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E-ALERT | Food & Drug

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SUMMARY OF FDA ADVERTISING AND PROMOTION ENFORCEMENT ACTIVITIES

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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 prescription drugs, medical devices, and biologics.

In September 2014, FDA's Office of Prescription Drug Promotion (OPDP) posted the following letters on FDA's website[1]:

- Untitled Letter to Cipher Pharmaceuticals, Inc. re: NDA 21612 LIPOFEN (fenofibrate capsules, USP) for oral use MA #128 (September 11, 2014) ("Cipher Untitled Letter")
- Warning Letter to Pacira Pharmaceuticals, Inc. re: NDA #022496 EXPAREL (bupivacaine liposome injectable suspension) ("Pacira Warning Letter")

The Office of Compliance and Biologics Quality (OCBQ) in FDA's Center for Biologics Evaluation and Research (CBER) and the Office of Compliance (OC) 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 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)

Cipher Untitled Letter

OPDP alleged that an "e-Pharm/alert" email for Lipofen (fenofibrate capsules, USP) for oral use (Lipofen) was "false or misleading" because it included unsubstantiated superiority claims.

Unsubstantiated Superiority Claims: OPDP contended that the email was misleading because it "implies that Lipofen offers a clinical advantage over other available fenofibrate products." OPDP noted that the email included several claims, such as "e-Pharm/alert: All fenofibrates are not created equal"; "When a patient is prescribed LIPOFEN® (fenofibrate capsules, USP), a generic fenofibrate may not be the best option. Only LIPOFEN offers Lidose® technology,…"; and "Other fenofibrates are formulated with small particles, which may affect absorption— With LIPOFEN, particle size is not an issue." OPDP stated that the email was misleading because the superiority

[1] Only enforcement letters posted to FDA's website in September 2014 are included herein. Letters issued in February but not posted to the website by September 30, 2014 will be summarized in our alerts for the months in which those letters are posted.

claims were not supported by substantial evidence. OPDP noted in the untitled letter that the email cited several references in support of the claims, but OPDP found that the identified references failed to support a superiority claim. In addition, OPDP noted that it was unaware of "head-to-head clinical trials" that compared Lipofen and other fenofibrate products. OPDP also stated that it was unaware of evidence supporting the claim that Lipofen's "Lidose" technology offered a "clinical advantage over other fenofibrate products."

Pacira Warning Letter

OPDP alleged that educational technique flashcards (administration guides) for Exparel (bupivacaine liposome injectable suspension) (Exparel) offered evidence that Exparel "is intended for new uses for which it lacks approval" and for which the labeling lacked adequate directions for use. OPDP also alleged that a journal ad for Exparel was "false or misleading" because the journal ad "overstates the efficacy of Exparel."

Lack of Adequate Directions for Use: OPDP contended that claims in the administration guides "suggest that Exparel is safe and effective for use in cholecystectomy and colectomy." However, Exparel's approved labeling lacked instructions or information regarding the safety and efficacy of Exparel for "postsurgical pain if used in surgical procedures other than hemorrhoidectomy or bunionectomy." OPDP stated that the disclaimers and disclosures included in the administration guides failed to alter the impression that Exparel would be "safe and effective" if used in cholecystectomy and colectomy. OPDP concluded its discussion by noting its concern with other "professionally-directed promotional materials" for Exparel that suggest that Exparel is safe and effective for "various other surgical procedures."

Overstatement of Efficacy: OPDP also claimed that a journal ad for Exparel overstated the efficacy of Exparel and was "misleading" because it suggested that Exparel was "shown to provide pain control beyond 24 hours." The journal ad identified by OPDP stated: "Patient-Focused Pain Control That Lasts For Up To 72 Hours," and "The only single-dose local analgesic to . . . Reduce or eliminate opioids with pain control for up to 3 days." FDA noted that neither a hemorrhoidectomy trial nor the bunionectomy trial provided substantial evidence of pain control beyond 24 hours.

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