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E-ALERT | Food & Drug

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SUMMARY OF FDA ADVERTISING AND PROMOTION ENFORCEMENT ACTIVITIES

JUNE 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 June 2014, FDA's Office of Prescription Drug Promotion (OPDP) posted the following two letters on FDA's website[1]:

- Untitled Letter to Citius Pharmaceuticals, LLC, re: Suprenza (phentermine hydrochloride) orally disintegrating tablets, CIV MA #25 (June 9, 2014) ("Citius Untitled Letter")
- Untitled Letter to Gilead Sciences, Inc., re: Viread (tenofovir disoproxil fumarate) Tablets and Powder, for oral use MA #285,3 (June 27, 2014) ("Gilead 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)

Citius Untitled Letter

OPDP alleged that the homepage for Suprenza (phentermine hydrochloride) orally disintegrating tablets ("Suprenza") was "false or misleading" because it omitted risk information, contained unsubstantiated efficacy claims, and omitted material facts.

Omission of Risk Information: OPDP claimed that the webpage was misleading because it failed to disclose "all of the contraindications and adverse reactions associated" with Suprenza's use. OPDP noted that the webpage included "information regarding the risk of co-administration of Suprenza with other drug products for weight loss." However, OPDP contended that the webpage omitted other "warnings and precautions" for Suprenza. OPDP also stated that a link to the full prescribing information failed to "mitigate" the omission of risk information.

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

Unsubstantiated Efficacy Claims: Suprenza is indicated as a short-term adjunct in a regimen of weight reduction based on exercise, behavior modification, and caloric restriction in the management of exogenous obesity in certain patients. Suprenza's webpage claimed the following: "Stay on course for success with The Suprenza LEAN Program"; "It's time to take control . . . and get LEAN"; and "www.leanonsuprenza.com." OPDP alleged that those claims "misleadingly suggest[ed]" that Suprenza would result in patients becoming "lean." OPDP claimed it was unaware of substantial evidence or substantial clinical experience supporting such a suggestion. OPDP explained that the term "lean" generally means "thin, slim, or slender," and the term "was not associated" with the clinical endpoints of phentermine studies.

Omission of Material Facts: OPDP also stated that Suprenza's webpage included representations regarding the use of Suprenza for weight loss. However, OPDP contended that the webpage "misleadingly omits material information regarding the FDA-approved indication for the drug." In particular, OPDP alleged that the webpage failed to disclose (1) the "minimum initial body mass index" for use of Suprenza and (2) the required "presence of other risk factors in patients" with a certain body mass index.

Gilead Untitled Letter

OPDP's letter cited a Gilead sponsored link on Google for Viread (tenofovir disoproxil fumarate) Tablets and Powder, for oral use ("Viread"). OPDP alleged that this link was evidence that Viread was intended for an unapproved new use. OPDP also claimed that Viread's labeling lacks adequate directions for the unapproved use. OPDP also alleged that the sponsored link was misleading because it made efficacy representations, but it omitted any risk information concerning Viread's use.

Lack of Adequate Directions for Use: The sponsored link claimed: "Hepatitis B Prevention – viread.com www.viread.com/Treating HBV Looking for A Hep B Treatment Option? Click to Learn More!" According to OPDP, that statement "misleadingly" implied that Viread is "safe and effective" to prevent hepatitis B. OPDP stated that Viread's approved labeling does not specify that Viread is safe and effective for preventing hepatitis B.

Omission of Risk Information: OPDP contended that the sponsored link was misleading because it made representations or suggestions concerning Viread's efficacy, but it omitted "any risk information." In particular, OPDP noted that the sponsored link omitted the Boxed Warning for Viread. OPDP also stated that a link to Viread's website included in the sponsored link failed to mitigate the omission. According to OPDP, the omission of risk information in the sponsored link "misleadingly suggests that Viread is safer than has been demonstrated."

Inadequate Presentation of Established Name: OPDP claimed that the sponsored link omitted Viread's established name despite the requirement that it include such information.

Failure to Submit Under Form FDA-2253: OPDP also maintained that it did not receive a copy of the sponsored link on Form FDA-2253 when the sponsored link was initially published.

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

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