DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 20-439/S-011

Santen Oy
c/o Santen Incorporated
Attention: Mark A. Mannebach, Ph.D.
Vice President, Regulatory Affairs
555 Gateway Drive
Napa, California 94558

Dear Dr. Mannebach:

Please refer to your supplemental new drug application dated April 20, 2004, received April 21, 2004, submitted pursuant to section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act for Betimol (timolol ophthalmic solution) 0.25% and 0.5%.

This "Changes Being Effected in 30 Days" supplemental new drug application provides for changes to the carton and container labeling.

We completed our review of this application, as amended. This application is approved, effective on the date of this letter, for use as recommended in the agreed-upon labeling text. However, the company name, Vistakon is recommended to be reduced in size and prominence as per CFR 201.15.

The final printed labeling (FPL) must be identical to the enclosed draft labeling submitted on April 20, 2004.

The electronic labeling rule 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). The guidances specify that labeling should be submitted in *pdf* format. To assist in our review, we request that labeling also be submitted in MS Word format. For administrative purposes, designate this submission "**FPL for approved NDA 20-439/S-011**." Approval of this submission by FDA is not required before the labeling is used.

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 reporting requirements for an approved NDA (21 CFR 314.80 and 314.81).

If you have any questions, call Michael Puglisi, Project Manager, at (301) 827-2090.

Sincerely,

{See appended electronic signature page}

Linda L. Ng, Ph.D.
Chemistry Team Leader for the
Division of Anti-Inflammatory, Analgesic
and Ophthalmic Drug Products, HFD-550
DNDC III, Office of New Drug Chemistry
Center for Drug Evaluation and Research

Enclosure

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

/s/

Linda Ng

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