



TRANSMITTED BY FACSIMILE

Scott Krueger
Senior Director, Regulatory Affairs
Alcon Research, Ltd.
6201 South Freeway
Fort Worth, TX 76134-2099

RE: **NDA 20-688**
Patanol (olopatadine hydrochloride ophthalmic solution) 0.1%
MACMIS # 9718

Dear Mr. Krueger:

This letter objects to Alcon Research, Ltd.'s (Alcon) violative promotional materials for Patanol submitted on January 31, 2001, under cover of Form FDA 2253. This submission included two journal advertisements identified as PT01500JA and PT01501JA. The Division of Drug Marketing, Advertising, and Communications (DDMAC) reviewed these promotional materials and concluded that they are false or misleading under the Federal Food, Drug, and Cosmetic Act and its implementing regulations because they lack fair balance and thus de-emphasize risk information. Our specific objections follow:

Fair Balance

Promotional materials are lacking fair balance if they fail to present information relating to side effects and contraindications with a prominence and readability reasonably comparable with the presentation of information relating to the effectiveness of the drug. Your advertisements present information regarding the effectiveness of the drug using bolded text, easy-to-read bulleted statements, and colored text. However, the risk information associated with the use of Patanol is presented in difficult-to-read block text at the bottom of the page.

Established Name

Your presentation of the established name is violative because it does not have a prominence comparable with the proprietary name. Although the established name is printed in letters that are at least half as large as the letters comprising the proprietary name, you have used a difficult to read font type similar to that used for your presentation of the risk information. Thus the established name is difficult to read.

Requested Action

Because these journal advertisements lack fair balance and have a violative presentation of the established name, we request that you immediately cease their dissemination and any other

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violative promotional materials for Patanol that have similar violations. You should respond to me regarding this violation by March 20, 2001, providing a list of the promotional materials discontinued and the date Alcon ceased the dissemination of the promotional materials.

If you have any questions, please contact me by telephone at (301) 827-2831, by facsimile at (301) 594-6771, or write to me at the Division of Drug Marketing, Advertising, and Communications, HFD-42; Room 17B-20; 5600 Fishers Lane; Rockville, MD 20857.

In all future correspondence regarding this matter, please refer to MACMIS # 9718 and NDA 20-688.

Sincerely,

{See appended electronic signature page}

Warren Rumble
Regulatory Review Officer
Division of Drug Marketing,
Advertising, and Communications

/s/

Warren Rumble

3/6/01 01:30:09 PM



**When all
eyes are
on you,
performance
is everything.**

- The only **mast-cell stabilizer and antihistamine** approved to treat all the **signs and symptoms** of allergic conjunctivitis
- Convenient **b.i.d.** dosing
- **Safe and comfortable** for patients 3 years and older



Patanol[®]
*(OLOPATADINE HYDROCHLORIDE
OPHTHALMIC SOLUTION) 0.1%*



First in their eyes. And yours.

www.patanol.com

PATANOL[®] is contraindicated in patients with a hypersensitivity to any component of this product. Ocular effects, such as burning or stinging, were reported at an incidence of less than 5%. Headaches were reported at an incidence of 7%.

Please see brief summary of prescribing information on following page.



Allergies don't stop at the nose.

- The **#1 prescribed** allergic conjunctivitis therapy¹
- The only **mast-cell stabilizer and antihistamine** approved to treat all the **signs and symptoms** of allergic conjunctivitis
- Convenient **b.i.d.** dosing
- **Safe and comfortable** for patients 3 years and older

PATANOL[®] is contraindicated in patients with a hypersensitivity to any component of this product. Ocular effects, such as burning or stinging, were reported at an incidence of less than 5%. Headaches were reported at an incidence of 7%. Please see brief summary of prescribing information on following page.



First in their eyes. And yours.

www.patanol.com