Introduction to Food Law and Regulation

The Regulation of Cosmetics

Hi!

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Biography

Kelly A. Bonner is a trial attorney at Duane Morris LLP in Philadelphia whose practice focuses on consumer protection**,** products liability, cross-jurisdictional and other complex commercial disputes**.**

Much of Kelly's work focuses on helping consumer products companies navigate complex legal issues they face related to regulatory compliance, deal diligence, and litigation. Kelly has represented clients in a broad array of industries—including health care, pharmaceutical, manufacturing, consumer products, and financial services—in state and federal courts and arbitration proceedings throughout the country, as well as cross-border investigations by regulatory agencies.

Kelly has written and spoken widely on litigation risk and regulatory issues frequent affecting businesses in the cosmetics and personal care industries, and has been quoted in national publications on the Modernization of Cosmetics Regulation Act (MoCRA), and other state and federal laws and regulations concerning cosmetics, including *Women's Wear Daily*, *CosmeticsDesign*, *The Beauty Industry Review, Bloomberg Law*, and *Refinery29*. Kelly also was a featured guest on the award-winning beauty podcast, Fat Mascara, discussing cosmetics regulation.

Kelly is a graduate of Fordham University School of Law and New York University.

Agenda

- How cosmetics and other personal care products are regulated in the United States at the federal versus the state level
- Changes to cosmetics regulation as a result of the recent Modernization of Cosmetic Regulation Act (MoCRA)
- FDA's enforcement framework for cosmetics (pre- and post-MoCRA)
- State laws that regulate cosmetic ingredients
- Significant recent litigation involving cosmetic safety

Disclaimer

This program is intended to be educational, and not intended to be construed as legal advice.

Any opinions expressed during this presentation are personal, and not intended to speak for FDA.

MoCRA's rollout is ongoing, and we cannot say with certainty how FDA will interpret or implement its provisions.

FDA Enforcement Framework for Cosmetics

- Cosmetics are not FDA-approved, but "FDA regulated"
  - The Federal Food, Drug and Cosmetics Act of 1938 (FDCA) authorizes the Food and Drug Administration (FDA) to regulate and ensure the safety of cosmetics.
  - Cosmetics marketed in the United States must comply with FDCA, the Fair Packaging and Labeling Act of 1966 (FPLA), and regulations published by FDA under the authority of these two laws.
  - Cosmetics regulations are codified at 21 CFR, parts 700 to 740 (21 CFR 700 to 740). Color additive regulations that apply to cosmetics are found at 21 CFR 73, 74, 81 and 82.

Cosmetics versus Drugs

Cosmetic

- Intended to be rubbed, poured, sprinkled, or sprayed on, introduced into, or otherwise applied to the human body .. for
  - Cleansing
  - Beautifying
  - Promoting attractiveness, or
  - Altering the appearance

Drug

- Intended for therapeutic purpose, such as:
  - Treating or preventing disease, or
  - Affecting the structure or function of the body

Some cosmetics may be regulated as drugs even if they also affect appearance.

Cosmetics versus Drugs

Cosmetic Examples Include

- Suntan product
- Deodorant
- Clarifying shampoo
- Whitening Toothpaste
- Chemical exfoliant
- Mouthwash
- Hair thickener
- Acne concealer
- Skin moisturizer

Drug Examples Include

- Sunscreen product
- Antiperspirant
- Anti-dandruff shampoo
- Anti-cavity toothpaste
- Skin peel
- Gingivitis mouthwash
- Hair growth product
- Anti-acne cream
- Wrinkle remover

Federal Food, Drug and Cosmetics Act of 1938 (FDCA)

- Prohibits "the introduction or delivery for introduction into interstate commerce of any food, drug, device, or cosmetic that is **adulterated** or **misbranded**." FDCA, sec. 301(a).
  - Interstate commerce means (1) commerce between any State or Territory and any place outside thereof, and (2) commerce within the District of Columbia or within any other Territory not organized with a legislative body. FDCA sec. 201(b).
  - Applies to all steps in a product's manufacture, packaging, and distribution.

Adulterated (FDCA sec. 601)

- "bears or contains any poisonous or deleterious substance which may render it injurious to users under the conditions of use prescribed in the labeling ... except that this provision shall not apply to coal-tar hair dye";
- consists of "any filthy, putrid, or decomposed substance";
- was "prepared, packed, or held under insanitary conditions whereby it may have become contaminated" or "rendered injurious to health";
- is in a container composed of "any poisonous or deleterious substance which may render the contents injurious to health";
- contains an unsafe color additive, except for hair dyes;
- "has been manufactured or processed under conditions that do not meet the good manufacturing practice requirements of [FDCA] section 606"; or
- • "is a cosmetic product, and the cosmetic product, including each ingredient in the cosmetic product, does not have adequate substantiation for safety, as defined in [FDCA] section 608(c)."

Cosmetic Ingredients Prohibited or Restricted by FDA

- Bithionol – 21 CFR 700.11
- Chlorofluorocarbon propellants – 21 CFR 700.23
- Chloroform - 21 CFR 700.18
- Halogenated salicylanilides (di-, tri-, metabromsalan and tetrachlorosalicylanilide) - 21 CFR 700.15
- Hexachlorophene - 21 CFR 250.250
- Mercury compounds - 21 CFR 700.13
- Methylene chloride - 21 CFR 700.19
- Prohibited cattle materials - 21 CFR 700.27
- Vinyl chloride - 21 CFR 700.14
- Zirconium-containing complexes - 21 CFR 700.16

Misbranded (FDCA sec. 602)

- the "labeling is false or misleading in any particular";
- the label lacks required information such as the name and address of the manufacturer, packer, or distributor or the net quantity of contents;
- the required labeling information is not prominently placed and "in such terms as to render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use";
- the "container is so made, formed, or filled as to be misleading";
- the use of a color additive does not conform to packaging and labeling requirements; or
- the packaging or labeling violates the regulations issued under the Poison Prevention Packaging Act of 1970.
- Fails to comply with FPLA's requirements and ingredient labeling rules
- Fails to comply with MoCRA's labeling requirements

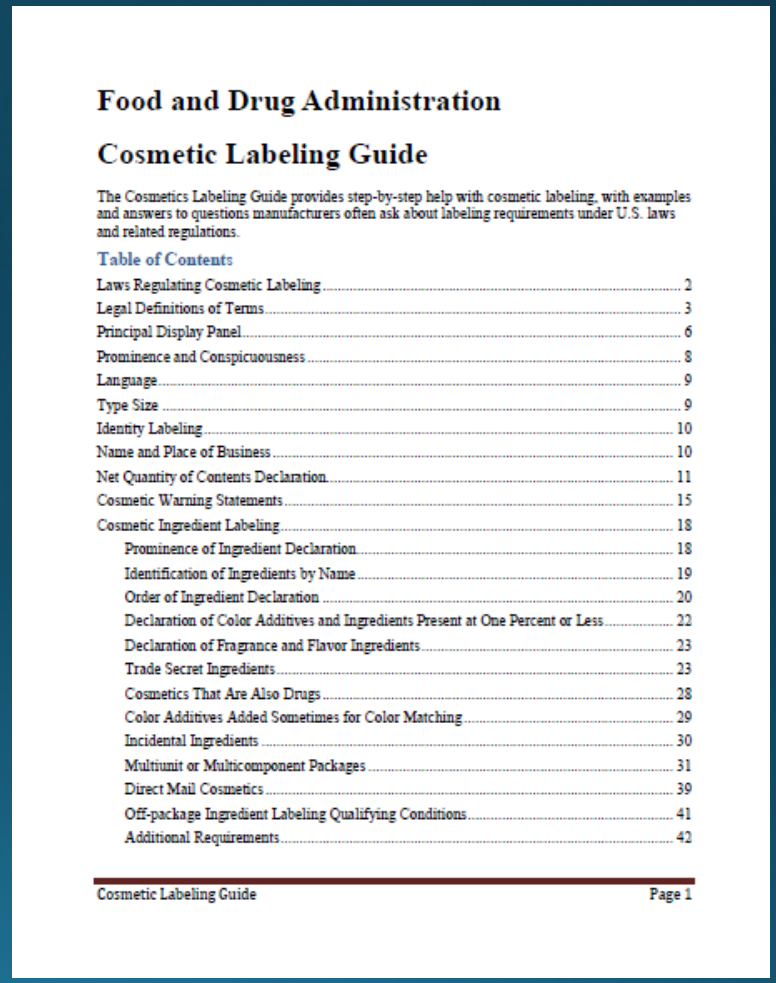
Fair Packaging and Labeling Act (FPLA) of 1966

- Applies to the packaging and labeling of "consumer commodities," including cosmetics:
  - "customarily produced or distributed for sale through retail sales agencies or instrumentalities
  - for consumption by individuals, or use by individuals for purposes of personal care ...
  - and which [are] usually consumed or expended in the course of such consumption or use."
- Does not apply to "wholesale or retail distributors of consumer commodities, except to the extent that such persons
  - are engaged in the packaging or labeling of such commodities, or
  - prescribe or specify ... the manner in which such commodities are packaged or labeled.

Fair Labeling and Packaging Act (FPLA) of 1966

The FPLA required cosmetics marketed on a retail basis to consumers in interstate commerce to be honestly and informatively labeled.

- Labeling means all labels and other written, printed or graphic matter on or accompanying a product.
- Cosmetics bearing false or misleading label statements or otherwise not labeled in accordance with these requirements may be considered misbranded and may be subject to regulatory action
- The labeling requirements are codified at 21 CFR 701 and 740, and available in FDA's Cosmetic Labeling Guide.



Food and Drug Administration

Cosmetic Labeling Guide

The Cosmetics Labeling Guide provides step-by-step help with cosmetic labeling, with examples and answers to questions manufacturers often ask about labeling requirements under U.S. laws and related regulations.

Table of Contents

When Is A Label "Misleading"

- Representations made or suggested
- Failure to reveal material facts
  - Labeling may be considered misleading not only because a label statement is deceptive but also because a material fact is not revealed on a label.
  - A fact may be material in light of:
    - A statement made on a label or
    - Because certain consequences may result from the recommended or intended use of a product.

Labeling Requirements Summarized

- The principal display panel, i.e., the part of the label most likely displayed or examined under customary conditions of display for sale (21 CFR 701.10), must state:
  - the name of the product,
  - identify by descriptive name or illustration the nature or use of the product,
  - bear an accurate statement of the net quantity of contents of the cosmetic in the package in terms of weight, measure, numerical count, or a combination of numerical count and weight or measure.
- The name and place of business of the firm marketing the product must be stated on an information panel of the label (21 CFR 701.12).
  - The address must state the street address, city, state, and zip code. If a firm is listed in a current city or telephone directory, the street address may be omitted.
  - If the distributor is not the manufacturer or packer, this fact must be stated on the label by the qualifying phrase "Manufactured for ....." or "Distributed by ....." or similar wording.
- The Tariff Act of 1930 requires that all imported articles state on the label the English name of the country of origin.

Ingredient Declarations

- Cosmetics produced or distributed for retail sale to consumers for their personal care are required to bear an ingredient declaration (21 CFR 701.3).
  - Cosmetics not customarily distributed for retail sale, e.g., hair preparations or make-up products used by professionals on customers at their establishments and skin cleansing or emollient creams used by persons at their places of work, are exempt from this requirement provided these products are not also sold to consumers at professional establishments or workplaces for their consumption at home.
- The ingredient declaration must be conspicuous so that it is likely to be read at the time of purchase.
- The ingredients must be declared in descending order of predominance.
- Color additives (21 CFR 701.3(f)(3)) and ingredients present at one percent or less (21 CFR 701.3(f)(2)) may be declared without regard for predominance.
- The ingredients must be identified by the names established or adopted by regulation (21 CFR 701.3(c)); those accepted by the FDA as exempt from public disclosure may be stated as "and other ingredients" (21 CFR 701.3(a)).
- Cosmetics which are also drugs must first identify the drug ingredient(s) as "active ingredient(s)" before listing the cosmetic ingredients (21 CFR 701.3(d)).
- All label statements required by regulation must be in the English language and must be prominently or conspicuously placed on the label or labeling. 21 CFR 701.2)

Warning Labels

Cosmetics which may be hazardous to consumers when misused must bear appropriate label warnings and adequate directions for safe use.

- The statements must be prominent and conspicuous.
- Some cosmetics must bear label warnings or cautions prescribed by regulation (21 CFR 740). Examples include:
  - Cosmetics in self-pressurized containers (aerosol products)
  - feminine deodorant sprays
  - children's bubble bath products

Cosmetic products or ingredients whose safety has not been adequately substantiated are misbranded without the following label warning: **Warning - The safety of this product has not been determined** - 21 CFR740.10

FDCA versus FPLA: Key Differences

- FDCA required finished cosmetic products to be safe when used by customers in accordance with product labeling or customary usage and to not be misbranded or adulterated.
- Enacted by Congress to protect consumers from unsafe or deceptively labeled or packaged products by prohibiting the movement in interstate commerce of adulterated or misbranded food, drug devices and cosmetics
- The label statements required under the authority of the FDCA must appear on the inside as well as any outside container or wrapper.

- FPLA required cosmetics marketed on a retail basis to consumers in interstate commerce to be honestly and informatively labeled.
- Passed by Congress to ensure that packages and their labels provide consumers with accurate information about the quantity of contents and facilitate value comparisons.
- FPLA requirements, e.g., ingredient labeling and statement of the net quantity of contents on the principal display panel, only apply to the label of the outer container.

Voluntary Cosmetics Registration Program (VCRP)

- Prior to MoCRA, there was no requirement to register or list cosmetic products in the U.S.
- FDA encouraged firms to voluntarily register facilities and file product formulations with its Voluntary Cosmetics Registration Program (VCRP)
  - FDA ended VCRP following MoCRA in March 2023.
  - Information provided to VCRP will not be transferred into the new registration and listing system.

Cosmetics Ingredient Review (CIR)

- The CIR studies individual chemical compounds as they are used in cosmetic products.
- Consists of a 7-member Steering Committee chaired by the President and CEO of the PCPC
  - Includes representatives from the American Academy of Dermatology, the Society of Toxicology, the Consumer Federation of America, an industry scientist (the current chair of the Councils CIR Committee), Chair of the Expert Panel for Cosmetic Ingredient Safety, and the Council's Executive Vice President for Science
- Established an expert panel to set priorities and review and assess ingredient safety data.

The Modernization of Cosmetics Regulation Act of 2022 ("MoCRA")

- First major statutory change to the FDA's ability to regulate cosmetics since the FDCA in 1938 and the FPLA in 1966.
- Passed as part of the $1.7 trillion omnibus Consolidated Appropriations Act, 2023, and the Food and Drug Omnibus Reform Act (FDORA)
- Significantly expands FDA rulemaking and enforcement over cosmetics, and creates substantial new compliance obligations for manufacturers, packers, and distributors of cosmetics in the United States.

Contextualizing MoCRA

- MoCRA comes amidst the largest proposed reorganization in FDA history.
  - In 2022, FDA proposed transforming its Office of Regulatory Affairs into the Office of Inspections and Investigations (OII), and narrowing its focus to inspections, investigations, and import operations.
  - In February 2023, FDA proposed moving its cosmetics functions out of Center for Food Safety and Applied Nutrition (CFSAN) and into the Office of the Chief Scientist (OSC).
    - Proposed move intended to align expertise of FDA's cosmetics subject-matter experts with those of the Chief Scientist
    - OSC will collaborate with the FDA's Human Foods Program, Center for Drug Evaluation and Research, Office of Minority Health and Health Equity and Office of Women's Health.
  - FDA's proposal includes development of a reorganization package that reflects the new structure, an established budget, and detailed staff mapping.

Key Topics

Facility Registration	Product Listing	Talc Rule	Adverse Events
Facility Suspension	Safety Substantiation	Fragrance Allergens	Good Manufacturing Practices
Recalls	Product Labeling	Records Access	PFAS Report

What's New: MoCRA Key Terms

Cosmetic Product

A preparation of cosmetic ingredients with a qualitatively and quantitatively set composition for use in a finished product.

Facility

Any establishment (including an establishment of an importer) that manufactures or processes cosmetic products distributed in the United States.

Responsible Person

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 [the FDCA] or section 4(a) of the FPLA.

What's New Post-MoCRA: Amendments to FDCA

New FDCA Sections Added by MoCRA	
§ 604	Definitions
§ 605	Adverse Events
§ 606	Good Manufacturing Practices
§ 607	Registration and Product Listing
§ 608	Safety Substantiation
§ 609	Labeling
§ 610	Records
§ 611	Mandatory Recall Authority
§ 612	Small Businesses
§ 613	Exemption for Certain Products and Facilities
§ 614	Preemption

What's New: MoCRA Obligations for Manufacturers, Processors, and Distributors

Provision	Pre-MoCRA Enactment	Post-MoCRA Enactment
Facility Registration and Product Listing	Companies **were not** required to register their firms, products, or ingredients used with FDA	Persons who own or operate a facility engaged in manufacturing or processing cosmetic products **must register** with FDA their facilities, **list products**, including ingredients used, and **renew registrations** periodically
Safety Substantiation	FDA **did not** have access to cosmetic manufacturers' safety substantiation records for their products	Cosmetics manufacturers **must** maintain safety substantiation records for their products and provide FDA access to the documentation under certain circumstances
Records	Cosmetic companies **were not** required to: • maintain adverse event reports • submit adverse event reports to FDA, or • permit FDA access to adverse event records during inspections	Cosmetic companies **must**: • maintain adverse event reports; • submit serious adverse event reports to FDA; • permit FDA access to adverse event records during inspections
Labeling	Cosmetic companies **were not required** to include on product labels: • Company contact information for reporting adverse events • List of fragrance allergens in the product	Cosmetic companies **must** include on product labels: • Company contact information for reporting adverse events • List of fragrance allergens in the product

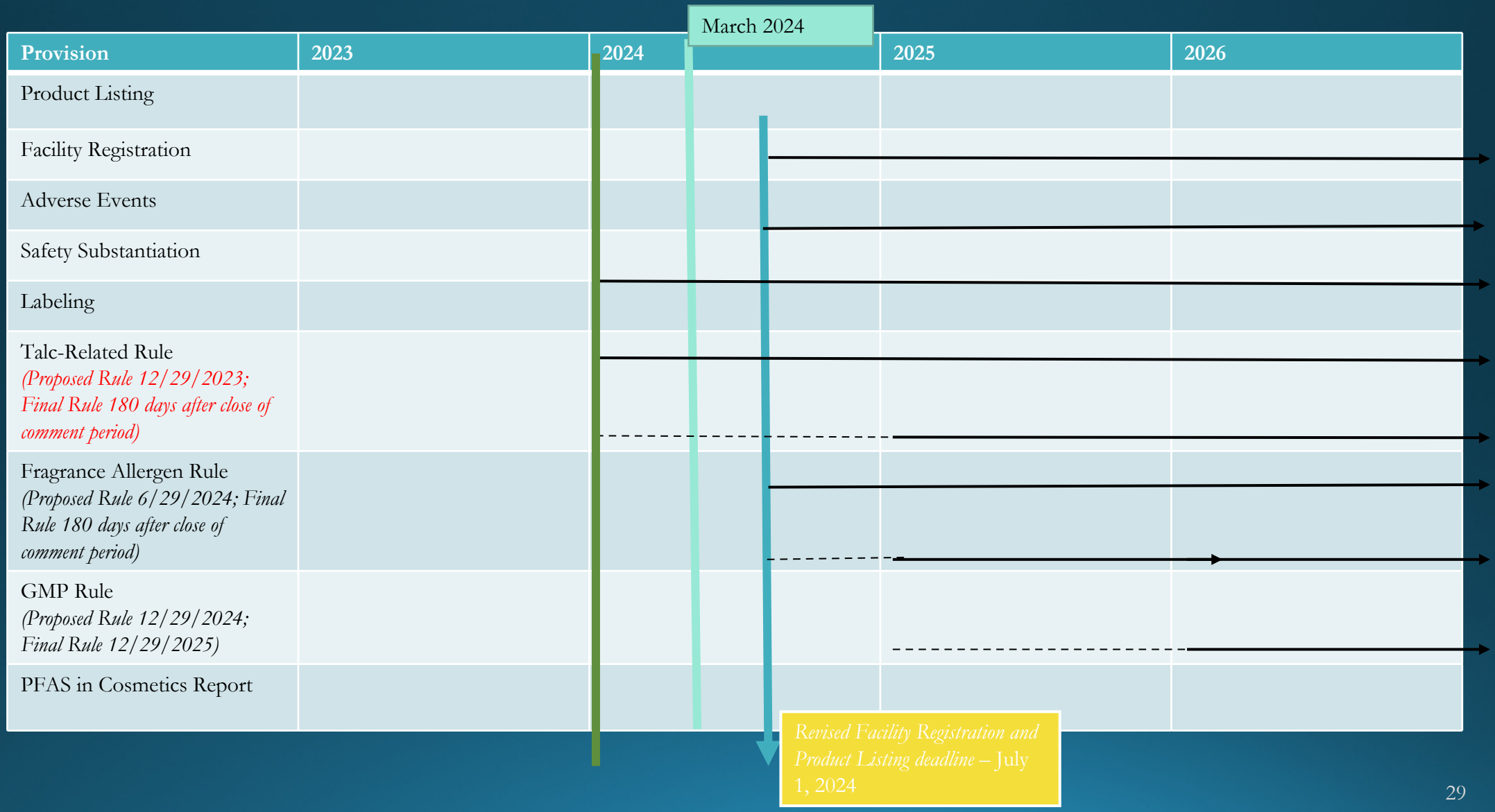
What's New: MoCRA Enforcement Authority

	Pre-MoCRA Enactment	Post-MoCRA Enactment
Premarket approval and review	FDA **did not** have authority to review and approve cosmetics for safety prior to their entry into the market	**No change** in FDA authority
Recalls	FDA **did not** have the authority to mandate recalls of cosmetics	FDA **may now** mandate recalls of cosmetics under certain circumstances
Records Inspection	Cosmetic companies **were** required to permit FDA access to certain records during facility inspections	Cosmetic companies **must** permit FDA access to adverse event and GMP records during routine inspections. FDA **may** access other cosmetic records, **including relevant safety substantiation records, if** FDA has (1) a reasonable belief that the product or an ingredient is likely to be adulterated; (2) the use of or exposure presents a threat of serious adverse health consequences or death; and (3) the records must be needed to assist FDA in its determination of whether the product is adulterated and presents a threat of serious adverse health consequences or death
Facility Suspension	Cosmetic companies **were not required** to register cosmetic manufacturing facilities with FDA	Cosmetic manufacturers **must** register cosmetic manufacturing facilities with FDA. FDA may suspend facility registration if it determines that a cosmetic has a reasonable probability of causing serious adverse health consequences or death to humans; and that other products manufactured or processed by the facility may be similarly affected

What's New: MoCRA Rulemaking Requirements

	Pre-MoCRA Enactment	Post-MoCRA Enactment
Per- and polyfluoroalkyl substances (PFAS)	FDA **did not** have the authority to mandate recalls of cosmetics	FDA **must** assess the use and evidence of the safety of PFAS in cosmetics
Asbestos in talc	FDA **did not** have specific authority to regulate methods for detecting asbestos in cosmetic talc	FDA **must** promulgate regulations to establish and require standardized testing methods for detecting and identifying asbestos in talc-containing cosmetics
Flavor and fragrance	Cosmetic manufacturers **were not required** to provide FDA with fragrance and flavor ingredients	FDA **may request**, and cosmetic manufacturers must provide, a list of flavor and fragrance ingredients that are believed to have cause or contributed to a serious adverse health event
Good manufacturing processes (GMP)	Cosmetic manufacturers we**re not specifically directed** to adhere to mandatory GMPs	FDA **must** establish GMPs for facilities that manufacture and process cosmetics

MoCRA Implementation Timeline



Facility Registration - FDCA sec. 607

- EXISTING FACILITIES: Every person that, on the date of enactment of MoCRA owns or operates a facility that engages in the manufacturing or processing of a cosmetic product … shall register each facility with FDA by **Dec. 29, 2023**.
- NEW FACILITIES: Every person that owns or operates a facility that first engages in manufacturing or processing of a cosmetic product, shall register with FDA such facility **within 60 days of first engaging** in such activity.
- Registration updates required biennially
- **FDA announced that it will not enforce registration and listing requirements until July 1, 2024**

Defining Facility

"Facility" Includes

- Any establishment (including an establishment of an importer) that manufactures or processes cosmetic products distributed in the United States."
  - To *manufacture* a cosmetic product means "the making of any cosmetic product by chemical, physical, biological, or other procedures, including manipulation, sampling, testing, or control procedures applied to the product." 21 CFR 700.3 (k)
  - "Manufacturing or processing means engaging in one or more steps in the making of any cosmetic product by chemical, physical, biological, or other procedures, including manipulation, sampling, testing, or control procedures applied to the product." Draft Guidance, August 2023

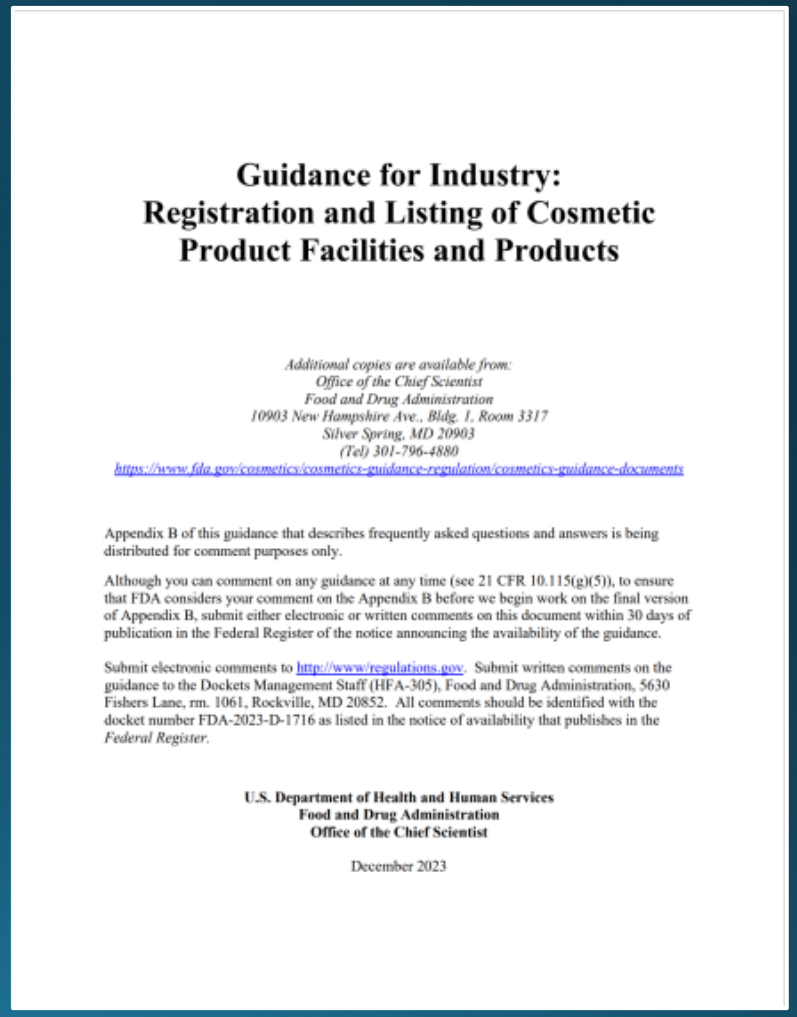
"Facility" Does Not Include

- Beauty shops and salons, cosmetic product retailers, including individual sales representatives, direct sellers, retail distribution facilities, and pharmacies, unless they manufacture or process products that are not sold directly to consumers at that location
- Hospitals, physicians' offices, and health care clinics.
- Public health agencies and other nonprofit entities that provide cosmetic products directly to the consumer.
- Entities (such as hotels and airlines) that provide complimentary cosmetic products to customers incidental to other services.
- Trade shows and other venues where cosmetic product samples are provided free of charge.
- 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.
- 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.

MoCRA - Registration and Listing

FDA Published final Cosmetic Registration & Listing Draft Guidance Outlining

- Who must register and list their products
- What information must be submitted as part of registration and listing
- When registration and listing submissions must be made
- How submissions can be made



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

Additional copies are available from:
Office of the Chief Scientist
Food and Drug Administration
10903 New Hampshire Ave., Bldg. 1, Room 3317
Silver Spring, MD 20903
(Tel) 301-796-4880
https://www.fda.gov/cosmetics/cosmetics-guidance-regulation/cosmetics-guidance-documents

Appendix B of this guidance that describes frequently asked questions and answers is being distributed for comment purposes only.

Although you can comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that FDA considers your comment on the Appendix B before we begin work on the final version of Appendix B, submit either electronic or written comments on this document within 30 days of publication in the Federal Register of the notice announcing the availability of the guidance.

Submit electronic comments to http://www/regulations.gov. Submit written comments on the guidance to the Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number FDA-2023-D-1716 as listed in the notice of availability that publishes in the *Federal Register*.

U.S. Department of Health and Human Services
Food and Drug Administration
Office of the Chief Scientist

December 2023

https://www.fda.gov/media/170732/download

What Information Must be Submitted to Register a Facility?

- Name of owner and/or operator of facility
- Facility's name, physical address, email, telephone number (for foreign facilities, contact information for U.S. based agent
- FEI number - facility must obtain an FDA Establishment Identifier (FEI) before registering or listing products
- All brand names of cosmetic products manufactured or processed at the facility
- Cosmetic product category and responsible person for each cosmetic manufactured or processed at facility
- Type of submission being made (i.e., initial registration, content update (annual), or abbreviated renewal)

Product Listing - - FDCA sec. 607

The responsible person of a cosmetic product that is marketed on the date of enactment of MoCRA shall submit to FDA a cosmetic product listing not later than 1 year after the date of enactment of MoCRA (**December 29, 2023**), or for a cosmetic product that is first marketed after the date of enactment of MoCRA, **within 120 days** of marketing such product in interstate commerce.

- Thereafter, any update to such listing shall be made annually..

MoCRA – Product Listing

Who Must List a Product?

- The "responsible person," defined as the manufacturer, packer, or distributor whose name is on the label of the product in accordance with section 609(a) of [the FDCA] or section 4(a) of the FPLA - FDCA §§ 604(4)

What Information Must be Submitted to List a Cosmetic Product? - FDCA § 607(c)

- Name and contact information of the responsible person;
- Name of the cosmetic product as it appears on the label;
- Applicable cosmetic category;
- List of ingredients in the cosmetic (including fragrances, flavors, or colors);
- Product listing number (if any) assigned by FDA; and
- Type of submission being made (i.e., initial, content update, etc.)

Safety Substantiation

SUBSTANTIATION OF SAFETY: A **responsible person** for a cosmetic product shall ensure, and **maintain records** supporting, that there is **adequate substantiation of safety** of such cosmetic product.

ADEQUATE SUBSTANTIATION OF SAFETY: means tests or studies, research, analyses, or other evidence or information that is considered, among **experts qualified by scientific training and experience** to evaluate the safety of cosmetic products and their ingredients, sufficient to support a reasonable certainty that a cosmetic product is safe.

Safety Substantiation - FDCA sec. 608

- The term ‘safe’ means that the cosmetic product, including any ingredient thereof, is **not injurious to users** under the conditions of use prescribed in the labeling thereof, or under such conditions of use as are customary or usual.
  - FDA shall not consider a cosmetic ingredient or cosmetic product injurious to users solely because it can cause **minor and transient reactions** or **minor and transient skin irritations** in some users.
  - In determining for purposes of this section whether a cosmetic product is safe, FDA may consider, as appropriate and available, the **cumulative** or other relevant exposure to the cosmetic product, including any ingredient thereof. 21 U.S. Code §364d(c)(2)

Adverse Event Recordkeeping - FDCA sec. 605

- The **responsible person** shall maintain records related to each report of an adverse event (serious or non-serious) associated with the use of a cosmetic product manufactured or distributed by such person received by such person, for a **period of 6 years** (3 years for small businesses).
- The responsible person shall allow an authorized person access to adverse events records during an inspection.
- Authorized person means an officer or employee of the Department of Health and Human Services (FDA).

Adverse Event Reporting Prior to MoCRA

Unlike for drugs and certain other regulated commodities, FDA lacked authority to require cosmetic manufacturers to

- Notify FDA of adverse events associated with their products, or
- Report information received from consumers regarding adverse events

FDA encouraged voluntary reporting of adverse events by consumers and companies

Defining Adverse Events

"Adverse Event" means

- Any health-related event associated with the use of a cosmetic product that is adverse. FDCA 604(1)

"Serious Adverse Event" means

- Any adverse event that results in, or requires medical intervention to prevent: death; a life-threatening experience; inpatient hospitalization; a persistent or significant disability or incapacity; a congenital anomaly or birth defect; an infection; or significant disfigurement (including serious and persistent rashes, second or third-degree burns, significant hair loss, or persistent or significant alteration of appearance) other than as intended, under conditions of use that are customary or usual. FDCA 604(5)

Serious Adverse Event Reporting - FDCA sec. 605

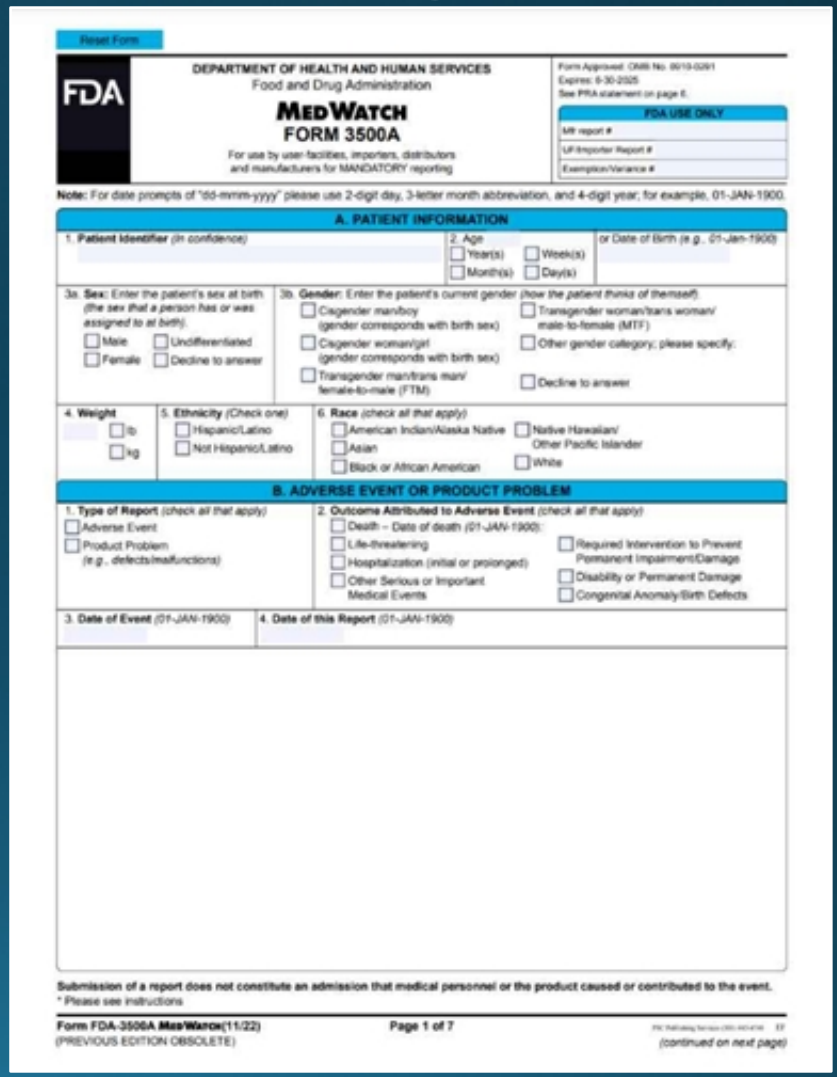
- The responsible person shall submit to the Secretary (FDA) any report received of a serious adverse event associated with the use, in the United States, of a cosmetic product manufactured, packed, or distributed by such person.
  - Report accompanied by a copy of the label on or within the retail packaging of such cosmetic product no later than **15 business days** after the report is received.
  - Submit any new and material medical information related to a serious adverse event report that is received by the responsible person within 1 year of the event, and no later than 15 business days after such information is received.
  - FDA shall develop systems to enable responsible persons to submit a single report that includes duplicate reports of, or new medical information related to, a serious adverse event.

MoCRA Adverse Event Reporting

How to Submit SAE Reports to FDA

- MedWatch 3500A is downloadable and fileable either via email or by mail;
  - Submit completed form along with information to support the report, such as scans of the product labels and images of the serious adverse event to FDA
  - FDA prefers email: CAERSCosmetics@fda.hhs.gov
  - Can also submit by mail to:

    FDA CDER Mail Center
    Attn: Cosmetics MedWatch Reports
    White Oak Campus, Building 22, G0207
    10903 New Hampshire Ave.
    Silver Spring, MD 20993



DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

MEDWATCH
FORM 3500A

For use by user facilities, importers, distributors and manufacturers for MANDATORY reporting

FDA USE ONLY

A. PATIENT INFORMATION

B. ADVERSE EVENT OR PRODUCT PROBLEM

Submission of a report does not constitute an admission that medical personnel or the product caused or contributed to the event.

Form FDA-3500A MedWatch (11/22) Page 1 of 7

(PREVIOUS EDITION OBSOLETE)

New Product Labeling Requirements Under MoCRA - FDCA sec. 609

- Domestic address OR domestic phone number OR electronic contact information through which a responsible person may be contacted regarding adverse events in response to usage of the product. (Sec. 609) Effective Dec. 29, 2024

- •Fragrance allergens Effective once FDA establishes rule –approx. Jan. 2025

Professional Use Product Labeling - FDCA sec. 609

A cosmetic product introduced into interstate commerce and intended to be used only by a professional shall bear a label that:

- contains a clear and prominent statement that the product shall be administered or used only by licensed professionals; and
- is in conformity with the requirements of FDA cosmetics labeling under this Act and section 4(a) of the Fair Packaging and Labeling Act.

The term 'professional' means an individual who is licensed by an official state authority to practice in the field of cosmetology, nail care, barbering, or esthetics.

Drug Exemption - FDCA sec. 613

- A cosmetic product or facility that is also subject to the requirements of chapter V (drugs) shall be exempt from the following MoCRA requirements:
  - 605 (serious adverse event reporting),
  - 606 (cosmetic GMPS), 607 (facility registration & product listing)
  - 608 (safety substantiation),
  - 609(a) (domestic or electronic contact info on label),
  - 610 (records access), and
  - 611 (mandatory recall).

- However, if that facility manufactures or processes cosmetic products that are not also drugs, it is still subject to MoCRA with respect to the cosmetic products.

Small Business Exemption - FDCA sec. 612

Responsible persons, and owners and operators of facilities, whose average gross annual sales in the US of cosmetic products for the previous 3-year period is less than $1,000,000, adjusted for inflation, and who do not engage in the manufacturing or processing of the cosmetic products described in subsection (b), shall be considered small businesses and exempt from the requirements of:

- Section 606 (Mandatory GMPs)
- Section 607 (facility registration and product listing).
- Only need to retain adverse event records for 3 years as opposed to 6 years.

Does not apply to products that:

1. come into contact with mucus membrane of the eye,
2. Are injected (tattoos)
3. Are intended for internal use (mouthwash), or
4. Are intended to alter appearance for more than 24 hours and removal by the consumer is not part of the intended conditions of use.

MoCRA – Expanded Rulemaking Authority

Good Manufacturing Practices (GMP) (FDCA sec. 606):

- FDA must propose regulations consistent with national and international standards by December 29, 2024, with a final rule no later than December 29, 2025

Fragrance Allergens (FDCA sec 609):

- FDA must propose regulations on fragrance allergens that must be disclosed on cosmetics labels and the format for disclosure, in line with EU and other international requirements by June 29, 2024, with a final rule no later than 180 days after the close of the public comment period.

Talc Containing Cosmetics:

- FDA must publish, no later than December 29, 2023, a proposed rule requiring standardized test methods for detecting and identifying asbestos in talc containing cosmetic products. Final rule to publish 180 days after close of the comment period on the proposed rule

PFAS in Cosmetics:

- FDA must assess the use of PFAS in cosmetic products, including the scientific evidence of its safety and any risks posed by its use in cosmetics. FDA to publish report of its findings on FDA website no later than December 29, 2025

MoCRA – Other Provisions

- **Animal Testing:** Animals should not be used to test the safety of cosmetics and such testing should be phased out with appropriate exceptions.
- **Preemption (FDCA sec. 614)**: MoCRA preempts state and local requirements for cosmetics that differ from MoCRA, with limited exceptions for prohibitions or limitations on the amount of an ingredient that can be used in a cosmetic under state law, and existing reporting requirements, such as California's Prop 65.

FDA Enforcement Authority Pre-MoCRA

- FDA may conduct examinations and investigations of products, inspect establishments in which products are manufactured or held, and seize adulterated (harmful) or misbranded (incorrectly or deceptively labeled or filled) cosmetics
  - Examples of products seized in recent years are nail preparations containing methyl methacrylate or formaldehyde, various eyebrow and eyelash dye products containing prohibited coal-tar dyes, and products contaminated with harmful microorganisms.
  - Adulterated or misbranded foreign products may be refused entry into the United States.
  - To prevent further shipment of an adulterated or misbranded product, the agency may request a federal district court to issue a restraining order against the manufacturer or distributor of the violative cosmetic.
- The FDA may also initiate criminal action against a person violating the law.

FDA "Enforcement Toolbox" for Violations

- Warning Letters
- Import Alert
- **FDA Inspection and Form 483 Observations (*)**
- **Recalls and Market Withdrawals (*)**
- Untitled Letters
- Voluntary Shutdown
- **Suspend Facility Registration (*)**
- Administrative Detention/Seizures
- Injunctions/Consent Decree
- Criminal Prosecution through the Department of Justice (DOJ)

* New/strengthened FDA legal authorities under MoCRA

Broad FDA Legal Authority for Import Alert ("Import Ban")

- Section 801(a) of FDCA – imported product may be refused entry if it "appears" to be:
  - Manufactured, processed, or packed under unsanitary conditions; or
  - Forbidden or restricted in sale in the country in which it was produced or from which it was exported
  - Otherwise adulterated or misbranded following MoCRA.
- Import Alert provides for automatic detention of product
  - **Comparatively low bar for FDA to initiate an import alert.**
  - **No requirement that FDA find an actual violation of the FDCA to block import.**

Import Alert Number	Import Alert Type	Publish Date	Import Alert Name
17-04	DWPE	12/10/2020	"Detention Without Physical Examination Bulk Shipments of High-Risk Bovine Tissue from BSE-Countries--Bovine Spongiform Encephalopathy"
45-02	DWPE	11/17/2023	"Detention Without Physical Examination and Guidance of Foods Containing Illegal and/or Undeclared Colors."
53-06	DWPE	11/17/2023	"Detention Without Physical Examination Of Cosmetics That are Adulterated and/or Misbranded Due to Color Additive Violations"
53-17	DWPE	09/06/2023	"Detention Without Physical Examination of Cosmetics Due To Microbiological Contamination"
53-18	DWPE	06/08/2022	"Detention Without Physical Examination of Skin Whitening Creams Containing Mercury"

FDA Inspection Authority

- FDA has long had the authority to inspect cosmetic facilities under FDCA section 704.
  - FDA is entitled to inspect "any factory, warehouse, or establishment in which drugs ... or cosmetics ... [are] manufactured, processed, packed, or held for introduction into interstate commerce, or after such introduction."
  - FDA can "inspect, at reasonable times and within reasonable limits and in a reasonable manner, such factory, warehouse, establishment, or vehicle and all pertinent equipment, finished and unfinished materials, containers, and labeling therein."

FDA Inspection Authority Post-MoCRA (FDCA sec. 610)

- If FDA has a reasonable belief that a cosmetic product (including ingredients), and any other cosmetic product that FDA reasonably believes is likely to be affected, is likely to be adulterated, shall, on request, permit access to and copy all records relating to such cosmetic product

FDA Inspection Authority Post-MoCRA

FDA inspection authority "**extend[s] to** all records and other information described in sections **605, 606,** and **610**, when the standard for records inspection" under each of those sections applies.

- Section 605 = All adverse events a responsible person is required to maintain
- Section 606 = Records necessary to demonstrate compliance with GMPs
- Section 610 = "Other records"

"Other Records" does not extend to "recipes or formulas for cosmetics, financial data, pricing data, personnel data (other than data as to qualification of technical and professional personnel performing functions subject to MoCRA), research data (other than safety substantiation data for cosmetic products and their ingredients), or sales data (other than shipment data regarding sales)

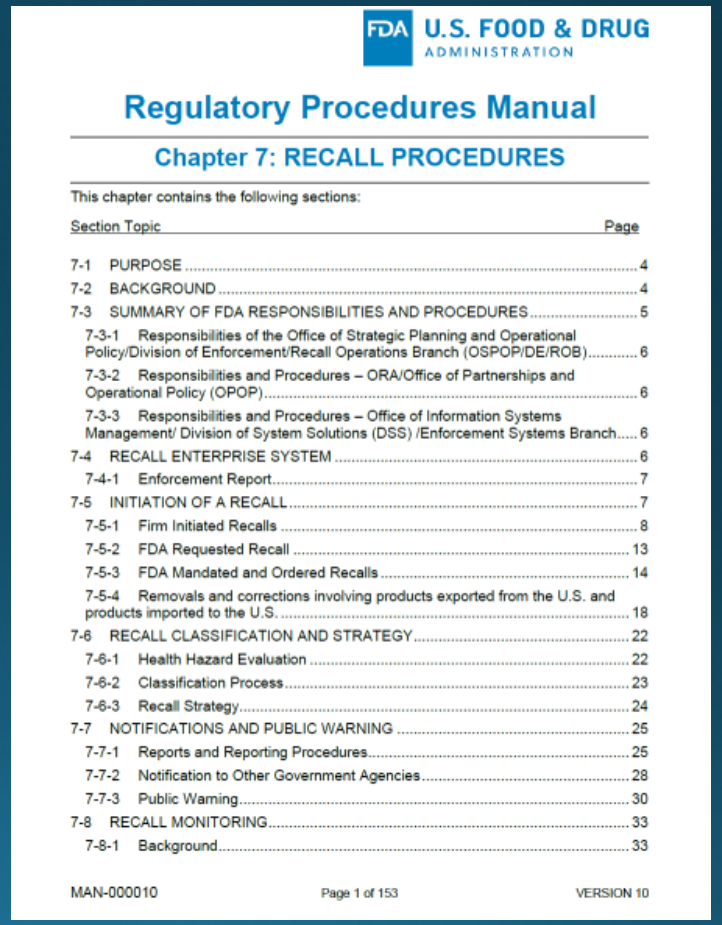
Fragrance/Flavor Ingredients

- If reasonable grounds to believe an ingredient or combination of ingredients in a fragrance or flavor has caused or contributed to a serious adverse event, they may request in writing a list of such ingredients or categories of ingredients from the responsible person. Must be provided within 30 days.

- •These will likely be provided by the ingredient supplier.

FDA Mandatory Recall Authority (FDCA sec. 611)

- If FDA determines that there is a reasonable probability that a cosmetic is adulterated or misbranded and the use of or exposure to such cosmetic will cause serious adverse health consequences or death, FDA shall provide 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 FDA, then FDA may, by order, require the responsible person to immediately cease distribution of such article.
- In conducting a recall, the FDA will notify the public through press releases and public notices, as appropriate.



FDA U.S. FOOD & DRUG ADMINISTRATION

Regulatory Procedures Manual

Chapter 7: RECALL PROCEDURES

This chapter contains the following sections:

Facility Registration Suspension (FDCA sec. 607)

FDA may suspend the registration of a facility if FDA:

- Determines that a cosmetic product manufactured or processed by a registered facility and distributed in the US has a reasonable probability of causing serious adverse health consequences or death to humans; and
- Has a reasonable belief that other products manufactured or processed by the facility may be similarly affected because of a failure that cannot be isolated to a product or products, or is sufficiently pervasive to raise concerns about other products manufactured in the facility.

If the registration of the facility is suspended under this section, no person shall introduce or deliver for introduction into commerce in the US cosmetic products from such facility pursuant to FDCA sec. 301.

Facility Registration Suspension

- Before suspending a facility, FDA must:
  - notify a facility registrant of its intent to suspend its registration
  - Provide the basis for the suspension; and
  - Provide the registrant 5 business days to provide a plan to address FDA's reasons for suspension.
- After FDA issues an order to suspend, a registrant is entitled to an informal hearing to be held within 5 business days, or some other date agreed upon by the parties.
  - If FDA determines that the suspension should remain in effect after the informal hearing, the registrant must submit a corrective action plan (CAP), and FDA must review the plan within 14 business days, or some other time period determined by FDA after submission.
  - If FDA determines that adequate grounds no longer exist to continue the suspension, FDA must promptly vacate the suspension and reinstate the registration.
- Only FDA commissioner can issue an order suspending a registration or vacating a suspension order. This authority cannot be delegated.

What Doesn't MoCRA Change?

- MoCRA does not …
  - Prohibit ingredients like PFAS or so-called endocrine disruptors,
  - Change regulations for products containing CBD or other hemp-derived products.
  - prohibit or restrict the use of animal testing for cosmetics.
  - Cosmetics containing active pharmaceutical ingredients, or that make drug claims (such as claiming to affect bodily structure or function) will still be deemed "drugs" rather than cosmetics, and subject to heavier regulatory requirements under Chapter V of the FDCA.
  - Does not address existing regulatory framework for labeling & marketing, such as defining terms like natural, clean, nontoxic or safe, or "greenwashing" claims.

State-Level Cosmetics Regulation - California

- **California Proposition 65**
  - "No person in the course of doing business shall knowingly and intentionally expose any individual to a chemical known to the state to cause cancer or reproductive toxicity without first giving clear and reasonable warning to such individual."
  - State maintains list of over 900 chemicals, and can add more
    - "Safe harbor" exposure levels for some, but not all, listed chemicals
    - Burden on company to show amounts in product are lower than a "maximum allowable daily dose"
  - Companies can apply for a "Safe Use Determination" for specific products and uses
    - Requires extensive and expensive testing and submissions to the state
  - Includes private right of action

State-Level Cosmetics Regulation - California

- **“Toxic Free Cosmetics Act”:**
  - Effective, January 1, 2025, prohibits “manufacture, sale, delivery, holding, or offering for sale” of any cosmetic products containing 24 specified “intentionally added” ingredients, including certain PFAS
  - As of January 1, 2027, list grows to add 26 additional ingredients
  - Exempts “a technically unavoidable trace quantity of the ingredient stemming from impurities of natural or synthetic ingredients”

State-Level Cosmetics Regulation

- Cosmetic ingredient restrictions, prohibitions, or reporting requirements have been passed or are pending passage in over 20 states:

States Prohibiting or Restricting Cosmetic Substances			
California	Colorado	Florida	Hawaii
Illinois	Iowa	Maine	Maryland
Minnesota	Mississippi	Nevada	New Mexico
New Jersey	New York	Ohio	Oregon
Vermont	Virginia	Washington	Wisconsin

State-Level Cosmetics Ingredient Bans

- 1, 4-dioxane
- Quaternium-15
- Phthalates –Ortho-phthalates, dibutyl Phthalate, diethylhexyl phthalate
- Perfluoroalkyl and Polyfluoroalkyl substances “PFAS”
- Formaldehyde and formaldehyde releasing agents
- Paraformaldehyde
- Methylene glycol
- Mercury and mercury compounds
- m-Phenylenediamine, o-Phenylenediamine and their salts
- Isobutylparaben, Isopropylparaben

Litigation

- Cosmetics are popular target for consumer class actions nationwide
- Often brought under false advertising and other consumer protection statutes such as the NY General Business Law ("GBL") §§ 349-350 or California's Consumer Legal Remedies Act ("CLRA")
  - Alleging consumers paid a "purchase premium" for products they would not have otherwise purchased but for the specific claims
  - Commonly targeted advertising representations include:
    - "All natural," "natural," or "100% natural"
    - "Safe", "non-toxic," "healthy" or "clean"
    - "Free-of"
    - Anti-aging claims highlighting certain ingredients
    - Sustainability and environmental impact claims
  - Expensive and time-intensive to litigate

HAVE A QUESTION?