Judging a Book by Its Cover: FDA's Scrutiny of Personal Care Products in 2012

By Raqiyyah R. Pippins

We are often told "never to judge a book by its cover." While it stands true that no book should be judged by its cover alone, a review of 2012 Food & Drug Administration (FDA) enforcement activity reinforces that the *covers* (or labeling) for personal care products are of great importance to FDA. This article highlights important regulatory considerations for personal care product manufacturers and marketers, as evidenced by FDA enforcement activity over the past year.

FDA Regulation of Personal Care Products

For the purposes of this article, "personal care products" are defined to include any product that is topically applied to improve a person's appearance. Importantly, "personal care products" has no legal definition, but is commonly used to refer to over-the-counter (OTC) products used by consumers to enhance and maintain their appearance. Generally, FDA-regulated personal care products fall into two regulatory categories: "cosmetics" and OTC "drugs". The Federal Food Drug and Cosmetic Act (FDCA) grants FDA the authority to regulate a number of products, including all cosmetic and OTC drug products destined for the U.S. market. All FDA-regulated products must comply with the FDCA and FDA's related implementing regulations. Violations of the FDCA can result in both civil and criminal penalties.

A personal care product's regulatory classification can deeply impact the regulatory standards governing the product's manufacturing, marketing and labeling. For example, before being marketed, products classified as OTC drugs must either receive pre-market approval by FDA or conform to FDA monographs--essentially an FDA-approved formula for a drug product. While cosmetic manufacturers are responsible for ensuring product safety, products classified as cosmetics do not

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Generally, FDA-regulated personal care products fall into two categories:

CLASSIFICATION	LEGAL DEFINITION	EXAMPLES
Cosmetic	1. any article that is "intended to be rubbed, poured, sprinkled, or sprayed on, introduced into or otherwise applied to the human body or any part thereof for cleansing, beautifying, promoting attractiveness, or altering the appearance; and 2. [any] article intended for use as a component of any such article, except that such term shall not include soap."	Lipstick, nail polish, eye make-up, hair color, skin moisturizers
Drug	1. articles recognized in the official United States Pharmacopoeia, official Homoeopathic Pharmacopoeia of the United States, or official National Formulary, or any supplement to any of them; 2. articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals; and 3. articles (other than food) intended to affect the structure or any function of the body of man or other animals	Antiperspirant, wrinkle reducers, shampoos intended to treat scalp diseases (e.g., seborrheic dermatitis), facial creams intended to treat acne or rosacea

need to obtain pre-market FDA approval or conform to a specified pre-approved FDA formula. In fact, color additives are the only cosmetic ingredients that must be pre-approved by FDA.

FDA Regulation of Personal Care Products in 2012

How FDA categorizes a personal care product is determined, in part, by what FDA concludes to be the manufacturer's "intended use" for the product. Among other things, FDA reviews product covers (e.g., advertisements, websites, labeling, and ingredient statements) as evidence of a product's intended use. A personal care product can be both a drug and a cosmetic (i.e., an antiperspirant that also deodorizes). In these cases, the product must comply with FDA requirements that apply to drugs as well as cosmetics.

In 2011 FDA hinted at its intent to more closely scrutinize the classification of personal care products through several warning letters alleging that the labeling for certain personal care products marketed as cosmetics contained claims or ingredient statements that caused the products to be unapproved drugs under the FDCA.[1] In 2012, FDA reinforced its intent to further distinguish "cosmetic" claims from those FDA has reserved for drugs through targeted letters to companies marketing products with claims regarding anti-aging skin care benefits, hair restoration, and scar removal.

Anti-aging claims. Anti-aging claims have been the subject of increasing FDA scrutiny. In Spring 2011, FDA updated an import alert, entitled "Skin Care Products Labeled As Anti-Aging Creams" to reflect FDA's position that statements that products "counteract," "retard," or "control" the aging process are presumptively viewed as evidence of an intent to sell a product as a drug, while statements that a product can "rejuvenate," "repair," or "restructure" would be viewed as drug claims, depending on context.[2] Last year, FDA put teeth to its position, by sending several warning letters[3] to companies using these terms in advertising for products marketed as cosmetic products, alleging that the claims caused the products to be unapproved drugs. Specifically FDA alleged that claims that a product can "rebuild collagen," "repair the structural damage that…causes… wrinkles," "reduce [the] depth of wrinkles," "help repair aged skin while preventing future damage," and "help[ ] stimulate circulation in the under eye area, thus reducing or eliminating… 'Dark Circles'" indicate that such products are "intended to affect the structure or function of the human body, rendering them drugs under the Act."

The letters also indicate FDA's position that comparing a personal care product to drugs or medical procedures may be viewed by the agency as evidence that the product is intended for use as a drug. For example, in its 2012 letters, FDA alleges that claims that a product "has the muscle-relaxing properties of Botox," "can extend the results of a Botox injection," or is "inspired by eye-lifting surgical techniques" cause a product to be a drug under the FDCA.[4]

Hair restoration or loss prevention claims. FDA has taken the position that claims regarding hair restoration or loss prevention are drug claims. In 2012, FDA sent warning letters to personal care product companies alleging that claims that hair care products marketed as cosmetics could "stimulate hair growth," "help revitalize hair," or "combat…hair loss" caused the products to be misbranded

drugs marketed in violation of the FDCA.[5] Specifically, the letters alleged that the "products are not generally recognized as safe and effective for the above referenced uses; therefore the products are 'new drugs' as defined in section 201(p) of the Act," and cannot be "legally marketed in the United States without an approved New Drug Application (NDA)."

Blemish removal claims. FDA's 2012 letters also mark FDA's intent to closely monitor claims that a product can improve the color or pigmentation of skin. In September 2012, FDA sent two letters to companies alleging that claims that their products could lighten "the scars in. . . upper arms," remove acne scars, or "take.. away acne, rosacea, scars, skin blemishes and deep under skin lesions accumulated by excess UV exposure," "indicate[d] that these products are intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease and/or are intended to affect the structure or any function of the human body, rendering them drugs under the Act."[6]

What Does This Mean For Companies?

An unanticipated FDA warning letter can be costly for a company. In addition to adverse publicity, an unexpected "drug" classification or safety concern can destroy a product launch or marketing schedule, or subject the company to unforeseen premarket clearance requirements. Moreover, FDA warning letters can make a manufacturer vulnerable to piggy back class action law suits under state law.

FDA's 2012 enforcement activity highlights three steps that can be taken by companies to limit the risk profile for personal care products:

- **Avoid product claims that imply physiological improvements to the body or hair.** FDA's 2012 warning letters emphasize the care with which claims must be made for personal care products. According to FDA , cosmetic products are intended to exert a *physical* but not *physiological* effect on the human body.[7] Generally, claims which represent a product to have a physical effect, without causing the product to be a "drug," include "moisturize," "refresh," "soften," "clean," and "deodorize." Approved cosmetic claims also include claims that a product causes a body part to "appear" different (e.g., "makes lashes appear longer"). In contrast, such claims as "revitalize cells," "restore hair growth," and "reduce cellulite" are believed by FDA to represent a product to have physiological effects on the structure or function of the body and, consequently, are reserved for "drug" products under FDA enforcement policies.
- **Avoid comparing products to drugs or surgical procedures.** FDA considers comparisons of personal care products to products recognized as drugs or medical procedures as evidence that the products are intended for use as drugs. Companies should establish guidelines encouraging marketing teams to avoid comparing cosmetic products to products regulated as drugs by FDA.
- **Closely monitor testimonials provided on websites to ensure they do not contain drug claims.** Many FDA warning letters stem from testimonials provided by consumers. Under FDA and FTC guidelines, marketers are responsible for claims made by endorsers and consumers on company sponsored websites. Companies should closely monitor their websites and other social media tools to ensure that products are not touted for uses FDA typically reserves for drugs.

FDA enforcement activity in 2012 serves as a reminder that FDA has increased its scrutiny of personal care products in an effort to ensure compliance with the FDCA. By giving special attention to product *covers*, companies can significantly reduce the risk profile for personal care products in 2013.

1. Raqiyyah R. Pippins, FDA's Scrutiny of Personal Care Products in 2011, *Household and Personal Products Industry* (February 2012).
2. See FDA Import Alert 63-88 available at http://www.accessdata.fda.gov/cms_ia/importalert_188.html last updated January 22, 2013. In January 2013, FDA further updated the import alert to note that "a claim such as 'molecules absorb and expand, exerting upward pressure to 'lift' wrinkles upward' is a claim for an inner structural change that would usually cause a product to be a drug." *Id.*
3. See FDA, "Warning Letters Address Drug Claims Made for Products Marketed as Cosmetics: Warning Letters Addressing Topical Skin Care Preparations" available at http://www.fda.gov/Cosmetics/GuidanceComplianceRegulatoryInformation/ComplianceEnforcement/WarningLetters/ucm081086.htm.
4. See e.g., FDA Warning Letter to Bioque Technologies (Oct. 2012) and FDA Warning Letter to Janson Beckette (Sep. 2012).
5. See FDA, "Warning Letters Address Drug Claims Made for Products Marketed as Cosmetics: Warning Letters Addressing Hair Care Preparations" available at http://www.fda.gov/Cosmetics/GuidanceComplianceRegulatoryInformation/ComplianceEnforcement/WarningLetters/ucm081086.htm.
6. See e.g., FDA Warning Letter to Andes Natural Skin Care LLC (Sep. 2012).
7. FDA, "Is It a Cosmetic, a Drug, or Both? (Or Is It Soap?)," available at http://www.fda.gov/Cosmetics/GuidanceComplianceRegulatoryInformation/ucm074201.htm.