agree to terms & conditions
  - Enter access code: cactus4237 (access code is case sensitive)
- Please place all devices on silent mode
- The Expo Hall is open today from 10am – 5:30pm.
- There is an LGBTQ + Allies Networking reception tonight from 5:30-7:30pm in South Pacific Ballroom F.

  This reception is in partnership with the Naturally Proud Network.

The Modernization of Cosmetics Regulation Act of 2022 (MoCRA): ***The basics***

- **New FDA authorities**: Records access, mandatory recall authority
- **New requirements for industry**: Facility registration, product listing, safety substantiation, adverse event reporting
- Some initial compliance required by: **Dec. 29, 2023**

"It's noteworthy that when you look at the cosmetics regulations, they do provide a sort of telegraphing for DSHEA reform."

"Our products are a lot different than they were in 1994. We're not just selling alcohol-based tinctures and vitamins. We have hi-tech nanomaterials and 1,000 times bioavailability, and complex mixtures and synthetic ingredients."

"It's a different animal today than it was back then (in 1994)."

Douglas 'Duffy' MacKay, ND

SVP, Dietary Supplements

Consumer Healthcare Products Association

“So now we have an industry where the stuff you put on your skin is more tightly regulated than the stuff we put in our mouth.”

Speakers in today's program:

Michael McGuffin

President

American Herbal Products Association

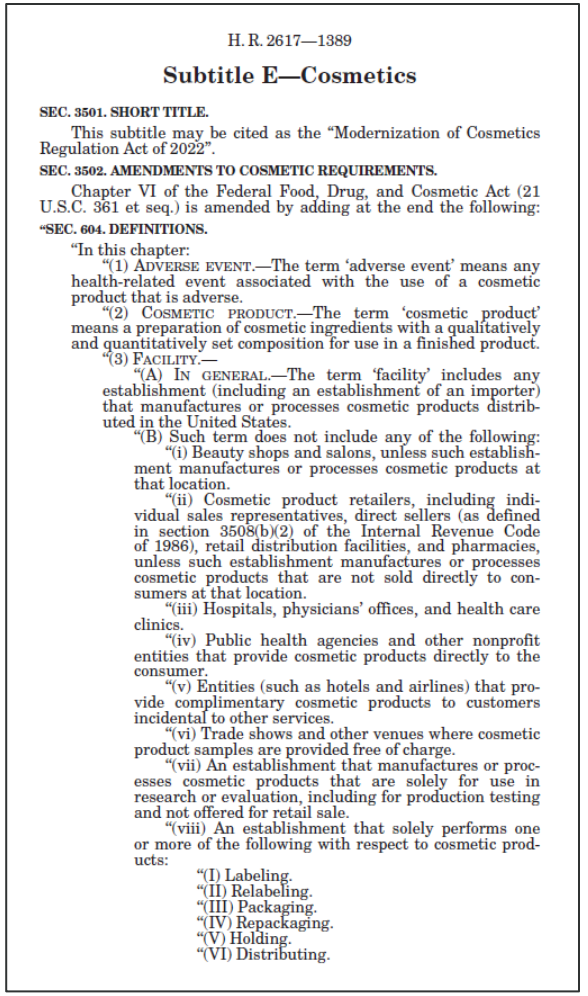
Ryan Seaverson

Director, Quality & Compliance

SafetyCall International, LLC

MoCRA

- Modernization of Cosmetics Regulation Act of 2022 (MoCRA) -- enacted on Dec. 29, 2022
- Passed as part of the Consolidated Appropriations Act, 2023, by the 117th Congress
- Most significant expansion of the U.S. Food & Drug Administration's (FDA's) authority to regulate cosmetic products in the United States since the Food, Drug, and Cosmetic (FD&C) Act was enacted in 1938



H. R. 2617—1389

Subtitle E—Cosmetics

SEC. 3501. SHORT TITLE.

This subtitle may be cited as the "Modernization of Cosmetics Regulation Act of 2022".

SEC. 3502. AMENDMENTS TO COSMETIC REQUIREMENTS.

Chapter VI of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 361 et seq.) is amended by adding at the end the following:

"SEC. 604. DEFINITIONS.

"In this chapter:

"(1) ADVERSE EVENT.—The term 'adverse event' means any health-related event associated with the use of a cosmetic product that is adverse.

"(2) COSMETIC PRODUCT.—The term 'cosmetic product' means a preparation of cosmetic ingredients with a qualitatively and quantitatively set composition for use in a finished product.

"(3) FACILITY.—

"(A) IN GENERAL.—The term 'facility' includes any establishment (including an establishment of an importer) that manufactures or processes cosmetic products distributed in the United States.

"(B) Such term does not include any of the following:

"(i) Beauty shops and salons, unless such establishment manufactures or processes cosmetic products at that location.

"(ii) Cosmetic product retailers, including individual sales representatives, direct sellers (as defined in section 3508(b)(2) of the Internal Revenue Code of 1986), retail distribution facilities, and pharmacies, unless such establishment manufactures or processes cosmetic products that are not sold directly to consumers at that location.

"(iii) Hospitals, physicians' offices, and health care clinics.

"(iv) Public health agencies and other nonprofit entities that provide cosmetic products directly to the consumer.

"(v) Entities (such as hotels and airlines) that provide complimentary cosmetic products to customers incidental to other services.

"(vi) Trade shows and other venues where cosmetic product samples are provided free of charge.

"(vii) An establishment that manufactures or processes cosmetic products that are solely for use in research or evaluation, including for production testing and not offered for retail sale.

"(viii) An establishment that solely performs one or more of the following with respect to cosmetic products:

"(I) Labeling.
"(II) Relabeling.
"(III) Packaging.
"(IV) Repackaging.
"(V) Holding.
"(VI) Distributing.

New industry responsibilities

- **Facility registration**
  - Existing facilities must register by Dec. 29, 2023
  - New facilities must register within 60 days of first manufacture or 60 days after Dec. 29, 2023, whichever is later
- **Product listing**
  - A listing for each existing cosmetic product must be submitted by Dec. 29, 2023
  - A listing for a cosmetic product first marketed after Dec. 29, 2022, must be submitted within 120 days of entering interstate commerce
- **GMP**
  - FDA must issue proposed rulemaking by Dec. 29, 2024, and a final rule by Dec. 29, 2025

New industry responsibilities

- **Serious adverse event reporting**
  - Effective date: Dec. 29, 2023
- **Labeling**
  - Effective date: Dec. 29, 2024
  - Labels must include **domestic address**, **domestic phone number**, *or* **electronic contact information** (e.g., website) to receive adverse event reports
  - Fragrance allergens: FDA must issue proposed rulemaking by June 29, 2024, and a final rule within 180 days of the comment period's closing
  - Cosmetic products for professional use require additional labeling, effective Dec. 29, 2023
- **Safety substantiation**
  - Effective date: Dec. 29, 2023

New FDA authority

- **Mandatory recall**
  - Effective date: Dec. 29, 2023
- **Records inspection**
  - Effective date: Dec. 29, 2022

"SEC. 611. MANDATORY RECALL AUTHORITY.

"(a) IN GENERAL.—If the Secretary determines that there is a reasonable probability that a cosmetic is adulterated under section 601 or misbranded under section 602 and the use of or exposure to such cosmetic will cause serious adverse health consequences or death, the Secretary shall provide the responsible person with an opportunity to voluntarily cease distribution and recall such article. If the responsible person refuses to or does not voluntarily cease distribution or recall such cosmetic within the time and manner prescribed by the Secretary (if so prescribed), the Secretary

SEC. 3504. RECORDS INSPECTION.

Section 704(a)(1) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 374(a)(1)) is amended by inserting after the second sentence the following: "In the case of a facility (as defined in section 604) that manufactures or processes cosmetic products, the inspection shall extend to all records and other information described in sections 605, 606, and 610, when the standard for records inspection under such section applies.".

Exemptions for small businesses

+ **A manufacturer is exempt from GMP, facility registration, and product listing requirements if:**
  + Average gross sales of cosmetic products in U.S. for last 3 years = <$1 million

    and
  + Cosmetic products being manufactured are not:
    - x regularly coming into contact with mucus membrane of the eye
    - x injected
    - x intended for internal use
    - x intended to alter appearance for >24 hours

When is a topical not a cosmetic?

"The term 'cosmetic' means…articles intended to be rubbed, poured, sprinkled, or sprayed on, introduced into, or otherwise applied to the human body or any part thereof for cleansing, beautifying, promoting attractiveness, or altering the appearance...; except that such term shall not include soap."

21 USC § 321(i)(1)

When is a topical not a cosmetic product?

"The term 'cosmetic product' means a preparation of cosmetic ingredients with a qualitatively and quantitatively set composition for use in a finished product."

21 USC § 364(2) *-- as added by MoCRA*

SafetyCall® INTERNATIONAL – Who We Are

SafetyCall International, LLC is an independent, professional health care practice licensed by the ***Boards of Medicine, Pharmacy and Veterinary Medicine***, dedicated to providing our industry clients with product safety-related services to meet federal regulatory compliance obligations.

SafetyCall INTERNATIONAL - Adverse Event Reporting Under MoCRA

Meeting the Letter of the Law

- Standardized process of handling spontaneously reported allegations of product associated injury:

SafetyCall INTERNATIONAL - Adverse Event Reporting Under MoCRA

- The definition of adverse event is “any health related event associated with the use of a product that is adverse.”
- Reporting an adverse event is not an admission of guilt.
- Adverse event surveillance starts as passive and allegation based but then requires sensitive systems for assessment and analysis.

SafetyCall INTERNATIONAL - Adverse Event Reporting Under MoCRA

+ Have a plan for…
  + A collection system to meet consumer expectations and internal needs.
  + Training to identify Adverse Events and appropriately escalate.
  + Medical support with expertise and appropriate organizational structure.
  + Process to ensure that all regulatory reporting requirements are met.

Documentation and evaluation of all adverse events is the cornerstone of GOOD PRODUCT STEWARDSHIP

End –
Thank You

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By Informa Markets