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Summary of FDA Advertising and Promotion Enforcement Activities

September 14, 2015

Food & Drug

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

- Warning Letter to ECR Pharmaceuticals, re: TussiCaps (hydrocodone polistirex and chlorpheniramine polistirex) Extended-release Capsules CII MA #86 (July 27, 2015) ("ECR Warning Letter")

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.

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

Letters Issued by Office of Prescription Drug Promotion (OPDP)

ECR Warning Letter

OPDP contended that a professional sales aid ("sales aid") for TussiCaps (hydrocodone polistirex and chlorpheniramine polistirex) Extended-release Capsules CII (TussiCaps) was false or misleading because it omitted risk information, inadequately communicated the full indication for the drug, and included unsubstantiated claims.

Omission of Risk Information: OPDP alleged that the sales aid was misleading because it included "numerous efficacy claims" regarding TussiCaps, but omitted any risk information about the product. OPDP noted that the omission of any risk information included the omission of potentially serious and fatal risks. OPDP alleged that this omission implied that the drug is safer "than has been demonstrated," which was especially concerning in light of the drug's potential public health impact.

Inadequate Communication of Indication*:* OPDP also contended that the sales aid failed to convey the full approved indication for TussiCaps. OPDP noted that the sales aid included the

claim that TussiCaps is used "for the relief of cough and upper respiratory symptoms associated with colds or allergies."

However, OPDP noted that TussiCap is indicated "for relief of cough and upper respiratory symptoms associated with allergy or a cold in adults and children 6 years of age and older." OPDP also noted that TussiCaps is contraindicated for children less than 6 years old. OPDP acknowledged that the sales aid provided usual dosages for "patients six years of age and older," but explained that this statement did not "mitigate" the "misleading impression" created by the sales aid. OPDP also noted that the omission of age information was particularly misleading in light of an image in the sales aid of a "coughing young child."

***Unsubstantiated Claims**:* OPDP contended that the sales aid was misleading because it included statements suggesting that patients prefer TussiCaps over oral liquid formulations because TussiCaps is a capsule. OPDP identified claims in the sales aid, such as "Patient Preferred Capsule" and "73% of adult prescription cough syrup users said they prefer capsules over liquid medications." OPDP also identified an image with a zip bag with liquid medication spilled at the bottom.

OPDP alleged that these claims in total suggested that patients prefer TussiCaps capsules over liquid formulations. OPDP noted that the study cited to support these claims did not "specifically evaluate" whether patients preferred TussiCaps to liquid formulations. Accordingly, OPDP concluded that the cited study was "insufficient" to support the claims in the sales aid.

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
Scott Cunningham	+1 415 591 7089	scunningham@cov.com
Scott Danzis	+1 202 662 5209	sdanzis@cov.com
Stefanie Doebler	+1 202 662 5271	sdoebler@cov.com
Meghan Monaghan	+1 202 662 5531	mmonaghan@cov.com