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E-ALERT | Food & Drug

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SUMMARY OF FDA ADVERTISING AND PROMOTION ENFORCEMENT ACTIVITIES

JULY 2014

This e-alert is part of a series of 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 July 2014, FDA's Office of Prescription Drug Promotion (OPDP) posted the following letter on FDA's website[1]:

- Untitled Letter to Concordia Pharmaceuticals, Inc. re: NDA 022331 KAPVAY (clonidine hydrochloride) extended-release tablets MA #133 (July 7, 2014) ("Concordia Untitled Letter")

The Office of Compliance and Biologics Quality (OCBQ) in FDA's Center for Biologics Evaluation and Research (CBER) and the Office of Compliance (OC) in FDA's Center for Devices and Radiological Health (CDRH) did not post any enforcement letters relating to advertising and promotion on FDA's website.

This alert merely summarizes the allegations contained in FDA's letters. It does not contain any analysis, 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.

LETTERS ISSUED BY OFFICE OF PRESCRIPTION DRUG PROMOTION (OPDP)

Concordia Untitled Letter

OPDP alleged that a professional telephone script for Kapvay (clonidine hydrochloride) extended-release tablets was "false or misleading" because it omitted risk information and omitted material facts.

Omission of Risk Information: OPDP contended that the telephone script was misleading because it included efficacy claims for Kapvay but failed to disclose Kapvay's "contraindication, all of the warnings and precautions, and common adverse reactions associated with" the product's use. OPDP noted that the script contained a "general statement about adverse events in the Add-On trial." OPDP also recognized that the script included the following: "I can email the full prescribing for Kapvay or you can also access it at the Kapvay website www.kapvay.com. Which do you prefer?" However, OPDP concluded that those statements failed to "mitigate" the omission of risk information.

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[1] Only enforcement letters posted to FDA's website in July 2014 are included herein. Letters issued in February but not posted to the website by July 30, 2014 will be summarized in our alerts for the months in which those letters are posted.

Omission of Material Facts: OPDP also claimed that the script was misleading because it omitted material information about the FDA-approved indication for Kapvay. Kapvay is FDA-approved for the treatment of attention deficit hyperactivity disorder ("ADHD") as monotherapy and as adjunctive therapy to stimulant medications. The Indications and Usage section of Kapvay's PI also includes "information regarding long term use, special diagnostic considerations and the need for comprehensive treatment." OPDP stated that although the script included claims such as "KAPVAY, a treatment for ADHD," it omitted information about the need for comprehensive treatment, which "may include other measures (psychological, educational, and social) for patients with this syndrome." OPDP also contended that the script's statement that "[d]oses should be taken twice a day, with either an equal or higher split dosage being given at bedtime" was misleading in light of the fact that the script was intended for healthcare professionals. OPDP stated that the script omitted information from the prescribing information regarding the initial dosage of Kapvay and the "increment[al]" increase of dosages.

Inadequate Presentation of Established Name: OPDP claimed that the script omitted the established name in "direct conjunction with the proprietary name."

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