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FDA Advertising and Promotion Enforcement Activities: Update

April 1, 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 March, the Office of Prescription Drug Promotion (OPDP) posted the following warning letter on FDA's website, issued earlier this year:

- Warning Letter to Outlook Pharmaceuticals, Inc. re: ANDA 040776 PROCENTRA® (dextroamphetamine sulfate) oral solution, CII MA 60 (Feb. 21, 2020) (ProCentra Warning Letter)

In February, the Office of Medical Device and Radiological Health Operations (OMDRHO) in the Office of Regulatory Affairs (ORA) posted the following warning letter, which was cosigned by the Office of Product Evaluation and Quality (OPEQ)[1] at the Center for Devices and Radiological Health (CDRH) and issued earlier this year:

- Warning Letter to CPAPNEA Medical Supply (Jan. 22, 2020) ("CPAPNEA Warning Letter")

The ProCentra Warning Letter is the first enforcement letter OPDP has issued this year. The CPAPNEA Warning Letter is the first enforcement letter related to advertising and promotion of devices issued by FDA this year. 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.

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[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.

Office of Prescription Drug Promotion (OPDP)

ProCentra Warning Letter (February 2020)

OPDP's warning letter to Outlook Pharmaceutics states that a sponsored link on the search engine Google.com misbrands ProCentra, a schedule II controlled substance indicated for the treatment of Attention Deficit Disorder with Hyperactivity in pediatric patients. OPDP alleges that the sponsored link fails to include "**any** risk information about the drug" (emphasis by OPDP) and does not present the required established name of the drug. The letter further states that the link was reported to FDA pursuant to its Bad Ad Program.

False or Misleading Risk Presentation

OPDP alleges that the sponsored link provides information about the drug's uses and/or benefits without including any risk information, thereby misbranding the drug. The link states, in its entirety:

> Explore Your ADHD Medication Options for Your Child. ProCentra® May be the Solution You've Been Looking for. Learn About ProCentra® Today. Liquid Treatment Option. Copay Card Available. Types: Immediate-release, Sugar Free, Bubblegum Flavor.

OPDP alleges the sponsored link includes statements that constitute claims about the drug's uses and benefits, such as "Explore Your ADHD Medication Options for Your Child." It further alleges that the link does not include any risk information, thereby creating a misleading impression about the drug's safety.

According to OPDP, the sponsored link is "particularly alarming" because statements promoting liquid treatment options and bubblegum flavoring could appeal to parents. However, it does not disclose that ProCentra is a schedule II controlled substance with a boxed warning regarding the potential for abuse and serious consequences associated with misuse, including death.

Failure to Use Required Established Name

OPDP alleges that the sponsored link fails to include the established name of the product (dextroamphetamine sulfate), thereby misbranding ProCentra. Under 21 C.F.R. 201.10(g)(1), "the established name shall be placed in direct conjunction with the proprietary name or designation."

CDRH Office of Product Evaluation and Quality (OPEQ) and ORA Office of Medical Device and Radiological Health Operations (OMDRHO)

CPAPNEA Warning Letter (January 2020)

In its letter to CPAPNEA Medical Supply (CPAPNEA), OMDRHO and OPEQ allege that the Optipillows Expiratory Positive Airway Pressure (EPAP) Mask is adulterated and misbranded,

because the company promoted the device beyond the cleared indications for use and because statements in the product labeling are "false or misleading."[2]

FDA previously cleared the Optipillows EPAP mask for the sole intended use to alleviate snoring during sleep in adults. In its warning letter, FDA alleges that product labeling and statements on the company's website suggest that (1) "the Optipillows EPAP Mask is intended to treat obstructive sleep apnea," and (2) the device can "be a substitute for CPAP [Continuous Positive Airway Pressure] devices." FDA states that marketing the EPAP device for the treatment of obstructive sleep apnea represents a "major change or modification" requiring the submission of a new premarket notification (commonly referred to as a "510(k)"), including appropriate performance data. Additionally, FDA alleges that CPAPNEA's statements suggesting the mask can be a substitute for CPAP devices and that FDA has cleared EPAP for treating obstructive sleep apnea are false and misleading.

FDA provides the following examples of "violative statements":

- "Optipillows uses EPAP technology, which is FDA cleared for treating snoring and obstructive sleep apnea."
- "This device is intended for treatment of snoring, however, it may also treat obstructive sleep apnea."
- "Works like a nasal pillow CPAP mask but without tubing or a machine."
- "There is evidence that EPAP devices are as effective as CPAP in some patients with snoring and mild obstructive sleep apnea."
- "If you snore or suspect you have obstructive sleep apnea, this mask may be for you."

FDA alleges that the statements cited above raise serious public health concerns, noting that "CPAP devices are class II devices that are prescribed after a patient is evaluated by a licensed dentist or other health professional and is determined to be an appropriate candidate for the device." The agency also notes that CPAPNEA has not provided any evidence that supports use of the company's mask to treat obstructive sleep apnea of any severity level, and FDA is not aware of any such evidence.

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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[2] The letter also discusses other inspectional findings unrelated to the promotion of the Optipillows EPAP Mask.