Editorial-Cosmetic Warning Letters/Labeling Claims

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The cosmetic industry is one of the fastest growing industries in the United States, with annual sales in the tens of billions of dollars, and thousands of facilities in the United States alone. During the past 5-10 years, Americans have also seen an explosion in the numbers and types of cosmetic products sold annually, including imported products. From fiscal year (FY) 2004 through 2010, the number of cosmetic products imported has almost doubled, growing from approximately 968,000 lines in FY 2004 to over 1.9 million lines in FY 2010. The technologies have also become more sophisticated and the ingredients more complex. The incorporation of ingredients derived through from nanotechnology is but one example. In addition, labeling has become more creative, including the types of claims made for cosmetic products.

The definitions of a "cosmetic" and of a "drug" under the Federal Food, Drug, and Cosmetic Act (FD&C Act) are critical to understanding the warning letters recently issued by FDA related to the claims made for cosmetic products. The FD&C Act defines "cosmetic" as "(1) articles 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) articles intended for use as a component of an such articles; except that such term shall not include soap." By contrast, a "drug," is defined under the FD&C Act as "(A) articles recognized in the official Unites States Pharmacopeia, official Homeopathic Pharmacopeia of the United States, or official National Formulary, or any supplement to any of them; and (B) articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals; and (C) articles (other than food) intended to affect the structure or any function of the body of man or other animals; and CD) articles intended for use as a component of any articles specified in clause (A), (B), or (C). "

The FD&C Act has different requirements for cosmetics and for drugs. For example, the FD&C Act does not require pre-market approval for cosmetics; however, companies are responsible for ensuring that their cosmetics are safe under their conditions of use. Drugs must be approved by FDA through new drug application process or must conform to a final monograph for an over-the-counter drug. Cosmetics that also meet the definition of a drug would be required to comply with the requirements for both classes of products.

To understand how the definitions of cosmetics and drugs apply to claims on cosmetics, a brief historical perspective will be presented. During 1986-1987, FDA issued 40 regulatory letters regarding anti-aging claims found on cosmetic products that rendered them drugs. Examples of claims included references that the products would "retard", "counteract", "control" aging as well as "repair", "renew" or "rejuvenate" the skin. The agency interpreted these to be drug claims, even if the effect was only

described as temporary, since they indicated that the products would affect the structure and function of the body, in particular by affecting the epidermis or dermis. In response to these letters, industry formed a coalition to meet with FDA to discuss the issues and problems identified, as well as the definitions of drug and of cosmetic. Following these discussions, FDA reiterated its position regarding the cosmetic/drug distinctions made in the statutory definitions --specifically that a structure/function claim makes a product a drug --in a letters to members of the industry coalition dated November 18, 1987.

FDA has continued to make this position clear in educational materials available on its website, such as FDA's Cosmetic Labeling Manual. However, many cosmetics products have included claims that make these products drugs. Such products have not gone through the drug approval process required under the FD&C Act. In addition, FDA has issued several warning letters intermittently, since the early 1990s, because of claims that would make the specific products drugs.

Since September 2012, FDA has issued 7 warning letters to manufacturers of cosmetic products, again identifying numerous products that appear to be promoted for uses that cause these products to be drugs. Specifically, the claims for these products indicate that these products are intended to affect the structure or any function of the human body, and/or are intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease, rendering them drugs under the FD&C Act. Examples of some of these claims are shown below:

- Provide antibacterial and ant-inflammatory benefits
- Heal and prevent scarring and stretch marks
- Reduces breakouts and blemishes
- Stimulate the production of "youth proteins"
- Boost the activity of genes
- Promote collagen production
- Repair structural damage
- Repair aged skin

These letters were based on the claims made for these products, and not on any specific safety issues, since FDA does not, at this time, have evidence of any significant safety problems associated with the products/firms receiving the letters.

FDA has been asked "why now?" As noted above, claim creep is not new but appears to be escalating in more recent years. In addition, consumers are asking more questions and have raised a number of concerns to FDA's attention. FDA issued these letters so companies understand the statutory requirements for products which are drugs due to the claims made for these products. As needed, FDA will continue to issue warning letters and take other regulatory action.