DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration
Rockville MD 20851

NDA 21-127

MAY 22 2000

ASTA Medica, Inc.
Attention: Ingeborg Amy, M.D.
Senior Regulatory Affairs Associate
890 East Street
Tewksbury, MA 01876-1496

Dear Dr. Amy:

Please refer to your new drug application dated August 3, 1999, received August 4, 1999, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for OPTIVAR (azelastine hydrochloride ophthalmic solution), 0.05%.

We acknowledge receipt of your submissions dated August 19 and 24, September 2, November 24 and 29, and December 2, 10, 13 (two), 17, and 21, 1999; and January 17 and 25, February 7, 14, 18, and 29, March 9 (two), 10, 17, and 24, April 26, 27, and 28, and May 2, 4, 5, 10, 12, and 16, 2000.

This new drug application provides for the use of OPTIVAR (azelastine hydrochloride ophthalmic solution), 0.05% for the treatment of itching of the eye associated with allergic conjunctivitis.

We have completed the review of this application, as amended, and have concluded that adequate information has been presented to demonstrate that the drug product is safe and effective for use as recommended in the agreed upon labeling text submitted May 16, 2000. Accordingly, this application is approved effective on the date of this letter.

The final printed labeling (FPL) must be identical in content to the labeling dated May 16, 2000. Marketing the product with FPL that is not identical to the approved labeling text may render the product misbranded and an unapproved new drug.

Please submit 20 copies of the FPL as soon as it is available, in no case more than 30 days after it is printed. Please individually mount ten of the copies on heavy-weight paper or similar material. For administrative purposes, this submission should be designated "FPL for approved NDA 21-127." Approval of this submission by FDA is not required before the labeling is used.

Be advised that, as of April 1, 1999, all applications for new active ingredients, new dosage forms, new indications, new routes of administration, and new dosing regimens are required to contain an assessment of the safety and effectiveness of the product in pediatric patients unless this requirement is waived or deferred (63 FR 66632). We are waiving the pediatric study requirement for this action on this application for children below the age of 3 years.

Validation of the regulatory methods has not been completed. At the present time, it is the policy of the Center not to withhold approval because the methods are being validated. Nevertheless, we expect your continued cooperation to resolve any problems that may be identified.

In addition, please submit three copies of the introductory promotional materials that you propose to use for this product. All proposed materials should be submitted in draft or mock-up form, not final print. Please submit one copy to this Division and two copies of both the promotional materials and the package insert directly to:

Division of Drug Marketing, Advertising, and Communications, HFD-40
Food and Drug Administration
5600 Fishers Lane
Rockville, Maryland 20857

Please submit one market package of the drug product when it is available.

We remind you that you must comply with the requirements for an approved NDA set forth under 21 CFR 314.80 and 314.81.

If you have any questions, contact Raphael R. Rodriguez, Project Manager, at (301) 827-2090.

Sincerely,

5/22/00

Wiley A. Chambers, M.D.
Deputy Director
Division of Anti-Inflammatory, Analgesic and
Ophthalmic Drug Products, HFD-550
Office of Drug Evaluation V
Center for Drug Evaluation and Research