


FDA Regulation of Cosmetics – Modernization of Cosmetics Regulation Act

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Presented to: Retail Industry Leaders Association

June 8, 2023 Washington, DC

Introduction

- Current framework
  - “Cosmetic” vs. other products (definitions)
  - Adulteration
  - Misbranding
  - Voluntary and self-regulatory programs
    - Cosmetic Ingredient Review (CIR)
  - FDA enforcement tools
- Modernization of Cosmetics Regulation Act of 2022 (MoCRA)
  - Amends existing and adds new provisions to Federal Food, Drug, and Cosmetic Act (FDCA)

Definitions

- "Cosmetic" means articles (excluding soap) (FDCA 201(i):

  (1) 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," and

  (2) intended for use as a component of any such articles

- No FDA pre-market review for cosmetics (except for "color additives")
- "Cosmeceutical" has no legal meaning

Definitions (2)

- "Drug" means articles (FDCA 201(g):

  (A) recognized in the official USP, HPUS, or NF, or any supplement;
  (B) intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals;
  (C) (other than food) intended to affect the structure or any function of the body of man or other animals;
  (D) intended for use as a component of any article specified in clause (A), (B), or (C).

- "Device" (FDCA 202(h)) – similar, but does not achieve "primary intended purpose" through chemical action in or on the body, or by being metabolized

Adulteration

- Cosmetic is “adulterated” if it:
  - FDCA 601(a): “bears or contains any poisonous or deleterious substance which may render it injurious to users” under label conditions
  - 601(b): “consists in whole or in part of any filthy, putrid, or decomposed substance”
  - 601(c): “has been prepared, packed, or held under insanitary conditions whereby it may have”:
    - become contaminated with filth, or
    - been rendered injurious to health
  - 601(d): container is made with “any poisonous or deleterious substance which may render the contents injurious to health”
  - 601(e): contains any “unsafe” (i.e., unapproved) color additive (except coal-tar hair dyes)

Misbranding

- Cosmetic is “misbranded” if:
  - FDCA 602(a): labeling is “false or misleading in any particular”
  - 602(b): label does not include
    - Name and place of business of manufacturer, packer, or distributor
    - Quantity-of-contents statement (number, weight, volume)
  - 602(c): required label information lacks prominence or conspicuousness
  - 602(d): container is “made, formed, or filled as to be misleading”
  - 602(e): is a color additive and packaging/labeling do not comply with regulation
  - 602(f): does not comply with childproof closure requirements (Poison Prevention Packaging Act)

Cosmetic Claims

- Focus on cleaning, beautifying, altering appearance, enhancing attractiveness:
  - “Helps reduce the appearance of fine lines and wrinkles”
  - “Gives your hair a radiant glow”
  - “Moisturizes to improve the feel of your skin”
  - “Helps hide unsightly blemishes”

FDA Enforcement – Claims

- FDA Warning Letter to Be Natural Organics (7/19/17)
- "CoQ10 Eye Protection Cream"
  - "CoenzymeQ10 (aka Ubiquinone) -… is used by the cells to make ATP which provides energy to carry out their metabolic functions at an optimal rate"
- "Amaretto Body Scrub"
  - "Boosts circulation and helps drain lymph nodes by increasing blood flow to the skin's surface"
- "Pomme D'Or Anti-Aging Crème"
  - "Stimulates new healthy cell production and growth"

Cosmetic Ingredient Review (CIR)

- Independent, industry-funded effort to review cosmetic ingredient safety
- Program began in 1976
- CIR Steering Committee:
  - 7 members, including medical/scientific experts and representative of Consumer Federation of America (CFA)
- CIR Expert Panel:
  - Scientific experts appointed for 6-year terms
  - Liaisons with: FDA, PCPC, CFA

CIR (2)

- Panel meets 4 times yearly
  - Meetings open to the public

- Over 8400 ingredients reviewed (as of 6/23):
  - ~ 4200 safe as used
  - ~ 4100 safe “with qualifications”
  - ~ 140 “insufficient data”
  - 30 insufficient data and use not supported
  - 7 “unsafe”

Available FDA Enforcement Tools

- Enforcement discretion
- Inspections (FDCA 704)
- Warning Letters
- Import authority (refusals and Import Alerts)
- Product recalls (typically voluntary)
- Litigation-based tools
  - Seizure (FDCA 304)
  - Injunction (FDCA 302)
  - Criminal Prosecution
- Publicity

Modernization of Cosmetics Regulation Act of 2022 (MoCRA)

- Enacted on December 29, 2022 (part of "Consolidated Appropriations Act, 2023")

- Main provisions:
  - Adverse event (AE) reporting
  - Good manufacturing practices (GMPs) for cosmetic facilities
  - Facility registration and product listing
  - Suspension of registration
  - Safety substantiation requirements
  - AE reporting information and identification of fragrance allergens on product labels
  - Expanded FDA authority to access, review, and copy records
  - Mandatory recall authority
  - Small business exemption
  - Combination drug/cosmetic products
  - Preemption
  - New prohibited acts/adulteration/misbranding

- Focused on finished "cosmetic products"
  - "preparation of cosmetic ingredients with a qualitatively and quantitatively set composition" (FDCA 604(2))

Adverse Event Reporting (FDCA 605)

- Similar to dietary supplements and OTC drugs
- "Responsible person" named on finished cosmetic product label
  - Submit reports of "serious adverse events" (SAEs) "associated with the use" of the cosmetic product to FDA within 15 business days (along with new information received within one year)
    - SAEs include: death; a life-threatening experience; inpatient hospitalization; significant disability; birth defect; infection; significant disfigurement (e.g., serious or persistent rashes, second- or third-degree burns, significant hair loss); or medical or surgical intervention to prevent any of these outcomes
  - Keep records of all adverse events (AEs) for 6 years (3 years for small businesses that are distributors only)
  - FDA can request list of fragrance, flavor, or other ingredients believed to have caused or contributed to the SAE
    - Must provide list(s) with 30 days

GMPs for Cosmetic Facilities (FDCA 606)

- Timing:
  - Proposed rule published within 2 years (12/29/24)
  - Final rule in not more than 3 years (by 12/29/25)
- To be “consistent, to the extent practicable, and appropriate, with national and international standards”
  - Intended to protect public health, ensure that cosmetic products are not adulterated
  - Are to “provide sufficient flexibility to be practicable for all sizes and types of facilities”
  - May allow adoption (or modification) of ISO 22716
  - [FDA “listening session” with industry held on 6/1/23]
  - “Small businesses” will be exempt
- FDA to have access to records to verify compliance

Facility Registration/Product Listing (FDCA 607(a) – (c))

- Registration applies to domestic and foreign cosmetic product manufacturers and processors
  - Required information: facility's location, contact information, cosmetic product brand names, cosmetic product categories
  - Timing once effective: within 60 days of starting operations
- Cosmetic product listing
  - Listing to include: ingredients, including any fragrances, flavors, or colors, and facility registration number where cosmetic product is manufactured
  - Listing can cover multiple products if:
    - Same formulation, or
    - Formulations differ only in colors, fragrances or flavors, or quantity of contents
  - To be updated annually
  - Timing once effective: within 120 days of the start of marketing
- "Small businesses" will be exempt

Suspension of Registrations (FDCA 607(f))

- Standard:
  - (1) FDA determines cosmetic product has a “reasonable probability” of causing “serious adverse health consequences or death to humans” (Class I recall threshold) and
  - (2) FDA has “reasonable belief” that other cosmetic products “may be similarly affected” by a failure that can’t be isolated or is “sufficiently pervasive” to raise concerns about other products manufactured in the facility
- Before suspension, FDA must provide notice to facility and 5 days to present corrective action plan
- Facility can request an informal hearing on the suspension and actions needed to reinstate registration
- Impact? Essentially shuts down facility

Safety Substantiation (FDCA 608)

- Responsible person to "ensure, and maintain records supporting," that there is "adequate substantiation of safety" of each cosmetic product
- "Adequate substantiation"
  - Information sufficient for appropriately-qualified experts to conclude to "a reasonable certainty that a cosmetic product is safe"
- "Safe"
  - "The cosmetic product, including any ingredient thereof, is not injurious to users" under labeled or customary or usual conditions of use
    - Excludes "minor and transient" reactions or skin irritations in some users
- May put greater pressure on ingredient suppliers to provide information to finished cosmetic product manufacturers

Labeling (FDCA 609)

- Cosmetic product labels must include:
  - Domestic address, domestic phone number, or electronic contact information (e.g., website) for responsible person to receive adverse event reports (effective date: December 29, 2024);
  - List of “fragrance allergens” as established through rulemaking; and
  - Clearly and prominently indicate if product is for use by licensed professionals only
- For fragrance allergens, FDA’s rulemaking process to consider:
  - International (including EU), state, and local requirements; and
  - Threshold amounts that trigger disclosure

FDA Records Access (FDCA 610)

- (1) If FDA has "reasonable belief" that cosmetic product at issue or other one "likely to be affected in similar manner" is
  - Adulterated and
  - Presents threat of serious adverse health consequences or death to humans; OR
- (2) If FDA believes "reasonable probability" that use of or exposure to product will cause serious adverse health consequences or death to humans

- If (1) or (2), FDA can and copy access "all" records relating to such cosmetic product
  - Except recipes, formulas, financial, pricing, personnel (except worker qualifications), research (except safety substantiation), and sales (other than shipment) data
  - No time frame, but access to be provided "at reasonable times and within reasonable limits and in a reasonable manner"
- General records inspection authority (FDCA 704(a)) expanded to cover "all records" related to SAERs, GMPs, and new FDCA 610

Mandatory Recall Authority (FDCA 611)

- FDA can issue mandatory "cease distribution" order if
  - (1) It finds there is a "reasonable probability" that a cosmetic is adulterated or misbranded under the FDCA;
  - (2) It determines use of or exposure to the cosmetic will cause "serious adverse health consequences or death"; and
  - (3) Responsible person refuses to voluntarily cease distribution or recall the cosmetic upon request
- FDA to provide an informal hearing within 10 days of any order
  - Order may then be amended to require product recall
- FDA to issue a press release in connection with any mandatory recall

Small Businesses (FDCA 612)

- "Small business" defined as an entity:
  - Gross annual sales in the U.S. for cosmetic products for prior three years are less than $1 million (adjusted for inflation); and
  - Do not engage in manufacture or processing of cosmetics that:
    - Come into contact with the mucus membrane of the eye;
    - Are injected;
    - Are intended for internal use; or
    - Alter the appearance for more than 24 hours under normal use.
- These companies are exempt from GMPs and facility registration/product listing provisions

Combination Drug/Cosmetic Products (FDCA 613)

- Cosmetic product or facility also subject to FDA's drug regulatory requirements is exempt from MoCRA requirements for:
  - Adverse event reporting (§ 605);
  - GMPs (§ 606);
  - Establishment registration and product listing (§ 607);
  - Safety substantiation (§ 608);
  - Adverse event reporting contact details (§ 609(a));
  - Records access (§ 610); and
  - Mandatory recall (§ 611)

- For such combination products, corresponding drug requirements apply

- If facility manufactures cosmetics that are not also drug products, then MoCRA requirements apply to such cosmetic products

Preemption (FDCA 614)

- No State or local authority may establish any requirement for cosmetics that is "different from or in addition to, or otherwise not identical with," MoCRA requirements for:
  - Registration and product listing
  - GMPs
  - Records
  - Recalls
  - Adverse event reporting, or
  - Safety substantiation

- Additional labeling not preempted (like California's Prop 65)

- Does not prevent States from prohibiting use or limiting amount of an ingredient in cosmetic products
  - (like 2013 Minnesota ban on formaldehyde in children's personal care products (e.g., shampoos, bubble bath))

- Does not preempt State ingredient reporting requirements in effect when MoCRA was enacted
  - (like California's Safe Cosmetic Program)

Enforcement Provisions (MoCRA 3503)

- Generally, take effect 1 year after enactment (December 29, 2023) unless stated otherwise
- New “prohibited acts”
  - Failure to register/submit product listing information
  - Refusal/failure to follow cease distribution and/or recall order
  - [Shipping product from facility with suspended registration]
- New adulteration:
  - Failure to meet GMPs
  - Finished cosmetic and each ingredient do not have “adequate substantiation for safety”
- New misbranding:
  - Label fails to include AE reporting information, fragrance allergens, or “professional use” designation

Miscellaneous (MoCRA 3505 – 3507)

- Talc-containing cosmetics
  - 1 year for FDA to propose rule on standardized testing for asbestos in cosmetics containing talc
- PFAS in cosmetics:
  - perfluoroalkyl and polyfluoroalkyl substances
  - 3 years for FDA to assess use, evaluate safety, and publish report
- Animal testing:
  - “Sense of the Congress” that animal testing should not be used for safety evaluation “and should be phased out”
  - Already prohibited in other regions (e.g., EU)

Thank you!

Questions? Please contact:

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