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SUMMARY

The Food and Drug Administration (FDA) has the authority to regulate cosmetic products and their ingredients. This authority was granted by the 1938 Federal Food, Drug, and Cosmetic Act (FFDCA), which included provisions regarding the adulteration and misbranding of cosmetics. Cosmetic products are also regulated under the Fair Packaging and Labeling Act (FPLA) and related legislation. Although the Color Additive Amendments Act of 1960 and the Poison Prevention Packaging Act of 1970 amended some of FFDCA's provisions, cosmetics regulation remained largely unchanged from the original FFDCA until 2022, when the Modernization of Cosmetics Regulation Act (MoCRA) was enacted. Most of MoCRA's provisions will take effect at the close of 2023.

Prior to the passage of MoCRA, FDA had limited authority regarding cosmetic product registration; testing; premarket notification, clearance, or approval; good manufacturing practices; mandatory risk labeling; adverse event reports; and recalls. FDA could not impose registration requirements on cosmetic manufacturers. Rather, manufacturers could voluntarily comply with FDA registration regulations. Additionally, with the exception of color additives, FDA did not require premarket notification, safety testing, review, or approval of the chemicals used in cosmetic products. Although FDA had released draft good manufacturing practices (GMP) guidelines for cosmetic manufacturers, they were not required to adhere to them, nor were manufacturers required to file ingredient information with, or report adverse reactions to, the agency. Instead, under a voluntary FDA program, cosmetic manufacturers and packagers could choose to report the ingredients used in their product formulations. FDA also did not have the authority to require a manufacturer to recall a cosmetic product from the marketplace, although the agency did issue general regulations on voluntary recalls.

With the passage of MoCRA, FDA's regulatory authority over cosmetics has been expanded. Under MoCRA, FDA will now require facility registration and listing of cosmetics products with the agency, as well as certain product labeling information. FDA will also promulgate final GMP regulations, require the reporting of serious adverse events, and gain the ability to issue mandatory product recalls. Moreover, manufacturers must substantiate cosmetic product safety and maintain related records. The passage of MoCRA, however, will not require cosmetics to be subject to premarket review.

FDA's authority over cosmetics, both pre- and post-MoCRA, overlaps in some ways with other FDA-regulated products, such as food, drugs, medical devices, and tobacco. For example, prior to MoCRA, FDA had the authority to take certain enforcement actions—such as seizures, injunctions, and criminal penalties—against adulterated or misbranded cosmetics, as it does with foods, drugs, devices, and tobacco products. In addition, FDA could inspect cosmetic manufacturing facilities, as it may with drug and food companies, and prohibit the importation of cosmetics that violate the FFDCA. Moreover, the agency has issued rules restricting the use of ingredients that it determines are poisonous or deleterious.

Despite these similarities in applicability FDA's authority over cosmetics in certain respects remains less comprehensive than its authority over other FDA-regulated products.

Contents

Tables

Contacts

Introduction

The U.S. cosmetic, beauty supply, and perfume retail industry consists of over 184,000 establishments, with a projected combined annual revenue of about $45.2 billion by the close of 2023.[1] Worldwide, the cosmetics and personal care products industry collects more than $529.3 billion in annual retail sales.[2] The cosmetic market includes numerous personal care products other than the facial makeup that the term "cosmetics" typically implies.[3] Domestic industry sales are concentrated in the following areas (percentage of sales by product category): (1) cosmetics, 37.9%; (2) haircare products, 27.1%; (3) skincare products, 20.9%; and (4) nail products, deodorants, and other products, 14.1%.[4]

The Food and Drug Administration (FDA) has the authority, generally under the Federal Food, Drug, and Cosmetic Act (FFDCA), to regulate cosmetic products and their ingredients. In this context, the agency's primary regulatory responsibilities include ensuring that cosmetics are not adulterated or misbranded.[5] FDA's authority over cosmetic products has been greatly expanded via the passage of the Modernization of Cosmetics Regulation Act of 2022 (MoCRA).

This report (1) describes the definitional differences between cosmetics, drugs, and cosmetic/drug combinations; (2) outlines the statutory provisions and rules under which FDA regulates cosmetics, including those newly introduced under MoCRA; and (3) identifies outstanding considerations about FDA's authority over cosmetics. The report focuses on FDA regulation of cosmetics under MoCRA; it does not discuss Federal Trade Commission (FTC) regulation of cosmetics advertising or the regulation of potentially dangerous chemicals, pesticides, or other products by other agencies.[6]

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[1] Alexia M. Zambrano, *Beauty, Cosmetics & Fragrance Stores in the US: Industry Performance*, IBISWorld, April 2023, https://my.ibisworld.com/us/en/industry/44612/industry-performance.

[2] Personal Care Products Council, "About PCPC," https://www.personalcarecouncil.org/about-us/. Note: this value was calculated using data from 2021. Personal Care Products Council, *Year in Review 2022*, p. 7, https://www.personalcarecouncil.org/wp-content/uploads/2023/03/PCPC_YIR2022_DIGITAL-SINGLE.pdf.

[3] The Food and Drug Administration (FDA) estimates that most Americans use 6 to 12 cosmetic products every day. FDA, "Modernization of Cosmetics Regulation Act of 2022," https://www.fda.gov/cosmetics/cosmetics-laws-regulations/modernization-cosmetics-regulation-act-2022. Additionally, the gender distribution of traditional makeup product usage has shifted in recent years. Surveys have documented that anywhere between 20% and 50% of American men have reported using traditional makeup products, including concealer, foundation, bronzer, lip products, and eye makeup, among others. See, for example, Forbes, "Why Cosmetic Companies Targeting Male Consumers are Marketing on the Down-Low," https://www.forbes.com/sites/jackiehuba/2020/10/22/why-cosmetic-companies-targeting-male-consumers-are-marketing-on-the-down-low/?sh=6d3f95839b46; NPR, "My Journey Into the World of Men's Beauty," https://www.npr.org/2019/11/12/776744697/my-journey-into-the-world-of-mens-beauty; Prim&Prep, "The Changing Views of Men Using Makeup (2019 Survey Results)," https://www.primandprep.com/the-changing-views-of-men-using-makeup/.

[4] Alexia M. Zambrano, IBISWorld, "Beauty, Cosmetics & Fragrance Stores in the US: Products & Markets," https://my.ibisworld.com/us/en/industry/44612/products-and-markets.

[5] Federal Food, Drug, and Cosmetic Act (FFDCA) §§601, 602 (21 U.S.C. §§361, 362). See the "Adulterated and Misbranded Cosmetics" section of this report.

[6] P.L. 117-328, Division FF, Title III, Subtitle E—Cosmetics. Under Section 12 of the Federal Trade Commission Act, "[i]t shall be unlawful for any person ... to disseminate, or cause to be disseminated, any false advertisement—(1) By United States mails, or in or having an effect upon commerce, by any means, for the purpose of inducing, or which is likely to induce, directly or indirectly the purchase of ... cosmetics; or (2) By any means, for the purpose of inducing, or which is likely to induce, directly or indirectly, the purchase in or having an effect upon commerce, of ... cosmetics" (15 U.S.C. §52). In addition, cosmetics are explicitly excluded from the definition of "consumer product" in Section 3(a)(5)(H) of the Consumer Product Safety Act, which is enforced by the Consumer Product Safety Commission (15 U.S.C. §2052(a)(5)(H)).

History of FDA's Cosmetics Regulation Authority

Scope and Definitions: Cosmetics, Drugs, and Cosmetic/Drug Combinations

This section discusses how the FFDCA defines cosmetics and drugs. The distinction between them, which determines how products are classified, is a concern for manufacturers because cosmetics are not subject to the same approval, regulatory, or registration requirements as drugs, unless the cosmetic also meets the definition a drug.[7] Having a product classified as cosmetic only—not as a drug or cosmetic/drug combination—saves manufacturers time and expense and enables them to market their products with less regulatory oversight.

Cosmetics

FFDCA defines a "cosmetic" as an article intended to be "applied to the human body … for cleansing, beautifying, promoting attractiveness, or altering the appearance."[8] The term covers a broad range of FDA-regulated products that may be used externally and internally.[9] Cosmetics include products for the eyes, face, nails, hair, skin, and mouth, such as makeup, nail polish, hair dyes and coloring, suntan preparations, fragrances, oral care, and bath products.[10] Although soap was explicitly exempted from the definition of a cosmetic, it may be regulated by the FDA as a cosmetic product in certain instances.[11] In addition, coal-tar hair dye was provided a limited exemption from the FFDCA's adulteration provisions.[12] Inks used for tattooing are also classified as cosmetics under the FFDCA.[13] Under MoCRA, FFDCA will separately define a "cosmetic product" as "a preparation of cosmetic ingredients with a qualitatively and quantitatively set composition for use in a finished product."[14]

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[7] FFDCA §509 (21 U.S.C. §359). Under MoCRA, cosmetic/drug combinations are treated as drugs for listing and selected other provisions. See FFDCA §613(a) (21 U.S.C. §364i(a)).

[8] FFDCA §201(i) (21 U.S.C. §321(i)).

[9] Examples of cosmetics "that may be introduced into the body are limited, but include mouthwashes, breath fresheners, and vaginal douches." John E. Bailey, "Organization and Priorities of FDA's Office of Cosmetics and Colors," in *Cosmetic Regulation in a Competitive Environment*, Norman F. Estrin & James M. Akerson, eds., p. 217, 2000.

[10] 21 C.F.R. §720.4(c).

[11] FDA regulations define "soap" as applying only to articles for which "(1) [t]he bulk of the nonvolatile matter in the product consists of an alkali salt of fatty acids and the detergent properties of the article are due to the alkali-fatty acid compounds; and (2) [t]he product is labeled, sold, and represented only as soap" (21 C.F.R. §701.20(a)). A product intended not only for cleansing, but also for other cosmetic uses, such as beautifying, moisturizing, or deodorizing, would be regulated by FDA as a cosmetic. A soap-like product may also be a drug if it is intended to cure, treat, or prevent disease, or to affect the structure or any function of the human body. For example, a soap-like product that is not only intended for cleansing, but also for moisturizing or deodorizing and that contains a medication preventing fungal growth, may be regulated as both a cosmetic and a drug product. The intended use of a product is determined by several factors, including claims stated on the product label, in advertising, or other promotional materials; consumer perception and the product's reputation; and ingredients that may cause the product to be considered a drug by industry standards or public perception. See FDA, "Is It a Cosmetic, a Drug, or Both (Or Is It Soap?)," https://www.fda.gov/cosmetics/cosmetics-laws-regulations/it-cosmetic-drug-or-both-or-it-soap.

[12] FFDCA §601(a) (21 U.S.C. §361(a)). Coal-tar hair dyes include permanent, semipermanent, and temporary hair dyes. FDA, "Hair Dyes," https://www.fda.gov/cosmetics/cosmetic-products/hair-dyes.

[13] FDA, "Tattoos, Temporary Tattoos & Permanent Makeup," https://www.fda.gov/cosmetics/cosmetic-products/tattoos-temporary-tattoos-permanent-makeup.

[14] FFDCA §604(2) (21 U.S.C. §364(2)).

Drugs

The FFDCA defines a "drug" in part as "articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease"; articles "(other than food) intended to affect the structure or any function of the body"; and "articles intended for use as a component" of such drugs.[15]

Drug manufacturers must comply with Current Good Manufacturing Practices (CGMP) rules for drugs.[16] Failure to comply will cause a drug to be considered adulterated.[17] Drug manufacturers are required to register their facilities,[18] list their drug products with the agency,[19] and report adverse events to FDA, among other requirements.[20]

Unlike cosmetics and their ingredients (with the exception of color additives), drugs are subject to FDA approval before entering interstate commerce. Drugs must either (1) receive the agency's premarket approval under a new drug application (NDA), or an abbreviated NDA (ANDA),[21] in the case of a generic drug, or (2) conform to a set of FDA requirements known as a monograph.[22] Monographs govern the manufacture and marketing of most over-the-counter (OTC) drugs and specify the conditions under which OTC drugs in a particular category (such as antidandruff shampoos or antiperspirants) will be considered generally recognized as safe and effective (GRASE).[23] Monographs also indicate how OTC drugs must be labeled so they are not deemed misbranded.[24]

[15] FFDCA §201(g)(1) (21 U.S.C. §321(g)(1)).

[16] Current Good Manufacturing Practices set the "minimum requirements for the methods, facilities, and controls used in manufacturing, processing, and packing of a drug product." For general information, see FDA, "Current Good Manufacturing Practice (CGMP) Regulations," https://www.fda.gov/drugs/pharmaceutical-quality-resources/current-good-manufacturing-practice-cgmp-regulations.

[17] FFDCA §501(a)(2)(B) (21 U.S.C. §351(a)(2)(B)).

[18] FFDCA §510 (21 U.S.C. §360), 21 C.F.R. Part 207.

[19] Ibid.

[20] 21 C.F.R. §310.305; 21 C.F.R. §314.80; 21 C.F.R. §314.98.

[21] FFDCA §505 (21 U.S.C. §355). A new drug application (NDA) is the process through which drug sponsors propose that FDA approve a new pharmaceutical for sale and marketing in the United States. The agency approves an NDA after examining reports and investigations that demonstrate the drug's safety and effectiveness, among other considerations.

[22] An OTC drug monograph is similar to a recipe in that it covers active ingredients, dosages, formulations, and labeling claims. If an OTC drug product complies with the relevant monograph, it does not need FDA approval prior to marketing. FDA assesses monograph compliance as part of its inspection process. Historically, monographs have been established and amended through rulemaking. The Coronavirus Aid, Relief, and Economic Security Act (CARES Act; P.L. 116-136), enacted on March 27, 2020, replaced the rulemaking process with the administrative order process—a less burdensome alternative. For additional information, see CRS Report R46985, *FDA Regulation of Over-the-Counter (OTC) Drugs: Overview and Issues for Congress*.

[23] 21 C.F.R. §§330-358.

[24] Labels must include a Drug Facts panel, which lists the product's active ingredients, purposes, uses, applicable warnings, directions, other information, and inactive ingredients, and may contain a telephone number for questions about the product. See 21 C.F.R. §201.66(c).

Cosmetics Containing Drug Ingredients

Although the term "cosmeceutical" has been used to refer to combination cosmetic/drug products, such products have no statutory or regulatory definition.[25] Historically, FDA has indicated that cosmetic/drug combinations are subject to FDA's regulations for both cosmetics and drugs.[26]

Determining whether a cosmetic is also a drug, and therefore subject to the additional statutory requirements that apply to drugs, depends on the distributor's claims regarding the drug's intent or intended use.[27] A product's intended use may be established in several ways, such as claims on the label or in advertising or promotional materials, customer perception of the product, and the inclusion of ingredients that cause the product to be considered a drug because of a known therapeutic use.[28] For example, if a lipstick (a cosmetic) contains sunscreen (a drug), historically, the mere inclusion of the term "sunscreen" in the product's labeling required the product to be regulated as a drug as well as a cosmetic.[29] The text box below provides examples of other cosmetic/drug combinations and compares cosmetic and drug classifications.[30]

Comparison of Cosmetic and Drug Product Classifications

A suntan product is a cosmetic, but a sunscreen product is a drug.

A deodorant is a cosmetic, but an antiperspirant is a drug.

A shampoo is a cosmetic, but an antidandruff shampoo is a drug.

A toothpaste is a cosmetic, but an anticaries toothpaste is a drug.

A skin exfoliant is a cosmetic, but a skin peel is a drug.

A mouthwash is a cosmetic, but an antigingivitis mouthwash is a drug.

A hair bulking product is a cosmetic, but a hair growth product is a drug.

A skin product to hide acne is a cosmetic, but an antiacne product is a drug.

An antibacterial deodorant soap is a cosmetic, but an antibacterial anti-infective soap is a drug.

A skin moisturizer is a cosmetic, but a wrinkle remover is a drug.

A lip softener is a cosmetic, but a product for chapped lips is a drug.

Source: Peter B. Hutt, "Legal Distinction in the United States between a Cosmetic and a Drug," in *Cosmeceuticals and Active Cosmetics*, ed. Raja K. Sivamani et al., 3rd ed. (Boca Raton, FL: Taylor & Francis Group, 2016), p. 432.

[25] FDA, "Cosmeceutical," https://www.fda.gov/cosmetics/cosmetics-labeling-claims/cosmeceutical.

[26] FDA, "Is it a Cosmetic, a Drug, or Both (Or Is it Soap?)," https://www.fda.gov/cosmetics/cosmetics-laws-regulations/it-cosmetic-drug-or-both-or-it-soap. Note, however, that this will no longer always be the case post-MoCRA. See FFDCA §613(a) (21 U.S.C. §364i(a)); FDA, *Registration and Listing of Cosmetic Product Facilities and Products: Guidance for Industry (Draft Guidance)*, August 2023, p. 11, https://www.fda.gov/media/170732/download.

[27] FFDCA §201(g) (21 U.S.C. §321(g)).

[28] FDA, "Is It a Cosmetic, a Drug, or Both (Or Is It Soap?)," https://www.fda.gov/cosmetics/cosmetics-laws-regulations/it-cosmetic-drug-or-both-or-it-soap.

[29] 21 C.F.R. §700.35(a). "A product that includes the term 'sunscreen' in its labeling ... comes within the definition of a drug.... [T]he use of the term 'sunscreen' or similar sun protection terminology in a product's labeling generally causes the product to be subject to regulation as a drug."

[30] In addition, some of the products commonly referred to as "personal care products" may be considered either cosmetics, drugs, or other regulatory categories, depending on the intended use of the product. For more information, see FDA, "Are All 'Personal Care Products' Regulated as Cosmetics?," https://www.fda.gov/industry/fda-basics-industry/are-all-personal-care-products-regulated-cosmetics. FDA has distinguished between cosmetics and medical devices in the past as well. FDA, "Warning Letters Highlight Differences Between Cosmetics and Medical Devices," https://www.fda.gov/cosmetics/warning-letters-related-cosmetics/warning-letters-highlight-differences-between-cosmetics-and-medical-devices.

History

Prior to the enactment of the Federal Food, Drug, and Cosmetic Act (FFDCA) in 1938, cosmetics were not regulated by the federal government.[31] Instead, they were regulated under a collection of state laws that had been enacted to regulate food and drugs.[32] At that time, multiple "cosmetics and drugs were made from the same natural materials" and often the "laws did not include explicit definitions of the products regulated."[33] Following several incidents in which cosmetics were allegedly the cause of serious health problems, as well as industry concerns about states enacting their own laws, provisions were included in the FFDCA that prohibited the sale of adulterated or misbranded cosmetics in interstate commerce.[34] The FFDCA also established uniform regulation of FDA-regulated cosmetic products nationwide.[35] However, state laws regarding cosmetics regulation have continued to evolve since FFDCA's passage, with some states implementing stricter measures than others.[36]

In addition to their regulation under the FFDCA, cosmetics are regulated under the Fair Packaging and Labeling Act (FPLA) and related regulations.[37] The FPLA applies to the packaging and labeling of "consumer commodities," which include 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."[38] The FPLA 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."[39]

The FFDCA prohibits the adulteration and misbranding of cosmetics in interstate commerce and the introduction, receipt, and delivery of adulterated or misbranded cosmetics into interstate commerce.[40] From 1938 until 2022, with the exception of provisions governing color additives, the FFDCA statutory provisions addressing cosmetics remained basically unchanged, though the

[31] Senate Committee on Commerce, S.Rept. 91, 75th Cong., p. 5, 1937.

[32] Peter B. Hutt, "A History of Government Regulation of Adulteration and Misbranding of Cosmetics," in *Cosmetic Regulation in a Competitive Environment*, ed. Norman F. Estrin & James M. Akerson (New York, NY: Marcel Dekker, Inc., 2000), p. 2, (hereinafter, Hutt, "A History of Government Regulation of Adulteration and Misbranding of Cosmetics").

[33] Hutt, "A History of Government Regulation of Adulteration and Misbranding of Cosmetics," p. 2.

[34] Hutt, "A History of Government Regulation of Adulteration and Misbranding of Cosmetics," p. 6; Jacqueline A. Greff, "Regulation of Cosmetics That are Also Drugs," *Food and Drug Law Journal*, vol. 51, no. 2 (1996), pp. 243-244.

[35] Hutt, "A History of Government Regulation of Adulteration and Misbranding of Cosmetics," pp. 2-3, 6.

[36] See, for example, Lisa Benson and Karen Reczek, *A Guide to United States Cosmetic Products Compliance Requirements*, National Institute of Standards and Technology, NISTIR 8178, May 31, 2017, pp. 22-28, https://nvlpubs.nist.gov/nistpubs/ir/2017/nist.ir.8178.pdf.

[37] P.L. 89-755 (15 U.S.C. §1451 et seq.).

[38] FPLA §10(a) (15 U.S.C. §1459(a)). FPLA specifically regulates "any person engaged in the packaging or labeling of any consumer commodity … for distribution in commerce, or … any person [(with some exceptions)] … engaged in the distribution in commerce of any packaged or labeled consumer commodity." §3(a) (15 U.S.C. §1452(a)).

[39] FPLA §3(b) (15 U.S.C. §1452(b)).

[40] FFDCA §§301(a)-(c) (21 U.S.C. §§331(a)-(c)). See the "Adulterated and Misbranded Cosmetics" section of this report.

cosmetic industry has continuously grown over the past 80 years. Consequently, the concerns of consumer and industry groups have often remained similar since the enactment of the FFDCA.

Prior to MoCRA, due to statutory authority limitations, certain FDA cosmetics regulations and procedures relied on voluntary manufacturer compliance, even though similar regulations and procedures were mandatory for other FDA-regulated products (such as drugs). For example, FDA had promulgated regulations for the voluntary registration of establishments that manufactured or packaged cosmetics.[41] In contrast, mandatory registration requirements existed for other FDA product-category manufacturers (e.g., drugs, food).[42] Moreover, unlike drug manufacturers, cosmetic manufacturers were not required to submit safety data on ingredients or to report cosmetic-related injuries to FDA.[43] Instead, under a voluntary FDA program, cosmetic manufacturers and packagers could choose to report the ingredients used in their product formulations.[44] Furthermore, consumers, health care professionals, and cosmetic manufacturers could voluntarily report adverse reactions to cosmetics to FDA.[45] Finally, FDA did not have mandatory recall authority to require a cosmetic manufacturer to recall a product from the marketplace. However, the agency could request a voluntary recall, and FDA has issued general regulations outlining its expectations for manufacturers during such recalls.[46] Although FDA did not have the authority to require compliance with these regulations, it could take action against adulterated or misbranded cosmetics.[47]

FDA's authority over cosmetics prior to MoCRA was less comprehensive than its authority over other FDA-regulated products with regard to good manufacturing practices (GMP), premarket clearance or approval, testing, and mandatory risk labeling.[48] FDA released GMP guidelines for cosmetic manufacturers[49] and stated that "[f]ailure to adhere to GMP may result in an adulterated or misbranded product."[50] FDA did not review or approve ingredients used in cosmetic products other than color additives, although cosmetic manufacturers were responsible for substantiating the safety of their products and ingredients before marketing.[51] Drug products, on the other hand,

[41] 21 C.F.R. Part 710; FDA, "Voluntary Cosmetic Registration Program," https://www.fda.gov/cosmetics/voluntary-cosmetic-registration-program.

[42] FFDCA §415 (21 U.S.C. §350d) (food); FFDCA §510 (21 U.S.C. §360) (drugs and devices); FFDCA §905 (21 U.S.C. §387e) (tobacco).

[43] Donald R. Johnson, "Not in My Makeup: The Need for Enhanced Premarket Regulatory Authority Over Cosmetics in Light of Increased Usage of Engineered Nanoparticles," *Journal of Contemporary Health Law and Policy*, vol. 26, no. 1 (2009), pp. 82, 114.

[44] 21 C.F.R. §720.4.

[45] FDA, "Using Adverse Event Reports to Monitor Cosmetic Safety," https://www.fda.gov/cosmetics/how-report-cosmetic-related-complaint/using-adverse-event-reports-monitor-cosmetic-safety.

[46] 21 C.F.R. Part 7, Subpart C. Note: these regulations apply to all products subject to FDA's jurisdiction.

[47] FFDCA §§301-304 (21 U.S.C. §§331-334).

[48] FDA's authority over cosmetic products is based primarily on FFDCA provisions on cosmetics, color additives, and drugs. The agency also has authority under FPLA for labeling requirements. Other agencies may use their own authorities to regulate certain aspects of cosmetic products (e.g., the Federal Trade Commission regulates the advertising of cosmetics).

[49] FDA, "Good Manufacturing Practice (GMP) Guidelines/Inspection Checklist," https://www.fda.gov/cosmetics/cosmetics-guidance-documents/good-manufacturing-practice-gmp-guidelinesinspection-checklist-cosmetics.

[50] FDA, "Inspection of Cosmetics," https://www.fda.gov/cosmetics/cosmetics-compliance-enforcement/inspection-cosmetics.

[51] FFDCA §721 (21 U.S.C. §379e); FFDCA §509 (21 U.S.C. §359). Premarket approval for color additives was established in 1960 with the Color Additive Amendments of 1960 (P.L. 86-618). A color additive is basically defined as a substance that, when added or applied to a cosmetic or the body, is capable of imparting coloring. Examples of cosmetics with color additives include lipstick, blush, and eye makeup. FFDCA §201(t) (21 U.S.C. §321(t)). Regarding (continued...)

generally are reviewed by FDA prior to marketing to ensure they meet FFDCA requirements for safety and effectiveness.[52]

After decades of minimal regulatory development for cosmetic products, on December 29, 2022, Congress enacted the Consolidated Appropriations Act, 2023 (CAA, 2023).[53] The CAA, 2023, included MoCRA,[54] which has established several new FDA authorities and responsibilities related to cosmetics regulation. Although MoCRA addresses many stakeholder concerns, some remain outstanding.

The Modernization of Cosmetics Regulation Act of 2022 (MoCRA)

Table 1. New FFDCA Sections Added by MoCRA Section 3502

FFDCA Section 604	Definitions
FFDCA Section 605	Adverse Events
FFDCA Section 606	Good Manufacturing Practice
FFDCA Section 607	Registration and Product Listing
FFDCA Section 608	Safety Substantiation
FFDCA Section 609	Labeling
FFDCA Section 610	Records
FFDCA Section 611	Mandatory Recall Authority
FFDCA Section 612	Small Businesses
FFDCA Section 613	Exemption for Certain Products and Facilities
FFDCA Section 614	Preemption

Source: P.L. 117-328, Division FF, Title III, Subtitle E—Cosmetics, §3502.

According to FDA, MoCRA is "the most significant expansion of the FDA's authority to regulate cosmetics since the [FFDCA] was passed in 1938."[55] The bulk of amendments made to the FFDCA are outlined in Section 3502 of MoCRA.[56] Broadly, MoCRA grants FDA a host of new authorities to protect consumer safety. These authorities include the ability, under some circumstances, for FDA to access specific types of cosmetic product records and issue mandatory cosmetic product recalls.[57] In addition, MoCRA establishes new industry requirements, including reporting adverse events to FDA, registering manufacturing and processing facilities with FDA, listing marketed products and their ingredients with FDA, and maintaining records of safety

safety substantiation expectations, see 21 C.F.R. §740.10 and FDA, "Food, Drug, and Cosmetic Products Warning Statements," 40 *Federal Register* 8912, 8916, March 3, 1975.

[52] FFDCA §505 (21 U.S.C. §355).

[53] P.L. 117-328.

[54] P.L. 117-328, Division FF, Title III, Subtitle E—Cosmetics.

[55] FDA, "Modernization of Cosmetics Regulation Act of 2022," https://www.fda.gov/cosmetics/cosmetics-laws-regulations/modernization-cosmetics-regulation-act-2022.

[56] MoCRA §3502.

[57] Ibid.

substantiation for cosmetic products.[58] Furthermore, MoCRA requires that industry follow forthcoming FDA regulations regarding good manufacturing practices (GMP) for cosmetic manufacturing facilities, fragrance allergen labeling, and standardized testing methods for detecting and identifying asbestos in talc-containing cosmetics.[59] For some small businesses, certain exemptions to specific requirements introduced under MoCRA may also apply.[60] These new requirements for cosmetics pursuant to MoCRA, as well as select enforcement mechanisms related to those requirements, are described below.

Cosmetic Regulatory Controls

Premarket Requirements

Unlike its authority over drugs and some devices, FDA does not have the authority, either pre- or post-MoCRA, to require premarket approval of cosmetics or their ingredients, except for color additives.[61] Prior to MoCRA, it was FDA's position that manufacturers were responsible for substantiating the safety of their products and ingredients before the products were marketed.[62]

With the passage of MoCRA, manufacturers are now statutorily required to substantiate the safety of their products. MoCRA also expands upon required recordkeeping by manufacturers, packers, and distributors. A "responsible person"[63] for a cosmetic product must ensure that it has been adequately tested to substantiate safety,[64] and that records supporting this substantiation are maintained by the same responsible person.[65] Certain products and facilities already regulated under Chapter V of FFDCA as a drug or device are exempt from MoCRA's safety substantiation and recordkeeping requirements.[66] However, if such a facility also manufactures or processes cosmetic products not subject to FFDCA Chapter V, the exemption does not apply to those particular cosmetic products.[67]

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[58] Ibid.

[59] Ibid.

[60] Ibid.

[61] FDA, "FDA Authority Over Cosmetics: How Cosmetics Are Not FDA-Approved, but Are FDA-Regulated," https://www.fda.gov/cosmetics/cosmetics-laws-regulations/fda-authority-over-cosmetics-how-cosmetics-are-not-fda-approved-are-fda-regulated. FFDCA §721 (21 U.S.C. §379e) addresses color additive safety.

[62] FDA, "Product Testing of Cosmetics," https://www.fda.gov/cosmetics/cosmetics-science-research/product-testing-cosmetics.

[63] Under the newly MoCRA-added FFDCA §604(4) (21 U.S.C. §364(4)), a "responsible person" is defined as "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 FFDCA] or section 4(a) of the Fair Packaging and Labeling Act."

[64] Under FFDCA §608(c)(1) (21 U.S.C. §364d(c)(1)), "adequate substantiation of safety" is defined as "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." In turn, "safe" means "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." It is noted that a cosmetic ingredient will not be considered injurious if it simply causes "minor and transient reactions or minor and transient skin irritations in some users." To determine safety, "the Secretary may consider, as appropriate and available, the cumulative or other relevant exposure to the cosmetic product, including any ingredient thereof." FFDCA §608(c)(2) (21 U.S.C. §364d(c)(2)).

[65] FFDCA §608(a) (21 U.S.C. §364d(a)). The coal-tar hair dye exemption is preserved under MoCRA, though a responsible person must maintain records related to the safety of coal-tar hair dye products. FFDCA §608(b) (21 U.S.C. §364d(b)). For more information on the coal-tar hair dye exemption, see footnote 96.

[66] FFDCA §613(a) (21 U.S.C. §364i(a)).

[67] FFDCA §613(b) (21 U.S.C. §364i(b)).

Enforcement

Among various enforcement mechanisms, under MoCRA, FDA may access and copy all records related to a cosmetic product that it reasonably believes is likely adulterated and a serious danger to humans. FDA may access and copy all records necessary to determine whether a cosmetic or related product is adulterated and a serious threat to human health, barring certain cosmetic formula, personnel, research, and financial data records. Accessible records include those related to safety substantiation data for cosmetic products and their ingredients.[68]

Registration and Listing

Prior to MoCRA, cosmetic manufacturers were not required to register their establishments or list their products with FDA. Instead, according to FDA regulations, owners or operators of establishments that manufactured or packaged cosmetics were *requested* to register with FDA.[69] Likewise, previous to MoCRA, manufacturers, packers, and distributors of cosmetic products were *requested* to file a cosmetic product ingredient statement (CPIS) containing certain information on each cosmetic product they marketed.[70] Entities could submit registration information and CPISs to FDA's Voluntary Cosmetic Registration Program (VCRP).[71]

Under MoCRA, both facility[72] registration and product listings are now required.[73] Existing and new facilities that manufacture or process cosmetic products for distribution in the United States must be registered with FDA. These registrations must be renewed every two years and updated within 60 days of a content revision.[74] Domestic facilities registering with FDA must provide the facility's name, physical address, email address, and phone number, while foreign facilities must provide contact information for an agent within the United States and, if available, electronic contact information. Additionally, a facility must include its registration number, if one was previously assigned, and all brand names associated with cosmetic products sold that were manufactured or processed at that facility. The product categories and responsible person for each cosmetic product manufactured or processed at the facility must also be provided.[75]

Each responsible person must also ensure the submission of a cosmetic product listing with FDA that is renewed and updated annually.[76] The product listing must contain the manufacturing or processing facility's registration number, the responsible person's name and contact number, the name of the cosmetic product as it appears on the label, the categories the cosmetic product falls under, and the product's listing number. Additionally, the product listing must include a list of the cosmetic product's ingredients, "including any fragrances, flavors, or colors, with each ingredient

[68] FFDCA §610 (21 U.S.C. §364f).

[69] 21 C.F.R. §710.

[70] 21 C.F.R. Part 720.

[71] FDA, "Voluntary Cosmetic Registration Program," https://www.fda.gov/cosmetics/voluntary-cosmetic-registration-program.

[72] A "facility" is generally defined as "any establishment (including an establishment of an importer) that manufactures or processes cosmetic products distributed in the United States." FFDCA §604(3) (21 U.S.C. §364(3)).

[73] FFDCA §607 (21 U.S.C. §364c).

[74] FFDCA §607(a) (21 U.S.C. §364c(a)).

[75] FFDCA §607(b) (21 U.S.C. §364c(b)).

[76] For existing facilities engaging in the manufacturing or processing of cosmetic products at the time of MoCRA's enactment, such registration must occur no later than December 29, 2023. For facilities that begin manufacturing or processing cosmetic products after MoCRA's enactment, such registration must occur within 60 days of initial activity or 60 days after December 29, 2023, whichever is later. FFDCA §607(a) (21 U.S.C. §364c(a)).

identified by name."[77] FDA will assign private product and facility identification numbers upon initial listing submission or registration.[78]

With the advent of MoCRA, FDA reported the VCRP had been discontinued and was no longer accepting submissions. In a draft guidance released in August 2023, FDA stated it is developing a new electronic submission portal for registration and listing information.[79] FDA noted that this new portal is expected to be available by October 2023.[80] In the interim, FDA requests that no registration or listing information be sent to the agency, adding that information previously listed in the VCRP will not be transferred.[81] In September 2023, FDA released for comment draft versions of the prospective electronic submission portal, Cosmetics Direct, and paper forms.[82]

MoCRA exempts certain small businesses[83] from both facility registration and product listing requirements.[84] However, a small business is not exempt from these requirements if it is engaged in the manufacturing or processing of higher-risk cosmetic products that "regularly come into contact with [the] mucus membrane of the eye under conditions of use that are customary or usual," "[c]osmetic products that are injected" (see the text box below), "intended for internal use," or that are meant to "alter [one's] appearance for more than 24 hours under conditions of use that are customary or usual and removal by the consumer is not part of such conditions of use that are customary or usual."[85]

Injected Cosmetics: Tattoo Inks

In 2019, one in three Americans reported having at least one tattoo. The ink used in tattooing, including for both decorative and medical purposes, is classified by FDA as a cosmetic. Consequently, the pigments used in tattoo inks are considered color additives and would typically be subject to premarket review. Traditionally, FDA has chosen not to enforce this authority, citing "competing public health priorities and a previous lack of evidence of safety problems specifically associated with these pigments." However, over the years, reports of adverse events related to tattooing have prompted increased FDA scrutiny. For example, there have been multiple voluntary recalls of tattoo inks, often due to microbial contamination. In one independent survey of sealed tattoo and permanent makeup inks in the United States cited by FDA, 49% were contaminated with microorganisms, including fungi and pathogenic bacteria. Other pigments that have been identified in tattoo inks are chemically similar or identical to industrial paints and printer inks. MoCRA specifically amends FFDCA by adding Section 612(b)(2), which ensures that injected cosmetics may not be exempted from future GMP and registration and product listing requirements. In June 2023, FDA released a draft guidance for industry entitled "Insanitary Conditions in the Preparation, Packing, and Holding of Tattoo Inks and the Risk of Microbial Contamination."

[77] FFDCA §607(c) (21 U.S.C. §364c(c)).

[78] FFDCA §607(d) (21 U.S.C. §364c(d)).

[79] FDA, *Registration and Listing of Cosmetic Product Facilities and Products: Guidance for Industry*, FDA-2023-D-1716, August 2023, p. 10.

[80] FDA, "FDA Issues Draft Guidance on Registration and Listing of Cosmetic Product Facilities and Products," https://www.fda.gov/cosmetics/cosmetics-news-events/fda-issues-draft-guidance-registration-and-listing-cosmetic-product-facilities-and-products?utm_medium=email&utm_source=govdelivery.

[81] FDA, "FDA Has Stopped Accepting Submissions to the Voluntary Cosmetic Registration Program (VCRP)," https://www.fda.gov/food/cfsan-constituent-updates/fda-has-stopped-accepting-submissions-voluntary-cosmetic-registration-program-vcrp.

[82] FDA, "FDA Issues Draft Guidance on Registration and Listing of Cosmetic Product Facilities and Products," https://www.fda.gov/cosmetics/cosmetics-news-events/fda-issues-draft-guidance-registration-and-listing-cosmetic-product-facilities-and-products.

[83] A "small business" is defined as a facility that has "average gross annual sales in the United States of cosmetic products for the previous 3-year period [that are] less than $1,000,000, adjusted for inflation." FFDCA §612(a) (21 U.S.C. §364h(a)).

[84] FFDCA §612(a) (21 U.S.C. §364h(a)).

[85] FFDCA §612(b) (21 U.S.C. §364h(b)).

Sources: Jessica C. Dixon, "The Perils of Body Art: FDA Regulation of Tattoo and Micropigmentation Pigments," *Administrative Law Review*, vol. 58, no. 3 (Summer 2006), p. 668; FDA, *Insanitary Conditions in the Preparation, Packing, and Holding of Tattoo Inks and the Risk of Microbial Contamination: Guidance for Industry*, FDA-2023-D-1083, June 2023; FDA, "Tattoos & Permanent Makeup: Fact Sheet," https://www.fda.gov/cosmetics/cosmetic-products/tattoos-permanent-makeup-fact-sheet; and S.W. Nho et al., "Microbiological Survey of Commercial Tattoo and Permanent Makeup Inks Available in the United States," *Journal of Applied Microbiology*, vol. 124, no. 5 (May 2018), p. 1296.

Additionally, certain products and facilities already regulated under Chapter V of FFDCA as a drug or device are exempt from facility registration and product listing requirements.[86] However, if such a facility also manufactures or processes cosmetic products not subject to FFDCA Chapter V, the exemption does not apply.[87]

Enforcement

Under MoCRA, if FDA determines that a cosmetic product has a reasonable probability of causing serious harm to human health, and if FDA has a reasonable belief that other products manufactured or processed at the same facility may be similarly affected, FDA may suspend the registration of the facility connected with such products.[88] If a facility's registration is suspended, any cosmetic product from that facility is barred from introduction or delivery for introduction into U.S. commerce.[89]

Before suspending a facility's registration, the FDA must provide notice to a responsible person for the facility specifying the reason for suspension, as well as an opportunity, within five business days of the notice, to present a plan to correct the issue identified.[90] FDA must provide the responsible person with the opportunity for an informal hearing to review actions required for registration reinstatement and why the facility registration should be reinstated.[91] If, based upon the evidence presented at this informal hearing, FDA determines there are inadequate grounds to continue the suspension, the facility registration will be restored.[92] However, if there is insufficient evidence presented, the suspension may continue, and FDA shall require the responsible person to submit a corrective action plan for review.[93]

If at any point FDA determines there is inadequate evidence to justify the continued suspension of a facility's registration, the registration shall be promptly reinstated.[94]

Adulterated and Misbranded Cosmetics

Since its passage in 1938, the FFDCA has prohibited the adulteration and misbranding of cosmetics. It also prohibits the introduction, receipt, and delivery of adulterated or misbranded cosmetics into interstate commerce and may take enforcement actions in such instances.[95]

A cosmetic is deemed adulterated—and potentially subject to FDA enforcement actions—if it

[86] FFDCA §613(a) (21 U.S.C. §364i(a)).

[87] FFDCA §613(b) (21 U.S.C. §364i(b)).

[88] FFDCA §607(f) (21 U.S.C. §364c(f)).

[89] Ibid.

[90] Ibid.

[91] Ibid.

[92] Ibid.

[93] Ibid.

[94] Ibid.

[95] FFDCA §§301(a)-(c) (21 U.S.C. §§331(a)-(c)).

- "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";[96]
- 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;[97]
- "has been manufactured or processed under conditions that do not meet the good manufacturing practice requirements of [FFDCA] 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 [FFDCA] section 608(c)."[98]

FDA has issued rules restricting the use of certain ingredients in cosmetic products. If FDA determines that a cosmetic's ingredients are poisonous or deleterious, that cosmetic is considered adulterated.[99] One example of an adulterated cosmetic is the use of henna, also known as mehndi, for temporary skin decoration.[100] Although the color additive used in henna products is allowed for hair dye, it is not allowed for direct skin contact.[101] Therefore, under FDA regulations, the use of henna for skin decoration renders the product "adulterated."[102]

Under the FFDCA, a cosmetic is deemed misbranded if

- the "labeling is false or misleading in any particular";
- the label lacks required information;[103]

[96] FFDCA §601 (21 U.S.C. §361). 21 C.F.R. §740.18. "The coal tar hair dye exemption allows coal tar hair dyes, not intended for use on eyelashes or eyebrows, to be marketed to consumers, even if they have been found to be injurious to the user under conditions of use" (see footnote 9, Bailey, p. 220). The label for coal-tar hair dye products must contain the statutorily required caution statement to be considered unadulterated, as well as "adequate directions for conducting such preliminary testing," which are not specified by FDA, but rather have been set as a self-evaluation patch test with a wait time of 48 hours by the industry-established Cosmetic Ingredient Review (CIR) (Bailey, pp. 219-220). If the coal-tar hair dye product does not contain that information, the coal-tar dye is "subject to regulation as a cosmetic coal additive and must be approved by FDA and listed in the CFR before marketing" (Bailey, p. 220). In 1952, a congressional committee report recommended the elimination of the coal-tar hair dye exemption (Hutt, "A History of Government Regulation of Adulteration and Misbranding of Cosmetics," p. 25). The Government Accountability Office (GAO) also issued a report in the late 1970s recommending the elimination of this exemption (Hutt, p. 27).

[97] FFDCA §601 (21 U.S.C. §361).

[98] FFDCA §601 (21 U.S.C. §361). Note that the last two bullets were added under MoCRA §3503.

[99] FFDCA §601(a) (21 U.S.C. §361(a)).

[100] Henna, also known as mehndi, is a form of temporary body-decoration that uses a colored paste, derived from the henna plant, directly applied to the skin. Carrie G. Basas, "Henna Tattooing: Cultural Tradition Meets Regulation," *Food and Drug Law Journal*, vol. 62, no. 4 (2007), pp. 779, 781.

[101] Ibid. FDA Import Alert 53-19, December, 2010, https://www.accessdata.fda.gov/cms_ia/importalert_138.html.

[102] Ibid.

[103] FFDCA §602 (21. U.S.C. §362). 21 C.F.R. §701.11 (identity labeling); 21 C.F.R. §701.12 (name and place of business or manufacturer, packer, or distributor); 21 C.F.R. §701.13 (declaration of net quantity of contents); 21 C.F.R. 701.3 (designation of ingredients); 21 C.F.R. §201.66 (format and content requirements for over-the-counter [OTC] drug product labeling); 21 C.F.R. §1.21 (failure to reveal material facts); 21 C.F.R. Parts 700 (general) and 740 (continued...)

- 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.[104]

Cosmetic products that meet the FPLA's definition of a "consumer commodity"[105] are considered misbranded under the FFDCA if they do not comply with FPLA's requirements.[106] Consumer commodity (retail) cosmetic products subject to the FPLA are required to bear a label that identifies the product and the name and place of business of the manufacturer, packer, or distributor, as well as the net quantity of contents on the principal display panel.[107] The net quantity of contents information must be declared in a legible type size that is uniform for packages of about the same size.[108] FDA's ingredient labeling rules, issued under the authority of the FPLA, require ingredients be listed on cosmetic products in descending order of predominance.[109]

(cosmetic product warning statements). Note that FFDCA §602(b) (21 U.S.C. §362(b)) has been amended under MoCRA §3503.

[104] FFDCA §602 (21 U.S.C. §362). FDA regulations provide that "[t]he labeling of a cosmetic which contains two or more ingredients may be misleading by reason ... of the designation of such cosmetic in such labeling by a name which includes or suggests the name of one or more but not all such ingredients, even though the names of all such ingredients are stated elsewhere in the labeling." 21 C.F.R. §701.1(b).

[105] "Consumer commodity" refers to those cosmetic items as defined by FFDCA §201(i) that are usually produced or distributed for sale for use by individuals. FPLA §10(a) (15 U.S.C. §1459(a)).

[106] FPLA §7(a) (15 U.S.C. §1456(a)). The FPLA provision on unfair and deceptive packaging and labeling makes it unlawful for persons engaged in packing or labeling consumer commodities to distribute, or cause to be distributed, a consumer commodity in a package or with a label that does not meet the FPLA provisions. FPLA §3(a) (15 U.S.C. §1452(a)).

[107] FPLA §4 (15 U.S.C. §1453). The principal display panel is "that part of a label that is most likely to be displayed, presented, shown, or examined under normal and customary conditions of display for retail sale." FPLA §10(f) (15 U.S.C. §1459(f)); 21 C.F.R. §701.10.

[108] FPLA §4(a)(3) (15 U.S.C. §1453(a)(3)); 21 C.F.R. §701.2 (form of stating labeling requirements).

[109] FPLA §5(c)(3) (15 U.S.C. §1454(c)(3)); 21 C.F.R. §701.3(a). However, FDA's regulation does "not require the declaration of incidental ingredients that are present in a cosmetic at insignificant levels and that have no technical or functional effect in the cosmetic," such as processing aids. 21 C.F.R. §701.3(l).

Enforcement

If a cosmetic is deemed adulterated or misbranded, FDA may take enforcement actions.[110] FDA may issue import alerts[111] and warning letters[112] to entities that manufacture or distribute a violative product. Other enforcement actions may include, with assistance from the Department of Justice, seeking an injunction (which could prevent a company from making or distributing the violative product), seizing the violative product, or seeking criminal penalties.[113]

Mandatory Recall

Prior to MoCRA, FDA did not have the authority to order mandatory recalls of cosmetic products. The agency could, however, request a company to voluntarily recall cosmetic products of concern.[114] Under MoCRA, a responsible person may still have the opportunity to voluntarily recall an adulterated or misbranded cosmetic; however, now FDA also has the authority to issue a mandatory recall.[115] A mandatory recall may be initiated "[i]f the Secretary 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," and the responsible person refuses to comply with a voluntary recall in a timely manner. Upon FDA issuing an order for a mandatory recall, the responsible person must immediately stop distributing the identified product.[116]

If such an order is issued, the responsible person is entitled to an opportunity for a timely informal hearing to review the adequacy of evidence for the order.[117] Depending on the outcome of this review, the order may be vacated, continued until a specified date, or amended to further require the recall of the cosmetic product, along with other measures regarding notifications, timetables, and updates.[118] FDA may require the responsible person to issue a notice of recall or ceased distribution to appropriate persons, including manufacturers, distributors, importers, and

[110] FDA, "FDA Authority Over Cosmetics: How Cosmetics Are Not FDA-Approved, but Are FDA-Regulated," https://www.fda.gov/cosmetics/cosmetics-laws-regulations/fda-authority-over-cosmetics-how-cosmetics-are-not-fda-approved-are-fda-regulated. Note, however, that FDA has enforcement discretion, meaning the agency may choose not to enforce certain provisions of the FFDCA depending on factors such as agency priorities and available resources. See CRS Report R43609, *Enforcement of the Food, Drug, and Cosmetic Act: Select Legal Issues* (particularly the "Does FDA Address Every Violation of the FD&C Act?" section).

[111] FDA, "Cosmetics Importers," https://www.fda.gov/cosmetics/cosmetics-international-activities/cosmetics-importers. Import alerts inform both FDA employees and members of the public that FDA has enough evidence to detain certain products that appear to be in violation of FDA regulations. For more information, see FDA, "Import Alerts," https://www.fda.gov/industry/actions-enforcement/import-alerts.

[112] Warning letters notify entities that FDA believes they have violated a regulation or law and sets forth what corrective action the entity needs to take to rectify the situation. Warning letters have been issued to a number of entities for a variety of cosmetics-related issues. For more information, see FDA, "Warning Letters Related to Cosmetics," https://www.fda.gov/cosmetics/cosmetics-compliance-enforcement/warning-letters-related-cosmetics.

[113] FDA, "FDA Authority Over Cosmetics: How Cosmetics Are Not FDA-Approved, but Are FDA-Regulated," https://www.fda.gov/cosmetics/cosmetics-laws-regulations/fda-authority-over-cosmetics-how-cosmetics-are-not-fda-approved-are-fda-regulated; FFDCA §§301-304 (21 U.S.C. §§331-334).

[114] FDA, "FDA Recall Policy for Cosmetics," https://www.fda.gov/cosmetics/cosmetics-recalls-alerts/fda-recall-policy-cosmetics; 21 C.F.R. §7.40(b); FDA, *Regulatory Procedures Manual*, July 2021, chap. 7, at https://www.fda.gov/media/71814/download.

[115] FFDCA §611 (21 U.S.C. §364g).

[116] FFDCA §611(a) (21 U.S.C. §364g(a)).

[117] FFDCA §611(b) (21 U.S.C. §364g(b)).

[118] FFDCA §611(c) (21 U.S.C. §364g(c)).

sellers.[119] If a product is recalled, FDA must ensure that a press release announcing the action is published, as well as appropriate alerts and public notices, to provide consumers and retailers with information about the cosmetic product and the circumstances of the recall. If an image of the product is available and appropriate, FDA shall also ensure the publication of that image on its website.[120] Certain products and facilities already regulated under Chapter V of FFDCA as a drug or device are exempt from MoCRA's mandatory recall authority.[121] However, if such a facility also manufactures or processes cosmetic products not subject to FFDCA Chapter V, the exemption does not apply to those particular cosmetic products.[122]

Enforcement

Again, under MoCRA, FDA may access and copy all records related to a cosmetic product that it reasonably believes is likely adulterated and a serious danger to humans.[123]

Labeling

Consumers may seek out particular cosmetics based on their labeling, such as those claiming to be made with organic ingredients or not tested on animals. However, FDA does not define certain terms used by manufacturers, including "organic" and "not tested on animals."[124] Though this specifically has not changed under MoCRA, the new act does introduce certain labeling requirements.[125]

Under MoCRA, cosmetic product labels must include a domestic address, domestic phone number, or electronic contact information (e.g., a website) through which a responsible person may be contacted regarding adverse events in response to usage of the product.[126] Cosmetic product labels must also identify each fragrance allergen contained in the product.[127] For cosmetic products intended only for professional use,[128] labels must include "a clear and prominent statement that the product shall be administered or used only by licensed professionals," and meet the labelling requirements of the FFDCA and FPLA Section 4(a).[129]

[119] FFDCA §611(e) (21 U.S.C. §364g(e)).

[120] FFDCA §611(f) (21 U.S.C. §364g(f)).

[121] FFDCA §613(a) (21 U.S.C. §364i(a)).

[122] FFDCA §613(b) (21 U.S.C. §364i(b)).

[123] FFDCA §610 (21 U.S.C. §364f). For further details on records access, see the "Enforcement" subsection in the "Premarket Requirements" section of this report.

[124] FDA, "'Organic' Cosmetics," https://www.fda.gov/cosmetics/cosmetics-labeling-claims/organic-cosmetics; FDA, "'Cruelty Free'/'Not Tested on Animals,'" https://www.fda.gov/cosmetics/cosmetics-labeling-claims/cruelty-freenot-tested-animals.

[125] MoCRA §3507 does, however, state that "[i]t is the sense of the Congress that animal testing should not be used for the purposes of safety testing on cosmetic products and should be phased out with the exception of appropriate allowances."

[126] FFDCA §609(a) (21 U.S.C. §364e(a)). FFDCA §609(a) is to take effect on December 29, 2024. MoCRA §3503(b)(2) (21 U.S.C. §364e note). FFDCA §609(a) does not apply if the cosmetic product or facility is already regulated under Chapter V of FFDCA as a drug or device. FFDCA §613(a) (21 U.S.C. §364i(a)). However, if such a facility also manufactures or processes cosmetic products not subject to FFDCA Chapter V, the exemption does not apply to those particular cosmetic products. FFDCA §613(b) (21 U.S.C. §364i(b)).

[127] FFDCA §609(b) (21 U.S.C. §364e(b)).

[128] In this context, "professional" is defined as "an individual who is licensed by an official State authority to practice in the field of cosmetology, nail care, barbering, or esthetics." FFDCA §609(c)(1) (21 U.S.C. §364e(c)(1)).

[129] FFDCA §609(c)(2) (21 U.S.C. §364e(c)(2)).

Enforcement

What constitutes a fragrance allergen is to be decided by FDA via rulemaking. Pursuant to this rulemaking, FDA is to consider "international, State, and local requirements for allergen disclosure, including the substance and format of requirements in the European Union, and may establish threshold levels of amounts of substances subject to disclosure."[130] A notice of proposed rulemaking must be issued no later than June 29, 2024, with a final rule promulgated no later than 180 days after the close of the proposed rule's public comment period.[131]

Good Manufacturing Practices

Prior to MoCRA, cosmetic product manufacturing was not subject to good manufacturing practices (GMP). Instead, FDA had published a draft guidance in 1997, which was later updated in 2008 and 2013, recommending GMP for cosmetic products.[132] FDA had also published a web page containing cosmetic establishment instructions, adapted from its Inspection Operations Manual, meant to "serve as guidelines for effective [establishment] self-inspection." FDA noted that "[a] good inspection score means that an establishment follows good manufacturing practices."[133]

With the passage of MoCRA, FDA has been tasked with establishing GMP via rulemaking.[134] Subsequently, FDA announced that it plans to withdraw or revise, then reissue, the 2013 draft guidance.[135] Under MoCRA, these GMP should be consistent with, to the degree practicable, national and international standards.[136] The intent of the GMP should be to "protect the public health and ensure that cosmetic products are not adulterated."[137] These requirements must also be scalable to the size and scope of the businesses subject to them to ensure that smaller businesses are not exposed to undue hardship.[138] In developing these GMP, FDA is to consult with cosmetic manufacturers, including smaller businesses.[139]

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[130] FFDCA §609(b) (21 U.S.C. §364e(b)).

[131] Ibid.

[132] FDA, *Guidance for Industry: Cosmetic Good Manufacturing Practices (Draft Guidance)*, June 2013.

[133] FDA, "Good Manufacturing Practice (GMP) Guidelines/Inspection Checklist for Cosmetics," https://www.fda.gov/cosmetics/cosmetics-guidance-documents/good-manufacturing-practice-gmp-guidelinesinspection-checklist-cosmetics.

[134] FFDCA §606(a) (21 U.S.C. §364b(a)).

[135] FDA, "Draft Guidance for Industry: Cosmetic Good Manufacturing Practices," https://www.fda.gov/regulatory-information/search-fda-guidance-documents/draft-guidance-industry-cosmetic-good-manufacturing-practices.

[136] FFDCA §606(a) (21 U.S.C. §364b(a)).

[137] Ibid.

[138] FFDCA §606(b) (21 U.S.C. §364b(b)). FFDCA Section 606 (GMP) does not apply to certain small businesses. FFDCA §612(a) (21 U.S.C. §364h(a)). However, a small business is not exempt from these GMP requirements if it is engaged in the manufacturing or processing of cosmetic products that "regularly come into contact with [the] mucus membrane of the eye under conditions of use that are customary or usual," "[c]osmetic products that are injected," "intended for internal use," or that are meant to "alter [one's] appearance for more than 24 hours under conditions of use that are customary or usual and removal by the consumer is not part of such conditions of use that are customary or usual." FFDCA §612(b) (21 U.S.C. §364h(b)). Additionally, certain products and facilities that are already regulated under Chapter V of FFDCA as a drug or device are exempt from GMP. FFDCA §613(a) (21 U.S.C. §364i(a)). However, if such a facility also manufactures or processes cosmetic products not subject to FFDCA Chapter V, the exemption does not apply to those particular cosmetic products. FFDCA §613(b) (21 U.S.C. §364i(b)).

[139] Ibid. FDA held a listening session to facilitate these consultations on June 1, 2023. FDA, "Public Meeting: Good Manufacturing Practices for Cosmetic Products," https://www.fda.gov/cosmetics/cosmetics-news-events/public-meeting-good-manufacturing-practices-cosmetic-products-06012023.

Enforcement

To ensure these GMP are followed, MoCRA allows for the inspection of facility records to demonstrate compliance during a larger facility inspection, an authority that predated MoCRA.[140] Regarding a timeline for the implementation of these GMP, MoCRA requires that a notice of proposed rulemaking be published no later than December 29, 2024, and that a final rule published no later than December 29, 2025.[141]

Reporting Adverse Events and Reactions to Cosmetics

Prior to MoCRA, FDA did not have the statutory authority to require cosmetic manufacturers to notify the agency of adverse events associated with their products, nor could it require cosmetic companies to report information received from consumers and others regarding adverse events.[142] Consequently, before MoCRA was enacted, FDA relied exclusively on voluntary reports of adverse events from cosmetic companies and consumers. The public could report adverse events to FDA via MedWatch, the FDA's product safety reporting program.[143]

Under MoCRA, a responsible person for a particular cosmetic product used domestically must report associated serious adverse events[144] to FDA.[145] It is expected that the responsible person will be informed of such events via the required contact information listed on the product's label.[146] Upon learning of an adverse event, a responsible person must relay this information to FDA, along with a copy of the specific product's label, within 15 business days.[147] For one year following this initial report, the responsible person must update FDA on "any new and material medical information" related to the serious adverse event within 15 business days of receipt.[148] In addition to reporting a serious adverse event, the responsible person must also maintain related records for a period of six years.[149] However, if a responsible person represents a small business that does not engage in the manufacturing or processing of higher-risk cosmetic products, records

[140] FFDCA §606(a) (21 U.S.C. §364b(a)). FDA has the authority to inspect any establishment in which cosmetics are manufactured, processed, packed, or held, before or after introduction into interstate commerce, and any vehicle used to transport such cosmetics in interstate commerce. FFDCA §704(a) (21 U.S.C. §374(a)).

[141] FFDCA §606(c) (21 U.S.C. §364b(c)).

[142] FDA, "How to Report a Cosmetic Related Complaint," https://www.fda.gov/cosmetics/cosmetics-compliance-enforcement/how-report-cosmetic-related-complaint.

[143] FDA, "MedWatch: The FDA Safety Information and Adverse Event Reporting Program," https://www.fda.gov/safety/medwatch-fda-safety-information-and-adverse-event-reporting-program.

[144] An "adverse event" is defined as "any health-related event associated with the use of a cosmetic product that is adverse." FFDCA §604(1) (21 U.S.C. §364(1)). A "serious adverse event" is categorized as "an adverse event that … results in … 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." Additionally, an event that "requires, based on reasonable medical judgment, a medical or surgical intervention to prevent … outcome[s] [previously] described" qualifies as a serious adverse event. FFDCA §604(5) (21 U.S.C. §364(5)).

[145] FFDCA §605(a) (21 U.S.C. §364a(a)).

[146] FFDCA §605(d) (21 U.S.C. §364a(d)).

[147] FFDCA §605(b)(1) (21 U.S.C. §364a(b)(1)). It appears that this information should still be submitted to FDA through MedWatch under MoCRA. FDA, "FDA Provides Draft Recommendations to Help Reduce Microbial Contamination in Tattoo Inks," https://www.fda.gov/news-events/press-announcements/fda-provides-draft-recommendations-help-reduce-microbial-contamination-tattoo-inks.

[148] FFDCA §605(b)(2) (21 U.S.C. §364a(b)(2)).

[149] FFDCA §605(e)(1) (21 U.S.C. §364a(e)(1)).

need only be maintained for three years.[150] Exemptions to the requirements surrounding serious adverse events may be established by regulation if FDA determines they "would have no significant adverse effect on public health."[151]

Additionally, if FDA reasonably believes that a fragrance or flavor ingredient contributed to a reported serious adverse event, the agency may request a written list of ingredients or ingredient categories in the fragrance or flavor of concern. A responsible person must convey this information to FDA within 30 days of the request.[152]

Enforcement

Under MoCRA, records kept regarding adverse events are subject to inspection.[153] A responsible person must allow an authorized person[154] access to these records during a larger facility inspection.[155]

Regulation of Specific Cosmetic Ingredients

Some ingredients used in cosmetic products have received particular attention due to concerns about their potential health risks. For example, there have been long-standing concerns regarding the use of coal-tar hair dyes as color additives. Concerns have also been raised about a group of synthetic compounds known as per- and polyfluoroalkyl substances (PFAS).[156] Both coal-tar hair dyes and PFAS have been the focus of congressional interest. However, these substances are not the only ingredients to have raised concern. FDA has online resources with information regarding other ingredients that consumers have inquired about, including talc, parabens, and phthalates, among others.[157]

Talc

Talc is a naturally occurring mineral composed of magnesium, silicon, oxygen, and hydrogen.[158] It is used in many cosmetics, often to "absorb moisture, … prevent caking, … make facial makeup opaque, … [and] improve the feel of a product."[159] Safety concerns regarding talc have existed for decades, with published literature in the 1960s suggesting a possible connection between talc and ovarian cancer, followed in the 1970s by concerns about asbestos contamination. Asbestos, also a naturally occurring mineral, is a proven carcinogen, and often

[150] Ibid.

[151] FFDCA §605(c) (21 U.S.C. §364a(c)).

[152] FFDCA §605(f) (21 U.S.C §364a(f)).

[153] FFDCA §605(e)(2) (21 U.S.C. §364a(e)(2)).

[154] An "authorized person" is "an officer or employee of the Department of Health and Human Services who has … appropriate credentials, as determined by the Secretary; and … been duly designated by the Secretary to have access to the records required under this section." FFDCA §605(e)(2)(B) (21 U.S.C. §364a(e)(2)(B)).

[155] FFDCA §605(e)(2) (21 U.S.C. §364a(e)(2)). FFDCA Section 605 does not apply if the cosmetic product or facility is already regulated under Chapter V of FFDCA as a drug or device. FFDCA §613(a) (21 U.S.C. §364i(a)). However, if such a facility also manufactures or processes cosmetic products not subject to FFDCA Chapter V, the exemption does not apply to those particular cosmetic products. FFDCA §613(b) (21 U.S.C. §364i(b)).

[156] FDA, "Per and Polyfluoroalkyl Substances (PFAS) in Cosmetics," https://www.fda.gov/cosmetics/cosmetic-ingredients/and-polyfluoroalkyl-substances-pfas-cosmetics.

[157] FDA, "Cosmetic Products & Ingredients," https://www.fda.gov/cosmetics/cosmetic-products-ingredients.

[158] FDA, "Talc," https://www.fda.gov/cosmetics/cosmetic-ingredients/talc.

[159] Ibid.

geologically forms in proximity to talc. Thus, when talc is mined, asbestos may sometimes become inadvertently commingled. FDA conducts ongoing research on the safety of talc, and in 2022, the agency published a report testing selected talc-containing cosmetics for asbestos.[160] Of the 50 cosmetic samples tested for the report, none contained asbestos.[161]

Due to the potential for talc to be contaminated by asbestos, FDA has noted the importance of selecting "talc mining sites carefully and tak[ing] steps to test the ore sufficiently."[162] Consequently, MoCRA directs FDA to, no later than December 29, 2023, "promulgate proposed regulations to establish and require standardized testing methods for detecting and identifying asbestos in talc-containing cosmetic products."[163] FDA must publish a final regulation within 180 days after the public comment period closes.[164]

PFAS

PFAS are a group of synthesized chemical compounds used in a range of industrial and consumer products, including cosmetics. Although PFAS are sometimes referred to as "forever chemicals," their persistence varies—both between longer-chain versus shorter-chain PFAS, and between more fluorinated versus less fluorinated PFAS—thus potential health effects may also vary.[165] PFAS ingredients may intentionally be added to certain cosmetics to improve their texture or consistency, condition and smooth skin, or give skin a shiny appearance.[166] PFAS are used as ingredients in lotions, cleansers, nail polishes, shaving creams, and some makeup products (e.g., lipstick, eyeliner, eyeshadow, and mascara).[167] PFAS may be unintentionally added to cosmetics via raw material impurities or the breakdown of PFAS ingredients that form other types of PFAS.[168] Although intentionally added PFAS ingredients are typically declared on a cosmetic product's label, unintentional PFAS may not be.[169]

According to FDA, research on the presence of PFAS in cosmetics is limited, and it is unclear whether PFAS in cosmetics are absorbed through the skin at levels harmful to humans. Studies have found varying concentrations of PFAS in cosmetics, ranging "from the parts per billion level

[160] Ibid.

[161] FDA, "FDA Releases Data from the Agency's 2022 Testing of Talc-Containing Cosmetic Products for Asbestos," https://www.fda.gov/food/cfsan-constituent-updates/fda-releases-data-agencys-2022-testing-talc-containing-cosmetic-products-asbestos.

[162] FDA, "Talc," https://www.fda.gov/cosmetics/cosmetic-ingredients/talc.

[163] MoCRA §3505(1) (21 U.S.C. §364d note).

[164] MoCRA §3505(2) (21 U.S.C. §364d note).

[165] CRS Report R45986, *Federal Role in Responding to Potential Risks of Per- and Polyfluoroalkyl Substances (PFAS)*.

> Any compound that has the chemical structure of at least one carbon atom attached to two or more fluorine atoms, or a chain of at least two carbon atoms attached to two or more fluorine atoms, may be considered a PFAS. Individual PFAS vary in terms of the numbers of fluorinated carbon atoms. The extent to which a chain of carbon atoms is fluorinated would determine whether a chemical may be considered a perfluoroalkyl substance or a polyfluoroalkyl substance. Given the possible variations in the length of the carbon chain, number of fluorinated carbon atoms, and other atoms attached to the chain, PFAS potentially could include thousands of chemical compounds if every possible combination were created. Ibid.

[166] FDA, "Per and Polyfluoroalkyl Substances (PFAS) in Cosmetics," https://www.fda.gov/cosmetics/cosmetic-ingredients/and-polyfluoroalkyl-substances-pfas-cosmetics.

[167] Ibid.

[168] Ibid.

[169] Ibid.

to the 100s of parts per million range."[170] FDA has called for more research into PFAS, and some Members of Congress have introduced legislation regarding research needs and the use of these compounds in certain consumer goods.[171]

MoCRA directly addresses this lack of information. Under Section 3506, FDA is tasked with assessing the use of PFAS "in cosmetic products and the scientific evidence regarding the safety of such use in cosmetic products, including any risks associated with such use."[172] FDA may consult with the National Center for Toxicological Research during this assessment.[173] FDA must publish a report summarizing the assessment on its website no later than December 29, 2025.[174]

FDA's Authority to Regulate Cosmetics in the Future

Prior to MoCRA, various stakeholders, GAO, and some Members of Congress identified limitations to FDA's authority to regulate cosmetics, noting that these limitations could expose consumers to unnecessary health risks. Some advocacy groups, for example, cited regulatory schemes adopted by foreign governments for cosmetic products and contended that these schemes allowed those governments a greater degree of control over the manufacturing and selling of cosmetic goods.[175] Some of the limitations identified by stakeholders included FDA's lack of authority to require premarket approval for cosmetic products,[176] order mandatory recalls,[177] require cosmetics facility registration,[178] make risk assessments more robust,[179] require mandatory reporting of adverse events related to cosmetics,[180] and issue cosmetic GMP regulations.[181]

The passage of MoCRA may alleviate many stakeholder concerns regarding FDA's cosmetic regulatory capacity, such as FDA's authority to issue a mandatory recall, require cosmetics

[170] Ibid.

[171] Ibid., and see, for example, the No PFAS in Cosmetics Act (117th Congress, S. 2047 and H.R. 3990).

[172] MoCRA §3506(a).

[173] Ibid.

[174] MoCRA §3506(b).

[175] See, for example, Brandon Inouye, Environmental Working Group, "On Protecting Consumers from Toxics in Cosmetics, U.S. Lags at Least 80 Countries," https://www.ewg.org/news-insights/news/2021/08/protecting-consumers-toxics-cosmetics-us-lags-least-80-countries.

[176] FDA, "Using Adverse Event Reports to Monitor Cosmetic Safety," https://www.fda.gov/cosmetics/how-report-cosmetic-related-complaint/using-adverse-event-reports-monitor-cosmetic-safety.

[177] See, for example, the Cosmetic Safety Enhancement Act of 2019 (116th Congress, H.R. 5279), the Safe Cosmetics and Personal Care Products Act of 2019 (116th Congress, H.R. 4296), and the Personal Care Products Safety Act (117th Congress, S. 2100).

[178] See, for example, the Cosmetic Modernization Amendments of 2017 (115th Congress, H.R. 575), the FDA Cosmetic Safety and Modernization Act (115th Congress, S. 2003), the Cosmetic Safety Enhancement Act of 2019 (116th Congress, H.R. 5279), the Safe Cosmetics and Personal Care Products Act of 2019 (116th Congress, H.R. 4296), and the Personal Care Products Safety Act (117th Congress, S. 2100).

[179] Grace Wallack, "Rethinking FDA's Regulation of Cosmetics," *Harvard Journal on Legislation*, vol. 56, no. 1 (2019), p. 336.

[180] See, for example, the Cosmetic Modernization Amendments of 2017 (115th Congress, H.R. 575), the FDA Cosmetic Safety and Modernization Act (115th Congress, S. 2003), the Cosmetic Safety Enhancement Act of 2019 (116th Congress, H.R. 5279), the Safe Cosmetics and Personal Care Products Act of 2019 (116th Congress, H.R. 4296), and the Personal Care Products Safety Act (117th Congress, S. 2100).

[181] See, for example, the FDA Cosmetic Safety and Modernization Act (115th Congress, S. 2003), the Cosmetic Safety Enhancement Act of 2019 (116th Congress, H.R. 5279), the Safe Cosmetics and Personal Care Products Act of 2019 (116th Congress, H.R. 4296), and the Personal Care Products Safety Act (117th Congress, S. 2100).

facility registration, require mandatory reporting of adverse events, and issue cosmetic GMP. Furthermore, the safety assessment report required for PFAS may allay some concerns about a lack of risk assessment robusticity.

However, even with the enactment of MoCRA, some previously identified issues remain—primarily the ongoing lack of premarket approval for cosmetics and many other ingredients of concern not selected for risk assessment. Among these unaddressed ingredients are parabens, "a family of related chemicals that are commonly used as preservatives" to prevent the contamination and spoilage of many cosmetic products.[182] The most common types of parabens found in cosmetics include methylparaben, propylparaben, butylparaben, and ethylparaben.[183] FDA has received many consumer inquiries about the safety of parabens due to public concerns, often raised by advocacy groups, primarily about potential links between the ingredient family and endocrine disruption.[184] According to the Centers for Disease Control and Prevention (CDC), "[h]uman health effects from environmental exposure to low levels of parabens are unknown."[185] In turn, FDA states that it does not currently "have information showing that parabens as they are used in cosmetics have an effect on human health."[186] However, FDA notes that it continuously reviews published studies on paraben safety and will alert industry and consumers if a health hazard is determined to exist.[187]

At present, the implementation of MoCRA introduces some uncertainties, such as certain enforcement timelines and what constitutes sufficient safety substantiation. Regarding timelines, some stakeholders have pointed out that enforcement timelines for certain provisions may differ; for example, adulteration provisions are slated for enforcement by the close of 2023, even though they are predicated in part on the promulgation of GMP, which could remain in the rulemaking process until the close of 2025.[188] Others have pointed out that MoCRA does not specifically state what will satisfy the requirement for adequate cosmetic product safety substantiation, and have noted that cosmetics companies may need to look elsewhere for guidance.[189] Moreover, in the context of these uncertainties, FDA has indicated that cosmetics regulation may be moved to a new office within FDA, in part to better implement MoCRA.[190]

[182] Examples of some cosmetic product types that may contain parabens include makeup, moisturizers, hair products, shaving products, and potentially some deodorants. FDA, "Parabens in Cosmetics," https://www.fda.gov/cosmetics/cosmetic-ingredients/parabens-cosmetics. Parabens are also used in many drug and food products. Ibid.

[183] Often, multiple parabens are used in combination with one another or other preservatives to increase efficacy. Ibid.

[184] See, for example, Campaign for Safe Cosmetics, "Parabens," https://www.safecosmetics.org/chemicals/parabens/; Environmental Working Group, "What Are Parabens, and Why Don't They Belong in Cosmetics?," https://www.ewg.org/what-are-parabens.

[185] CDC, "Parabens Factsheet," https://www.cdc.gov/biomonitoring/Parabens_FactSheet.html.

[186] FDA, "Parabens in Cosmetics," https://www.fda.gov/cosmetics/cosmetic-ingredients/parabens-cosmetics.

[187] Ibid.

[188] See, for example, Cooley, "FDA Regulatory Framework for Cosmetics Gets Major Overhaul," https://www.cooley.com/news/insight/2023/2023-01-06-fda-regulatory-framework-for-cosmetics-gets-major-overhaul.

[189] See, for example, Food and Drug Law Institute, "MoCRA is Here—Now What? Unpacking Litigation and Regulatory Risk for Cosmetics Brands Following MoCRA's Enactment," https://www.fdli.org/2023/02/mocra-is-here-now-what-unpacking-litigation-and-regulatory-risk-for-cosmetics-brands-following-mocras-enactment/.

[190] FDA, "FDA Provides Update on Proposed Human Foods Program and Office of Regulatory Affairs Restructuring," https://www.fda.gov/news-events/press-announcements/fda-provides-update-proposed-human-foods-program-and-office-regulatory-affairs-restructuring.

Conclusion

Historically, FDA's regulatory authority over cosmetics has been more limited and static than its regulatory authority over other FDA-regulated products. However, 84 years after the passage of the FFDCA, the enactment of MoCRA represents a significant expansion of FDA's cosmetic regulatory authority. MoCRA authorizes for appropriation funds through 2027 to accomplish its goals.[191] MoCRA's full effect will be determined over the course of its future implementation.

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For assistance with legal issues on this topic, congressional clients may contact Jennifer Staman, Legislative Attorney.

Disclaimer

[191] Under MoCRA Section 3508, "[t]here is authorized to be appropriated $14,200,000 for fiscal year 2023, $25,960,000 for fiscal year 2024, and $41,890,000 for each of fiscal years 2025 through 2027."