While Not Quite a Rash of Enforcement, FDA Takes Action in 2015 Against Cosmetic Products Making Unapproved Drug Claims

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To paraphrase, admittedly horribly, the Cole Porter classic, "I've Got You Under My Skin," a number of cosmetic companies got under the Food and Drug Administration's (FDA) skin in 2015 for making unapproved new drug claims. While the number of Warning Letters issued in 2015 does not necessarily indicate a rash (pun intended) of new enforcement, the number was not insignificant and is a reminder that the agency regulates cosmetic product claims and will take action if it believes the promotional statements are unlawful.

Cosmetic vs. Drug - - A High-Level Overview

The Federal Food, Drug, and Cosmetic Act defines a cosmetic as an article "intended to be rubbed, poured, sprinkled, or sprayed on, introduced into, or otherwise applied to the human body … for cleansing, beautifying, promoting attractiveness, or altering the appearance."[1] In contrast, a drug is defined, in part, as an article "intended for use in the diagnosis, cure, mitigation, treatment or prevention of disease" and "articles (other than food) intended to affect the structure or any function of the body of man or other animals."[2] Cosmetics can be sold without prior FDA approval; new drugs require prior approval. In some cases, a product might meet the statutory definition of a "cosmetic" and a "drug" when there are different intended uses. For example, an anti-dandruff shampoo is both a cosmetic (to cleanse the hair) and a drug (to treat dandruff). These products must comply with applicable requirements for both drugs and cosmetics.

While the term, "cosmeceuticals," is frequently used by companies in the marketplace, and FDA is aware of this, there is no statutory or regulatory definition, and the agency does not have a separate regulatory classification for such products.

Enforcement Actions in 2015

FDA has issued a number of Warning Letters and continues to enforce an Import Alert (#66-38, originally issued in 1988) against skin care products that make unapproved new drug claims.[3] For example, the Import Alert applies to skin care products labeled as "anti-aging" creams, which make claims to "counteract," "retard," or "control" the aging process. Similarly, the agency contends that products which claim to "rejuvenate," "repair," or "restructure" the skin are drug claims. As such, FDA can detain or refuse to allow such products to enter the United States.

Distinct from the Import Alert, FDA issued a number of Warning Letters in 2015 against skin care companies that the agency contended were making unapproved drug claims.[4] In all of the letters, FDA referred to product websites. Some of the unlawful claims included:

1 21 U.S.C. § 321(i).
2 21 U.S.C. § 321(g)(1).
3 www.accessdata.fda.gov/cms_ia/importalert_188.html.
4 See e.g., www.fda.gov/ICECI/EnforcementActions/WarningLetters/2015/ucm434560.htm; www.fda.gov/ICECI/EnforcementActions/WarningLetters/2015/ucm439818.htm; www.fda.gov/ICECI/EnforcementActions/WarningLetters/2015/ucm440960.htm; www.fda.gov/ICECI/EnforcementActions/WarningLetters/2015/ucm453709.htm; www.fda.gov/ICECI/EnforcementActions/WarningLetters/2015/ucm476560.htm; and www.fda.gov/ICECI/EnforcementActions/WarningLetters/2015/ucm476132.htm

- "mimic the activity of the youth hormone thymopoietin ... reinforcing the cutaneous immune defenses in the skin ... stimulate the growth of new cells in the epidermis;"
- "Clinically proven to change the anatomy of a wrinkle;"
- "Potent elastin-stimulating peptides help enhance skin structure …;"
- "to help stimulate collagen, to help inhibit cellular breakdown…;"
- "to help activate wound healing fostering new skin growth, to help reduce scar tissue, and to help form stronger blood vessels;"
- "to help restore blood cell response to the breakdown of skin structure, to help counteract infection (e.g., acne), to help even-out discolored appearance (e.g., hyperpigmentation), to help reduce inflammation (e.g., Rosacea)…;"
- "The anti-aging formula speeds healing and increases surface circulation;"
- "helps control acne by reducing inflammation and bacteria production;"
- "reduces puffiness by draining excess fluids;"
- "the perfect solution to help improve the visible skin conditions associated with diabetes;"
- "the perfect solution to quickly hydrate and restore skin barrier function while reducing inflammatory factors;"
- "is the perfect solution to help relieve the symptoms of psoriasis...;"
- "the perfect solution to help prepare and improve skin function before, during, and after cancer therapy."

AGG Observations

- Companies should review product labeling and promotional claims, particularly when made through electronic media, such as websites, Facebook, and other social media, where FDA frequently first reviews products.
- The internal review should include representatives from Medical, Regulatory, and Legal.
- FDA can take immediate, if not easier, enforcement action by detaining potentially violative products at the border and stopping their importation. Therefore, firms should review labeling and packaging claims prior to shipment that could raise red flags. "Anti-aging," "lightening," and disease-specific statements are examples of such higher-risk claims.
- If a company wants to market a product as a drug, consider whether it might comply with an applicable over-the-counter drug monograph, so that it is not a "new" drug, requiring FDA approval.
- FDA has a number of enforcement tools at its disposal to cleanse its proverbial irritated skin. Proactive planning can be the salvo.

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