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E-ALERT | Food & Drug

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SUMMARY OF RECENT FDA INITIATIVES RELATING TO ADVERTISING AND PROMOTION ENFORCEMENT

Covington & Burling LLP provides monthly e-alerts summarizing publicly-available FDA enforcement letters (i.e., warning letters and untitled letters) relating to the advertising and promotion of prescription drugs, medical devices, and biologics. In September 2013, FDA did not post any enforcement letters relating to advertising and promotion on its website.

In place of a summary of enforcement letters, this e-alert summarizes recent FDA initiatives relating to advertising and promotion enforcement activities.

FDA PLANS TO INCREASE OVERSIGHT OF ADVERTISING AND PROMOTION ACTIVITIES FOR MEDICAL DEVICES

FDA plans to reorganize the Office of Compliance within the Center for Devices and Radiological Health ("CDRH") to increase its monitoring of industry compliance with advertising and promotion rules for medical devices. The reorganization will take effect on November 17, 2013.

As we previously reported, FDA's director of the Office of Compliance announced that FDA is reorganizing the Office of Compliance to allow staff to spend more time monitoring advertising and promotion and premarket approval compliance, which he classified as "historically underserved areas." The reorganization will replace Divisions of Enforcement A and B with the following two new divisions within the Office of Compliance:

- the Division for Premarket and Labeling Compliance, which will be tasked with ensuring device manufacturers fulfill premarket approval and clearance requirements and comply with advertising, promotion, and labeling requirements; and
- the Division of Manufacturing Quality, which will review inspections within the US, classify recalls, and develop policy on quality issues.

According to the director of the Office of Compliance, the reorganization will create an improved "functional structure" as opposed to the existing "product-based structure" of the divisions of enforcement. In particular, FDA plans to be "more intentional" in its oversight of advertising and promotional activities and to increase headcount devoted to monitoring industry compliance (two staffers were previously dedicated to promotional compliance). The agency also hopes the new division will address compliance challenges resulting from the less developed regulatory framework for device promotion, in comparison to the framework for drug promotion, and the increased use of social media as a promotional tool.[1]

[1] The reorganization will also add a new Division of International Compliance Operations in recognition of a significant amount of device manufacturing overseas. Further, the current Division of Risk Management Operations will not undergo significant changes but will be called the Division of Analysis and Program Operations, and the current Division of Bioresearch Monitoring will remain as is.

FDA CREATES NEW COURSE ON "BAD ADS" FOR HEALTHCARE PROVIDERS AND PROFESSIONALS

In late October, FDA announced its launch of an e-learning course and a series of educational case studies relating to the Office of Prescription Drug Promotion's ("OPDP") Bad Ad Program. The Bad Ad Program was created in 2010 and was designed to "raise awareness among health care professionals . . . about misleading prescription drug advertising and promotion and to encourage the reporting of potentially misleading prescription drug advertising and promotion to FDA. . . ."

OPDP's Continuing Education ("CE/CME") course is a one-hour, self-paced training that FDA hopes will help healthcare professionals identify and report suspected misleading prescription drug promotion. The course can be taken for one hour of CE/CME credit by physicians, physician assistants, nurse practitioners, pharmacists, and nurses. As part of the course, OPDP has also developed educational case studies based on examples of misleading promotion.

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