

E-ALERT | Food & Drug

January 19, 2012

SUMMARY OF FDA ADVERTISING AND PROMOTION ENFORCEMENT ACTIVITIES

DECEMBER 2011

This e-alert is part of a monthly series of 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 2011, FDA's Office of Prescription Drug Promotion (OPDP) posted the following four enforcement letters on its website:¹

- Untitled letter to Alcon Research, Ltd. re: PATADAY™ (olopatadine hydrochloride ophthalmic solution) 0.2% (October 14, 2011) ("Alcon Untitled Letter")²
- Untitled letter to EUSA Pharma (USA), Inc. re: ProstaScint® Kit (Capromab Pendetide) (December 13, 2011) ("EUSA Untitled Letter")
- Untitled letter to NeurogesX, Inc. re: QUTENZA® (capsaicin) 8% patch (December 13, 2011) ("NeurogesX Untitled Letter")
- Untitled letter to Sunovion Pharmaceuticals, Inc. re: LATUDA® (lurasidone HCl) Tablets (December 14, 2011) ("Sunovion Untitled Letter")

The Office of Compliance in FDA's Center for Devices and Radiological Health (CDRH) posted five warning letters to the following companies regarding the LapBand gastric banding system (collectively referred to herein as the "LapBand Warning Letters"):

- Beverly Hills Surgery Center, LLC (December 9, 2011)
- Bakersfield Surgery Institute, Inc., Palmdale Ambulatory Surgery Center, Valley Surgical Center, Top Surgeons, LLC, Cosmopolitan Plastic & Reconstructive Surgery (December 9, 2011)
- San Diego Ambulatory Surgery Center, LLC (December 9, 2011)
- Valencia Ambulatory Surgery Center, LLC (December 9, 2011)
- 1-800-GET-THIN, LLC (December 12, 2011)

The letters raise a variety of allegations and conclude that the cited advertising/promotional issues render the subject products misbranded.

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,

¹ Only enforcement letters posted to FDA's website in December 2011 are included herein. Letters issued in December but not posted to the website by December 31, 2011 will be summarized in our alerts for the months in which those letters are posted. The Office of Compliance and Biologics Quality (OCBQ) in FDA's Center for Biologics Evaluation and Research (CBER) did not post any applicable letters in December.

² The date referenced for the letters are the issue dates.

the information presented herein does not necessarily reflect the views of Covington & Burling LLP or any of its clients.

De Facto Omission of Risk Information

FDA's letters contain the following allegations under a "De Facto Omission of Risk Information" subheading:

NeurogesX Untitled Letter: An exhibit booth for Qutenza prominently presented effectiveness claims for the drug. Risk information, however, "was not visible to viewers as a practical matter." According to FDA, three OPDP representatives viewed the booth on three separate occasions and observed that "the risk information was presented on the bottom of the display panels, behind bags, boxes, and other materials; thus it was completely obscured from view and inaccessible to viewers." The booth therefore misleadingly suggested that Qutenza is safer than has been demonstrated by substantial evidence or substantial clinical experience.

Inappropriate Reminder Labeling

FDA's letters contain the following allegations under an "Inappropriate Reminder Labeling" subheading:

Alcon Untitled Letter: A rebate card for Pataday misbranded the drug because the card did not include risk information or the full indication and did not qualify as reminder labeling. Pursuant to FDA regulation at 21 CFR § 201.100(f), reminder labeling calls attention to the name of a drug, but does not include its indication, dosage recommendations, or other "representation[s] or suggestion[s] relating to the drug." The rebate card included a large image of an eye with superimposed images of plant allergens and the phrase "this *Most Relief* Rebate" (Italics added by OPDP). The totality of this presentation made "a representation regarding the use of Pataday for the 'relief' of symptoms of allergic conjunctivitis caused by plant allergens." In addition, the rebate card included the words "Once Daily," which made a dosage recommendation for the product. Therefore, the rebate card did not qualify as reminder labeling and needed to include risk information and the full indication.

Failure to Reveal Material Facts³

LapBand Warning Letters: FDA became aware that several companies, most of which were surgical centers that provide bariatric surgical services, were promoting the LapBand device and procedure through a toll free number, 1-800-GET-THIN.⁴ CDRH thus issued nearly identical letters to these companies after reviewing, among other things, two billboards and several "advertising inserts." One billboard stated, for example, "LOSE WEIGHT WITH THE LAP-BAND! SAFE 1 HOUR, FDA APPROVED 1-800-GET-THIN; 1-800-953-5000; PPO INSURANCE; FREE INSURANCE VERIFICATION." One insert read "Celebrate Black History Month! Let Your New Life Begin! 1-800-GET-THIN." On the reverse side of the insert, in very small print, was information about who would be a candidate for the procedure. According to CDRH, the "advertisements fail to reveal material facts, including relevant risk information regarding the use of the LapBand, age and other qualifying requirements for the LapBand procedure, and the need for ongoing modification of eating habits." CDRH thus concluded that the advertisements misbranded the device.

³ CDRH's letters did not use a "Failure to Reveal Material Facts" subheading, but the promotional allegations therein would fit within this category.

⁴ These letters were issued to surgical centers (and the operator of the 1-800 number), rather than the manufacturer of the device, which apparently was not involved in the promotional activities at issue. Last year, CDRH issued similar letters to several health care providers for promotional activity for LASIK procedures.

Inadequate Communication of Indication

FDA's letters contain the following allegations under an "Inadequate Communication of Indication" subheading:

EUSA Untitled Letter: A fact sheet for ProstaScint included general information regarding the product's indication for use as a diagnostic imaging agent, but omitted information from the Indications and Usage section in the PI relating to clinical settings in which the product had not been studied and the fact that information provided by ProstaScint should be considered in conjunction with other diagnostic information. The fact sheet therefore failed to communicate the "full approved" indication.

Overstatement of Efficacy

FDA's letters contain the following allegations under an "Overstatement of Efficacy" subheading:

EUSA Untitled Letter: The fact sheet contained claims promoting the use of the ProstaScint scans to achieve "higher confidence in patient selection for definitive and salvage treatment options" and to determine cancer prognosis. These claims suggested that "ProstaScint is effective for confidently determining specific treatment options (i.e., definitive and salvage) or as a prognostic indicator for prostate cancer patients, when this has not been demonstrated by substantial evidence or substantial clinical experience." ProstaScint was evaluated in two phase three trials that compared the accuracy of ProstaScint images to the results of surgical staging and histopathologic analysis. The overall accuracy of the ProstaScint images ranged from 63% to 68%, depending on the patient population. Moreover, the PI warns that patient management should not be based on scan results alone because there was a high rate of false positive and false negative image interpretations in the trials. As discussed above, the PI also indicates that the information provided by the product should be considered in conjunction with other diagnostic information.

Omission of Risk Information

FDA's letters contain the following allegations under an "Omission of Risk Information" subheading:

EUSA Untitled Letter: The fact sheet for ProstaScint contained efficacy claims for the product, but omitted all contraindications, important warnings and precautions, and the most commonly reported adverse events. The piece therefore suggested that the product is safer than has been demonstrated by substantial evidence or substantial clinical experience.

LapBand Warning Letters:⁵ CDRH's letters regarding the LapBand device alleged that the promotional pieces failed to adequately state the warnings, precautions, side effects, and contraindications for the product. Moreover, some of the risk information that was provided was presented in illegible font size.

Promotion of Unapproved Uses

FDA's letters contain the following allegations under a "Promotion of Unapproved Uses" subheading:

Sunovion Untitled Letter: In May 2011, a sales representative from Sunovion made a sales call to a psychiatrist's office. During the visit, the sales representative stated that Latuda is approved only for treatment of schizophrenia, but that "studies for use in bipolar disorder are being done and it is only

⁵ CDRH's letters did not use an "Omission of Risk Information" subheading, but the promotional allegations therein would fit within this category.

a matter of time before it is approved for bipolar disorder.” The representative also pointed out that two other psychiatrists in the area were using Latuda for the treatment of bipolar disorder and that both were “pleased” with the results. These statements therefore misbranded the drug by suggesting a new intended use for which the Latuda PI lacks adequate directions of use.

Unsubstantiated Claim

FDA’s letters contain the following allegations under an “Unsubstantiated Claim” subheading:

Sunovion Untitled Letter: During the same Latuda sales call, the sales representative stated that somnolence can occur during treatment, but that “it usually goes away after a week.” The PI, however, does not include any information about a decreased risk of somnolence over time and does include information regarding warning patients that the drug can cause somnolence. This claim was therefore unsubstantiated and minimized the risks associated with the drug.

Unsubstantiated Superiority Claim

FDA’s letters contain the following allegations under an “Unsubstantiated Superiority Claim” subheading:

Alcon Untitled Letter: The combination of the plant allergen image and the claim “Most Relief” on the rebate card misleadingly suggested that Pataday provides superior relief when compared to other available therapies. OPDP is not aware of substantial evidence or substantial clinical experience to support this claim.

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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:

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