DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

MAR 20 1998

TRANSMITTED VIA FACSIMILE

Richard Gural, Ph.D.
Vice President, Regulatory Affairs
Alcon Laboratories, Inc.
6201 South Freeway
Fort Worth, TX 76134-2099

RE: **NDA 20-688**
Patanol (olopatadine hydrochloride ophthalmic solution) 0.1%
MACMIS # 6379

Dear Dr. Gural:

This letter concerns Alcon Laboratories, Inc.'s (Alcon) broadcast product advertisement for Patanol (olopatadine hydrochloride ophthalmic solution) 0.1%. Based on Alcon's representation in our telephone conference on March 17, 1998, that this is a currently running television broadcast advertisement, DDMAC has determined that the advertisement is in violation of the Federal Food, Drug, and Cosmetic Act and its implementing regulations.

Specifically, the advertisement is misleading for the following reasons:

1. The risk information disclosed as part of the required "major statement" is not presented in a manner comparable to that used to present the information relating to efficacy. Alcon stated in the advertisement that "a few people may experience side effects, like a headache." DDMAC does not consider that this is an adequate representation of the risk information. Consumers should also be told, for example, that Patanol may cause burning and stinging. In addition, consumers should be advised in language they can understand not to instill Patanol while wearing soft contact lenses.

2. In an effort to fulfill the adequate provision requirement for broadcast advertising, the advertisement refers the viewer to People magazine for further information. However, this reference is inadequate. The size and color of the print together with an overlapping visual background of a similar color makes the reference difficult to discern. Therefore, the reference should be more legible such as having larger print or a more contrasting color.

3. The claim that Patanol "soothes your itchy allergy eyes for 8 hours" is misleading. The approved product labeling for Patanol states that it was shown to be effective for up to 8 hours. In addition, the recommended dosing for Patanol is one to two drops in the affected eye two times per day at an interval of 6 to 8 hours. Further, Patanol is indicated for the

temporary prevention of itching of the eye due to allergic conjunctivitis, not for soothing itchy eyes.

4. The claim "it seems like you have tried everything, but now there is Patanol" is a claim of superiority. DDMAC is unaware of any substantial evidence to support this claim.

5. The brand name Patanol is presented with the established name during its first mention, but does not present the established name of the drug in a legible manner. DDMAC requests that Alcon present the established name in a legible manner.

In a telephone conference on March 19, 1998, between Thomas Abrams, Nancy Ostrove, and Warren Rumble representing DDMAC and Richard Gural, Scott Krueger, and Ashish Pal representing Alcon, DDMAC provided Alcon our general objections to the advertisement and requested that Alcon immediately discontinue the use of the above television advertisement. You stated that Alcon would stop airing the advertisement as soon as possible, and that Alcon would send confirmation of its action to DDMAC by facsimile.

In a follow up telephone conference on March 19, 1998, you proposed that Alcon replace the subject advertisement with a revised ad with new voice-over. Thomas Abrams stated that if the replacement ad was violative, DDMAC would determine appropriate regulatory action. Mr. Abrams also stated that DDMAC would provide detailed comments on the above referenced advertisement as soon as possible so that Alcon would have adequate information to make revisions.

Alcon should respond to DDMAC in writing regarding this issue no later than April 3, 1998, and its response should include a description of its actions regarding this issue. Alcon's response should be directed to the undersigned at the Food and Drug Administration, Division of Drug Marketing, Advertising and Communications, HFD-40, Rm 17-B-20, 5600 Fishers Lane, Rockville, MD 20857. DDMAC reminds Alcon that only written communications are considered official.

In all future correspondence regarding this matter, please refer to MACMIS # 6379 and NDA 20-688.

Sincerely,

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