DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-079/S-006
NDA 21-079/S-008

Santen Incorporated
Attention: Lisa Ann Suchar, PhD
Director, Regulatory Affairs
555 Gateway Drive
Napa, CA 94558

Dear Dr. Suchar:

Please refer to your supplemental new drug applications dated April 20 (S-006), and July 16, 2004 (S-008), 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 November 9, 2004, and May 3, 4, and 9, 2005. Your submission dated November 9, 2004, constituted a complete response to our October 20, 2004, approvable letter.

These supplemental new drug applications provide for labeling changes for the drug product.

We have completed our review of these supplemental new drug applications. They are approved, effective on the date of this letter, for use as recommended in the agreed-upon labeling text.

The final printed labeling (FPL) must be identical to the enclosed labeling for immediate container and carton labels submitted November 9, 2004 (2.5mL) and May 3, 2005 (10 mL). Approval of the FPL submission by FDA is not required before the labeling is used.

For future supplements, the electronic labeling rule that was published December 11, 2003, (68 FR 69009) requires submission of labeling content in electronic format effective June 8, 2004. For additional information, consult the following guidances for industry regarding electronic submissions: *Providing Regulatory Submissions in Electronic Format - NDAs* (January 1999) and *Providing Regulatory Submissions in Electronic Format – Content of Labeling* (February 2004). These guidances specify that labeling is to be submitted in *pdf* format. To assist in our review, we request that labeling also be submitted in MS Word format with proposed revisions clearly indicated. If formatted copies of all labeling pieces are submitted electronically, labeling does not need to be submitted in paper.

In addition, submit three copies of the introductory promotional materials that you propose to use for this product. Submit all proposed materials in draft or mock-up form, not final print. Send 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-42
Food and Drug Administration
5600 Fishers Lane
Rockville, MD 20857

If you issue a letter communicating important information about this drug product (i.e., a "Dear Health Care Professional" letter), we request that you submit a copy of the letter to this NDA and a copy to the following address:

MEDWATCH, HFD-410
FDA
5600 Fishers Lane
Rockville, MD 20857

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, call Alison Rodgers, Regulatory Project Manager, at (301) 827-2019.

Sincerely,

{See appended electronic signature page}

Janice M. Soreth, M.D.
Director
Division of Anti-Infective and Ophthalmology Products, HFD-520
Office of Drug Evaluation IV
Center for Drug Evaluation and Research

Enclosure carton and container labeling

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

/s/

Janice Soreth

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