COVINGTON

Summary of FDA Advertising and Promotion Enforcement Activities

January 2015

February 13, 2015

Food & Drug

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 December 2014, FDA's Office of Prescription Drug Promotion (OPDP) posted the following letter on FDA's website[1]:

- Untitled Letter to Sunovion Pharmaceuticals, Inc. re: NDA 022416 Aptiom (eslicarbazepine acetate) Tablets MA #143 (December 15, 2014) ("Sunovion 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)

Sunovion Untitled Letter

OPDP alleged that a print advertisement for Aptiom (esclicarbazepine acetate) Tablets ("Aptiom") was misleading because the advertisement overstates Aptiom's efficacy.

Unsubstantiated Superiority Claims: OPDP contended that the print advertisement was misleading because it implied that Aptiom "has been shown to have treatment benefits on patients' feelings of confinement associated with seizures." Specifically, the print advertisement included the statement that "Seizures can keep patients feeling confined" and showed an image

[1] Only enforcement letters posted to FDA's website in December 2014 are included herein. Letters issued in December but not posted to the website by December 31, 2014 will be summarized in our alerts for the months in which those letters are posted.

of a man looking out of a house. On the next page, the print advertisement included an image of a man and woman walking away from an empty house.

In the letter, FDA states that it is not aware of substantial evidence establishing the efficacy of Aptiom on "patients' feelings of confinement associated with seizures." FDA also notes that the primary endpoint in clinical studies of Aptiom was "standardized seizure frequency during the Maintenance Phase over 28 days." FDA requests that Sunovion provide it with a written response listing all promotional materials that contain similar presentations and indicating whether it intends to comply with FDA's request.

If you have any questions concerning the material discussed in this client alert, please contact the following members of our Food & Drug Practice Group:

Michael Labson	+1 202 662 5220	mlabson@cov.com
Scott Cunningham	+1 415 591 7089	scunningham@cov.com
Scott Danzis	+1 202 662 5209	sdanzis@cov.com
Stefanie Doebler	+1 202 662 5271	sdoebler@cov.com
Meghan Monaghan	+1 202 662 5531	mmonaghan@cov.com