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Client Alert

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FDA's Center for Devices and Radiological Health Issues Warning Letters

Recently, the Food and Drug Administration's (FDA's) Center for Devices and Radiological Health (CDRH) issued warning letters to medical device companies for improperly advertising and promoting their products in violation of the Federal Food, Drug and Cosmetic Act (FDC Act). The recent CDRH warning letters are another example of the agency's efforts to play a more active role in reviewing promotional materials and, where applicable, issuing enforcement letters. CDRH continues to lap its drug compliance counterpart in the promotional enforcement area and has increased the number of personnel devoted to such review, and the recent issuances might signal more enforcement. In addition, these enforcement letters are posted on the FDA's website and described in industry publications. CDRH is aware of the trickle-down elements that its enforcement activities will have. This Client Alert summarizes the recent warning letters issued by CDRH.[1]

August 23, 2010—Warning Letter

CDRH issued a warning letter to a medical device company and cited, among other things, the company's improper promotion of its product. According to CDRH, a brochure listed on the company's website made certain claims that represented a major change or modification in the intended use for which the product was approved. Therefore, the new intended use required premarket notification. CDRH concluded that, because of the claims on the brochure, the product was adulterated under 21 U.S.C. § 351(f)(1)(B); the company did not have an approved premarket approval application (PMA) or an approved application for an investigational device exemption. The FDA also noted that the device was misbranded, because the company failed to notify the FDA with respect to the changes to the intended use of the device as required by 21 U.S.C. § 360(k); *ie*, lack of a 510(k) premarket notification application. The FDA requested that the company immediately cease marketing the device for the unapproved uses. The company must also take prompt action to correct its violations.

July 28, 2010—Warning Letter

CDRH issued a warning letter based on the medical device company improperly promoting intended uses for which it had not obtained marketing approval or clearance from the FDA. After a review of claims made in several

1 Although these letters have been issued by the FDA and are a matter of public record, we have chosen not to identify the specific medical device manufacturers or device products and, instead, focus on the substantive issues raised in each letter. The letters may be accessed at http://www.fda.gov/ICECI/EnforcementActions/WarningLetters/2010/default.htm?fragment25_NextRow=51.

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advertisements from peer-reviewed journals, articles and video presentations on the medical device company's website, CDRH determined that the claims were inconsistent with the intended uses for which the device had been cleared under a 510(k) and, thus, caused the medical device product to be adulterated and misbranded. The company must immediately cease the dissemination of promotional materials for its products and take prompt corrective action.

July 2, 2010—Warning Letter

The warning letter was issued after CDRH reviewed a White Paper and a brochure on the medical device company's website. The promotional materials contained several claims that were outside the scope of the company's 510(k) clearance and caused the product to be adulterated and misbranded. The FDA had imposed the following limitation to appear in the warnings section of the device's labeling and any promotional materials: "The safety and effectiveness of this device for reducing the incidence, severity, and extent of post-operative adhesion formation have not been established." The claims in the promotional materials were inconsistent with the required warning statement and represented a different intended use of the device. Further, the FDA determined that the claims caused the device to be a Class III device, requiring a PMA. The company must immediately cease the dissemination of promotional materials for the product and take prompt corrective action.

By issuing these warning letters, CDRH has demonstrated its intention to continue to investigate and take enforcement action against advertising and promotional materials that are violative of the FDC Act.