The First Cut is the Deepest: FDA Issues a Warning Letter to a Skincare Company for Marketing Unapproved New Drugs

Alan G. Minsk

The Food and Drug Administration recently issued a Warning Letter to a skincare company for promoting and selling unapproved new drugs.[1] While the letter itself is not unusual in content, the enforcement action continues a trend we are seeing where the agency, whether at Headquarters or at the District Office level, will take action against products with purported cosmetic claims that FDA contends are unapproved new drugs. As Cat Stevens sang, "The first cut is the deepest."

We have summarized some of these cases in previous Bulletins.

In the specific enforcement example, FDA objected to a product that referenced a stem cell renewal treatment. Claims referred to "wrinkles," "stem cells," "skin lightening," "skin healing," "eliminates age spots," and "boosts collagen synthesis," to name a few, which raised the agency's scrutiny. The agency said the product was not generally recognized as safe and effective for the uses promoted and, thus, was an unapproved new drug.

Some AGG Observations

- FDA cited the company's website. It recommended that the company re-review its website, labels, and labeling to ensure compliance. In our experience, many cosmetic companies do not utilize an internal review process, such as a Promotional Review Committee, frequently seen with pharmaceutical and medical device companies.
  Such committees, though, can help minimize risk by allowing representatives from commercial, marketing, medical, regulatory, and legal, to review product claims to maximize compliance while also attempting to achieve business objectives. We sit on a number of PRC-type committees and see the value of such collective wisdom. A company's website is an easy place to start such a review; it is likely where FDA will first turn.
- Rarely does FDA issue an enforcement letter due to one term or phrase (although it can); it is more often that a number of claims are made that raise FDA scrutiny. In the aforementioned case, we described several terms cited by the agency as unlawful.
- While FDA issued the Warning Letter, companies must also consider challenges from other federal and state regulatory bodies for deceptive advertising, as well as competitor and plaintiff lawyer's complaints.
- It is clear that FDA is continuing to review purported cosmetic claims and taking enforcement action if the agency believes the product is making drug-like statements. There are public health and consumer deception considerations at issue.
- While, in this case, FDA issued a Warning Letter, we have also seen (and advised clients), the agency will issue Import Alerts to stop violative products from entering the United States market. FDA has a number of enforcement tools at its disposal.
- Companies must continue reviewing product labels, labeling, and promotional materials to maximize compliance and minimize enforcement action.

1 The Warning Letter can be found at www.fda.gov/ICECI/EnforcementActions/WarningLetters/2016/ucm504411.htm.

Authors and Contributors

Alan G. Minsk
Partner, Atlanta Office
404.873.8690
alan.minsk@agg.com

not *if*, but *how*.®

About Arnall Golden Gregory LLP

Arnall Golden Gregory, a law firm with more than 150 attorneys in Atlanta and Washington, DC, employs a "business sensibility" approach, developing a deep understanding of each client's industry and situation in order to find a customized, cost-sensitive solution, and then continuing to help them stay one step ahead. Selected for The National Law Journal's prestigious 2013 Midsize Hot List, the firm offers corporate, litigation and regulatory services for numerous industries, including healthcare, life sciences, global logistics and transportation, real estate, food distribution, financial services, franchising, consumer products and services, information services, energy and manufacturing. AGG subscribes to the belief "not if, but how.®" Visit www.agg.com.

Atlanta Office
171 17th Street, NW
Suite 2100
Atlanta, GA 30363

Washington, DC Office
1775 Pennsylvania Avenue, NW
Suite 1000
Washington, DC 20006

To subscribe to future alerts, insights and newsletters: **http://www.agg.com/subscribe/**