DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration
Rockville MD 20857

NDA 21-079

SEP 24 1999

Santen Incorporated
Attention: Merwin Jerry Hansen
Chief Executive Officer
555 Gateway Drive
Napa, CA 94558

Dear Mr. Hansen:

Please refer to your new drug application (NDA) dated March 25, 1999, received March 26, 1999, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Alamast (pemirolast potassium ophthalmic solution), 0.1%.

We acknowledge receipt of your submissions dated March 26, April 23 and 28, May 12 and 18, June 14, 21, 25 and 29, July 14 (two), 15, 22, 23 (two) and 28, August 4, 5, 11, 12, and 25, and September 9, 20, and 23, 1999.

This new drug application provides for the use of Alamast (pemirolast potassium ophthalmic solution), 0.1% for the prevention of itching of the eye due to 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 labeling text submitted September 23, 1999. Accordingly, the application is approved effective on the date of this letter.

The final printed labeling (FPL) must be identical in content to the submitted package insert dated September 23, 1999. 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 21-079." Approval of this submission by FDA is not required before the labeling is used.

We remind you of the Phase 4 commitment specified in your submission dated September 20, 1999. This commitment is for the submission of the full testing results for the next 6 production batches of both the drug substance and the drug product. For administrative purposes, all submissions relating to this Phase 4 commitment must be clearly designated "Phase 4 Commitments."

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 send one copy to the Division of Anti-Inflammatory, Analgesic and Ophthalmic Drug Products 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,

/S/ 24 September 1999

Robert DeLap, M.D., Ph.D.
Director
Office of Drug Evaluation V
Center for Drug Evaluation and Research