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E-ALERT | Food & Drug

July 31, 2013

SUMMARY OF FDA ADVERTISING AND PROMOTION ENFORCEMENT ACTIVITIES

JUNE 2013

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 drugs, medical devices, and biologics.

In June 2013, FDA's Office of Prescription Drug Promotion (OPDP) posted the following enforcement letter on FDA's website[1]:

- Untitled letter to Johnson & Johnson International, Inc., re: NDA #202439 Xarelto (rivaroxaban) tablets MA #215 (June 6, 2013) ("J&J 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 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)

J&J Untitled Letter

OPDP alleged that a print advertisement for Xarelto tablets was false or misleading because it minimized the risks associated with Xarelto and made a misleading claim in violation of 21 U.S.C. § 352(n). Xarelto is indicated to reduce the risk of stroke and systemic embolism in patients with nonvalvular atrial fibrillation.

Minimization of Risk Information: According to OPDP, the print advertisement prominently displayed various efficacy claims for Xarelto in large, bolded, or colorful text with graphics. Risk information, however, allegedly was presented in adjacent pages without any of the emphasis such as color schemes, borders, and graphics. OPDP stated that the "overall presentation misleadingly minimize[d] the risks associated with Xarelto because it fail[ed] to convey this important risk information with a prominence and readability reasonable comparable to the efficacy claims." OPDP noted that although the advertisement contained the statement "**Please see accompanying**

[1] Only enforcement letters posted to FDA's website in June 2013 are included herein. Letters issued in June but not posted to the website by June 31, 2013 will be summarized in our alerts for the months in which those letters are posted.

Medication Guide on the following pages,"[2] OPDP did not believe that the statement mitigated the allegedly misleading presentation.

Misleading Claim: OPDP also alleged that the print advertisement's claim that "there are **no dosage adjustments** . . ."[3] was misleading. OPDP asserted that Xarelto's approved product label states that dosage adjustments may be necessary for patients with renal impairment. OPDP cited the dosage and administration section of the approved product label, which states that doses should be lowered for patients with renal impairment, and that patients with renal impairments may need to adjust therapy based on periodic clinical assessments.

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[2] Emphasis in print advertisement.
[3] Emphasis in print advertisement.