*Periodically, we will send you a **concise** update on current events in the healthcare compliance arena **as it relates specifically to pharmaceutical and medical device manufacturers** that may have an impact upon your business and operating procedures. These news items and analyses are intended for informational purposes only.*

DDMAC Warning Letters

The FDA has clearly stepped up its oversight of drug-marketing materials, issuing 68 letters so far this year, compared with just 41 in 2009 (well on track to more than double last year's total). The agency has signaled their amplified intensity with the aforementioned increased issuance of letters with the launch of its "Bad Ad" program. The OIG reported that it already received about 125,000 phone complaints and roughly 17,000 e-mail complaints in 2009 prior to the launch of the hotline. *Eye on FDA* recently reported that DDMAC has staffed up, so more eyes are looking at more media.

According to Ayse Yeaton, an FDA spokesperson, "the increase in the number of regulatory letters are the result of DDMAC putting more resources into enforcement." What has also led to the increase in letters according to Yeaton is that "the agency has also streamlined its review process for regulatory letters, making it more efficient for DDMAC to stop more misleading promotion."

In response to the increase of letters, Arnold Friede, an FDA legal expert and former attorney at Pfizer, said "People [in the pharmaceutical industry] aren't paying attention to these letters." He further added that we are "seeing repeated instances of the same kinds of violations," such as non-disclosure of risk information and unsubstantiated efficacy claims.

FDA Commissioner Margaret Hamburg stated last year that, "the FDA will prioritize enforcement follow-up. After a warning letter is issued…, we will make it a priority to follow up promptly with appropriate action, such as an inspection or investigation to assess whether or not a company has made required changes in its practices."

This has been recently evidenced in the FDA Warning Letter sent to Baxter Healthcare dated August 3rd of this year, stating

> **"Additionally, since we have cited you for similar violations in the recent past, we request a response in writing indicating what policies and procedures your firm intends to adopt to ensure your prescription drug promotional activities comply with the Act and its implementing regulations, and an explanation of why/how you expect these policies and procedures to succeed."**

Thus, in this case the FDA is requiring not only a procedural explanation as to how to remedy the alleged violation, but a substantial justification related to the company compliance enforcement efforts implemented to insure a successful remedy to the reported situation.

In sum, it appears that the DDMAC is putting more "teeth" behind the corrective measures mandated via Warning and Notice of Violation letters to manufacturers, thus stressing the ever increasing importance for manufacturers to be able to demonstrate a robust compliance effort related to their sales and marketing activities.

As always, if you have any questions, comments, or concerns we can be reached at sreardo23@centurylink.net or at (908) 370-4085.