COVINGTON

COVINGTON & BURLING LLP

E-ALERT | Food & Drug

April 30, 2014

SUMMARY OF FDA ADVERTISING AND PROMOTION ENFORCEMENT ACTIVITIES

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

- Untitled letter to Institut Biochimique SA re: NDA#021924 Tirosint (levothyroxine sodium) capsules, for oral use MA#42 (February 24, 2014) ("IBSA Untitled Letter")

The Office of Compliance (OC) in the FDA's Center for Devices and Radiological Health (CDRH) posted the following letter on FDA's website:

- Warning Letter to NeoMedix Corporation re: Trabectome High Frequency Generator/LP K061258 (February 26, 2014) ("NeoMedix Warning Letter")

The Office of Compliance and Biologics Quality (OCBQ) in FDA's Center for Biologics Evaluation and Research (CBER) 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)

IBSA Untitled Letter

OPDP alleged that a Facebook webpage for Institut Biochimique SA ("IBSA") was false or misleading because it omitted risk information and omitted material facts.

Omission of Risk Information: OPDP contended that IBSA's Facebook page for Tirosint was misleading because it included representations concerning Tirosint's efficacy, but it omitted any reference to risks associated with the drug's use. The webpage included the following statement:

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

- "Tirosint® (Levothyroxine Sodium) Capsules. . . If you have just been diagnosed with hypothyroidism or are having difficulty controlling your levothyroxine blood levels, talk to your doctor about prescription Tirosint, a unique liquid gel cap form of levothyroxine."

According to OPDP, the omission of risk information on the webpage was "particularly concerning considering that the Tirosint PI includes a Boxed Warning." OPDP concluded that because the webpage failed to communicate the most serious and frequent risks, it "misleadingly suggests" that the drug is safer than has been proven.

Omission of Material Facts: OPDP also stated that the Facebook webpage "fails to provide material information regarding Tirosint's FDA-approved indication." OPDP acknowledged that the webpage suggested that the drug is used for patients with hypothyroidism. However, OPDP contended that the webpage failed to disclose that "Tirosint is not indicated for transient hypothyroidism during the recovery phase of subacute thyroiditis."

LETTER ISSUED BY OFFICE OF COMPLIANCE (OC) IN CDRH

NeoMedix Warning Letter

In its Warning Letter to Neomedix, OC concluded that promotional claims used by the company for the Trabectome High Frequency Generator/LP ("Trabectome") caused the device to be adulterated and misbranded. According to the Warning Letter, Trabectome was cleared under K061258 for "use with compatible electrosurgical instruments in low power microsurgical applications for the removal, destruction and coagulation of tissue."

OC's review of Neomedix's website found evidence that the company promoted the device for "minimally invasive surgical management of glaucoma," "for minimally invasive treatment of glaucoma," and "33% IOP [intraocular pressure] Reduction on Average." OC noted that the submission lacked data on the "treatment of glaucoma, and the device was not cleared for the treatment glaucoma." Accordingly, OC alleged that these claims represented a "major change or modification" of the device that required either a new 510(k) clearance or a premarket approval application. OC concluded, therefore, that Trabectome was adulterated under 21 U.S.C. § 351(f)(1)(B) and misbranded under 21 U.S.C. § 352(o).

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	+1.202.662.5275	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