



## FDA Unfriends Drug Company for Unlawful Promotion

Alan G. Minsk and Kelley C. Nduom

While the Food and Drug Administration (FDA) continues to promise more guidance on product promotion through social media, this hasn't stopped the agency from taking enforcement action when it believes a promotion is unlawful. Recently, FDA's Office of Prescription Drug Promotion (OPDP) issued an Untitled Letter to a drug company for its Facebook web page, contending that the page was "false or misleading," because it made product efficacy claims without providing risk information and omitted material facts.<sup>1</sup> The enforcement letter is consistent with past FDA action, but we believe it is instructive for a number of reasons.

1. The Facebook page referred to the medical condition for which the product is approved. It is noteworthy that there were no marketing claims, but FDA reiterated that the reference to the condition with the product name was an efficacy claim.
2. The product contains a Boxed Warning, but the page did not include any risk information. FDA said that this failure to disclose the most serious and frequently occurring risks, and the omission of the Boxed Warning, was misleading, because it suggested the product was safer than had been shown.
3. FDA noted that the Facebook page did not include the approved indication, although it mentioned, in general terms, the medical condition. By not using the specific indication verbatim, it failed to note a particular exception in the indication. Thus, the agency said that the company omitted material facts.

### AGG Observations

We continue to remind clients, as does FDA to the industry through its enforcement actions, of the following:

- Provide the indication verbatim from the approved package insert. This way, one minimizes, if not eliminates, the omission of this important fact.
- A "claim" does not have to be overly promotional to be considered a claim. The Facebook page merely said that, if one had been diagnosed with a particular medical condition, to talk to a doctor about the specific drug product. The reference to both the drug and the medical condition was sufficient to constitute a claim, thereby requiring fair balance and the inclusion of Important Safety Information.
- A promotion should always include a link to the approved PI.
- Boxed Warnings cannot use reminder ads or labeling.
- Products with a Boxed Warning or a Risk Evaluation and Mitigation Strategy (REMS) program are typically scrutinized more by OPDP due to the higher safety risk concern (although all products must be FDA-compliant).
- OPDP does not provide an exception or latitude for social media promotion, whether it is Facebook, Twitter, or some other forum. Product labeling is broad, and OPDP considers

<sup>1</sup> The Untitled Letter can be accessed at [www.fda.gov/downloads/drugs/guidancecomplianceregulatoryinformation/enforcementactivitiesbyfda/warninglettersandnoticeofviolationletterstopharmaceuticalcompanies/ucm388800.pdf](http://www.fda.gov/downloads/drugs/guidancecomplianceregulatoryinformation/enforcementactivitiesbyfda/warninglettersandnoticeofviolationletterstopharmaceuticalcompanies/ucm388800.pdf).

prescription drug product references, in written form, to be labeling, regardless of the outlet. As such, all labeling and promotional rules apply.

## Authors and Contributors

---

**Alan G. Minsk**

Partner, Atlanta Office  
404.873.8690  
alan.minsk@agg.com

**Kelley C. Nduom**

Associate, Atlanta Office  
404.870.5796  
kelley.nduom@agg.com

not *if*, but *how*.<sup>®</sup>

## 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](http://www.agg.com).

**Atlanta Office**

171 17th Street NW  
Suite 2100  
Atlanta, GA 30363

**Washington, DC Office**

1775 Pennsylvania Ave., NW,  
Suite 1000  
Washington, DC 20006

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

©2014. Arnall Golden Gregory LLP. This legal insight provides a general summary of recent legal developments. It is not intended to be, and should not be relied upon as, legal advice. Under professional rules, this communication may be considered advertising material.