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ADVERTISING, MARKETING & PROMOTIONS

>>ALERT

FDA ISSUES WARNING LETTER FOR STATEMENTS MADE DURING TALK SHOW

The FDA's Office of Prescription Drug Promotion (OPDP) recently issued a Warning Letter to Aegerion Pharmaceuticals indicating that statements made by the CEO of Aegerion during the CNBC talk show "Fast Money" promoted the drug Juxtapid for new and unapproved uses, rendering Juxtapid misbranded under the Federal Food Drug and Cosmetic Act. This letter comes almost a year after OPDP issued an Untitled Letter to Cornerstone Therapeutics for failing to include risk information in a media pitch letter.

BACKGROUND

In June and October of 2013, CNBC aired interviews with the CEO of Aegerion Pharmaceuticals. During the interviews, statements were made such as "[t]hese patients are going to die of a cardiac event, either a stroke or a heart attack, if we don't have them on therapy," and "[homozygous familial hypercholesterolemia "HoFH"] is a devastating disease that causes early death. And the drug is corrective against that disease and that's the most important thing." Juxtapid is approved in combination with a low-fat diet and other treatments to reduce specific lipids in patients with HoFH. Juxtapid is not approved for use to treat the disease on its own, separately from treatment with a low-fat diet and other treatments.

FDA'S REACTION

In the Warning Letter, the FDA's OPDP found that these statements indicated that Juxtapid can be used as a monotherapy, which is a new and unapproved intended use for the drug. As the statements promoted Juxtapid for a new and unapproved use, the statements caused Juxtapid to be misbranded and made the distribution of the drug a violation of the Federal Food, Drug, and Cosmetic Act.

This is the first Warning Letter issued by OPDP to a company for statements aimed at financial investors. However, last year OPDP issued an Untitled Letter to Cornerstone Therapeutics for failing to include risk information associated with the drug Curosurf in a pitch letter, even though the press release accompanying the pitch letter included the risk information. OPDP found the pitch letter false and misleading for suggesting that Curosurf is safer than demonstrated. Therefore, OPDP found Curosurf to be misbranded in violation of the Federal Food, Drug, and Cosmetic Act.

THE BOTTOM LINE

As the FDA continues to target companies for statements made in public appearances and in media pitch materials, pharmaceutical companies need to be aware that these statements can cause their products to be misbranded.

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