

E-ALERT | Food & Drug

July 2, 2014

SUMMARY OF FDA ADVERTISING AND PROMOTION ENFORCEMENT ACTIVITIES

May 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 May 2014, FDA's Office of Prescription Drug Promotion (OPDP) posted the following letter on FDA's website¹:

- Untitled Letter to Alvogen, Inc., re: ANDA 091681 Disulfiram Tablets, USP MA#1 (May 6, 2014) ("Alvogen 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.

Letter Issued by Office of Prescription Drug Promotion (OPDP)

Alvogen Untitled Letter

OPDP alleged that a printed Alvogen sales aid for disulfiram tablets, USP (Disulfiram) was misleading because it made efficacy representations concerning Disulfiram but omitted risk information and omitted material facts.

Omission of Risk Information: OPDP contended that the sales aid was misleading because it included efficacy claims regarding Disulfiram, but it omitted any discussion of risks. OPDP stated that the omission of risk information was "particularly concerning" because Disulfiram's prescribing information contains a "Boxed Warning regarding the administration of Disulfiram." OPDP alleged that the sales aid is misleading because the omission of risk information "suggests that Disulfiram is safer than has been demonstrated."

Omission of Material Facts: The sales aid claimed the following: "Indications and Usage: Disulfiram is an aid in the management of selected chronic alcohol patients who want to remain in a state of

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

enforced sobriety so that supportive and psychotherapeutic treatment may be applied to best advantage.” OPDP alleged that the statement omitted material facts because it neglected to include information concerning the “full FDA-approved indication” for alcohol management. According to OPDP, the sales aid failed to communicate the following from Disulfiram’s Indication and Usage section: “Disulfiram is not a cure for alcoholism. When used alone, without proper motivation and supportive therapy, it is unlikely that it will have any substantive effect on the drinking pattern of the chronic alcoholic.”

If you have any questions concerning the material discussed in this client alert, please contact the following members of our firm:

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

This information is not intended as legal advice. Readers should seek specific legal advice before acting with regard to the subjects mentioned herein.

In an increasingly regulated world, Covington & Burling LLP provides corporate, litigation, and regulatory expertise to help clients navigate through their most complex business problems, deals and disputes. Founded in 1919, the firm has more than 800 lawyers in offices in Beijing, Brussels, London, New York, San Diego, San Francisco, Seoul, Shanghai, Silicon Valley, and Washington. This communication is intended to bring relevant developments to our clients and other interested colleagues. Please send an email to unsubscribe@cov.com if you do not wish to receive future emails or electronic alerts.

© 2014 Covington & Burling LLP, 1201 Pennsylvania Avenue, NW, Washington, DC 20004-2401. All rights reserved.