# FDA and the FTC Unfriend a Dietary Supplement Product

Alan G. Minsk and Alexander B. Foster

In an interesting Warning Letter recently issued, both the Food and Drug Administration (FDA)and the Federal Trade Commission (FTC) issued a Warning Letter to a dietary supplement company for promoting its product as a drug. Without going into the details of the case, we will highlight some of the issues we thought noteworthy and instructive.[1]

## Some Basic Facts

- The objectionable claims were posted on the product websites.
- The company used Facebook, Tumblr, Pinterest, YouTube, and Twitter to promote the product, and linked to the product website.
- The claims referred to cold sores, fever blisters, genital herpes, shingles and other disease-type claims. As such, FDA considered the purported dietary supplement to be an unapproved new drug. The agency noted that the product lacked adequate directions for use, as the conditions referenced in the claims required medical intervention.
- The dietary supplement was misbranded, as it failed to include a domestic address and domestic phone number to receive a report of serious adverse event.
- The product failed to identify the part of the plant from which each botanical ingredient extract of the product was derived.
- The FTC added the advertising was unsubstantiated. The agency reiterated that for a company to make disease-type claims, it must possess competent and reliable scientific evidence, such as well-controlled human clinical studies to support the claims. The FTC threatened a Federal District Court Order injunction or Administrative Cease and Desist Order. Repayment to customers is also a possibility.

## AGG Observations

- We have spoken and written enough about the need to ensure social media promotion is compliant that we won't repeat our advice here, except to reiterate our cautionary note. Particularly, in the area of dietary supplement promotion, the FDA and the FTC will challenge drug-like claims for dietary supplements.
- Both the FDA and the FTC can assert jurisdiction of product promotion in certain cases. While the standards are, at times, similar, each agency has its own rules and enforcement tools.
- As the FTC reiterated, competent and reliable scientific evidence is needed to support disease-type claims.
- Companies should review company social postings and links to product websites to ensure compliance.
- Remember the basic FDA label requirements about adequate directions for use and plant identification, where applicable. While these might not seem as high-risk as, for example, unapproved and unsubstantiated new drug claims, they are legal requirements.

1 The Warning Letter can be accessed at www.fda.gov/ICECI/EnforcementActions/WarningLetters/2015/ucm447670.htm.

## Authors and Contributors

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

**Alexander B. Foster**
Associate, Atlanta Office
404.873.8598
alexander.foster@agg.com

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

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