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FDA Advertising and Promotion Enforcement Activities: Update

October 10, 2017

Food, Drugs, and Devices

This e-alert is part of a series of 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.

Earlier in the year, CDRH Office of Compliance posted the following two letters:[1]

- Warning Letter to QLRAD Netherlands re: RectalPro Endorectal Balloon (July 20, 2017) ("RectalPro Warning Letter")
- Warning Letter to SyncThink, Inc. re: EYE-SYNC (July 31, 2017) ("Eye-Sync Warning Letter")

The FDA's Office of Prescription Drug Promotion, CDRH's Office of Compliance, and FDA's Office of Compliance and Biologics Quality (OCBQ) did not post any enforcement letters relating to advertising and promotion on FDA's website in September.

This alert merely summarizes the allegations contained in FDA's letters. It does not contain any analyses, opinions, characterizations, or conclusions by or of Covington & Burling LLP. As a result, the information presented herein does not necessarily reflect the views of Covington & Burling LLP or any of its clients.

CDRH Office of Compliance (OC)

RectalPro Warning Letter (July 2017)

In the RectalPro Warning Letter, FDA alleges that QLRAD's website (http://qlrad.com/products/endo-rectal-balloon/) and brochures, distributed at the American Society for Radiation Oncology (ASTRO) conferences in San Antonio (2015) and Boston (2016), misbranded the RectalPro ERB because they promoted the product for intended uses different from those uses legally marketed under an exemption from the requirement to obtain clearance of a premarket notification (commonly referred to as a 510(k)) for manual gastroenterology-urology surgical instruments and accessories.

Under 21 CFR § 876.4730, manual gastroenterology-urology surgical instruments and accessories are 510(k)-exempt if they are intended to be used for gastroenterological and

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[1] These letters had not been posted in time for our previous alert.

urological surgical procedures. FDA alleges, however, that QLRAD's website and brochures marketed the RectalPro ERB "to immobilize the prostate in patients undergoing radiation therapy."

FDA further states that when using the RectalPro ERB to immobilize the prostate during external beam prostate radiotherapy, "the balloon becomes a major component in … [a] high risk radiation therapy procedure," which "raises a series of new safety concerns related to anorectal toxicity, tissue damage, perforation of the rectum, irradiation of healthy tissue and patient intolerance." FDA alleges that because the intended use of the RectalPro ERB was different from the 510(k)-exempt intended uses set forth in 21 CFR § 876.4730, the RectalPro ERB required a cleared 510(k) for this use.

EYE-SYNC Warning Letter (July 2017)

In the EYE-SYNC Warning Letter, FDA alleges that SyncThink's website (www.syncthink.com) misbranded EYE-SYNC because it promoted EYE-SYNC for uses outside the scope of its 510(k) clearance. Specifically, FDA states that EYE-SYNC was misbranded because SyncThink introduced EYE-SYNC into interstate commerce with major changes or modifications to the intended use without submitting a new premarket notification to FDA as required by section 510(k) of the Federal Food, Drug, and Cosmetic Act and 21 CFR § 807.81(a)(3)(ii).

EYE-SYNC was cleared as a prescription device with indications for use of recording, viewing, and analyzing eye movements in support of identifying visual tracking impairment in human subjects. FDA alleges that SyncThink promoted EYE-SYNC on its website, however, for use in "cognitive assessment/testing of concussions and head trauma, including in injured athletes and soldiers." FDA provides the following examples, among others, from SyncThink's website:

- "Introducing the future of mobile assessment technology: EYE-SYNC® by SyncThink overcomes the limitations of traditional cognitive testing to provide an easy-to-use, rapid, objective tool for initial screening and recovery monitoring."
- "Mobile, precise assessment of visual attention after a force to the head: EYE-SYNC® uses high-performance, cutting-edge eye tracking technology to monitor eye movement in a handheld virtual reality environment. If your brain is out of sync after an on-field incident, SyncThink®'s technology will let you know in less than a minute."
- "EYE-SYNC® is fast. Every second counts when assessing cognitive state on the field. EYE-SYNC®'s core technology takes less time than a medical timeout to administer."
- "EYE-SYNC® is reliable. SyncThink® has tested its metrics on over 10,000 soldiers and athletes and shown a greater than 0.8 test-retest reliability-far exceeding other cognitive tests."

FDA's letter states that these claims constitute a major change or modification to the intended use of EYE-SYNC®, which require the submission and clearance of a new 510(k).

If you have any questions concerning the material discussed in this client alert, please contact the following members of our Food, Drugs, and Devices practice:

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