

FDA Advertising and Promotion Enforcement Activities: Update

September 20, 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 August, FDA's Office of Prescription Drug Promotion (OPDP) posted the following letter on FDA's website:

- Warning Letter to Cipher Pharmaceuticals, Inc. re: NDA 022370 CONZIP® (tramadol hydrochloride) Extended-Release Capsules for Oral Use (Aug. 24, 2017) ("[ConZip Warning Letter](#)")

This is the second 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 August (or previously in 2017).

This alert merely summarizes the allegations contained in FDA's letter. It does not contain any analyses, 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)

ConZip Warning Letter (August 2017)

ConZip, an opioid agonist, is manufactured by Cipher Pharmaceuticals, Inc. In the ConZip Warning Letter, OPDP alleges that a professional detail aid used to promote ConZip misbrands ConZip within the meaning of the Federal Food, Drug, and Cosmetic Act. Specifically, OPDP alleges that the professional detail aid is false or misleading because it omits important risk information associated with the use of ConZip and omits other material facts.

False or Misleading Risk Presentation:

In the warning letter, OPDP emphasizes the serious risks associated with ConZip, including, but not limited to addiction, abuse, and misuse; life-threatening respiratory depression; and

neonatal opioid withdrawal syndrome. Furthermore, ConZip is contraindicated in a number of patient populations, including, but not limited to, patients with significant respiratory depression; acute or severe bronchial asthma in an unmonitored setting or in the absence of resuscitative equipment; known or suspected gastrointestinal obstruction, including paralytic ileus; and hypersensitivity to tramadol. The most common adverse reactions with use of ConZip include nausea, constipation, dry mouth, somnolence, dizziness, and vomiting.

OPDP alleges that, although the detail aid makes representations and/or suggestions about the efficacy of ConZip, it fails to communicate *any* risk information about the product. OPDP states that this omission “creates a misleading impression about the drug’s safety, a concern heightened by the serious public health impacts of opioid addiction, abuse and misuse.”

Omission of Material Facts

OPDP also alleges that the detail aid is misleading because it fails to provide material information regarding ConZip’s full FDA-approved indication. For example, the detail aid represents that, “ConZip® is an opioid agonist indicated for the management of moderate to moderately severe chronic pain in adults who require around-the-clock treatment of their pain for an extended period of time.” The full, FDA-approved indication for ConZip states, however, that “CONZIP is an opioid agonist indicated for the management of pain severe enough to require daily around-the-clock, long-term opioid treatment *and for which alternative treatment options are inadequate*” (emphasis added). The italicized language is omitted from the representation in the detail aid.

OPDP also alleges that the detail aid fails to include “Limitation of Use” information. Specifically, the prescribing information for ConZip includes limitations of use that (1) ConZip should be reserved “for use in patients for whom alternative treatment options (e.g., non-opioid analgesics or immediate-release opioids) are ineffective, not tolerated, or would be otherwise inadequate to provide sufficient management of pain,” and (2) ConZip “is not indicated as an as-needed (prn) analgesic.” According to OPDP, neither of these limitations of use are included in the detail aid.

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