

FDA and FTC Legal Boundaries for Cosmetics

August 11, 2025

By Michael H. Cohen

The FDA regulates the safety and labeling of cosmetics under the Federal Food, Drug, and Cosmetic Act (FDCA). It ensures products are not adulterated or misbranded and monitors whether certain claims transform a cosmetic into a “drug” under the law.

On the other hand, **the FTC oversees advertising practices, ensuring that cosmetic marketing is truthful, not misleading, and backed by reliable evidence.** The FTC can take enforcement action against deceptive or unfair business practices in cosmetic advertising.

This post covers why cosmetics companies must understand FDA and FTC roles. It also lets you know how to protect your brand from regulatory action.

What is the FDA’s Role in Cosmetics Regulation?

The U.S. Food and Drug Administration (FDA) plays an important role in overseeing the safety and labeling of cosmetic products sold in the United States. Under the Federal Food, Drug, and Cosmetic Act (FDCA), the FDA is responsible for ensuring that cosmetics are not adulterated or misbranded and that consumers are not misled by false or deceptive labeling.

However, unlike drugs or certain medical devices, cosmetics do not require FDA pre-approval before they reach the market. This places a greater responsibility on manufacturers and distributors to ensure product compliance.

Cosmetics, as defined by the FDA, are products intended to be applied to the human body for cleansing, beautifying, promoting attractiveness, or altering the appearance. This includes items like makeup, skin moisturizers, shampoos, deodorants, perfumes, and certain skin treatments.

It’s important to note that if a product is marketed with claims that it treats or prevents disease or affects the structure or function of the body, it may be classified as a drug, even if it’s also a cosmetic. For example, a lotion marketed to moisturize the skin is a cosmetic, but one that claims to treat eczema would be regulated as a drug.

Under FDA regulations, cosmetics must meet specific standards to be legally marketed. They must be safe for use under labeled or customary conditions, and their labeling must be truthful and not misleading. Cosmetic labels are required to include the name and address of the manufacturer or distributor, an accurate statement of the quantity of contents, and a complete listing of ingredients in descending order of predominance. The FDA also monitors for prohibited ingredients and contaminants that could pose a risk to consumer health.

The FDA's role is reactive rather than proactive. **It typically steps in after products are already on the market if there are reports of adverse events, labeling violations, or safety concerns.**

One of the most significant distinctions in FDA law is the difference between cosmetics and drugs. Drugs are subject to much stricter regulations, including premarket approval, clinical trials, and adherence to Good Manufacturing Practices (GMP). A cosmetic becomes a drug if it makes claims to affect the structure or function of the body or to treat or prevent disease.

What are FDA Legal Boundaries for Cosmetics?

Cosmetics are products intended to be applied to the human body for cleansing, beautifying, promoting attractiveness, or altering appearance. These include personal care products such as skin moisturizers, fingernail polishes, perfumes, shampoos, and makeup.

Under the Food, Drug, and Cosmetic Act (FD&C Act), the FDA classifies these products based on their intended use. If a product claims to affect the structure or function of the human body such as "treating acne," "stimulating collagen production," or "removing wrinkles", it may be reclassified as a drug or even a medical device. Therefore, it is subject to far stricter regulations and requires FDA premarket approval.

Cosmetic companies must stay within clear legal boundaries to avoid crossing into drug claims. While cosmetic products do not require FDA premarket approval, the FDA has authority over several aspects of cosmetic regulation.

These include ensuring that products are not adulterated, meaning they contain harmful or contaminated substances, and that they are not misbranded, meaning their labeling is false, misleading, or lacking required information. **The FDA does not evaluate the efficacy of cosmetics, unlike drugs, but it will take enforcement action if advertising claims are deceptive or if products are deceptively packaged.** When cosmetic manufacturers make implied claims that a product has therapeutic benefits without proper substantiation, they risk violating both FDA and FTC legal boundaries.

FDA Regulations for Cosmetic Ingredients and Safety

Cosmetic manufacturers are responsible for ensuring that ingredients used in their products are safe for their intended use. Although there is no mandatory premarket approval for most cosmetic ingredients, **color additives are an exception and must receive specific FDA approval before they can be used in cosmetic formulations.** The FDA has banned or restricted certain harmful substances in cosmetics, such as **mercury compounds and chlorofluorocarbons**, to protect consumers from dangerous products.

To comply with FDA law, cosmetic firms must implement internal quality control systems and conduct necessary safety testing. The agency does not require companies to submit clinical studies or other scientific data before marketing a product, but it does expect that adequate substantiation of safety exists behind the scenes.

Any product found to be contaminated with harmful bacteria, improperly formulated, or otherwise unsafe may be considered adulterated under the FD&C Act, which could trigger regulatory action and even product recall. Cosmetic companies should also consider potential issues related to microbial contamination, especially in products like eye creams and hair dyes that may come into contact with sensitive areas of the body.

FDA Requirements for Cosmetic Labeling and Claims

The FDA enforces strict labeling requirements to inform consumers and prevent misleading or deceptive advertising claims. **Cosmetic labels must include the product's identity, the name and address of the manufacturer or distributor, the net quantity of contents, and a full list of ingredients in descending order of predominance.** Usage instructions and required warnings must also be clearly visible and easy for consumers to understand. Products that are deceptively packaged or contain false or unsubstantiated claims may be considered misbranded.

While cosmetics may make certain claims such as "moisturizes dry skin" or "adds shine to hair," they must avoid language that

implies a medical or therapeutic benefit unless the product has undergone drug-level scrutiny. For example, terms like “hypoallergenic” or “natural” may not have a standard FDA definition but should still be adequately substantiated to avoid potential FTC and FDA enforcement.

Similarly, claims involving “anti-aging” or “reversing skin damage” must be carefully crafted to remain within the boundaries of cosmetic law. The FDA, in collaboration with the Federal Trade Commission, may pursue enforcement action against cosmetic manufacturers or distributors making deceptive or inadequately substantiated claims.

FDA Adverse Event Reporting and Safety Monitoring

Although reporting adverse events is not mandatory for cosmetic products, it is strongly encouraged under FDA guidelines. **Serious adverse events, including those resulting in hospitalization, significant disability, or death, can be reported through the FDA’s Voluntary Cosmetic Registration Program (VCRP) or MedWatch system.** These reports help the FDA monitor the safety of cosmetics on the market and take swift action when dangerous products emerge.

Cosmetic manufacturers and distributors should develop internal systems to track and investigate consumer complaints. These systems can help identify trends in product safety issues and inform the need for corrective action, including product reformulation or voluntary recall.

Adverse event data also helps the FDA evaluate whether certain products, ingredients, or packaging methods pose a risk to public health. Maintaining transparency with the FDA by reporting safety incidents not only demonstrates good faith but can also reduce the risk of severe enforcement action later on.

FDA Enforcement Actions and Penalties for Non-Compliance

If a cosmetic product is found to violate FDA regulations, the agency may initiate a range of enforcement actions. **These include issuing warning letters, seizing products, seeking injunctions, or even pursuing criminal prosecution in extreme cases.** While most FDA enforcement actions begin with informal discussions or warning letters, failure to take prompt corrective action can escalate the situation quickly.

In some cases, the FDA may mandate or recommend a recall. Although most cosmetic recalls are initiated voluntarily by the manufacturer, the FDA has the authority to intervene if public safety is at risk. Legal issues associated with non-compliance can lead to product bans, reputational harm, or long-term scrutiny from regulators.

FDA Guidelines for Cosmetic Product Recalls

The FDA recommends that companies initiate a voluntary recall when they discover a product to be unsafe, mislabeled, or adulterated. **Having a recall plan in place allows cosmetic manufacturers to respond quickly, communicate effectively with distributors, retailers, and consumers, and minimize harm.** Recalls must be documented thoroughly and executed transparently to meet FDA expectations.

The FDA may choose to monitor the recall process and evaluate its effectiveness. Public notices may be required to ensure that all affected consumers are informed. Proper record-keeping and traceability systems help cosmetic firms demonstrate compliance in the event of future inspections or audits. A prompt and transparent recall reduces legal risk and shows consumers that the brand prioritizes their safety.

What is the FTC’s Role in Cosmetics Marketing and Advertising?

The Federal Trade Commission (FTC) plays a central role in regulating advertising and marketing claims made by cosmetic companies in the United States. While the Food and Drug Administration (FDA) focuses on product safety, labeling, and classification, **the FTC is the government agency responsible for ensuring that all advertising claims related to cosmetic products are truthful, not misleading, and adequately substantiated.**

The FTC's jurisdiction covers everything from print and digital advertising to social media marketing, influencer endorsements, and product packaging that includes promotional language. The cosmetics industry must carefully observe both the FDA and FTC legal boundaries to prevent regulatory action and legal issues.

Deceptive or misleading advertising is defined by the FTC as any marketing practice that misrepresents a product or omits important information in a way that is likely to mislead reasonable consumers. This includes both express claims and implied claims. For example, a claim that a skin moisturizer "eliminates wrinkles overnight" must be supported by solid scientific evidence; otherwise, the advertising is considered deceptive.

The FTC also scrutinizes terms like "hypoallergenic," "natural," "organic," or "dermatologist-recommended," especially when such claims are used to suggest that a product is safer or more effective than it truly is. Without adequate substantiation, such claims can result in FTC enforcement action.

Substantiation is a key requirement under FTC law. Cosmetic firms must be able to provide competent and reliable evidence to support any marketing claims, including clinical studies, consumer perception data, or other scientific backing. Claims made about consumer products, such as hair dyes or permanent waves, must not only reflect the intended use of the product but also align with consumer expectations based on the language used. The FTC emphasizes that advertising must inform consumers without misleading them, which means all claims must be truthful and not exaggerated.

What Are the FTC Legal Boundaries for Cosmetics Marketing?

Cosmetic companies must adhere to strict FTC guidelines that govern how products are marketed to consumers. Claims must be truthful, not misleading, and backed by evidence.

Even statements that seem harmless, like "improves skin tone" or "revitalizes tired eyes," can be considered deceptive if the advertiser cannot provide adequate substantiation. Implied claims, such as the suggestion that a product is "FDA approved" when it is not, are also prohibited. In fact, the use of government symbols, false certifications, or deceptive imagery that implies regulatory endorsement can result in swift enforcement action by the FTC.

Endorsements and testimonials are another area of focus under FTC authority. When a cosmetic firm uses influencers, celebrities, or customer testimonials to promote their products, the FTC requires that any material connection between the endorser and the company be disclosed. This includes sponsored content, gifted products, paid partnerships, and affiliate links.

If a social media influencer is compensated to promote a skin moisturizer or hair color, they must clearly state that the post is sponsored or that they received compensation. Failure to disclose these relationships can result in regulatory penalties for both the influencer and the brand.

The FTC also requires that **disclosures in advertising be "clear and conspicuous."** This means that disclaimers or qualifying information must be easy for consumers to see and understand, not hidden in fine print or buried at the bottom of a page.

For example, if a cosmetic product has limited benefits that apply only under certain conditions, this must be stated clearly in the advertisement. The FTC monitors advertising claims through consumer complaints, marketplace surveillance, and collaboration with other agencies like the FDA. Companies that ignore these guidelines risk facing enforcement actions that could include fines, cease-and-desist orders, and public corrective advertising.

Violating FTC advertising rules can lead to significant legal and financial consequences. Penalties may range from civil fines to injunctive relief, and in some cases, companies may be required to refund consumers or undergo long-term compliance monitoring.

For small businesses and growing cosmetic firms, these penalties can be devastating. The FTC's involvement in the

cosmetics industry ensures that consumers are protected from dangerous products, misleading marketing, and deceptive advertising. It also holds cosmetic manufacturers accountable for maintaining ethical marketing practices and adequately substantiating every claim they make.

How Do FDA and FTC Regulations for Cosmetics Differ?

The FDA and the FTC are two government agencies that regulate cosmetic products, but their responsibilities are distinct and complementary. **The FDA (Food and Drug Administration) focuses primarily on product safety, labeling accuracy, and ensuring that cosmetics are not adulterated or misbranded under the Federal Food, Drug, and Cosmetic Act (FD&C Act).** Its role centers around how products are formulated, labeled, and packaged, and whether they comply with safety standards, particularly regarding color additives, banned substances, and proper disclosure of ingredients.

In contrast, the FTC (Federal Trade Commission) regulates the advertising and marketing claims made by cosmetic companies under its authority to prevent deceptive or misleading business practices. The FTC's jurisdiction extends to all forms of advertising, including digital content, influencer partnerships, endorsements, product packaging, and traditional media. The agency ensures that cosmetic firms do not make false, unsubstantiated, or exaggerated claims about product performance, such as suggesting a cosmetic can cure, treat, or prevent a medical condition.

These different approaches significantly impact how cosmetic businesses operate. While the FDA might inspect a product for microbial contamination, inadequate labeling, or banned ingredients, the FTC will scrutinize whether the product's marketing is backed by adequate substantiation, particularly when it includes terms like "natural," "clinically proven," or "hypoallergenic." For example, a brand selling skin moisturizers might pass an FDA inspection for safety but still face FTC enforcement if its ad falsely claims that the product reverses aging without credible clinical evidence.

Despite their different focus areas, FDA and FTC legal boundaries often intersect, especially when cosmetic claims stray into drug territory. If a company markets a cosmetic with language like "treats acne" or "heals eczema," the FDA may classify that product as a drug, subjecting it to far more stringent regulations, including premarket approval. At the same time, the FTC could step in if those claims lack scientific backing, even if they fall short of FDA-defined drug claims. In such cases, both agencies may pursue regulatory action, making it critical for businesses to stay alert to overlapping rules.

To remain compliant, cosmetic firms should build strong internal systems to ensure their product formulations, labels, packaging, and advertising meet the expectations of both agencies. Working with regulatory experts who understand the nuanced requirements of the FDA and FTC, like the experts at Cohen Healthcare Law Group, can help avoid costly missteps.

What Are the Legal Risks of Violating FDA and FTC Rules?

Violating FDA and FTC regulations poses serious legal risks for cosmetic companies. The FDA may issue **warning letters** to companies whose products are considered misbranded or adulterated, demanding immediate corrective action. In more serious cases, the FDA can escalate enforcement through **product seizures, injunctions, import bans**, or even **criminal prosecution**, especially when companies continue to market dangerous products or ignore FDA orders.

Meanwhile, the **FTC can impose civil penalties, cease-and-desist orders**, and require companies to issue **corrective advertising** when marketing claims are found to be deceptive or misleading. These actions often come with costly fines and force businesses to halt sales until compliance is achieved. For example, if a firm advertises a hair dye as "clinically proven to regrow hair" without substantiating the claim, the FTC can step in to stop the ad campaign and demand refunds to consumers.

Beyond regulatory fines, companies may be forced into **expensive product recalls**, especially if labeling errors or false claims affect large volumes of product already in circulation. A recall can **erode consumer trust**, lead to **negative media attention**, and damage a brand's long-term reputation. Even worse, legal actions from these agencies can lead to **lengthy investigations**, mounting legal fees, and **lost revenue** from paused operations or delisted products.

Non-compliance doesn't only affect large brands. **Small businesses** in the cosmetics industry are equally at risk and may be less prepared to absorb the financial fallout of enforcement actions. This makes **proactive compliance** a key business

strategy, ensuring that every product launched is legally sound from formulation to final advertisement.

How Can Businesses Ensure Compliance with FDA and FTC Regulations?

To stay compliant, cosmetic companies must first ensure they **understand and follow all applicable FDA and FTC requirements**. This includes knowing the difference between a cosmetic and a drug under FDA law, using only FDA-approved color additives, and avoiding ingredients known to be banned or restricted. Labels must clearly identify the product, include the required information, and avoid misleading claims that could make a product appear FDA approved when it is not.

Businesses must also **align their marketing strategies with FTC standards**, which require that all advertising claims be truthful, non-deceptive, and adequately substantiated. Before using terms like “organic,” “non-toxic,” or “clinically tested,” companies should gather and document credible evidence, such as lab testing, clinical studies, or expert evaluations. Testimonials and influencer partnerships must follow FTC rules for disclosure, particularly when financial or material relationships are involved.

One of the most effective ways to ensure compliance is to **work closely with experienced healthcare or regulatory attorneys**. Legal professionals can review claims, labeling, website content, and promotional campaigns for red flags, helping businesses adjust messaging before a regulator intervenes. In addition, companies should **keep detailed documentation** of ingredient sourcing, safety testing, and marketing claim substantiation so they are prepared in the event of an audit, product recall, or regulatory complaint.

By creating an **internal compliance process** that covers both product safety and advertising practices, cosmetic manufacturers can operate confidently within the legal boundaries set by both the FDA and FTC. The stakes are high, but with the right systems in place, businesses can protect their brand, avoid costly penalties, and earn consumer trust in an increasingly competitive market.

Want to Stay Compliant with FDA & FTC Rules?

For the cosmetics industry, compliance with FDA and FTC regulations is essential. The FDA ensures that your cosmetic products are safe, properly labeled, and not adulterated or misbranded. Meanwhile, the FTC holds you accountable for truthful, non-deceptive advertising and marketing practices.

Failing to comply with either agency’s standards can result in serious consequences, including product recalls, warning letters, financial penalties, lawsuits, and long-term damage to your brand reputation. That’s why it’s important to stay informed, proactive, and legally prepared as you grow your cosmetic business.

FAQs

Here are answers to common questions about cosmetic regulations in the U.S.

When Can the FDA Take Legal Action Against a Cosmetic on the Market?

The FDA can take legal action if a cosmetic is adulterated (unsafe or contaminated) or misbranded (improperly labeled or misleading). This includes actions like warning letters, seizures, injunctions, and even criminal prosecution.

What Are the Two Most Important Laws Pertaining to Cosmetic Sales in the US?

The primary laws are the Federal Food, Drug, and Cosmetic Act (FDCA) and the Fair Packaging and Labeling Act (FPLA). These govern product safety, labeling, and truthful marketing.

Can You Sell Cosmetics Without FDA Approval?

Yes, cosmetics do not require FDA premarket approval before being sold, except for color additives, which must be FDA-approved for their intended use.

What Claims Can Cosmetics Companies Legally Make?

Cosmetic companies can make claims related to enhancing appearance (like moisturizing or smoothing) but cannot claim to treat or prevent diseases or affect the structure or function of the body without being classified as a drug.