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FDA Advertising and Promotion Enforcement Activities: Update

June 6, 2017

Food, Drugs, and Devices

This e-alert is part of a series of 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, FDA's Office of Prescription Drug Promotion (OPDP) posted the following letter on FDA's website:

- Untitled letter to Orexigen Therapeutics, Inc. re: NDA 200063 CONTRAVE (naltrexone HCl and bupropion HCl) Extended-Release Tablets (May 18, 2017) ("Contrave Untitled Letter")

This is the first enforcement letter OPDP has posted in 2017, continuing a trend of declining enforcement activity from the office. Covington discussed that trend in a previous alert.

The Office of Compliance (OC) in FDA's Center for Devices and Radiological Health (CDRH) and FDA's Office of Compliance and Biologics Quality (OCBQ) did not post any enforcement letters relating to advertising and promotion on FDA's website in May (or previously in 2017).

This alert merely summarizes the allegations contained in FDA's letter. 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.

Office of Prescription Drug Promotion (OPDP)

Contrave Untitled Letter (May 2017)

OPDP found that Orexigen Therapeutics' direct-to-consumer ("DTC") broadcast television advertisement about weight-loss drug Contrave misbranded the drug within the meaning of the Federal Food, Drug and Cosmetic Act. Specifically, OPDP alleged that the television advertisement made false or misleading representations about the risks associated with Contrave, thereby creating a misleading impression about Contrave's safety.

The letter's focus on risk presentation aligns with recent OPDP practice; in 2016, over 40% of OPDP's enforcement letters addressed promotional materials that contained false or misleading

risk information.[1] In previous years, OPDP typically categorized allegations of this type as "Minimization of Risk Information" (or "Omission and Minimization of Risk Information") and only recently shifted to the term "False or Misleading Risk Presentation." OPDP's continued recasting of these allegations as "False or Misleading Risk Presentation" is noteworthy and perhaps reflects a response to the recent court decisions holding that truthful and non-misleading communications are constitutionally protected.

The letter also continues a recent trend of focusing on DTC advertisements. In 2016, two of the 11 letters related to branded television advertisements and two related to YouTube.com videos targeting patients.

False or Misleading Risk Presentation:

In the untitled letter, OPDP emphasized the serious risks associated with Contrave, including suicidal thoughts, seizures, and allergic reactions. Contrave is also associated with a number of adverse reactions, such as nausea, constipation, vomiting, and diarrhea. Additionally, Contrave is contraindicated for use in a variety of situations, including hypertension, use of other bupropion-containing products, and pregnancy.

Although the advertisement included efficacy claims for Contrave, it failed to discuss all the conditions for which Contrave is contraindicated. The advertisement also failed to disclose any information about the neuropsychiatric reactions listed in the Boxed Warning section of Contrave's prescribing information. OPDP found Orexigen's inclusion of the statements "CONTRAVE is not for everyone" and "Other side effects may occur" insufficient to mitigate the omission of these risks from the advertisement.

OPDP also criticized the advertisement's communication of important risk information through visuals only (i.e., as SUPERs) and presentation of unrelated risk information in competing audio messages. OPDP concluded that the "overall effect . . . undermines the communication of important risk information and thereby misleadingly minimizes the risks" associated with Contrave.

Finally, OPDP noted that this misleading presentation was especially problematic from a public health perspective because of the "serious and potentially life-threatening risks associated with the drug."

If you have any questions concerning the material discussed in this client alert, please contact the following members of our Food, Drugs, and Devices practice:

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[1] *See 2016 End-of-Year Summary of FDA Advertising and Promotion Enforcement Activity*, Covington & Burling Client Alert (Jan. 9, 2017), available here.