



## CDRH Issues Warning Letter for Unlawful Product Promotion

Alan G. Minsk

---

While we don't see quite as much Food and Drug Administration enforcement against medical device companies as we see for pharmaceutical firms in the product promotional area, FDA's Center for Devices and Radiological Health recently issued a Warning Letter to a company for unlawful promotion.<sup>1</sup> Here are some highlights of the letter.

- The company's website and product brochure for a 510(k)-cleared medical device promoted the product for major changes in design and in the intended use of the device.
- The product changes "may incur new risk factors, which would need to be evaluation and mitigated."
- CDRH told the company to immediately cease selling the misbranded and adulterated device.

We remind clients that, despite limited personnel resources at CDRH compliance to monitor promotional activities, CDRH will take enforcement action when it believes appropriate. Changes to cleared 510(k) products that might raise potential safety issues and which are promoted to a wide audience, such as on a company website, are likely targets for enforcement. Companies must continue to evaluate product changes to determine if new regulatory submissions are required. Similarly, firms must review all promotional materials distributed, particularly when product changes are made, to ensure regulatory compliance.

---

<sup>1</sup> We will not identify the company, but the Warning Letter can be accessed at [www.fda.gov/ICECI/EnforcementActions/WarningLetters/2014/ucm395273.htm](http://www.fda.gov/ICECI/EnforcementActions/WarningLetters/2014/ucm395273.htm).

## Authors and Contributors

---

**Alan G. Minsk**

Partner, Atlanta Office  
404.873.8690  
alan.minsk@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.