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E-ALERT | Food & Drug

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SUMMARY OF FDA ADVERTISING AND PROMOTION ENFORCEMENT ACTIVITIES

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

- Untitled Letter to Sciecure Pharma, Inc. re: NDA 018708 DORAL (quazepam) Tablets for oral use C-IV MA #46 (October 29, 2014) ("Sciecure 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)

Sciecure Untitled Letter

OPDP alleged that a sales aid for DORAL (quazepam) Tablets for oral use C-IV ("Doral") was misleading because it omitted important risk information, made unsubstantiated superiority claims, and omitted material facts.

Omission of Risk Information: OPDP alleged that the sales aid was misleading because it did not include facts that were material in light of the sales aid's representations. In particular, FDA contended that the sales aid included several benefits of Doral, but failed to provide the contraindications listed in Doral's FDA-approved prescribing information ("PI"). FDA also stated that the sales aid omitted several serious risks of Doral, including "benzodiazepine withdrawal syndrome, the need to evaluate for co-morbid diagnoses, severe anaphylactic or anaphylactoid reactions, abnormal thinking and behavior changes, and worsening of depression."

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

FDA also alleged that even though the sales aid included "some risk information" concerning CNS-depressant effects and daytime impairment "associated with Doral," the sales aid failed to include material information about those particular risks. Specifically, FDA noted that the sales aid omitted information about activities that patients should be "cautioned" to avoid. In addition, FDA noted that the sales aid included some common adverse reactions, but it omitted "other common adverse reactions associated with the drug."

Unsubstantiated Superiority Claims: FDA alleged that the sales aid misleadingly implied that Doral is safer and more effective than other similar products due to its unique mechanism of action. The sales aid included statements such as "Discover a surprisingly unique sleep agent"; "Doral is the only benzodiazepine that is uniquely BZ1 selective…"; Doral® (quazepam tablets, USP) – the only benzodiazepine that provides BZ1 receptor selectivity…"; and "DORAL. . . .for the effective treatment of insomnia acts selectively on BZ1 receptors…." FDA contended that these claims constitute superiority claims unsupported by substantial evidence, noting that the four references cited did not include "adequate and well-controlled head-to-head clinical trials comparing" Doral and comparator drugs. Finally, FDA noted that the claims were misleading because they indicated a "greater degree of certainty" concerning Doral's mechanism of action than is known.

Omission of Material Facts: FDA found that the sales aid did not include material information from Doral's PI. In particular, FDA noted that the sales aid claimed that "Doral is indicated for the treatment of insomnia, characterized by difficulty in falling asleep, frequent nocturnal awakenings, and/or early morning awakenings." However, FDA stated that the sales aid omitted information from the Indications and Usage section of the PI cautioning that "prolonged administration of" Doral is "generally not necessary or recommended" and that because of the nature of insomnia, "more specific treatment should be considered."

FDA also contended that "within the context of this sales aid," a statement regarding dosing and administration was misleading because the sales aid was intended for healthcare professionals. The sales aid included a claim that "Doral 15 mg @bedtime." However, FDA stated that the sales aid failed to include material information concerning Doral's dosage and administration. Specifically, Doral's PI recommends that physicians prescribe the lowest effective dose for the patient and that the recommended initial dose is 7.5 mg.

Failure to Submit Under Form FDA-2253: FDA noted that the sales aid was not submitted to OPDP under Form FDA-2253.

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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