ENFORCEMENT CORNER

"Cosmetics Product Enforcement" — Not an Oxymoron

by John R. Fleder

Cosmetic producers beware. Despite some who say that no one cares whether cosmetic products meet regulatory requirements, you may be the subject of an enforcement action. While the Food and Drug Administration (FDA) undoubtedly takes fewer enforcement actions against cosmetic companies and products than it does against companies selling foods, drugs or devices, FDA and others actively enforce legal requirements concerning cosmetics.

FDA Enforcement

Some believe that the Federal Food, Drug, and Cosmetic Act (FDCA) would more appropriately be called the Federal Food and Drug Act. They would be wrong. The FDCA prohibits selling adulterated and misbranded cosmetics.[1] Among other things, a cosmetic is adulterated if it bears an unsafe color additive or contains a poisonous or deleterious substance which may render it injurious to users.[2] Misbranded cosmetics include those that have false or misleading labeling or labeling that does not contain all required information.[3] FDA also regulates cosmetics under the Fair Packaging and Labeling Act (FPLA).[4] FDA's Center for Food Safety and Applied Nutrition (CFSAN) has primary responsibility for FDA's regulation of cosmetics.

FDA has a variety of tools for enforcing cosmetics' legal requirements, including issuing warning letters and asking the Department of Justice to initiate a seizure action.[5] FDA does not issue warning letters simply as a public reprimand. Rather, such letters should be viewed as a warning of more significant FDA enforcement action should the recipient not adequately address the agency's concerns. If a cosmetic is unsafe, FDA encourages cosmetic companies to recall the product.[6] FDA's enforcement of cosmetics' requirements is probably most active at the nation's borders, where products are often refused or detained. FDA has rarely initiated seizure, injunction or criminal prosecution for violations of cosmetic product legal requirements.

Instead, FDA is much more likely to use the warning letter enforcement tool against cosmetic-like products. For example, FDA has sent warning letters in which the agency found hair removal kits to be medical devices and anti-wrinkle skin creams to be drugs.[7] Indeed, the issue of drugs purportedly masquerading as cosmetics is significant enough that CFSAN and FDA's Center for Drug Evaluation and Research (CDER) have a Memorandum of Understanding on the topic.[8]

One interesting example of FDA's cosmetics enforcement is the saga of decorative contact lenses. The story begins with the Center for Devices and Radiological Health (CDRH) informing a company that decorative contact lenses were prescription medical devices, not cosmetics. In a decision that was controversial in both FDA and Congress, FDA's then Chief Counsel determined that these lenses were cosmetics. However, FDA effectively prohibited the marketing of such products when FDA identified allegedly serious safety concerns with the contact lenses and required companies that intended to market these lenses first "demonstrate to FDA that the product is safe and properly labeled."[9] FDA also issued an Import Alert calling for the detention without physical examination of decorative contact lenses and a press release warning consumers about decorative contact lenses.[10] FDA actively enforced its position that decorative contact lenses were cosmetics until late 2005 when Congress enacted a law that made all contact lenses medical devices.[11]

One of the nation's most active cosmetics enforcement groups is not a government agency, but an industry self-regulation group. The Council of Better Business Bureau's National Advertising Division (NAD) investigates the veracity of advertising, including cosmetics advertising. If NAD finds a claim is not adequately supported by competent and reliable evidence, it will

Mr. Fleder is a Principal in the law firm of Hyman, Phelps & McNamara, P.C., in Washington DC.

recommend that the subject company modify or discontinue the claim. For instance, in December 2007, NAD recommended that Preval modify or discontinue certain claims for its Acti-Fade Complete Age-Defying System because NAD found that the product's claims overstated the product's effectiveness.[12]

If a company does not participate in NAD's investigation or disregards NAD's recommendations, NAD will typically refer the case to the Federal Trade Commission (FTC). The FTC's Division of Advertising Practices "protects consumers from unfair or deceptive advertising and marketing practices that raise health and safety concerns, as well as those that cause economic injury."[13] The FTC takes quite seriously any NAD referral.[14] The FTC prioritizes cases by often focusing first on whether a product raises any safety concerns. The FTC has taken action against companies that made cosmetic claims for cosmetic-like products, such as "cosmeceuticals." For example, in 2003, Rexall Sundown had to pay $12 million to settle an FTC case and class action for Rexall's marketing of Cellasene, a pill Rexall claimed could "eliminate cellulite."[15] NAD has also referred some matters to FDA.

State Enforcement

Many states have long had laws prohibiting the marketing of adulterated or misbranded cosmetics. These laws often closely mirror the language of the FDCA.[16] However, there is a small, but growing trend of states tightening their regulation of cosmetic products. For instance, while the California Attorney General found that levels of lead in lipstick did not warrant action under Prop 65, the Attorney General did file suit against a handful of companies that market natural personal care products containing 1, 4-dioxane.[17]

Future Areas for Enforcement

A number of state legislatures have recently considered bills that would prohibit or require labeling disclosure of cosmetics' ingredients. In 2006, California enacted the California Safe Cosmetics Act, which requires a cosmetic manufacturer to notify the state of any ingredient in a cosmetic product that is on California's or a specified "authoritative body's" list of chemicals that cause cancer or reproductive toxicity.[18] In Massachusetts, one pending bill would temporarily require companies to disclose to its Department of Health any cosmetic product containing an ingredient deemed unsafe by FDA or the Personal Care Products Council's Cosmetic Ingredient Review.[19] If the bill is enacted, cosmetics containing such ingredients would be per se adulterated or misbranded two years after the bill's enactment. Another pending Massachusetts bill would require companies to phase in alternatives to 10 chemicals currently found in cosmetics, including lead and di-(2-ethylhexyl)phthalate.[20] Minnesota recently enacted a law prohibiting consumer products from containing mercury.[21]

Back in Congress, Representative John Dingell (D-MI) has circulated a draft of the Food and Drug Administration Globalization Act of 2008.[22] If enacted, the bill would require all cosmetic companies to register with FDA, to report all adverse events to FDA and to comply with good manufacturing practices to be established by regulation.

Bryon F. Powell, an Associate with Hyman, Phelps & McNamara, P.C., assisted in writing this article.

1 21 U.S.C. § 331.
2 21 U.S.C. § 361.
3 21 U.S.C. § 362.
4 15 U.S.C. §§ 1451-1461.
5 21 U.S.C. § 334.
6 21 C.F.R. § 7.45-49. FDA does not have authority to mandate cosmetic recalls.
7 See, e.g., Warning Letter from Douglas I. Ellsworth, District Director, New Jersey District, FDA, to Randi Schinder, President, Fusion Brands International, SRL (Apr. 24, 2007), available at http://www.fda.gov/foi/warning_letters/archive/s6371c.htm; Warning Letter from Timothy A. Ulatowski, Director, Office of Compliance, CDRH, FDA, to Hubert Lee Cole, Chairman and CEO, Rejuvenu International, Ltd. (Aug. 16, 2004), available at http://www.fda.gov/foi/warning_letters/archive/g4959d.htm.
8 Intercenter Agreement Between CDER and CFSAN to Assist FDA in Implementing the Drug and Cosmetic Provisions of the FDCA for Products that Purport to be Cosmetics But Meet the Statutory Definition of a Drug (June 1, 2006), available at http://www.cfsan.fda.gov/~dms/cos-mou.html.
9 Letter from Daniel E. Troy, Chief Counsel, FDA, to Paul M. Hyman and Frances K. Wu, Hyman, Phelps & McNamara, PC (Oct. 17, 2002).
10 FDA Press Release, FDA Warns Consumers Against Using Decorative Contact Lenses Obtained Without a Prescription or Professional Fitting (Oct. 21, 2002); FDA Import Alert #86-10, Detention Without Physical Examination of Decorative Contact Lenses (Oct. 22, 2002).
11 Public Law 109-96 (Nov. 9, 2005) (codified at 21 U.S.C. § 360j(n)). Between 2002 and 2005, FDA issued a warning letter and an additional press release regarding decorative contact lenses. Warning letter from Timothy A. Ulatowski, Director, Office of Compliance, CDRH, to Brian Cohen, President, BWild Inc. (Sept. 16, 2003), available at http://www.fda.gov/foi/warning_letters/archive/g4292d.htm; FDA Press Release, FDA Warns Consumers of the Dangers of Using Decorative Contact Lenses Without Proper Professional Involvement (Oct. 28, 2004), available at http://www.fda.gov/bbs/topics/news/2004/NEW01127.html.
12 NAD Press Release, NAD Examines Claims Made by Preval for ActiFace Complete Age-Defying System (Dec. 5, 2007).
13 Division of Advertising, FTC, Division of Advertising Practices, available at http://ftc.gov/bcp/bcpap.shtm.
14 Jessica Lake, How Not to Cross FTC: Attorneys Offer Advice for Cosmeceutical Marketers, [The Rose Sheet], (July 14, 2008).
15 FTC Press Release, Rexall Sundown to Pay up to $12 Million to Settle Charges Regarding Cellulite Treatment Product (Mar. 11, 2003), available at http://www.ftc.gov/opa/2003/03/rexall.shtm.
16 See, e.g., Nev. Rev. Stat. §§ 585.500-.510.
17 Letter from Edward G. Weil, California Supervising Deputy Attorney General, to J.L. Sean Slattery, Del Mar Law Group, LLP, and David Lavine and Laralei Paras, Hirst & Chanler (Mar. 3, 2008); Louisa Tavlas, California Files Suit Against Avalon, Others for Cleansers with 1, 4-Dioxane, [The Rose Sheet] (June 16, 2008).
18 Cal. Stat. 11791-11793.5.
19 Mass. HB 4347.
20 Mass. SB 558.
21 Minn. SF 1085 (relevant section codified at Min. Stat. § 116.92(8i)).
22 Louisa Tavlas, Beauty Firms Face Adverse Event Reporting, GMP Requirements Under Bill, [The Rose Sheet] (Apr. 21, 2008).