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FDA Advertising and Promotion Enforcement Activities: Update

September 11, 2020

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

- Untitled Letter to Xeris Pharmaceuticals, Inc. re: NDA 212097 GVOKE™ (glucagon) injection, for subcutaneous use, MA 43 (Aug. 14, 2020) (Gvoke Untitled Letter)

The Gvoke Untitled Letter is the second enforcement letter OPDP has issued this year. The Office of Product Evaluation and Quality (OPEQ)[1] at the Center for Devices and Radiological Health (CDRH) and the Office of Medical Device and Radiological Health Operations (OMDRHO) in the Office of Regulatory Affairs (ORA) did not post any enforcement letters related to advertising and promotion in August. FDA's Advertising and Promotional Labeling Branch (APLB) in the Office of Compliance and Biologics Quality (OCBQ) has not yet posted any enforcement letters in 2020.

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

Gvoke Untitled Letter (August 2020)

OPDP's untitled letter to Xeris Pharmaceuticals, Inc. (Xeris) states that a direct-to-consumer broadcast television advertisement misbrands Gvoke, a drug that is indicated for the treatment

[1] In March 2019, FDA began implementing a reorganization of CDRH to integrate the center's premarket and postmarket program functions along product lines, rather than according to the stage of the product's life cycle. OPEQ combines the former Office of Compliance, Office of Device Evaluation, Office of Surveillance and Biometrics, and Office of In Vitro Diagnostics and Radiological Health into one super office.

of severe hypoglycemia. OPDP alleges that the advertisement, which Xeris submitted under cover of Form FDA 2253, "makes false or misleading claims and representations about the risks associated with and efficacy of Gvoke."

False or Misleading Risk Presentation

OPDP alleges that the advertisement is misleading because it includes efficacy claims for Gvoke while omitting important risk information. For example, OPDP states that the advertisement fails to include (1) the contraindication in patients with a known hypersensitivity to glucagon or to any of Gvoke's excipients or (2) warnings and precaution information related to hypersensitivity and allergic reactions. The Prescribing Information (PI) states that reported allergic reactions include "generalized rash, and in some cases anaphylactic shock with breathing difficulties and hypotension" and instructs health care providers to "[a]dvise patients to seek immediate medical attention if they experience any symptoms of serious hypersensitivity reactions" (emphasis by OPDP).

False or Misleading Claims about Efficacy

The advertisement states: "Easy to use. Easy to know you did it right. Pretty easy, huh?" OPDP alleges that these claims "misleadingly suggest that the Gvoke pre-filled syringe can be easily used and individuals can confidently recognize that they have correctly administered the product." With regard to ease of use, OPDP states that the PI and Instructions for Use describe multiple steps associated with preparing and administering the Gvoke pre-filled syringe and recommend that patients familiarize themselves with the instructions "before an emergency happens" (emphasis by OPDP). Additionally, OPDP states that there is no signal to indicate to patients that Gvoke was administered correctly.

Omission of Material Fact

OPDP alleges that the advertisement omits material information about (1) the seriousness of hypoglycemia, (2) the circumstances when it is appropriate to administer Gvoke, and (3) the need for administration by others. Specifically, OPDP states that the advertisement includes the statement as an audio-voiceover, "If you have diabetes and take insulin, you know low blood sugar can be scary. You might start to sweat, panic, worry you might pass out. You may even feel like you're falling." These claims, OPDP states, "include some of the early, mild symptoms of hypoglycemia," but not "the symptoms of severe hypoglycemia for which Gvoke is indicated." The advertisement also states that GVOKE "can be used even before passing out." With regard to this claim, FDA alleges the advertisement "fails to provide any information regarding the circumstances when it is appropriate to administer Gvoke and the need for administration by others." OPDP states that the Instructions for Use indicate that Gvoke is intended for third-party administration for patients who are unable to take sugar by mouth.

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* District of Columbia bar application pending; supervised by principals of the firm.