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FDA Regulation of Cosmetics and Personal Care Products

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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. Cosmetics 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 amended some of those provisions, they remain basically the same as those in the original FFDCA.

Some of FDA's authorities over cosmetic products are applicable to other FDA-regulated products, such as food, drugs, medical devices, and tobacco. For example, FDA has the authority to take certain enforcement actions—such as seizures, injunctions, and criminal penalties—against adulterated or misbranded cosmetics. In addition, FDA may conduct inspections of cosmetic manufacturers, as it may with drug and food companies, and prohibit imports 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, in many respects FDA's authority over cosmetics is less comprehensive than its authority over other FDA-regulated products. For example, the agency's authority is relatively limited when it comes to registration; testing; premarket notification, clearance, or approval; good manufacturing practices; mandatory risk labeling; adverse event reports; and recalls. Moreover, FDA does not impose registration requirements on cosmetic manufacturers. Rather, they may decide to comply with voluntary FDA regulations when they register with the agency. With the exception of color additives, FDA does not require premarket notification, safety testing, review, or approval of the chemicals used in cosmetic products. Although FDA has released good manufacturing practices (GMP) guidelines for cosmetic manufacturers, they are not required to use them, nor are manufacturers required to file ingredient information with, or report adverse reactions to, the agency. Instead, under a voluntary FDA program, cosmetic manufacturers and packagers may report the ingredients used in their product formulations. FDA does not have the authority to require a manufacturer to recall a cosmetic product from the marketplace, although the agency has issued general regulations on voluntary recalls. The agency's ability to issue regulations on cosmetic products is limited by the agency's statutory authorities or lack thereof.

As a result, cosmetics may appear to be more self-regulated than other FDA-regulated products. However, the manner in which a cosmetic product could or should be regulated is not always clear. FDA's guidelines give the cosmetic industry considerable flexibility regarding product development and claims. At issue is whether that flexibility and the extent of government oversight of cosmetic products are appropriate.

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Introduction

The U.S. cosmetic, beauty supply, and perfume retail industry consists of approximately 17,000 establishments, with a combined annual revenue of about \$23 billion.¹ Worldwide, the cosmetics and personal care products industry has more than \$250 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. Industry sales are concentrated in the following areas (percentage of sales by product category): (1) cosmetics, face cream, and perfume—75%; (2) hygienic products, including deodorant, shampoo, conditioner, hair color, and shaving products—20%; and (3) small appliances—4%.³

The Food and Drug Administration (FDA) has the authority 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.⁴ This report describes the definitional differences between cosmetics, drugs, and combination products; outlines the statutory provisions and rules under which FDA regulates cosmetics; and provides an overview of industry self-regulation programs. The report focuses on FDA regulation of cosmetics; it does not discuss Federal Trade Commission (FTC) regulation of cosmetics advertising or the regulation of potentially dangerous chemicals or pesticides of other products by other agencies.⁵

Cosmetics, Drugs, and Combination Products

This section discusses how the Federal Food, Drug, and Cosmetic Act (FFDCA) defines cosmetics and drugs, and how it differentiates between the two. This distinction, 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.⁶ Having a product classified as cosmetic only—not as a drug or combination product—saves manufacturers considerable time and expense and enables them to market their products with less regulatory oversight.

Cosmetics

FFDCA defines a “cosmetic” as a product that is intended to be applied to the human body for cleansing, beautifying, promoting attractiveness, or altering the appearance.⁷ The term covers a broad range of FDA-regulated products that may be used externally, internally, and with orifices.⁸

¹ First Research, *Industry Profile, Cosmetics, Beauty Supply, and Perfume Stores*, September 6, 2021.

² Personal Care Products Council, “About PCPC,” <https://www.personalcarecouncil.org/about-us/>.

³ First Research, *Industry Profile, Cosmetics, Beauty Supply, and Perfume Stores*, September 6, 2021.

⁴ Federal Food, Drug, and Cosmetic Act (FFDCA) §§601, 602 (21 U.S.C. §§361, 362).

⁵ Under 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 the Consumer Product Safety Act, which is enforced by the Consumer Product Safety Commission (15 U.S.C. §2052(a)(5)(H)).

⁶ FFDCA §509 (21 U.S.C. §359).

⁷ FFDCA §201(i) (21 U.S.C. §321(i)).

⁸ Examples of cosmetics “that may be introduced into the body are limited, but include mouthwashes, breath

Such cosmetics include products for the eyes, face, nails, hair, skin, and mouth, such as makeup, nail polish, hair dyes and coloring, sunscreens, fragrances, oral care, and bath products excluding soap.⁹ 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.¹⁰ In addition, coal tar hair dye was provided a limited exemption from the FFDCAs adulteration provisions (see the “Coal Tar Hair Dyes” section).¹¹

Drugs

The FFDCAs defines a “drug” as articles “intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease”; articles that are “intended to affect the structure or any function of the body”; and “articles intended for use as a component” of such drugs.¹²

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 of a new drug application (NDA),¹³ or an abbreviated NDA (ANDA) in the case of a generic drug, or (2) conform to a set of FDA requirements known as a monograph.¹⁴ 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

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.

⁹ 21 C.F.R. §720.4(c).

¹⁰ The FDA has defined “soap” in its regulations 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 which is not only intended for cleansing but for moisturizing or deodorizing and which also contains a medication which privates fungal growth may be regulated as both a cosmetic and drug product. The intended use of a product is determined by several factors, including claims stated on the product labeling, 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 Food and Drug Administration (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>.

¹¹ FFDCAs §601(a) (21 U.S.C. §361(a)).

¹² FFDCAs §201(g)(1) (21 U.S.C. §321(g)(1)).

¹³ FFDCAs §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. Among other considerations, the agency approves an NDA after examining reports and investigations that demonstrate the drug’s safety and effectiveness.

¹⁴ An OTC drug monograph functions similarly 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*.

shampoos or antiperspirants) will be considered to be generally recognized as safe and effective.¹⁵ Monographs also indicate how OTC drugs must be labeled so they are not deemed misbranded.¹⁶

Drug manufacturers must comply with Current Good Manufacturing Practices (CGMP) rules for drugs.¹⁷ Failure to comply may cause a drug to be considered adulterated.¹⁸ Among other requirements, drug manufacturers are required to register their facilities,¹⁹ list their drug products with the agency,²⁰ and report adverse events to FDA.²¹

Cosmetics Containing Drug Ingredients

Although the terms “cosmetic drugs” or “cosmeceuticals” have been used to refer to combination cosmetic-drug products, no statutory or regulatory definition exists for this terminology.²² Cosmetic-drug combination products are subject to FDA’s regulations for both cosmetics and drugs.²³ For example, combination drug and cosmetic products must meet both OTC drug and cosmetic labeling requirements. The drug ingredients must be listed alphabetically as “Active Ingredients,” followed by cosmetic ingredients either listed in a descending order of predominance as “Inactive Ingredients” or listed as “Inactive Ingredients” in particular groups, such as concentrations of greater than 1% of color additives.²⁴

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 intent or the intended use.²⁵ 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.²⁶ For example, if a lipstick (a cosmetic) contains sunscreen (a drug), the mere inclusion of the term “sunscreen” in the product’s labeling requires the product to be regulated as a drug as well as a

¹⁵ 21 C.F.R. Part 330; 21 C.F.R. §§331-358.

¹⁶ Such labeling includes a Drug Facts panel, which lists the product’s active ingredients as well as the drug’s purposes, uses, and applicable warnings, directions, inactive ingredients, other information, and a telephone number for questions about the product. See 21 C.F.R. §201.66(c).

¹⁷ Current Good Manufacturing Practices set the minimum requirements for the methods, facilities, and controls used in the manufacturing, processing, and packaging 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>.

¹⁸ FFDC 501(a)(2)(B) (21 U.S.C. §351(a)(2)(B)).

¹⁹ FFDC 510 (21 U.S.C. §360), 21 C.F.R. Part 207.

²⁰ *Ibid.*

²¹ 21 C.F.R. §310.305; 21 C.F.R. §314.80; 21 C.F.R. §314.98.

²² FDA, “Cosmeceutical,” <https://www.fda.gov/cosmetics/cosmetics-labeling-claims/cosmeceutical>.

²³ 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>.

²⁴ 21 C.F.R. §70.3(a) and (f) (setting forth the required designations of ingredients for the labeling of cosmetic products).

²⁵ 58 *Federal Register* 28194, 28204 (May 12, 1993). “When an ingredient can be used for either drug or cosmetic purposes, its regulatory status as a drug or cosmetic, or both, is determined by objective evidence of the distributor’s intent.”

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>.

cosmetic.²⁷ The text box below provides examples of other combination products and compares cosmetic/drug classifications.²⁸

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 anticavity 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 Barton Hutt, “Legal Distinction in USA between Cosmetic and Drug,” in *Cosmeceuticals and Active Cosmetics: Drugs versus Cosmetics*, p. 630 (Peter Elsner & Howard Maibach, eds., 2nd ed. 2005).

Overview of FDA’s Authority to Regulate Cosmetics

Prior to the enactment of the Federal Food, Drug, and Cosmetic Act (FFDCA) in 1938, cosmetics were not regulated by the federal government.²⁹ Instead, they were regulated under a collection of state laws that had been enacted to regulate food and drugs.³⁰ At that time, several “cosmetics and drugs were made from the same natural materials” and the “laws did not include explicit definitions of the products regulated.”³¹ 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.³² The FFDCA also established uniform regulation of FDA-regulated cosmetic products nationwide.³³

²⁷ 21 C.F.R. §700.35 “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.”

²⁸ 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>.

²⁹ Senate Committee on Commerce, S.Rept. 91, 75th Cong., p. 5, 1937.

³⁰ Peter Barton Hutt, “A History of Government Regulation of Adulteration and Misbranding of Cosmetics,” in *Cosmetic Regulation in a Competitive Environment*, Norman F. Estrin & James M. Akerson eds. 2000 (hereafter, Hutt, “A History of Government Regulation of Adulteration and Misbranding of Cosmetics”).

³¹ Hutt, “A History of Government Regulation of Adulteration and Misbranding of Cosmetics,” p. 2.

³² Hutt, “A History of Government Regulation of Adulteration and Misbranding of Cosmetics,” p. 5-6; Jacqueline A. Greff, *Regulation of Cosmetics That are Also Drugs*, 51 Food & Drug L. J. 243, 244 (1996).

³³ Hutt, “A History of Government Regulation of Adulteration and Misbranding of Cosmetics,” p. 2-3, 6.

In addition to their regulation under the FFDCFA, cosmetics are regulated under the Fair Packaging and Labeling Act (FPLA) and related regulations.³⁴ 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.”³⁵ For the purposes of “for professional use only” labeling (discussed below), 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.”³⁶

The FFDCFA prohibits the adulteration and misbranding of cosmetics and the introduction, receipt, and delivery of adulterated or misbranded cosmetics into interstate commerce.³⁷ With the exception of provisions governing color additives, the FFDCFA statutory provisions that address cosmetics have remained basically unchanged since 1938, although the cosmetic industry currently encompasses a greater number of products with different uses than those on the market more than 80 years ago. However, the concerns of consumer and industry groups today are similar to those expressed prior to the enactment of the FFDCFA. Consumer groups have raised concerns about particular ingredients, and states have legislated, or considered legislating, in areas not covered by the FFDCFA or federal regulations.³⁸

FDA has certain regulations and procedures for cosmetics that manufacturers may voluntarily choose to comply with, even though similar regulations and procedures are mandatory for other FDA-regulated products (such as drugs). For example, FDA has promulgated regulations for voluntary registration of establishments that manufacture or package cosmetics.³⁹ In contrast, mandatory registration requirements exist for other FDA product manufacturers (e.g., drugs, food).⁴⁰ Moreover, unlike drug manufacturers, cosmetic manufacturers are not required to submit safety data on ingredients or to report cosmetic-related injuries to FDA.⁴¹ Instead, under a voluntary FDA program, cosmetic manufacturers and packagers may choose to report the ingredients used in their product formulations.⁴² Furthermore, consumers, health care professionals, and cosmetic manufacturers may voluntarily report adverse reactions to cosmetics to FDA.⁴³ Finally, FDA does not have mandatory recall authority to require a cosmetic

³⁴ 15 U.S.C. §1451 et seq.

³⁵ 15 U.S.C. §1459(a).

³⁶ 15 U.S.C. §1452(b).

³⁷ FFDCFA §301(a)-(c) (21 U.S.C. §331(a)-(c)). See “Adulterated and Misbranded Cosmetics”.

³⁸ See for example Monica Amarelo, *California First State To Ban 24 Toxic Chemicals in Personal Care Products and Cosmetics*, Environmental Working Group, September 30, 2020, <https://www.ewg.org/news-insights/news-release/california-first-state-ban-24-toxic-chemicals-personal-care-products-and>.

³⁹ 21 C.F.R. Part 710; FDA, “Voluntary Cosmetic Registration Program,” <https://www.fda.gov/cosmetics/voluntary-cosmetic-registration-program>.

⁴⁰ 21 U.S.C. §350d (food); 21 U.S.C. §360 (drugs and devices); 21 U.S.C. §387e (tobacco).

⁴¹ Donald R. Johnson, *Not in my Makeup: The Need for Enhanced Pre-market Regulatory Authority Over Cosmetics in Light of Increased Usage of Engineered Nanoparticles*, 26 J. Contemp. Health L. & Policy 82, 114, 2009.

⁴² 21 C.F.R. §720.4.

⁴³ 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>.

manufacturer to recall a product from the marketplace. However, the agency may request a voluntary recall, and FDA has issued general regulations outlining its expectations of manufacturers during such a recall.⁴⁴ Although FDA does not have the authority to require compliance with these regulations, it may take action against adulterated or misbranded cosmetics.⁴⁵

FDA's authority over cosmetics is 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.⁴⁶ FDA has released GMP guidelines for cosmetic manufacturers⁴⁷ and stated that “[f]ailure to adhere to GMP may result in an adulterated or misbranded product.”⁴⁸ With the exception of color additives (see the “Color Additives” section), FDA does not review or approve ingredients used in cosmetic products, although cosmetic manufacturers are responsible for substantiating the safety of their products and ingredients before marketing.⁴⁹ This is in contrast to drugs, which generally are reviewed by FDA prior to marketing to assure that they meet FDCA requirements for safety and effectiveness.⁵⁰

Adulterated and Misbranded Cosmetics

The FDCA prohibits 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.⁵¹ The following sections describe the parameters regarding the adulteration and misbranding of cosmetics.

Adulteration

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

- “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”;⁵²

⁴⁴ 21 C.F.R. Part 7, Subpart C.

⁴⁵ FDCA §§301-04.

⁴⁶ The FDA's authority over cosmetic products is based primarily on the FDCA provisions on cosmetics, color additives, and drugs. The agency also has authority under the 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).

⁴⁷ FDA, “Good Manufacturing Practice (GMP) Guidelines/Inspection Checklist”, <https://www.fda.gov/cosmetics/cosmetics-guidance-documents/good-manufacturing-practice-gmp-guidelinesinspection-checklist-cosmetics>.

⁴⁸ FDA, Inspection of Cosmetics: An Overview, <https://www.fda.gov/cosmetics/cosmetics-compliance-enforcement/inspection-cosmetics>.

⁴⁹ FDCA §721 (21 U.S.C. §379e); FDCA §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. FDCA §201(t) (21 U.S.C. §321(t)).

⁵⁰ FDCA §505 (21 U.S.C. §355).

⁵¹ FDCA §301(a)-(c) (21 U.S.C. §331(a)-(c)).

⁵² 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 11, Bailey, p. 220). The label for coal tar hair dye products must contain the statutorily required caution statement in order to not be considered to be adulterated, as well as “adequate directions for conducting such

- 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”; or
- contains an unsafe color additive, except for hair dyes.⁵³

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.⁵⁴ One example of an adulterated cosmetic is the use of henna for a temporary skin decoration known as mehndi.⁵⁵ Although the color additive used in these products is approved for hair dye, it is not permitted for skin contact.⁵⁶ Therefore, under FDA regulations, the use of the dye product for skin decoration makes the product “adulterated.”⁵⁷

Misbranding and Mislabeling Claims

Under the FFDCFA, a cosmetic is deemed misbranded if

- the “labeling is false or misleading in any particular”;
- the label lacks required information;⁵⁸
- 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 1970.⁵⁹

preliminary testing,” which are not specified by the 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) issued a report in the late 1970s recommending the elimination of this exemption (Hutt, p. 27).

⁵³ FFDCFA §601 (21 U.S.C. §361).

⁵⁴ 21 C.F.R. Part 700.

⁵⁵ Henna is “a coloring made from a plant” that is directly applied to the skin “in the body-decorating process known as mehndi.” FDA, “Temporary Tattoos & Henna/Mehndi and ‘Black Henna’: Fact Sheet,” <https://www.fda.gov/cosmetics/cosmetic-products/temporary-tattoos-hennamehndi-and-black-henna-fact-sheet>.

⁵⁶ FDA Import Alert 53-19, December, 2010, https://www.accessdata.fda.gov/cms_ia/importalert_138.html.

⁵⁷ Ibid.

⁵⁸ 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 and 21 C.F.R. §201.66 (designation of ingredients, including active drug ingredients if the cosmetic product is also an over-the-counter drug product); 21 C.F.R. §1.21 (failure to reveal material facts on labeling); 21 C.F.R. Parts 700 and 740 (warning language or requirements for certain cosmetic products).

⁵⁹ FFDCFA §602 (21 U.S.C. §362). FDA regulations provide that “[t]he labeling of a cosmetic which contains two or

Cosmetic products that meet the FPLA’s definition of “consumer commodities”⁶⁰ are considered misbranded under the FFDCA if they do not comply with FPLA’s requirements.⁶¹ 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.⁶² The net quantity of contents information must be declared in a legible type size that is uniform for packages of about the same size.⁶³ FDA’s ingredient labeling rules, issued under the authority of the FPLA, require ingredients to be listed on cosmetic products in descending order of predominance.⁶⁴

Enforcement

If a cosmetic is deemed adulterated or misbranded, FDA may take enforcement actions.⁶⁵ FDA may issue import alerts⁶⁶ and warning letters⁶⁷ 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.⁶⁸ In addition, a cosmetic company may be subject to a product liability lawsuit for a product that is determined to be adulterated or misbranded, or that lacks adequate warning statements.⁶⁹

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). FDA regulations also provide that “[a]ny representation in labeling or advertising that creates an impression of official approval because of [the filing of Form FDA 2512, Cosmetic Product Ingredient Statement] will be considered misleading.” 21 C.F.R. §720.9.

⁶⁰ “Consumer commodity” refers to those cosmetic items as defined by the FFDCA that are usually produced or distributed for sale for use by individuals. 15 U.S.C. §§1459(a).

⁶¹ Although FDA may take enforcement action against consumer commodity products deemed misbranded because they do not conform to FPLA provisions, the relevant penalty provisions of the FFDCA do not apply to products deemed misbranded because they violate the FPLA’s provision on unfair and deceptive packaging and labeling. That FPLA provision 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. 15 U.S.C. §1452(a); 15 U.S.C. §1456(a).

⁶² 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.” 15 U.S.C. §1459(f); 21 C.F.R. §701.10.

⁶³ 15 U.S.C. §1453(a)(3); 21 C.F.R. §701.2—Form of stating labeling requirements.

⁶⁴ 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).

⁶⁵ For a summary of FDA Enforcement Activity by fiscal year, see, FDA, “Enforcement Activity,” <https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/compliance-actions-and-activities/enforcement-activity>.

⁶⁶ Import alerts inform both FDA employees and members of the public that FDA has enough evidence to detain all shipments from a company that is in violation of FDA regulations. For more information, see FDA, “Import Alerts,” <https://www.fda.gov/industry/actions-enforcement/import-alerts>.

⁶⁷ Warning letters notify entities that FDA believes they have violated a regulation or law, and sets forth what corrective action they to take to rectify the situation. Warning letters have been issued to a number of entities for a variety of cosmetic-related issues. For more information, see FDA, “Warning Letters Related to Cosmetics,” <https://www.fda.gov/cosmetics/cosmetics-compliance-enforcement/warning-letters-related-cosmetics>.

⁶⁸ FFDCA §§301-04 (21 U.S.C. §§331-334).

⁶⁹ Nicole Abramowitz, *The Dangers of Chasing Youth: Regulating the Use of Nanoparticles in Anti-Aging Products*, University of Illinois, *Journal of Law, Technology, and Policy* (spring 2008), pp. 208-209.

FDA's authority to regulate cosmetics allows it to conduct inspections of cosmetic establishments, without notifying the establishments in advance, as long as the inspections occur "at reasonable times and within reasonable limits and in a reasonable manner."⁷⁰ FDA conducts inspections to ensure product safety and to evaluate cosmetic products for potential adulteration or misbranding violations.⁷¹ The agency may decide to inspect a facility based on consumer or industry complaints, the establishment's compliance history, or FDA surveillance initiatives.⁷² The agency may collect samples for examination and analysis during plant and import inspections, and follow up on complaints of adverse events alleged to be caused by a given cosmetic product.⁷³ The agency does not have a required schedule for inspecting cosmetic facilities.

Consumer organizations and interested persons may submit citizen petitions to FDA asking the agency to determine whether a cosmetic is adulterated because it contains a particular deleterious substance.⁷⁴ For example, in 1996, FDA denied such a petition after conducting a review of the cosmetic ingredient urocanic acid and "conclud[ing] that the scientific evidence did not establish urocanic acid to be a deleterious substance."⁷⁵

Voluntary Recalls

FDA does not have the authority to order a mandatory recall of cosmetic products. In contrast, the agency does have the authority to order recalls of food (including dietary supplements),⁷⁶ infant formula,⁷⁷ medical devices,⁷⁸ controlled substances,⁷⁹ human tissue products,⁸⁰ biologics,⁸¹ and tobacco products.⁸² Although FDA may not require the recall of cosmetic products, the agency may request a company to voluntarily recall them.⁸³ Manufacturers and distributors may undertake voluntary recalls to remove from the market violative products that are hazardous to health, defective, or grossly deceptive, and "against which the agency would initiate legal action."⁸⁴

When a cosmetics firm conducts a product recall, FDA may take an active role in monitoring the recall by reviewing the firm's status reports and conducting its own audit checks to verify the recall's effectiveness.⁸⁵ FDA evaluates the health hazard presented by the product and classifies

⁷⁰ FFDCFA §704(a) (21 U.S.C. §374(a)).

⁷¹ FDA, "Inspection of Cosmetics: An Overview," <https://www.fda.gov/cosmetics/cosmetics-compliance-enforcement/inspection-cosmetics>.

⁷² *Ibid.*

⁷³ *Ibid.*; FFDCFA §704(c) (21 U.S.C. §374(c)).

⁷⁴ 21 C.F.R. §10.30. See footnote 11 (Bailey, p. 218).

⁷⁵ *Ibid.*

⁷⁶ FFDCFA §423 (21 U.S.C. §350l).

⁷⁷ FFDCFA §412(f) (21 U.S.C. 350a(f)).

⁷⁸ FFDCFA §518(e) (21 U.S.C. 360h(e)).

⁷⁹ FFDCFA §569D (21 U.S.C. §360bbb-8d).

⁸⁰ PHSFA §361 (42 U.S.C. §264); 21 C.F.R. §1271.440.

⁸¹ PHSFA §351(d) (42 U.S.C. §262(d)).

⁸² FFDCFA §908(c) (21 U.S.C. 387h(c)).

⁸³ 21 C.F.R. §7.40(b); *FDA Regulatory Procedures Manual*, Chapter 7: Recall Procedures, <http://www.fda.gov/downloads/ICECI/ComplianceManuals/RegulatoryProceduresManual/UCM074312.pdf>.

⁸⁴ 21 C.F.R. §7.3(g); 21 C.F.R. §7.40(a).

⁸⁵ 21 C.F.R. §7.53.

the degree of hazard posed by the recalled product, whether it is a cosmetic or another FDA-regulated product (see the **text box** below).⁸⁶ Either FDA or the cosmetic company issues a public notification of the recall.⁸⁷ The firm is responsible for the disposition of the recalled product, whether it is destroyed or brought into compliance.⁸⁸

Classification of Recall, by Degree of Health Hazard

FDA evaluates the health hazard presented by a recalled product and assigns a classification to indicate the degree of hazard.

Class I: the use of, or exposure to, a violative product will likely cause adverse health consequences or death.

Class II: the use of, or exposure to, a violative product may cause temporary or medically reversible adverse health consequences, or the probability of serious adverse health consequences is remote.

Class III: the use of, or exposure to, a violative product is unlikely to cause adverse health consequences.

Source: 21 C.F.R. §7.3(m).

Premarket Approval

In contrast to FDA’s authority over drugs and some devices, FDA does not have the authority to require premarket approval of cosmetics or their ingredients, except for color additives (see the “Color Additives” section).⁸⁹ Because there are no statutory requirements for premarket approval of cosmetic ingredients, manufacturers are responsible for substantiating the safety of their products and ingredients before the products are marketed to ensure that they are not adulterated or misbranded.⁹⁰ Products that do not have their safety adequately substantiated prior to marketing are considered misbranded, unless they bear a warning label that states: “The safety of this product has not been determined.”⁹¹ The Government Accountability Office (GAO) has noted that FDA’s regulation requiring warning labels “cannot be effectively enforced because FDA does not have the authority to require cosmetic manufacturers to test their products for safety or make their test results available to FDA.”⁹²

FDA has issued regulations that prohibit or limit the use of certain ingredients in cosmetics or require warning statements on the labels of certain types of cosmetics.⁹³ For example, FDA issued

⁸⁶ 21 C.F.R. §7.41.

⁸⁷ 21 C.F.R. §§7.42(b)(2), 7.50.

⁸⁸ 21 C.F.R. §§7.53, 7.55.

⁸⁹ 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>. FFDC A §721 (21 U.S.C. 379e) addresses color additive safety.

⁹⁰ The FDA has said that “the safety of a product can be adequately substantiated through (a) reliance on already available toxicological test data on individual ingredients and on product formulations that are similar in composition to the particular cosmetic, and (b) performance of any additional toxicological and other tests that are appropriate in light of such existing data and information. Although satisfactory toxicological data may exist for each ingredient of a cosmetic, it will still be necessary to conduct some toxicological testing with the complete formulation to assure adequately the safety of the finished cosmetic.” FDA, *Cosmetic Products: Warning Statements/Package Labels*, 40 *Federal Register* 8912, 8916, March 3, 1975; FDA, “Product Testing of Cosmetics,” <https://www.fda.gov/cosmetics/cosmetics-science-research/product-testing-cosmetics>.

⁹¹ 21 C.F.R. §740.10.

⁹² The Food and Drug Administration’s Regulation of Cosmetics: Testimony before the Subcommittee on Oversight and Investigations of the House Committee on Interstate and Foreign Commerce, p. 7, February 3, 1978, statement of Gregory J. Ahart, Director, Human Resources Division, GAO, <https://www.gao.gov/assets/104834.pdf>.

⁹³ FDA, “Prohibited & Restricted Ingredients in Cosmetics,” <https://www.fda.gov/cosmetics/cosmetics-laws->

a rule banning the use of methylene chloride in cosmetics after concluding that “methylene chloride is a poisonous or deleterious substance that may render cosmetic products injurious to users,” due to the potential cancer risks of exposure to the substance.⁹⁴ A cosmetic shown to contain methylene chloride would be considered adulterated, and FDA could take an enforcement action.

Except for color additives and those cosmetic ingredients prohibited or restricted for use by a specific regulation, any ingredient used in the formulations of cosmetics is allowed, provided that the safety of the ingredient has been adequately substantiated, it is properly labeled, and its use does not cause the product to be adulterated or misbranded under the law. FDA’s guidance document on inspections of cosmetic product manufacturers recommends cross-referencing the *Code of Federal Regulations* (C.F.R.) to ensure compliance with additional cosmetic ingredient requirements.⁹⁵

FDA Regulations for Certain Cosmetic Ingredients or Products

FDA has either restricted the use of the following ingredients in cosmetics or required warning statements on the labels of certain types of cosmetics.

21 C.F.R. §250.250—Hexachlorophene

21 C.F.R. §700.11—Cosmetics containing bithionol

21 C.F.R. §700.13—Use of mercury compounds in cosmetics, including use as skinbleaching agents in cosmetic reparations also regarded as drugs

21 C.F.R. §700.14—Use of vinyl chloride as an ingredient including propellant of cosmetic aerosol products

21 C.F.R. §700.15—Use of certain halogenated salicylanilides as ingredients in cosmetic products

21 C.F.R. §700.16—Use of aerosol cosmetic products containing zirconium

21 C.F.R. §700.18—Use of chloroform as an ingredient in cosmetic products

21 C.F.R. §700.19—Use of methylene chloride as an ingredient of cosmetic products

21 C.F.R. §700.23—Chlorofluorocarbon propellants

21 C.F.R. §700.27—Use of prohibited cattle materials in cosmetic products

21 C.F.R. §700.35—Cosmetics containing sunscreen ingredients

21 C.F.R. §740.10—Labeling of cosmetic products for which adequate substantiation of safety has not been obtained

21 C.F.R. §740.11—Cosmetics in self-pressurized containers

21 C.F.R. §740.12—Feminine deodorant sprays

21 C.F.R. §740.17—Foaming detergent bath products

21 C.F.R. §740.19—Suntanning preparations

Source: Title 21, *Code of Federal Regulations*.

Testing and Safety of Cosmetic Ingredients

As mentioned, manufacturers are responsible for substantiating the safety of both the ingredients and finished cosmetic products prior to marketing.⁹⁶ FDA has advised cosmetic firms to employ

regulations/prohibited-restricted-ingredients-cosmetics.

⁹⁴ 54 *Federal Register* 27328, 27340, June 29, 1989; 21 C.F.R. §700.19(b), “Any cosmetic product that contains methylene chloride as an ingredient is deemed adulterated and is subject to regulatory action under sections 301 and 601(a) of the [FFDCA].”

⁹⁵ FDA, *Cosmetic Good Manufacturing Practices* (June 2013), p. 8, <https://www.fda.gov/media/86366/download>.

⁹⁶ 21 C.F.R. §740.10; 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->

appropriate and effective testing to substantiate the safety of their products.⁹⁷ However, the FFDCAs and FDA regulations do not specify how cosmetic products and their ingredients are to be tested.⁹⁸

Traditional testing of cosmetic ingredients has used animal models to evaluate the safety of the ingredients on the human body. Such tests have historically measured skin irritancy, eye irritation, allergic reactions, and toxicity caused by various ingredients used in the manufacture of cosmetics on several different animals, including rabbits, mice, rats, and guinea pigs.⁹⁹ Although animal testing may be used to substantiate product safety, FDA does not specifically require such testing.¹⁰⁰

Concerns about the safety of cosmetics have been raised over the years, as have the concerns of animal rights advocates seeking an end to animal testing.¹⁰¹ FDA has said that it follows applicable laws on animal testing, such as the Animal Welfare Act.¹⁰² In addition, the agency has outlined its support for alternatives to whole-animal testing:

FDA supports and adheres to the provisions of applicable laws, regulations, and policies governing animal testing, including the Animal Welfare Act and the Public Health Service Policy of Humane Care and Use of Laboratory Animals. Moreover, in all cases where animal testing is used, FDA advocates that research and testing derive the maximum amount of useful scientific information from the minimum number of animals and employ the most humane methods available within the limits of scientific capability.

We also believe that prior to use of animals, consideration should be given to the use of scientifically valid alternative methods to whole-animal testing...

FDA supports the development and use of alternatives to whole-animal testing as well as adherence to the most humane methods available within the limits of scientific capability when animals are used for testing the safety of cosmetic products. We will continue to be a strong advocate of methodologies for the refinement, reduction, and replacement of animal tests with alternative methodologies that do not employ the use of animals.¹⁰³

Cosmetic Ingredient Review Program

Although the FFDCAs do not specify how ingredients in cosmetic products are to be tested, the cosmetic industry's trade association—the Personal Care Products Council (PCPC)—has

are-not-fda-approved-are-fda-regulated#Does_FDA_test.

⁹⁷ 21 C.F.R. §740.10.

⁹⁸ FDA, “Cosmetics and U.S. Law,” <https://www.fda.gov/cosmetics/cosmetics-laws-regulations/cosmetics-us-law>.

⁹⁹ Helen Northroot, “Substantiating the Safety of Cosmetic and Toiletry Products,” in *Cosmetic Regulation in a Competitive Environment*, Norman Estrin & James Akerson, eds., 2000.

¹⁰⁰ FDA, “Cosmetics Safety Q&A: Animal Testing,” <https://www.fda.gov/cosmetics/resources-consumers-cosmetics/cosmetics-safety-qa-animal-testing>.

¹⁰¹ For example, the Humane Society of the United States, People for the Ethical Treatment of Animals (PETA), and the American Anti-Vivisection Society have campaigns against animal testing for cosmetics. Humane Society, “‘Be Cruelty Free’ Campaign Launches to End Cosmetics Testing on Animals,” http://www.humanesociety.org/news/press_releases/2012/04/be_cruelty_free_campaign?042312.html; PETA, “Cosmetics and Household-Product Animal Testing,” <http://www.peta.org/issues/animals-used-for-experimentation/cosmetic-household-products-animal-testing.aspx>; and American Anti-Vivisection Society, “Who We Are,” http://www.aavs.org/site/c.bkLTKfOSLhK6E/b.6452345/k.24B3/Who_We_Are.htm.

¹⁰² FDA, “Animal Testing,” <https://www.fda.gov/cosmetics/product-testing-cosmetics/animal-testing-cosmetics>; P.L. 89-544 (codified as amended at 7 U.S.C. §2131 et seq.).

¹⁰³ *Ibid.*

established a Cosmetic Ingredient Review (CIR) program to review the safety of cosmetic product ingredients, based on published and unpublished data on individual ingredients. The purpose of the CIR program “is to determine those cosmetic ingredients for which there is a reasonable certainty in the judgment of competent scientists that the ingredient is safe under its conditions of use.”¹⁰⁴

Under the CIR program, an expert panel reviews cosmetic ingredients compiled from an annual priority list of ingredients used in commercially available cosmetics. The priority list is based on “the number of different products in which an ingredient is used,” as obtained from the Voluntary Cosmetic Registration Program (see the “Voluntary Cosmetic Registration Program” section), as well as “toxicological considerations.”¹⁰⁵ Panelists analyze data and determine whether an ingredient is (1) safe for the uses and concentrations in the safety assessment; (2) unsafe and therefore unsuitable for use in cosmetics; (3) safe, with qualifications, meaning it can be used under certain conditions; or (4) an ingredient for which data are insufficient.¹⁰⁶ Although CIR’s ingredient findings are published, the cosmetic industry is not required to follow them.¹⁰⁷

As of September 2020, CIR has determined that 2,512 ingredients are “safe as used,” 3,023 ingredients are safe with qualifications, 61 ingredients have insufficient data to support safety, and 8 ingredients are “unsafe for use in cosmetic products.” CIR further determined that there are 45 ingredients for which data are insufficient and their use in cosmetics is not supported.¹⁰⁸

The Research Institute for Fragrance Materials (RIFM) “conducts a companion program to review the safety of fragrance ingredients” that includes a “systematic evaluation of fragrance ingredients used in cosmetic products.”¹⁰⁹

In addition, the Environmental Working Group (EWG) Skin Deep cosmetic database, launched in 2004, allows consumers to navigate EWG’s ratings for almost 70,000 products and 9,000 ingredients on the market.¹¹⁰ According to EWG’s website, “Our aim is to fill in where industry and government leave off.... Our staff scientists compare the ingredients on personal care product labels and websites to information in nearly 60 toxicity and regulatory databases.”¹¹¹

¹⁰⁴ CIR, *Cosmetic Ingredient Review Procedures & Support to the Expert Panel for Cosmetic Ingredient Safety*, September 2019, p. 4, <https://www.cir-safety.org/sites/default/files/CIR%20Procedures%20-%20September%202019.pdf>.

¹⁰⁵ *Ibid.*, p. 9.

¹⁰⁶ CIR, “General Information, How Does CIR Work?,” <https://www.cir-safety.org/how-does-cir-work#>.

¹⁰⁷ Gary L. Yingling and Suzan Onel, “Cosmetic Regulation Revisited,” *Fundamentals of Law and Regulation, Vol. I*, p. 333, Robert P. Brady et al., eds. 1997.

¹⁰⁸ CRS analysis of CIR data, “Quick Reference Table Cosmetic Ingredient Review - September,” <https://cir-safety.org/sites/default/files/qrt-r.pdf>.

¹⁰⁹ RIFM, a nonprofit corporation, works in part to “encourage uniform safety standards related to the use of fragrance ingredients.” The corporation reportedly has the world’s largest database of flavor and fragrance materials, with more than 6,000 materials, RIFM, “About Us,” <http://www.rifm.org/about.php>.

¹¹⁰ Environmental Working Group (EWG), “EWG’s Skin Deep,” <https://www.ewg.org/skindeep/>. EWG is a nonprofit corporation. “Scientists, attorneys, analysts, data and communications specialists - our team is a diverse group of experts with deep knowledge about environmental health. We’re united behind our mission to empower you with breakthrough research to make informed choices and live a healthy life. We’re the leading experts on toxic chemicals, food and water, farming and agriculture, energy, family health – and many other issues,” <https://www.ewg.org/who-we-are/our-team>.

¹¹¹ EWG, “About EWG’s Skin Deep,” <https://www.ewg.org/skindeep/contents/about-page/>.

Color Additives

As discussed above, FDA does not require premarket approval of cosmetic ingredients, except for color additives. FDA regulates color additives—such as FD&C Blue No. 1—differently than other cosmetic ingredients.¹¹² Color additives include any dye, pigment, or substance that may impart a color when added to a food, drug, cosmetic, or the human body,¹¹³ and must be listed in a regulation before they may be used.¹¹⁴ All color additives must be approved as “safe-for-use” prior to being listed in regulation and therefore able to be used in cosmetics.¹¹⁵ A cosmetic that contains a color additive that does not comply with the applicable FDA regulation will cause the cosmetic product to be considered to be adulterated.¹¹⁶

Color additives must be used according to FDA regulations that prescribe “the conditions under which such additive may be safely used.”¹¹⁷ For example, the color additive FD&C Red No. 4 must meet the requirements of 21 C.F.R. §74.1304(a)(1) and (b), which discuss identity (the composition and specifications the color additive must meet, such as the maximum amounts of particular impurities that the color additive can contain) and restrict its use to “externally applied drugs and cosmetics.”¹¹⁸ Under FDA regulations, the external application of cosmetics does not include “the lips or any body surface covered by mucous membrane”; therefore, FDA regulations prohibit the use of certain colors in cosmetics such as lipsticks.¹¹⁹ As additional examples, FDA has specific regulations for an approved glow-in-the-dark color additive and for fluorescent color additives (some of which are approved for use in cosmetics) and for liquid crystal color additives (which are unapproved color additives and, therefore, not approved for use in cosmetics).¹²⁰ FDA regulations also contain restrictions on color additives used in the eye area, and in injections (such as for tattoos or permanent makeup).¹²¹

¹¹² FDA, “Color Additives and Cosmetics: Fact Sheet,” <https://www.fda.gov/industry/color-additives-specific-products/color-additives-and-cosmetics-fact-sheet>.

¹¹³ 21 C.F.R. §70.3(f); see also FFDCA §201(t) (21 U.S.C. §321(t)): “(1) The term ‘color additive’ means a material which—(A) is a dye, pigment, or other substance made by a process of synthesis or similar artifice, or extracted, isolated, or otherwise derived, with or without intermediate or final change of identity, from a vegetable, animal, mineral, or other source, and (B) when added or applied to a food, drug, or cosmetic, or to the human body or any part thereof, is capable (alone or through reaction with other substance) of imparting color thereto; except that such term does not include any material which the Secretary, by regulation, determines is used (or intended to be used) solely for a purpose or purposes other than coloring. (2) The term ‘color’ includes black, white, and intermediate grays.”

¹¹⁴ FFDCA §721(a) (21 U.S.C. §379e(a)).

¹¹⁵ The FDA’s “safe-for-use” principle “require[s] the presentation of all needed scientific data in support of a proposed listing to assure that each listed color additive will be safe for its intended use in or on ... cosmetics.” 21 C.F.R. §70.42. In this context, “safe” means “that there is convincing evidence that establishes with reasonable certainty that no harm will result from the intended use of the color additive.” 21 C.F.R. §70.3(i).

¹¹⁶ *Ibid*; FFDCA §601(e) (21 U.S.C. §361(e)).

¹¹⁷ FFDCA §721(a) (21 U.S.C. §379e(a)).

¹¹⁸ 21 C.F.R. §82.304.

¹¹⁹ 21 C.F.R. §70.3(v); FDA, “Color Additives and Cosmetics,” <http://www.fda.gov/ForIndustry/ColorAdditives/ColorAdditivesinSpecificProducts/InCosmetics/ucm110032.htm>.

¹²⁰ See, for example, 21 C.F.R. §73.2995—Luminescent zinc sulfide; FDA, Color Additives and Cosmetics, <http://www.fda.gov/ForIndustry/ColorAdditives/ColorAdditivesinSpecificProducts/InCosmetics/ucm110032.htm>.

¹²¹ 21 C.F.R. §70.5. The FDA notes that it has not approved any color additive for skin injections such as tattoos or permanent makeup. FDA, “Color Additives and Cosmetics,” <http://www.fda.gov/ForIndustry/ColorAdditives/ColorAdditivesinSpecificProducts/InCosmetics/ucm110032.htm>. In addition, color additives may be required to be labeled as “Do not use for coloring drugs for injection.” 21 C.F.R. §70.25.

If a regulation does not exist for a color additive, an interested party may submit to FDA a petition proposing that a color additive be listed in regulation for use in a cosmetic.¹²² A petition must include, among other things, “full reports of investigation made with respect to the safety of the color additive.”¹²³ After reviewing the data and information in the petition, FDA may issue a regulation listing the color additive for use generally in cosmetics, or FDA may prescribe the conditions under which the color additive may be safely used (e.g., the particular types of cosmetic).¹²⁴

In addition, some color additives must be certified by FDA before they can be used in cosmetics.¹²⁵ In these cases, FDA analyzes a color additive sample to determine whether it meets the specifications stated in the regulation.¹²⁶ Failure to certify a color additive used in a cosmetic may cause the entire product to be deemed adulterated.¹²⁷ Color additives subject to certification “are derived primarily from petroleum,” whereas color additives exempt from certification “are obtained primarily from mineral, plant, or animal sources.”¹²⁸ Regardless of whether a color additive is subject to certification or not, color additives are still considered artificial colors and must comply with the labeling requirements as stated in regulation.¹²⁹

Voluntary Cosmetic Registration Program

Cosmetic manufacturers are not required to register their establishments or list their products with FDA. Instead, according to FDA regulations, owners or operators of establishments that manufacture or package cosmetics are *requested* to register with FDA.¹³⁰ Likewise, manufacturers, packers, or distributors of cosmetic products are *requested* to file a cosmetic product ingredient statement (CPIS) containing certain information on each cosmetic product they market.¹³¹ Entities may submit registration information and CPISs to FDA’s Voluntary Cosmetic Registration Program (VCRP).¹³² Since 1974, FDA, in cooperation with the cosmetic industry, has operated the VCRP to facilitate registration of cosmetic establishments.¹³³ GAO has

¹²² 21 C.F.R. §71.1.

¹²³ 21 C.F.R. §71.1(c).

¹²⁴ 21 C.F.R. §71.20.

¹²⁵ FFDCA §721(c) (21 U.S.C. §379e(c)); 21 C.F.R. Part 73, Subpart C, Listing of Color Additives Exempt from Certification; 21 C.F.R. Part 74, Subpart C, Listing of Color Additives Subject to Certification; see also FDA, “Color Additives Permitted for Use in Cosmetics,” <https://www.fda.gov/cosmetics/cosmetic-ingredient-names/color-additives-permitted-use-cosmetics>.

¹²⁶ FD&C Act §721(c); (21 U.S.C. §379e(c)); 21 C.F.R. Part 80. “In the certification procedure, a representative sample of a new batch of color additive, accompanied by a ‘request for certification’ that provides information about the batch, must be submitted to FDA’s Office of Cosmetics and Colors. FDA personnel perform chemical and other analyses of the representative sample and, providing the sample satisfies all certification requirements, issue a certification lot number for the batch.” 76 *Federal Register* 10371, 10372 (February 24, 2011). FDA, “Color Certification Reports,” current as of April 1, 2021, <https://www.fda.gov/industry/color-certification/color-certification-reports>.

¹²⁷ FFDCA §721(a) (21 U.S.C. §379e(a)); 21 C.F.R. §71.25.

¹²⁸ *Ibid.*

¹²⁹ 21 C.F.R. §73

¹³⁰ 21 C.F.R. §710.

¹³¹ 21 C.F.R. Part 720.

¹³² FDA, “Voluntary Cosmetic Registration Program,” <https://www.fda.gov/cosmetics/voluntary-cosmetic-registration-program>.

¹³³ 21 C.F.R. Part 710—Voluntary Registration of Cosmetic Product Establishments. In May 2008, an estimated one-third of cosmetic establishments were registered. Discussion Draft of the “Food and Drug Administration Globalization Act” Legislation: Device and Cosmetic Safety, Hearing Before the Subcommittee on Health, House Committee on

noted that “[r]egistration is important because it serves as the basis for determining where FDA will conduct its inspections.”¹³⁴ FDA has also stated that VCRP information helps the Cosmetic Ingredient Review program (discussed in the “Cosmetic Ingredient Review Program” section) “in determining its priorities for ingredient safety review.”¹³⁵

Under its VCRP regulations, FDA recommends that establishments that manufacture or package cosmetic products voluntarily register within 30 days of starting operations, regardless of whether their products enter interstate commerce.¹³⁶ FDA regulations request that foreign cosmetic product manufacturers voluntarily register with the agency if their products are exported for sale in the United States.¹³⁷ Cosmetic manufacturers and packagers also are encouraged to report in the CPIS the ingredients used in their product formulations, in addition to other information.¹³⁸ FDA does not charge cosmetic establishments a fee for registering voluntarily.¹³⁹

Certain classes of establishments are exempt from FDA’s voluntary registration request “because the [FDA] Commissioner has found that such registration is not justified.”¹⁴⁰ These include beauty shops; cosmetologists; retailers; pharmacies; physicians; hospitals; clinics; public health agencies; persons who compound cosmetics at a location but do not otherwise manufacture or package cosmetics from that location; and persons who manufacture, prepare, compound, or process cosmetic products for activities such as teaching or research, but not for sale.¹⁴¹

It is not clear what percentage of cosmetic companies choose to participate in the VCRP or how many CPISs FDA receives relative to the total number of cosmetic products in the U.S. market. However, FDA has estimated that about one-third of cosmetics manufacturers voluntarily file CPISs for their products with the agency.¹⁴² The lack of mandatory registration poses enforcement challenges for the agency. As one FDA official noted, “We are hampered in tracking down tainted products ... by the lack of a facility registration requirement. For example, with tattoo inks, we don’t know the number of manufacturers, who they are, where they are, and what they make. With other regulated products [e.g., drugs and devices], the agency knows who the manufacturers are because they are required to register.”¹⁴³

Energy and Commerce, 110th Cong., May 14, 2008 (statement of Stephen Sundlof, FDA’s Center for Food Safety and Applied Nutrition).

¹³⁴ GAO, *Cosmetics Regulation: Information on Voluntary Actions Agreed to by FDA and the Industry*, report to the Chairman, Subcommittee on Regulation, Business Opportunities, and Energy, House Committee on Small Business, GAO/HRD-90-58, p. 3 (March 1990). The GAO report also commented on a “major disagreement” between FDA and the cosmetic industry’s trade group as to the number of companies that were not registered with FDA and stated that FDA’s inability to require registration inhibited the agency’s ability to “accurately assess how many companies may be avoiding registration.” *Ibid.*, pp. 3-4.

¹³⁵ FDA, “Voluntary Cosmetic Registration Program,” <https://www.fda.gov/cosmetics/voluntary-cosmetic-registration-program>.

¹³⁶ 21 C.F.R. §§710.1, 710.2.

¹³⁷ 21 C.F.R. §710.1.

¹³⁸ 21 C.F.R. §720.4.

¹³⁹ 21 C.F.R. §710.1.

¹⁴⁰ 21 C.F.R. §710.9.

¹⁴¹ *Ibid.*

¹⁴² Testimony of Susan Mayne, Director of the Center for Food Safety and Applied Nutrition at FDA, before the House Committee on Energy and Commerce, Subcommittee on Health, *Building Consumer Confidence by Empowering FDA to Improve Cosmetic Safety*, 116th Congress, December 4, 2019.

¹⁴³ FDA, “Using Adverse Event Reports to Monitor Cosmetic Safety: A Conversation with Linda Katz [then-director of the FDA’s Office of Cosmetics and Colors],” November 3, 2017, <https://www.fda.gov/cosmetics/how-report-cosmetic->

Reporting of Adverse Reactions to Cosmetics

FDA lacks the statutory authority to require cosmetic manufacturers to notify the agency of adverse events associated with their products, nor can it require cosmetic companies to report on information received from consumers and others regarding adverse events. As such, FDA relies on voluntary reports of adverse events from cosmetic companies and consumers. The agency currently advises consumers to self-report reactions to cosmetics such as “moisturizers, shampoos, hair dyes and tattoos” to either MedWatch¹⁴⁴ or the consumer’s local FDA complaint coordinator.¹⁴⁵ FDA maintains the Center for Food Safety and Applied Nutrition (CFSAN) Adverse Event Reporting System (CAERS), a database containing information on adverse events and product complaints that the agency has received for cosmetics and food and dietary supplements.¹⁴⁶ Adverse events reported to FDA include reactions to henna/mehndi, temporary tattoos, and keratin hair treatment products, as well as reports of infections related to tattoo inks.¹⁴⁷

FDA monitors adverse event reports in CAERS and uses those reports to guide enforcement activities. For example, FDA has issued an import alert for henna intended for use on the skin.¹⁴⁸ This is because FDA’s color additive regulations allow for use of henna in hair dye only,¹⁴⁹ not direct application to the skin. FDA also issued an import alert for temporary tattoo products that lack the required ingredient declaration on the label or contain colors not approved for use in cosmetics for the skin.¹⁵⁰ Cosmetics that do not comply with color additive regulations, including restrictions on use, are deemed adulterated. In addition, FDA has issued warning letters regarding cosmetic products found to have microbial contamination, thus rendering them adulterated.¹⁵¹

In the absence of FDA requirements regarding adverse event reporting, the cosmetic industry has made efforts to self-regulate. In 2007, the industry trade association, the Personal Care Products Council (PCPC), created a Consumer Commitment Code (the Code) that cosmetic product and ingredient manufacturers and marketers were “encouraged to acknowledge their support of” in

related-complaint/using-adverse-event-reports-monitor-cosmetic-safety.

¹⁴⁴ FDA, “MedWatch: The FDA Safety Information and Adverse Event Reporting Program,” <http://www.fda.gov/Safety/MedWatch/default.htm>.

¹⁴⁵ FDA, “Consumer Complaint Coordinators,” <https://www.fda.gov/safety/report-problem-fda/consumer-complaint-coordinators>.

¹⁴⁶ FDA, “CFSAN Adverse Event Reporting System (CAERS),” <https://www.fda.gov/food/compliance-enforcement-food/cfsan-adverse-event-reporting-system-caers>.

¹⁴⁷ FDA, “Tattoos & Permanent Makeup: Fact Sheet,” <https://www.fda.gov/cosmetics/cosmetic-products/tattoos-permanent-makeup-fact-sheet>. FDA, “Warning Letters Related to Cosmetics,” <https://www.fda.gov/cosmetics/cosmetics-compliance-enforcement/warning-letters-related-cosmetics>. 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>.

¹⁴⁸ FDA, Import Alert 53-19, “Detention Without Physical Examination of Henna Based Skin Color,” https://www.accessdata.fda.gov/cms_ia/importalert_138.html.

¹⁴⁹ 21 C.F.R. §73.2190.

¹⁵⁰ FDA, “Tattoos & Permanent Makeup: Fact Sheet,” <https://www.fda.gov/cosmetics/cosmetic-products/tattoos-permanent-makeup-fact-sheet>. FDA, Import Alert 53-06, “Detention Without Physical Examination Of Cosmetics That are Adulterated and/or Misbranded Due to Color Additive Violations,” https://www.accessdata.fda.gov/cms_ia/importalert_130.html.

¹⁵¹ FDA, “Warning Letters Cite Cosmetics as Adulterated Due to Microbial Contamination,” <https://www.fda.gov/cosmetics/warning-letters-related-cosmetics/warning-letters-cite-cosmetics-adulterated-due-microbial-contamination>.

writing.¹⁵² One of the Code's principles is that "a company should notify the [FDA] of any known serious and unexpected adverse event as a result of the use of any of its cosmetic products marketed and used in the United States," where the terms "serious" and "unexpected" mean the same as FDA regulations defining serious and unexpected adverse events for drugs.¹⁵³ The Code is not a binding legal standard and cannot be enforced by FDA. The PCPC has stated that it "will not terminate the Council's membership for noncompliance," but would instead encourage compliance with the Code.¹⁵⁴

Issues for Congress

Concerns About Specific 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. More recently, concerns have been raised about a group of synthetic compounds known as per- and polyfluoroalkyl substances (PFAS).¹⁵⁵ Both coal tar hair dyes and PFAS have been the focus of congressional interest. But these substances are not the only ingredients to have raised concern. FDA has online resources with information about other ingredients that consumers have inquired about, including talc, phthalates, and parabens, among others.¹⁵⁶ In addition, some consumer advocacy groups and researchers have stated that other commonly used cosmetic ingredients may pose a health threat to consumers.¹⁵⁷

Coal Tar Hair Dyes

Coal tar dyes have been a particularly controversial group of color additives due to their potential health risk. Coal tar dyes are "synthetic-organic" colors, so-named because coal tar colors were once byproducts of the coal industry, although most are now made from petroleum.¹⁵⁸ Most hair

¹⁵² PCPC, "Questions and Answers," <https://www.personalcarecouncil.org/science-safety/consumer-commitment-code/questions-and-answers/>. See also, [Cosmeticsinfo.org](https://www.cosmeticsinfo.org), which is sponsored by PCPC and its members.

¹⁵³ PCPC, "Consumer Commitment Code," <https://www.personalcarecouncil.org/science-safety/consumer-commitment-code/code/>. Under 21 C.F.R. §314.80(a), "serious adverse drug experiences" include "death, a life-threatening adverse drug experience, inpatient hospitalization ... a persistent or significant disability/incapacity, or a congenital anomaly/birth defect," as well as important medical events that "may require medical or surgical intervention to prevent one of the outcomes listed in this definition." An "unexpected adverse drug experience" is "[a]ny adverse drug experience that is not listed in the current labeling for the drug product," or an "adverse drug experience that has not been previously observed."

¹⁵⁴ [Cosmeticsinfo.org, "Consumer Commitment Code Principles," https://www.cosmeticsinfo.org/safety-basics/consumer-commitment-code/principles/](https://www.cosmeticsinfo.org/safety-basics/consumer-commitment-code/principles/). See also PCPC, "Consumer Commitment Code," <https://www.personalcarecouncil.org/science-safety/consumer-commitment-code/code/>.

¹⁵⁵ See the "Per- and Polyfluoroalkyl Substances (PFAS)" section.

¹⁵⁶ FDA, "Cosmetic Ingredients," <https://www.fda.gov/cosmetics/cosmetic-products-ingredients>.

¹⁵⁷ While not discussed here, examples of such ingredients may include butylated hydroxyanisole (BHA), butylated hydroxytoluene (BHT), and ingredients related to formaldehyde, among others. See Scott Faber, Environmental Working Group, "The Toxic Twelve Chemicals and Contaminants in Cosmetics," May 5, 2020, <https://www.ewg.org/the-toxic-twelve-chemicals-and-contaminants-in-cosmetics>. Also see the "Concerns About FDA's Authority to Regulate Cosmetic Market" section.

¹⁵⁸ FDA, "Color Additives and Cosmetics," <https://www.fda.gov/industry/color-additives-specific-products/color-additives-and-cosmetics-fact-sheet>. The FDA also states that coal tar colors are "materials consisting of one or more substances that either are made from coal-tar or can be derived from intermediates of the same identity as coal-tar intermediates," and "may also include diluents or substrata."

dyes on the market are in the coal-tar class.¹⁵⁹ These dyes, “which deposit and adhere to the hair shaft ... are either listed and certified color additives or dyes for which approval has not been sought.”¹⁶⁰ They were specifically exempted from the FFDC A adulteration and other color additive provisions for hair-dyeing products.¹⁶¹ As such, in contrast to other color additives, coal-tar hair dyes do not need FDA approval, and “FDA cannot take action against a coal-tar hair dye on the basis that it is or contains a poisonous or deleterious ingredient that may make it harmful to consumers, as long as the label includes a special caution statement and the product comes with adequate directions for consumers to do a skin test before they dye their hair.”¹⁶² Coal tar dyes are explicitly excluded from use in products intended to be dyes for eyelashes or eyebrows.¹⁶³ To avoid an adulteration determination, coal tar hair dyes must contain the FFDC A-mandated warning statement that informs consumers of the potential risks associated with their use:

Caution—This product contains ingredients which may cause skin irritation on certain individuals and a preliminary test according to accompanying directions should first be made. This product must not be used for dyeing the eyelashes or the eyebrows; to do so may cause blindness.¹⁶⁴

Given the potential health hazards of coal tar, FDA, GAO, policymakers, and consumer groups have questioned whether the FFDC A exemption for coal tar hair dyes should be repealed.¹⁶⁵ Throughout the late 1970s, FDA had unsuccessfully argued for the repeal of the coal tar hair dye exemption.¹⁶⁶ During that time, the GAO “recommended that FDA evaluate safety data on coal tar hair dye ingredients and require, where applicable, a cancer or other appropriate warning statement on product labels.”¹⁶⁷

¹⁵⁹ National Institutes of Health (NIH), National Institute of Environmental Health Sciences (NIEHS), “Cosmetics and Hair Dye,” February 2020, https://www.niehs.nih.gov/health/materials/cosmetics_and_hair_dye_508.pdf.

¹⁶⁰ FDA, “Hair Dyes,” <https://www.fda.gov/cosmetics/cosmetic-products/hair-dyes>.

¹⁶¹ FFDC A §601 (21 U.S.C. §361).

¹⁶² FDA, “Hair Dyes,” <https://www.fda.gov/cosmetics/cosmetic-products/hair-dyes>.

¹⁶³ FFDC A §601(a) (21 U.S.C. §361(a)); 21 C.F.R. §70.3(u).

¹⁶⁴ *Ibid.* In addition to the warning label, coal tar hair dyes must have “adequate directions for preliminary patch testing” to meet the exemption from the FFDC A §601(a) adulteration provisions.

¹⁶⁵ High concentrations of coal tar have been demonstrated to show deleterious health effects in laboratory experiments. See Cosmetic Ingredient Review Expert Panel, “Final Safety Assessment of Coal Tar as Used in Cosmetics,” *International Journal of Toxicology*, vol. 27, no. 2 (2008), <https://journals.sagepub.com/doi/pdf/10.1080/10915810802244405>.

¹⁶⁶ *The Review of the Adequacy of Existing Laws Designed to Protect the Public from Exposure to Cancer Causing and Other Toxic Chemicals in Hair Dyes and Cosmetic Products: Hearings Before the Subcommittee on Oversight and Investigations of the House Committee on Interstate and Foreign Commerce, 95th Cong., Serial No. 95-91 (January 23 and 26, February 2-3, 1978) at 370 (statement of Hon. Donald Kennedy, FDA Commissioner) (“But our ability to protect the public, particularly from the risk associated with long-term use of hair dyes, will continue to be severely limited until Congress repeals the exemptions for coal tar hair dye products. We have long stated that the coal tar exemptions of section 601(a) and (e) and 602(e) should be repealed.”). *The Food and Drug Administration’s Regulation of Cosmetics: Testimony before the Subcommittee on Oversight and Investigations of the House Committee on Interstate and Foreign Commerce*, p. 4, February 3, 1978, statement of Gregory J. Ahart, Director, Human Resources Division, GAO, p. 4; *Safety of Hair Dyes and Cosmetic Products: Hearing Before the Subcomm. on Oversight and Investigations of the House Committee on Interstate and Foreign Commerce, Serial No. 96-105 (July 19, 1979) p. 6 (statement of Sherwin Gardner, Acting Commissioner, FDA), p. 6 (“The law does contain an exemption for coal tar hair dyes from the principal adulteration provisions of the act... We have long urged that this outmoded exemption be eliminated, and the Department will shortly submit legislation that will accomplish this purpose”).**

¹⁶⁷ *The Food and Drug Administration’s Regulation of Cosmetics: Testimony before the Subcommittee on Oversight and Investigations of the House Committee on Interstate and Foreign Commerce*, p. 4, February 3, 1978, statement of Gregory J. Ahart, Director, Human Resources Division, GAO, p. 4. GAO, *Cancer and Coal Tar Hair Dyes: An*

More recently, FDA has stated that in the 1980s, “several coal-tar hair dye ingredients have been found to cause cancer in laboratory animals.”¹⁶⁸ FDA issued a regulation requiring the following warning on hair dyes containing two coal tar ingredients (4-methoxy-m-phenylenediamine 2, 4-diaminoanisole and 2, 4-methoxy-m-phenylenediamine sulfate 2,4-diaminoanisole sulfate): “Warning—Contains an ingredient that can penetrate your skin and has been determined to cause cancer in laboratory animals.”¹⁶⁹ However, the regulation was stayed indefinitely. According to FDA, the cosmetics industry no longer uses these two ingredients in hair dyes, and there is a lack of reliable evidence showing a link between cancer and the coal-tar hair dyes currently on the market.¹⁷⁰ The agency continues to monitor research on hair dyes. The National Institute of Environmental Health Sciences (NIEHS) within the National Institutes of Health (NIH), through its National Toxicology Program, conducts research on chemicals, including those in cosmetics and hairs dyes, to determine if they are harmful.¹⁷¹

Legislation has been introduced in the 116th and 117th Congresses that would either prohibit the use of coal tar hair dyes in cosmetics¹⁷² or allow FDA to review these ingredients for safety and limit or impose conditions on their use.¹⁷³

Per- and Polyfluoroalkyl Substances (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 among longer chain versus shorter chain PFAS, and among more fluorinated versus less fluorinated PFAS—thus potential health effects may also vary.¹⁷⁴ PFAS may be added intentionally as ingredients to certain cosmetics to improve their texture or consistency or to condition and smooth skin or give it a shiny appearance. Data from FDA’s VCRP indicates that PFAS are used as ingredients in lotions, cleansers, nail polish, shaving cream, and some makeup products (e.g., lipstick, eyeliner, eyeshadow, and mascara).¹⁷⁵ PFAS may be added unintentionally to cosmetics, due to raw material impurities or the breakdown of PFAS ingredients that form other types of PFAS. Although intentionally added PFAS ingredients are typically declared on a cosmetic product’s label, unintentional PFAS may not be.

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 that are harmful to humans. Studies have found varying concentrations of PFAS in cosmetics, ranging “from the parts per billion level to the 100s of parts per million range.”¹⁷⁶ However, because not all PFAS can be

Unregulated Hazard to Consumers, December 6, 1977.

¹⁶⁸ FDA, “Hair Dyes,” <https://www.fda.gov/cosmetics/cosmetic-products/hair-dyes>.

¹⁶⁹ 21 C.F.R. §740.18; see 47 *Federal Register* 7829 (February 23, 1982), which stayed this regulation until further notice, effective September 18, 1980; FDA, “Hair Dyes,” <https://www.fda.gov/cosmetics/cosmetic-products/hair-dyes>.

¹⁷⁰ FDA, “Hair Dyes,” <https://www.fda.gov/cosmetics/cosmetic-products/hair-dyes>.

¹⁷¹ NIH, NIEHS, “Cosmetics and Hair Dye,” February 2020, https://www.niehs.nih.gov/health/materials/cosmetics_and_hair_dye_508.pdf.

¹⁷² See, for example, in the 116th Congress, H.R. 4296, the Safe Cosmetics and Personal Care Products Act of 2019.

¹⁷³ See, for example, in the 117th Congress, S. 2100, the Personal Care Products Safety Act.

¹⁷⁴ CRS Report R45986, *Federal Role in Responding to Potential Risks of Per- and Polyfluoroalkyl Substances (PFAS)*, coordinated by David M. Bearden.

¹⁷⁵ FDA, “Per and Polyfluoroalkyl Substances (PFAS) in Cosmetics,” <https://www.fda.gov/cosmetics/cosmetic-ingredients/and-polyfluoroalkyl-substances-pfas-cosmetics>.

¹⁷⁶ *Ibid.*

readily measured, detecting and quantifying them can be challenging.¹⁷⁷ Data from FDA’s VCRP showed that over a nine-month period between 2019 and 2020, approximately 21 types of PFAS were used as ingredients in cosmetics.¹⁷⁸ Of these 21 types, 15 decreased in overall use from the first data report in 2019 to the second report in 2020. During that period, the number of formulations containing at least one of the 21 types of PFAS decreased from 506 to 235. FDA cautions that because VCRP registration and product listing are voluntary, “these data cannot be used to draw definitive conclusions about the types and amounts of PFAS present in registered cosmetics or to determine which cosmetics may contain PFAS but have not been registered in the VCRP.”¹⁷⁹

A study published in June 2021 tested 231 cosmetics across eight categories¹⁸⁰ that were purchased or obtained as free samples from retailers in the United States (in Michigan and Indiana) and Canada from 2016 through 2021.¹⁸¹ The 231 products were tested for fluorine, a marker of PFAS, and 29 products, including 20 with high total fluorine signals, were selected for further targeted analysis. The study found that the cosmetic categories with the highest percentage of fluorine products were foundations (63%), eye products (58%), lip products (55%), and mascaras (47%). The 29 cosmetic products selected for targeted analysis contained detectable levels of at least four PFAS, and one product contained a maximum of 13 individual PFAS. Of the 231 cosmetics tested, 8% had PFAS listed as ingredients; of the 29 targeted cosmetics, 3% had PFAS listed as ingredients.¹⁸²

Given gaps in research and concerns about PFAS being both ubiquitous and persistent, some Members of Congress have introduced legislation to address research and the use of these compounds in certain consumer goods. Some of this legislation would require FDA to issue regulations banning intentionally added PFAS in cosmetics.¹⁸³

Budget and Resources

Within FDA, the Center for Food Safety and Applied Nutrition (CFSAN) is responsible for oversight of cosmetic products. CFSAN also oversees the safety of food and dietary supplements. Under current law, FDA’s cosmetics activities are supported by funding provided through the annual appropriations process (referred to as *budget authority*, or BA, in FDA budget documents). This funding support differs from that of other products overseen by FDA, for which agency regulatory activities are funded by a combination of BA and industry-paid user fees (e.g., prescription drugs, medical devices) or user fees only (i.e., tobacco).

According to December 2019 testimony from CFSAN Director Susan Mayne, “In recent years, our program for cosmetics is approximately \$10 million and has represented about three percent of CFSAN’s total \$327 million budget.”¹⁸⁴ Data provided to CRS by FDA indicates that this

¹⁷⁷ Ibid.

¹⁷⁸ Ibid.

¹⁷⁹ Ibid.

¹⁸⁰ The eight categories were lip products, eye products, foundations, face products, mascaras, concealers, eyebrow products, and miscellaneous products.

¹⁸¹ Heather D. Whitehead, Marta Venier, Yan Wu, et al., “Fluorinated Compounds in North American Cosmetics,” *Environmental Science & Technology Letters*, June 2021, vol. 8, no. 7, pp. 538-544.

¹⁸² Ibid.

¹⁸³ See, for example, in the 117th Congress, S. 2047 and H.R. 3990, the No PFAS in Cosmetics Act.

¹⁸⁴ Ibid.

funding share was an increase from previous years; for example, between FY2014 and FY2018, the cosmetics program represented between 2.3% and 2.7% of CFSAN's total BA. In FY2008, the cosmetics program represented 1.5% of CFSAN's total BA.¹⁸⁵

FDA has noted that since the enactment of the law governing the agency's oversight of cosmetics products in 1938 (i.e., the FFDCA), the cosmetics industry has grown, and there has been an increase in cosmetics manufactured abroad. In FY2018, there were about 2.7 million lines of cosmetics products imported into the United States from 177 countries, compared with about 1.6 million lines in FY2008, an increase of more than 1 million lines.¹⁸⁶ Because cosmetic manufacturing establishments register and list their products voluntarily under the current regulatory scheme, FDA does not have a complete accounting of all the firms manufacturing cosmetics for the U.S. market or where they are located.¹⁸⁷

Legislation has been introduced that would expand FDA's authority to regulate cosmetic products. In addition, some bills have proposed to establish a new user fee program to help fund these activities and to allow FDA to hire additional staff.¹⁸⁸

Claims and Labeling

Consumers may seek out particular cosmetics based on their labeling, such as cosmetics made with organic ingredients or without being tested on animals. However, FDA does not define certain terms used by manufacturers to describe their cosmetic products. The sections below on "natural" or "organic" and "not tested on animals" claims address slight differences in how cosmetic products are marketed using certain claims and what consumers may believe such claims to mean. In addition, not all cosmetic products are required to be labeled in the same manner (see the "For Professional Use Only" Labeling" section below).

"Natural" or "Organic" Labeling Claims on Cosmetic Products

As with many statements made on cosmetic products, the terms "natural" and "organic" are not defined specifically in the FFDCA, which may lead to consumer confusion.¹⁸⁹ Consumers seeking "natural" or "organic" cosmetics may have different expectations about the materials in a product marketed as natural or organic. For example, consumers may believe that products labeled "natural" or "organic" have a health benefit, even though an ingredient's source does not determine whether it is safe.¹⁹⁰ FDA has noted that "many plants, regardless of whether they are organically grown, contain substances that may be toxic or allergenic."¹⁹¹ Moreover, FDA has

¹⁸⁵ Data provided to CRS by FDA's Office of Legislation on April 30, 2019.

¹⁸⁶ An import line refers to an individual shipment, regardless of size (e.g., one line can be for 10 cartons of lipstick or 10,000 cartons of lipstick). Testimony of Susan Mayne, Director of the Center for Food Safety and Applied Nutrition at FDA, before the House Committee on Energy and Commerce, Subcommittee on Health, *Building Consumer Confidence by Empowering FDA to Improve Cosmetic Safety*, 116th Congress, December 4, 2019.

¹⁸⁷ FDA, "Using Adverse Event Reports to Monitor Cosmetic Safety: A Conversation with Linda Katz [then-director of the FDA's Office of Cosmetics and Colors]," November 3, 2017, <https://www.fda.gov/cosmetics/how-report-cosmetic-related-complaint/using-adverse-event-reports-monitor-cosmetic-safety>.

¹⁸⁸ See, for example, S. 2100 (117th Congress), Personal Care Products Safety Act, and H.R. 5279 (116th Congress), Cosmetic Safety Enhancement Act.

¹⁸⁹ FDA, "Organic" Cosmetics, <https://www.fda.gov/cosmetics/cosmetics-labeling-claims/organic-cosmetics>.

¹⁹⁰ Ibid. See also Environmental Working Group (EWG), "'Natural' or 'Organic' Cosmetics? Don't Trust Marketing Claims," January 11, 2018, <https://www.ewg.org/news-insights/news/natural-or-organic-cosmetics-dont-trust-marketing-claims>.

¹⁹¹ FDA, "'Organic' Cosmetics," <http://www.fda.gov/Cosmetics/ProductandIngredientSafety/ProductInformation/>

stated that “[c]onsumers should not necessarily assume that an ‘organic’ or ‘natural’ ingredient or product would possess greater inherent safety than another chemically identical version of the same ingredient.”¹⁹² Some natural ingredients may cause consumers to have adverse reactions, and FDA has stated that “in fact, ‘natural’ ingredients may be harder to preserve against microbial contamination and growth than synthetic raw materials.”¹⁹³

Despite these uncertainties, data suggest that products labeled as “natural” continue to appeal to consumers. According to Nielsen data, in 2017, products featuring “natural” claims represented 3.1% of the U.S. personal care products market and generated \$1.3 billion in annual sales—an increase from 2013 when such products represented 2.1% of the market and generated \$230 million in sales.¹⁹⁴ According to Statista Research Department, in 2016, the U.S. “organic” personal care market revenue was about \$3.4 billion and was forecasted to reach \$7.6 billion by 2025.¹⁹⁵

Although FDA has authority over the labeling of cosmetics, the agency does not regulate the use of the term “organic.” Rather, the U.S. Department of Agriculture (USDA) regulates “organic” claims on cosmetic products.¹⁹⁶ In 2005, the USDA’s National Organic Program (NOP), which oversees voluntary organic labeling of certified foods, determined that cosmetic products that meet the requirements established under the NOP regulations¹⁹⁷ are eligible for certification as “organic.”¹⁹⁸ A cosmetic product “may be eligible to be certified under the NOP regulations” if the product “contains or is made up of agricultural ingredients, and can meet the USDA/NOP organic production, handling, processing and labeling standards.”¹⁹⁹

The NOP regulations provide four organic labeling categories:

1. 100% Organic—excluding water and salt, the product must be made of only organically produced ingredients and may use the USDA organic seal.
2. Organic—excluding water and salt, the product must be composed of at least 95% organically produced ingredients and may use the USDA organic seal.
3. Made with Organic Ingredients—excluding water and salt, the product must contain at least 70% organic ingredients and the label may list three of the organic ingredients or food groups, such as herbs, but the product may not use the USDA organic seal.

ucm203078.htm. The FDA also maintains a database of poisonous plants: FDA, FDA Poisonous Plant Database, <http://www.accessdata.fda.gov/scripts/plantox/index.cfm>.

¹⁹² Natasha Singer, “Natural, Organic Beauty,” *New York Times*, November 1, 2007 (quoting Dr. Linda M. Katz, Director of the FDA’s Office of Cosmetics and Colors).

¹⁹³ *Ibid.* (quoting Dr. Linda M. Katz, Director of the FDA’s Office of Cosmetics and Colors).

¹⁹⁴ Nielson, “The Future of Beauty,” 2018, p. 4, <https://www.nielsen.com/wp-content/uploads/sites/3/2019/04/the-future-of-beauty-report.pdf>.

¹⁹⁵ Statista, Natural and Organic Cosmetics in the U.S., “Estimated revenue of organic personal care market in the United States from 2014 to 2025 (in million U.S. dollars),” United States, as of November 2016, published February 2018, p. 12.

¹⁹⁶ United States Department of Agriculture (USDA), Agricultural Marketing Service (AMS), National Organic Program (NOP), Cosmetics, Body Care Products, and Personal Care Products, <http://www.ams.usda.gov/AMSV1.0/getfile?dDocName=STELPRDC5068442>.

¹⁹⁷ 7 C.F.R. Part 205.

¹⁹⁸ 7 C.F.R. §205.2; USDA, NOP, Cosmetics, Body Care Products, and Personal Care Products, <http://www.ams.usda.gov/AMSV1.0/getfile?dDocName=STELPRDC5068442>.

¹⁹⁹ *Ibid.*

4. Specific ingredients may be identified as organic if they are USDA-certified organic, but these products may not use the USDA organic seal or the term “organic.”²⁰⁰

In 2009, the Certification, Accreditation, and Compliance Committee of the USDA’s 15-member National Organics Standards Board made recommendations regarding “the problem of mislabeled organic personal care products.”²⁰¹ The committee stated that the “USDA is responsible for product organic claims but is not currently enforcing this in the area of personal care products.”²⁰² As a result, the committee noted that “[c]onsumers are not assured that organic claims are consistently reviewed and applied” to personal care products.²⁰³ The committee recommended amending the NOP regulations to include a definition of “personal care products” based on the definition of a “cosmetic” under the FFDCA, to clarify the use of the term “organic” in its application to personal care products, and to restrict the use of the USDA Organic Seal.²⁰⁴ To date, USDA has not amended its organic regulations to reflect the recommendations of the committee.

In addition to the USDA’s NOP, other entities have created their own standards programs for what constitutes “organic” in personal care products. For example, with input from industry stakeholders, the National Sanitation Foundation (NSF) International²⁰⁵ and the American National Standards Institute (ANSI)²⁰⁶ established a nonfederal, voluntary standard for personal care products containing organic ingredients.²⁰⁷ The standard (NSF/ANSI 305) allows a labeling claim of “contains organic ingredients” to be made for products with 70% or higher organic content, if the products comply with the standard’s requirements, including certification based on an application, onsite inspection, and technical review, among other steps.²⁰⁸ Manufacturers are required to list the exact percentage of organic content.²⁰⁹ The standard can be used for rinse-off and leave-on personal care products, as well as oral care and personal hygiene products, among others, if such products comply with “materials, processes, production criteria, and conditions”

²⁰⁰ 7 C.F.R. §§205.303-05; USDA, About Organic Labeling, <https://www.ams.usda.gov/rules-regulations/organic/labeling>.

²⁰¹ USDA, NOP, National Organic Standards Board, Certification, Accreditation, and Compliance Committee, *Recommendation: Solving the Problem of Mislabeled Organic Personal Care Products*, December 10, 2009, <https://www.ams.usda.gov/sites/default/files/media/NOP%20Final%20Rec%20Cosmetics.pdf>.

²⁰² *Ibid.*

²⁰³ *Ibid.*

²⁰⁴ *Ibid.*

²⁰⁵ NSF International is a nongovernmental, “not-for-profit, standards development and testing/certification organization” that provides education in the field of public health and safety and serves manufacturers operating in 80 countries. See NSF, “About NSF,” <https://www.nsf.org/about-nsf>; NSF, “Q&A on the American National Standard for Personal Care Products Containing Organic Ingredients,” https://www.qai-inc.com/media/docs/Contains_Organic_Ingredients_FAQ.pdf.

²⁰⁶ ANSI is “a private, non-profit organization that administers and coordinates the U.S. voluntary standardization and conformity assessment system. ANSI standards are developed on the principles of due-process, participation, and consensus.” “Q&A on the American National Standard for Personal Care Products Containing Organic Ingredients,” http://www.nsf.org/business/newsroom/press_releases/documents/110620_Contains-Organic-Ingredients-QA.pdf.

²⁰⁷ NSF, “Organic Personal Care Standards,” <https://www.nsf.org/standards-development/standards-portfolio/organic-personal-care-standards>.

²⁰⁸ NSF, “Q&A on the American National Standard for Personal Care Products Containing Organic Ingredients,” https://www.qai-inc.com/media/docs/Contains_Organic_Ingredients_FAQ.

²⁰⁹ *Ibid.*

specified in the standard.²¹⁰ One of the primary differences between the USDA NOP regulations and the NSF/ANSI standard is that the NSF/ANSI standard allows organic ingredients to “undergo certain chemical processes—methods considered synthetic under the NOP.”²¹¹ According to NSF International, compliance with this standard may “provide a competitive advantage to those certified products” that contain organic ingredients.²¹²

Related claims that appear on cosmetic products, such as “natural” or “clean,” remain undefined in federal law and regulation. Although FDA has asked for public comments on defining the use of the term “natural” in food, it has not done so for cosmetics.²¹³ In 2016, the FTC pursued action against five companies marketing their products as “all natural” or “100% natural” despite containing synthetic ingredients.²¹⁴ Legislation has been introduced to require that cosmetics bearing certain claims (e.g., “natural”) meet specific standards.²¹⁵

“Not Tested on Animals” Labeling

Many cosmetic products contain ingredients or raw materials that have been tested on animals in the past, but those products do not necessarily currently involve animal testing.²¹⁶ Although manufacturers may use “no animal testing” claims for their products, they still “may rely on raw material suppliers or contract laboratories to perform any animal testing necessary to substantiate product or ingredient safety.”²¹⁷ As such, consumers may find it confusing to distinguish cosmetic products with ingredients that have never been tested on animals from cosmetic products that may use or contract for the use of animal testing at some point in the product’s path to commerce.

Some companies promote their products as not having been tested on animals, either because they contain all-natural ingredients or because they are labeled with such terms as “finished product not tested on animals,” “no animal ingredients,” or “cruelty free.” FDA does not define or prescribe the use of these terms. In the absence of federal regulation on the use of such terms, animal rights groups have created programs in which companies that self-certify that they are “cruelty free” may license the organization’s logo for use on their products.²¹⁸ Legislation has

²¹⁰ Ibid.

²¹¹ Ibid.

²¹² Ibid.

²¹³ FDA, “Use of the Term Natural on Food Labeling,” <https://www.fda.gov/food/food-labeling-nutrition/use-term-natural-food-labeling>. Comments were submitted to docket folder FDA-2014-N-1207, <https://www.regulations.gov/docket/FDA-2014-N-1207/document>.

²¹⁴ FTC, “Four Companies Agree to Stop Falsely Promoting Their Personal-Care Products as ‘All Natural’ or ‘100% Natural’; Fifth is Charged in Commission Complaint,” April 12, 2016, <https://www.ftc.gov/news-events/press-releases/2016/04/four-companies-agree-stop-falsely-promoting-their-personal-care>.

²¹⁵ See, for example, in the 117th Congress, H.R. 5872, the Natural Cosmetics Act and S. 2100, the Personal Care Products Safety Act, Section 106(b).

²¹⁶ FDA, “Cruelty Free/Not Tested on Animals,” <https://www.fda.gov/cosmetics/cosmetics-labeling-claims/cruelty-freenot-tested-animals>.

²¹⁷ Ibid.

²¹⁸ PETA, “PETA’s ‘Global Beauty without Bunnies Program,’” <https://www.peta.org/living/personal-care-fashion/beauty-without-bunnies/>. As another example, the Coalition for Consumer Information on Cosmetics’ (CCIC) Leaping Bunny Program allows cosmetics products that meet certain criteria for non animal-tested cosmetic products to bear a “leaping bunny” logo. For this program, the company makes voluntary guarantees regarding the company’s and supplier’s commitment not to test on animals, and the CCIC may require an independent audit. Coalition for Consumer Information on Cosmetics, the Corporate Standard of Compassion for Animals (“the Standard”), <https://www.leapingbunny.org/about/corporate-standard-compassion-animals-standard>. The independent audit is commissioned either by the company or the CCIC, depending on the company’s gross annual sales, and is performed

been introduced that would, among other things, restrict the use of claims that a cosmetic product was not tested on animals, including use of “cruelty-free” claims or logos.²¹⁹

“For Professional Use Only” Labeling

Consumers and professionals who use “for professional use only” cosmetic products may be interested in certain information that is not required to appear on the label.

According to FDA regulations implementing the FPLA, cosmetics that are “consumer commodities” are required to list their ingredients.²²⁰ This requirement applies to products produced or distributed for retail sale and does not apply to “for professional use only” products used only by salons, if the salon does not also offer the product for purchase by its customers.²²¹ As a result, “cosmetologists and other professionals, as well as their clients, may not know what chemicals are in the cosmetics used in nonretail businesses, such as beauty salons.”²²² However, if a cosmetic product is labeled “for professional use only” but sold by a retailer, the ingredients must be listed, or the product is considered to be misbranded.²²³ Ingredients used in “for professional use only” cosmetic products are not included in the VCRP.²²⁴

FDA does not define which cosmetic products are “For Professional Use Only.” Cosmetic manufacturers and beauty supply companies that produce these products may limit distribution of such products to salons and salon professionals.²²⁵ Despite manufacturer sale restrictions, some distributors have sold “for professional use only” products to retail stores, potentially in contravention of contracts or agreements between distributors and manufacturers regarding the sale of such products, as well as the misbranding prohibition of the FFDCA and related provisions in the FPLA.²²⁶

Legislation has been introduced that would require cosmetic products for professional use to list ingredients and warnings for vulnerable populations and to be labeled for professional use only.²²⁷

Concerns About FDA’s Authority to Regulate Cosmetic Market

Various stakeholders, GAO, and some Members of Congress have identified limitations in FDA’s authority to regulate the cosmetics market, noting that these limitations may expose consumers to

by an accredited auditing firm.

²¹⁹ See, for example, in the 117th Congress, H.R. 6207, S. 3357, the Human Cosmetics Act of 2021, Section 2(j).

²²⁰ 21 C.F.R. §701.3.

²²¹ 15 U.S.C. §§1459(a), 1453.

²²² GAO, *Cosmetics Regulation: Information on Voluntary Actions Agreed to by FDA and the Industry*, Report to the Chairman, Subcommittee on Regulation, Business Opportunities, and Energy, House Committee on Small Business, GAO/HRD-90-58, (March 1990), p. 13.

²²³ FFDCA §602 (21 U.S.C. §362)(15 U.S.C. §1459(a)). The FPLA limits “consumer commodities” to those products sold at retail.

²²⁴ FDA, “Voluntary Cosmetic Registration Program,” <https://www.fda.gov/cosmetics/voluntary-cosmetic-registration-program>.

²²⁵ First Research, *Industry Profile, Cosmetics, Beauty Supply, and Perfume Stores*, December 6, 2021.

²²⁶ Ibid.; GAO, *Cosmetics Regulation: Information on Voluntary Actions Agreed to by FDA and the Industry*, Report to the Chairman, Subcommittee on Regulation, Business Opportunities, and Energy, House Committee on Small Business, GAO/HRD-90-58, (March 1990), pp. 13-14; 15 U.S.C. §§1452(a), 1456(a).

²²⁷ See, for example, in the 117th Congress, S. 2100, the Personal Care Products Safety Act, Section 106(a), and H.R. 5540, the Cosmetic Safety for Communities of Color and Professional Salon Workers Act of 2021, Section 6.

unnecessary health risks. Some advocacy groups, for example, cite regulatory schemes adopted by foreign governments for cosmetic products and contend that these schemes allow those governments a greater degree of control over the manufacturing and selling of cosmetic goods.²²⁸ These advocacy groups have proposed that FDA's ability to regulate the cosmetic market could be expanded through several actions:

- **Requiring premarket approval of cosmetic products.** Unlike other products regulated by FDA (e.g., drugs and tobacco), cosmetic products are not required to receive premarket approval from the agency before being introduced on the market. Furthermore, FDA does not have the authority to approve cosmetic ingredients (other than color additives) before those ingredients are introduced into the market.²²⁹ FDA's premarket approval process for other products generally allows the agency to determine that the products are safe and effective for their intended use. Manufacturers of these products can substantiate those claims by submitting an application for a product to the FDA and then adhering to the premarket product approval process.²³⁰ Some observers have argued that the FDA premarket approval process has various flaws that may curtail FDA's ability to verify the safety and efficacy of those products.²³¹ Other observers have stated that the approval process is time-consuming and extremely expensive.²³² FDA has previously noted that the requirements in the FFDCAs are based on risk; therefore, premarket approval is not required for cosmetics products because most cosmetics do not pose the same risks as medical products.²³³ Prior legislative proposals have included provisions that would have required cosmetic firms to submit a cosmetic ingredient statement to the FDA that includes information about the cosmetic and the facility in which it was manufactured.²³⁴ Such proposals would have required FDA to evaluate the safety of specific cosmetic ingredients. In determining whether to require premarket approval of cosmetics, Congress may consider the additional regulatory and financial burden that such a requirement might place on the entities involved in cosmetic production.
- **Authorizing FDA to issue mandatory recalls.** Although FDA can order mandatory recalls for some of the products it regulates,²³⁵ it is not authorized to

²²⁸ See, for example, Scott Faber, *On Cosmetics Safety, U.S. Trails More Than 40 Nations*, Environmental Working Group, March 20, 2019, <https://www.ewg.org/news-insights/news/cosmetics-safety-us-trails-more-40-nations>.

²²⁹ FDA, "Product Testing of Cosmetics," <https://www.fda.gov/cosmetics/cosmetics-science-research/product-testing-cosmetics>.

²³⁰ For more detail on the FDA approval process for drugs, biologics, and medical devices, see CRS In Focus IF11083, *Medical Product Regulation: Drugs, Biologics, and Devices*.

²³¹ See, for example, Michelle Llamas, *Misplaced Trust: Why FDA Approval Doesn't Guarantee Drug Safety*, drugwatch, May 16, 2017, <https://www.drugwatch.com/featured/misplaced-trust-fda-approval-concerns/>.

²³² Gail A. Van Norman, "Drugs, Devices, and the FDA: Part 1 An Overview of Approval Processes for Drugs," *JACC: Basic to Translational Science*, vol. 170, no. 9 (March 10, 2016), pp. 170-179.

²³³ FDA, "Statement from FDA Commissioner Scott Gottlieb, M.D., and Susan Mayne, Ph.D., director of the Center for Food Safety and Applied Nutrition, on tests confirming a 2017 finding of asbestos contamination in certain cosmetic products and new steps that FDA is pursuing to improve cosmetics safety," March 5, 2019, <https://www.fda.gov/news-events/press-announcements/statement-fda-commissioner-scott-gottlieb-md-and-susan-mayne-phd-director-center-food-safety-and>.

²³⁴ See, for example, S. 2100 (117th Congress), the Personal Care Products Safety Act, and H.R. 5279 (116th Congress), the Cosmetic Safety Enhancement Act.

²³⁵ See, for example, FDA, "Questions and Answers Regarding Mandatory Food Recalls: Guidance for Industry and

order mandatory recalls for cosmetic products. When FDA determines that a cosmetic may pose a health hazard, the agency can (1) request that a cosmetic manufacturer recall a product, (2) evaluate the product for its potential health hazard, (3) notify the public, (4) ensure that the product is destroyed, and (5) monitor the progress of the recall.²³⁶ Although most recalls are voluntary in nature, and companies generally comply with FDA's request for removal of a violative product from the market, FDA has identified at least one instance where a company refused to do so.²³⁷

- **Requiring registration of cosmetic firms.** Cosmetic firms are not required to register with FDA, nor are they required to obtain a registration number to import cosmetics into the United States. FDA “strongly” encourages firms to register their establishments and file a CPIS through a voluntary program that has existed since 1972.²³⁸ In 2018, FDA launched a new online portal through which cosmetic firms can file this information, and since then, over 6,700 online accounts have been created and over 24,000 products have been filed.²³⁹ Recent legislation has proposed, among other things, requiring cosmetic firms to register with FDA and to include information such as an ingredient listing for all cosmetic products manufactured or processed in each facility, or contact information for foreign facilities associated with the firm.²⁴⁰ Some estimates place the 2022 revenue of cosmetics products in the United States at over \$18 billion.²⁴¹ FDA estimates that about one-third of cosmetic product manufacturers file CPISs for their products with the agency.²⁴² However, it is difficult to assess what percentage of the cosmetic market the FDA voluntary registration program has captured. Some observers have suggested that a mandatory registration process may give FDA better insight into which manufacturers are possibly introducing harmful cosmetic products into the market.²⁴³

FDA Staff,” November, 2018, <https://www.fda.gov/media/117429/download>.

²³⁶ FDA, “FDA Recall Policy for Cosmetics,” <https://www.fda.gov/cosmetics/cosmetics-recalls-alerts/fda-recall-policy-cosmetics>.

²³⁷ FDA, “Statement from FDA Commissioner Scott Gottlieb, M.D., and Susan Mayne, Ph.D., director of the Center for Food Safety and Applied Nutrition, on tests confirming a 2017 finding of asbestos contamination in certain cosmetic products and new steps that FDA is pursuing to improve cosmetics safety,” March 5, 2019, <https://www.fda.gov/news-events/press-announcements/statement-fda-commissioner-scott-gottlieb-md-and-susan-mayne-phd-director-center-food-safety-and>.

²³⁸ FDA, “Are Cosmetic Companies Required to Register with FDA?,” <https://www.fda.gov/industry/fda-basics-industry/are-cosmetic-companies-required-register-fda>.

²³⁹ FDA, “Cosmetic Registration Reports,” accessed February 1, 2022, <https://www.fda.gov/cosmetics/voluntary-cosmetic-registration-program/cosmetic-registration-reports>.

²⁴⁰ See, for example, S. 2100 (117th Congress), the Personal Care Products Safety Act, and S. 2003 (115th Congress), the FDA Cosmetic Safety and Modernization Act.

²⁴¹ Statista, Cosmetics and Personal Care, “Revenue of the cosmetics market in the United States from 2012 to 2025,” October 28, 2021, <https://www.statista.com/forecasts/1272319/united-states-revenue-cosmetics-market>.

²⁴² Testimony of Susan Mayne, Director of the Center for Food Safety and Applied Nutrition at FDA, before the House Committee on Energy and Commerce, Subcommittee on Health, *Building Consumer Confidence by Empowering FDA to Improve Cosmetic Safety*, 116th Congress, December 4, 2019.

²⁴³ Scott Faber, *On Cosmetics Safety, U.S. Trails More Than 40 Nations*, Environmental Working Group, March 20, 2019, <https://www.ewg.org/news-insights/news/cosmetics-safety-us-trails-more-40-nations>. FDA, “Using Adverse Event Reports to Monitor Cosmetic Safety: A Conversation with Linda Katz [then-director of the FDA’s Office of Cosmetics and Colors],” November 3, 2017, <https://www.fda.gov/cosmetics/how-report-cosmetic-related-complaint/using-adverse-event-reports-monitor-cosmetic-safety>.

- **Expanding FDA’s risk assessment authority.** Some individuals have suggested that FDA should begin conducting human risk-assessment studies²⁴⁴ of cosmetics of concern.²⁴⁵ FDA’s CFSAN has already developed, in collaboration with other federal agencies, tools to address public health issues in food products.²⁴⁶ Some have suggested that FDA should develop similar tools focused on cosmetic products and their ingredients, which might help FDA determine if those products are exposing consumers to harm.²⁴⁷
- **Requiring mandatory reporting of adverse events related to cosmetics.** FDA does not have the authority to require cosmetic firms to report adverse events related to their products. Consumers who have suffered an adverse event, health professionals, and members of the cosmetic industry and other individuals are encouraged to report such events to FDA through a variety of mechanisms, including to CAERS through MedWatch. FDA then uses this information to determine whether the agency should take further action.²⁴⁸ From January 2004 to December 2020, nearly 36,000 adverse events were reported to CAERS for various cosmetics products.²⁴⁹ Because cosmetic manufacturers are not required to inform the FDA of adverse events, it is difficult to assess the true number of adverse events associated with cosmetic products.²⁵⁰
- **Authorizing FDA to issue cosmetic Current Good Manufacturing Practice (cGMP) regulations.** Good manufacturing practices are intended to ensure that cosmetic products are consistently manufactured to a quality that is appropriate for their intended use.²⁵¹ Although FDA has issued draft guidance for the cosmetic industry on cGMP, no federal regulations mandate cGMP.²⁵² Although the FFDCA requires cosmetic manufacturers to ensure that their products are not adulterated or misbranded, various entities have argued that cGMP regulations would ensure that cosmetic products are produced to a uniform, safe standard. When deciding whether to direct FDA to issue such regulations, Congress may consider the potential regulatory burden on small businesses and manufacturers.

²⁴⁴ A risk assessment study identifies potential hazards and analyzes the potential impact that hazard may have.

²⁴⁵ Grace Wallack, *Rethinking FDA’s Regulation of Cosmetics*, Harvard Law School, 2019, p. 336, https://harvardjoi.com/wp-content/uploads/sites/17/2019/05/HLL107_crop.pdf.

²⁴⁶ FDA, “Risk Analysis at FDA: Food Safety,” February, 2011, <https://www.fda.gov/media/81256/download>.

²⁴⁷ Grace Wallack, *Rethinking FDA’s Regulation of Cosmetics*, Harvard Law School, 2019, p. 336, https://harvardjoi.com/wp-content/uploads/sites/17/2019/05/HLL107_crop.pdf.

²⁴⁸ FDA, “How to Report a Cosmetic Related Complaint,” <https://www.fda.gov/cosmetics/cosmetics-compliance-enforcement/how-report-cosmetic-related-complaint>.

²⁴⁹ CRS analysis of data from FDA, “CFSAN Adverse Event Reporting System (CAERS),” <https://www.fda.gov/food/compliance-enforcement-food/cfsan-adverse-event-reporting-system-caers#files>.

²⁵⁰ For example, some proponents of cosmetics reform cite an example wherein FDA received 127 complaints for a hair conditioner. Upon investigation, FDA found that the company had received 21,000 complaints about that product but had failed to report to the FDA. See Beth Mole, *WEN hair loss scandal exposed dirty underbelly of personal care products*, Arstechnica, June 28, 2017, <https://arstechnica.com/science/2017/06/wen-hair-loss-scandal-cracked-open-dirty-underbelly-of-personal-care-products/>.

²⁵¹ FDA, “Good Manufacturing Practice (GMP) Guidelines/Inspection Checklist,” <https://www.fda.gov/cosmetics/cosmetics-guidance-documents/good-manufacturing-practice-gmp-guidelinesinspection-checklist-cosmetics>.

²⁵² *Ibid.*, p. 5.

Conclusion

FDA's authorities over cosmetic products are generally less comprehensive than those for other FDA-regulated products and exclude certain requirements imposed on other FDA-regulated products. The manner in which a cosmetic product could or should be regulated, however, is not always clear. FDA has issued regulations and procedures for cosmetics, but manufacturers' compliance is voluntary. In addition, the cosmetic industry's trade association has established a cosmetic ingredient review program for cosmetic manufacturers to determine which cosmetic ingredients are safe under certain conditions of use. Nevertheless, questions remain regarding the degree to which FDA's current oversight of cosmetic products and their ingredients is appropriate.

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

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