

**TRANSMITTED BY FACSIMILE**

Terry Dagnon
Senior Director, Regulatory Affairs
Alcon Research, Ltd.
6201 South Freeway R3-54
Fort Worth, TX 76134-2099

RE: NDA # 021545
PATADAY™ (olopatadine hydrochloride ophthalmic solution) 0.2%
MA # 203

Dear Mr. Dagnon:

As part of its routine monitoring and surveillance program, the Office of Prescription Drug Promotion (OPDP) of the U.S. Food and Drug Administration (FDA) has reviewed a rebate card (PAT10513RB) for PATADAY™ (olopatadine hydrochloride ophthalmic solution) 0.2% (Pataday) submitted by Alcon Research, Ltd. (Alcon) under cover of Form FDA-2253. The rebate card is violative because, although it has the form of reminder labeling, which is exempted by regulation from the requirements under the Federal Food, Drug, and Cosmetic Act (FD&C Act) for the disclosure of risk and other information, for the reasons set forth below, we have determined that it is not appropriate reminder labeling. Therefore, the rebate card misbrands Pataday in violation of the FD&C Act, 21 U.S.C. 352(a) & 321(n), and implementing regulations. 21 CFR 1.21; 21 CFR 200.200; 21 CFR 201.00(f). *Cf.* 21 CFR 202.1 (e)(3)(ii), (e)(5) & (e)(6)(ii), as it fails to include the drug product's indication and information addressing the risks associated with Pataday, and because it makes an unsubstantiated superiority claim.

Background

Below is the indication and summary of the most serious and most common risks associated with the use of Pataday.¹

Pataday is indicated for the treatment of ocular itching associated with allergic conjunctivitis. The FDA-approved product labeling (PI) for Pataday includes Warnings and Precautions regarding topical use only, contamination of tip and solution, and contact lens use. In addition, symptoms similar to cold syndrome and pharyngitis were reported at an incidence of approximately 10% with Pataday use.

¹ This information is for background purposes only and does not necessarily represent the risk information that should be included in the promotional piece cited in this letter.

Inappropriate Reminder Labeling/Omission of Indication and Risk Information

According to FDA regulations, reminder labeling is labeling that calls attention to the name of the drug product, but does not include its indication, dosage recommendations, or other representations or suggestions relating to the drug product. See 21 CFR 201.100(f). Although the rebate card cited above does not state the drug product's indication, the images combined with the claims presented on the card make representations about Pataday's use.

Specifically, the rebate card includes a large image of an eye with a plant allergen superimposed on the iris, as well as an image of another plant allergen presented on the same page. Accompanying this presentation is the following claim (bolded emphasis in original; italicized emphasis added):

- **“PAY NO MORE THAN \$25* with this *Most Relief* Rebate”**

The totality of this presentation makes a representation regarding the use of Pataday for the “relief” of symptoms of allergic conjunctivitis caused by plant allergens.

Also, the presentation of the Pataday logo, at the bottom of the rebate card, in conjunction with the words “Once Daily” makes a dosage recommendation for the drug product.

Because the rebate card includes representations about Pataday's use, as well as a dosage recommendation for the drug, it is not considered reminder labeling. Therefore, the rebate card needs to include appropriate risk information and Pataday's full indication, including the important limitation that Pataday is only indicated for the treatment of **ocular itching** associated with allergic conjunctivitis. The rebate card fails to include this important information. We note that the rebate card states, “For full prescribing information visit pataday.com”; however, this is not sufficient to mitigate the rebate card's misleading omission of indication and risk information.

Unsubstantiated Superiority Claim

The image of the eye with the superimposed plant allergen, accompanied by the claim of “*Most Relief*,” misleadingly suggests that Pataday provides superior relief as compared to other available therapies approved for the same indication as Pataday. In general, claims of superiority must be supported by adequate and well-controlled head-to-head clinical trials comparing appropriate doses and dose regimens of your drug and the comparator drug or drugs. OPDP is not aware of substantial evidence or substantial clinical experience to support any suggestion that Pataday demonstrates superior efficacy over other products approved for the same indication. If you have data to support this claim, please submit them to FDA for review.

Conclusion and Requested Action

For the reasons discussed above, the rebate card misbrands Pataday in violation of the FD&C Act, 21 U.S.C. 352(a) & 321(n), and implementing regulations. 21 CFR 1.21; 21 CFR 200.200; 21 CFR 201.00(f). Cf. 21 CFR 202.1 (e)(3)(ii), (e)(5) & (e)(6)(ii).

OPDP requests that Alcon immediately cease the dissemination of violative promotional materials for Pataday such as those described above. Please submit a written response to this letter on or before October 28, 2011, stating whether you intend to comply with this request, listing all promotional materials (with the 2253 submission date) for Pataday that contain violations such as those described above, and explaining your plan for discontinuing use of such violative materials. Please direct your response to the undersigned at the **Food and Drug Administration, Center for Drug Evaluation and Research, Office of Prescription Drug Promotion, Division of Direct-to-Consumer Promotion, 5901-B Amundson Avenue, Beltsville, Maryland 20705-1266** or by facsimile at (301) 847-8444. Please note that the Division of Drug Marketing, Advertising, and Communications (DDMAC) has been reorganized and elevated to OPDP. OPDP consists of the Immediate Office, the Division of Professional Promotion (DPP) and the Division of Direct-to-Consumer Promotion (DDTCP). To ensure timely delivery of your submissions, please use the full address above and include a prominent directional notation (e.g. a sticker) to indicate that the submission is intended for OPDP. In addition, OPDP recently migrated to a different tracking system. Therefore, OPDP letters will now refer to MA numbers instead of MACMIS numbers. Please refer to the MA # in addition to the NDA number in all future correspondence relating to this particular matter. OPDP reminds you that only written communications are considered official

The violations discussed in this letter do not necessarily constitute an exhaustive list. It is your responsibility to ensure that your promotional materials for Pataday comply with each applicable requirement of the FD&C Act.

Sincerely,

{See appended electronic signature page}

Adora Ndu, PharmD
LCDR, USPHS
Regulatory Review Officer
Division of Direct-to-Consumer Promotion
Office of Prescription Drug Promotion

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

ADORA E NDU
10/14/2011