COVINGTON

COVINGTON & BURLING LLP

E-ALERT | Food & Drug

March 28, 2013

SUMMARY OF FDA ADVERTISING AND PROMOTION ENFORCEMENT ACTIVITIES

FEBRUARY 2013

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 drugs, biologics, and medical devices. In February 2013, FDA's Office of Prescription Drug Promotion (OPDP) posted the following enforcement letters on FDA's website:[1]

- Untitled letter to Alcon Research, Ltd. re: PATADAY™ (olopatadine hydrochloride ophthalmic solution) 0.2% (February 5, 2013) ("Alcon Untitled Letter")
- Untitled letter to ParaPRO, LLC re: Natroba (spinosad) topical suspension, 0.9% (February 21, 2013) ("ParaPRO Untitled Letter")

The Office of Compliance and Biologics Quality (OCBQ) in FDA's Center for Biologics Evaluation and Research (CBER) posted the following enforcement letter on FDA's website:

- Warning letter to University of Berkley re: Berkley-Body-Immune Flu Prevention (February 7, 2013) ("Berkley Warning Letter")

During February 2013, the Office of Compliance 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, presented under the corresponding heading used by the agency in its letters. This alert 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.

Alcon Untitled Letter

Alcon's Pataday product is indicated for the treatment of ocular itching associated with allergic conjunctivitis. OPDP reviewed a patient education brochure for Pataday and alleged it was false or misleading for omitting material facts, making unsubstantiated efficacy claims, overstating the product's efficacy, and making unsubstantiated superiority claims.

[1] Only enforcement letters posted to FDA's website in February 2013 are included herein. Letters issued in February but not posted to the website by February 28, 2013 will be summarized in our alerts for the months in which those letters are posted.

Omission of Material Fact: In response to the question "**Can I use PATADAY™ Solution if I wear contact lenses?**,"[2] the brochure advised patients not to use Pataday to treat contact lens-related irritation, and to always remove contact lenses before administering Pataday. The response did not, however, include the direction that patients should wait 10 minutes after using Pataday before inserting contact lenses. Although a later page of the brochure included this information, OPDP contended it was misleading to omit this information from the section of the brochure dedicated to the use of Pataday while wearing contact lenses.

Unsubstantiated Efficacy Claims: The patient education brochure included the claim: "**It is important to identify and treat your allergy eye symptoms because** (citation omitted): **1** They can be uncomfortable; **2** They can lead to eye damage, due to excessive scratching or rubbing; **3** They can impact your overall eye health."[3] OPDP explained that this presentation misleadingly suggested that Pataday has demonstrated efficacy in treating all allergy eye symptoms, improving overall eye health, preventing eye damage, and positively impacting eye comfort. According to OPDP, there was no substantial evidence or substantial clinical experience to support these claims.

Overstatement of Efficacy: OPDP stated that a number of claims in the patient education brochure misleadingly suggested that all patients who use Pataday will experience "zero-itch" and be symptom-free. For example, the brochure stated:

- "You'll be free to go about your normal activities and not give those itchy allergy eyes a second thought."
- "**Zero-itch** within minutes and up to 16 hours later with just **one drop** daily."[4]
- "**What is the difference between minimal and zero-itch?**
  Different eye allergy medicines have different levels of effectiveness. Many only minimize itch, but PATADAY™ . . . eliminates it (zero-itch)."[5]

According to OPDP, the pivotal clinical trials for Pataday demonstrated that only 30 to 60 percent of patients treated with Pataday experienced complete ocular itching relief at the pre-specified time points. Additionally, OPDP commented that the reference cited in support of these claims—a post-hoc analysis discussed in a poster presentation—did not constitute substantial evidence in support of these claims.

Unsubstantiated Superiority: Pointing again to the claim "**What is the difference between minimal and zero-itch?**," OPDP contended that this claim misleadingly suggested that Pataday provides superior relief from ocular itching as compared to other available therapies. According to OPDP, FDA was not aware of any adequate, well-controlled, head-to-head clinical trials that supported this claim, and therefore the brochure's claim of superior efficacy was misleading.

ParaPRO Untitled Letter

ParaPRO's Natroba product is a pediculicide indicated for the topical treatment of head lice infestation in patients four years of age and older, to be used in the context of an overall lice management program. OPDP reviewed a video news release for Natroba, and determined it was misleading because it omitted risk information, made an unsubstantiated superiority claim, and inadequately communicated the indication for Natroba.

---

[2] Emphasis in original.
[3] Emphasis in original.
[4] Emphasis in original, citation omitted.
[5] Emphasis in original.

Omission of Risk Information: According to OPDP, the video news release failed to communicate any risk information for Natroba, including the drug's warning and precaution regarding benzyl alcohol toxicity, and the most common adverse side effects of application site and ocular erythema. This misleadingly suggested that Natroba is safer than had been demonstrated.

Unsubstantiated Superiority Claim: The video news release included the following narrated claim: "The FDA has approved what could be a game changing medication in the war against head lice; one that doesn't require nit combing to be effective." OPDP stated that this claim misleadingly implied that Natroba was superior to other treatments for head lice by suggesting that it was a "new or different approach" and a "significant advance" over other products. According to OPDP, several other prescription products for the treatment of head lice do not require nit combing to be effective—just like Natroba. Additionally, OPDP stated that it was unaware of adequate studies demonstrating that Natroba offers a significant advantage over other prescription head lice treatments.

Inadequate Communication of Indication: OPDP explained that the video news release failed to adequately communicate Natroba's full approved indication because it omitted that the drug should be used in the context of an overall lice management program. Specifically, although the video communicated that Natroba is indicated for the topical treatment of head lice infestation in patients four years of age or older, it did not convey that recently worn clothing and hats, used bedding and towels, and personal care items should be washed in hot water, or dry-cleaned, as appropriate.

Berkley Warning Letter

Promotion of Unapproved Use: In a warning letter to the University of Berkley,[6] OCBQ stated that claims on the university's website promoted Berkley-Body-Immune Flu Prevention for the diagnosis, mitigation, prevention, treatment, or cure of the flu virus, even though the product was not approved or cleared by FDA. For example, the website stated (emphasis added by OCBQ):

- "The **most effective alternative** to the flu shot"
- "Health experts at Berkley recommend Homeopathic/Naturopathic treatment to prepare for the upcoming flu season **due to shortage in flu vaccines**"
- "Natural **health and strength can still be yours without Flu Shots** or an office visit"
- "**Protect yourself** with the 'Body-Immune Flu Prevention'"

According to OCBQ, the product posed a potentially significant threat to the public health, and so urgent measures were being taken to protect consumers from this, and other products, that claimed to diagnose, prevent, treat, or cure the flu virus without FDA approval.

* * *

[6] The University of Berkley is an online degree-granting institution that has no affiliation or connection with the University of California, Berkeley.

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
Erika Lietzan	+1.202.662.5165	elietzan@cov.com
Scott Cunningham	+1.202.662.5275	scunningham@cov.com
Scott Danzis	+1.202.662.5209	sdanzis@cov.com
Julia Post	+1.202.662.5249	jpost@cov.com