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COVINGTON & BURLING LLP

E-ALERT | Food & Drug

January 28, 2013

SUMMARY OF FDA ADVERTISING AND PROMOTION ENFORCEMENT ACTIVITIES

DECEMBER 2012

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, biologics, and medical devices. In December 2012, FDA's Office of Prescription Drug Promotion (OPDP) posted the following enforcement letter on FDA's website:[1]

- Untitled letter to Salix Pharmaceuticals, Inc. and Napo Pharmaceuticals, Inc. re: Crofelemer tablets (crofelemer) (November 27, 2012) ("Salix/Napo Untitled Letter")[2]

During December 2012, 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 letter, presented under the corresponding heading used by the agency in its letter. This alert 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.

Salix/Napo Untitled Letter

Promotion of an Investigational New Drug: At the time FDA issued its letter, crofelemer (brand name Fulyzaq™) was not yet approved and was an investigational new drug.[3] OPDP reviewed the company website for Napo Pharmaceuticals, Inc. ("Napo") and statements made by a Napo Chief Executive in a podcast and concluded that the website and podcast contained claims that promoted crofelemer as safe and effective for the purposes for which it is being investigated. For example, the website stated:

- "Safety in children in the US as young as 3 months and appropriate mechanism for population."
- "Crofelemer does not affect gut motility and is not absorbed systematically to any significant level, two important characteristics associated with the product's demonstrated safety profile and suitability for chronic administration."

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[1] Only enforcement letters posted to FDA's website in December 2012 are included herein. Letters issued in December but not posted to the website by December 31, 2012 will be summarized in our alerts for the months in which those letters are posted.

[2] The date referenced for the letter is the issue date.

[3] On December 31, 2012, FDA approved Fulyzaq™ (crofelemer) to relieve symptoms of diarrhea in HIV/AIDS patients taking antiretroviral therapy.

- "[Crofelemer] is ideally suited to treat the secretory diarrhea produced by acute bacterial infections (traveler's diarrhea and cholera infection)."

The podcast of an interview with a Napo Chief Executive contained claims such as:

- "[I]t normalizes the abnormal ion flow that comes into the gut . . . and it does so without interfering with peristaltic activity so you don't cause constipation . . . . And that's opposed to what we think of with Imodium or loperamide . . . [which] can't be used on a chronic basis and they can be particularly unsafe in young children . . . ."
- "This product has so many different indications because the mechanism of action is a basic normalizing, it's sort of the holy grail . . . . So, it [crofelemer] works for diarrhea in AIDS patients . . . it works for the most severe acute, infectious, watery diarrhea, works for the most mild diarrhea . . . ."

OPDP determined that these claims suggested that crofelemer is safe and/or effective for the treatment of various types of diarrhea, and for the treatment of pediatric patients as young as three months, and otherwise promoted the drug in violation of 21 C.F.R. 312.7(a).

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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 & Drug Practice Group:

Michael Labson	+1.202.662.5220	mlabson@cov.com
Erika Lietzan	+1.202.662.5165	elietzan@cov.com
Scott Cunningham	+1.202.662.5275	scunningham@cov.com
Scott Danzis	+1.202.662.5209	sdanzis@cov.com
Julia Post	+1.202.662.5249	jpost@cov.com