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FDA Advertising and Promotion Enforcement Activities: Update

September 21, 2021

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 untitled letter on FDA's website:

- Untitled letter to Eton Pharmaceuticals, Inc. re: NDA 213876 ALKINDI® SPRINKLE (hydrocortisone) oral granules, MA 13 (Aug. 9, 2021) (Alkindi Sprinkle Untitled Letter)

The Alkindi Sprinkle Untitled Letter is the fifth enforcement letter OPDP has issued this year. The Office of Product Evaluation and Quality (OPEQ) 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 posted any enforcement letters since 2018.

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)

Alkindi Untitled Letter (August 2021)

OPDP's untitled letter to Eton Pharmaceuticals, Inc. (Eton) states that sponsored links on Google.com misbrand Alkindi Sprinkle by presenting information about the drug's benefits without including any risk information. Alkindi Sprinkle is indicated as replacement therapy in pediatric patients with adrenocortical insufficiency, and its product labeling includes warnings and precautions regarding adrenal crisis, infections, and growth retardation, among other adverse reactions. Eton submitted the sponsored links under cover of Form FDA 2253.

False or Misleading Risk Presentation

OPDP alleges that the advertisements are false or misleading because they "fail to communicate **any** risk information" (emphasis by OPDP). OPDP states that the sponsored links present the following claims:

- **Hydrocortisone Oral Granules l Alkindi Sprinkle Now Available**
  Accurate and individualized dosing for infants and children with adrenal insufficiency. Strengths as low as 0.5 mg without splitting or manipulation.

- **Hydrocortisone Oral Granules l Cortisol Replacement Therapy**
  ALKINDI SPRINKLE: low-strength hydrocortisone for children with adrenal insufficiency. Individualized hydrocortisone dosing with no bitter taste, pill cutting or dissolving.

- **Alkindi Sprinkle for Kids l Micro-Granular Hydrocortisone**
  Alkindi Sprinkle for pediatric adrenal insufficiency; strengths as low as 0.5 mg. No cutting, no splitting, just sprinkles for neonates and children <17 years of age.

"By omitting the risks associated with Alkindi Sprinkle," OPDP concludes, "the sponsored links fail to provide material information about the consequences that may result from the use of Alkindi Sprinkle and create a misleading impression about the drug's safety."

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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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