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FDA Advertising and Promotion Enforcement Activities: Update

January 9, 2018

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.

In December, the Office of Prescription Drug Promotion (OPDP) posted the following letter on FDA's website:

- Warning Letter to AVANTHI, INC. re: ANDA 203495 LOMAIRA™ (phentermine hydrochloride USP) tablets, CIV (Dec. 19, 2017) ("Lomaira Warning Letter")

This is the fourth enforcement letter OPDP posted in 2017. The FDA's Center for Drug Evaluation and Research (CDER) Office of Compliance, Center for Devices and Radiological Health (CDRH) 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 November.

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.

Office of Prescription Drug Promotion (OPDP)

Lomaira Warning Letter (December 2017)

OPDP states that Avanthi's exhibit booth panel for Lomaira, which was on display at the Endocrine Society's 99th Annual Meeting and Expo (April 2017) and the American College of Cardiology's 66th Annual Scientific Session and Expo (March 2017), makes false or misleading claims and/or representations about the risks associated with Lomaira and omits material facts.

False or Misleading Risk Presentation:

OPDP alleges that the panel makes representations and/or suggestions about the benefits of Lomaira, but it fails to communicate any risk information about the product. Lomaira's PI contains warnings and precautions regarding coadministration with other drug products for weight loss, primary pulmonary hypertension, valvular heart disease, risk of abuse and dependence, usage with alcohol, and others. Lomaira is also contraindicated in patients with a

history of cardiovascular disease; during or within 14 days following the administration of monoamine oxidase inhibitors; in patients with hyperthyroidism, glaucoma, agitated states, or history of drug abuse; in pregnant or nursing patients; and in patients with a known hypersensitivity, or idiosyncrasy to the sympathomimetic amines. These risks, some of which are serious and potentially fatal, are not discussed in the booth panel.

OPDP alleges that this failure to communicate risk information "creates a misleading impression about the drug's safety."

Omission of Material Facts:

OPDP states that the panel is misleading because it fails to communicate material information regarding the FDA-approved indication for Lomaira. The panel makes the following statements about the benefits of Lomaira:

- "THE POWER OF THREE"

  "Diet" "Exercise" "Lomaira™"

- "Consider adding Lomaira™ to your patients' weight-management plan"

OPDP states that these representations are misleading because they omit the following material information from the Indications and Usage section of the PI: "LOMAIRA™ tablets are indicated *as a short-term (a few weeks)* adjunct in a regimen of weight reduction . . . *in patients with an initial body mass index greater than or equal to 30 kg/m^2, or greater than or equal to 27 kg/m^2 in the presence of other risk factors (e.g., controlled hypertension, diabetes, hyperlipidemia)*"; "*The limited usefulness of agents of this class, including phentermine, should be measured against possible risk factors inherent in their use* . . ." (emphasis added by OPDP).

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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