

NDA 21-199/S-002

Santen Incorporated  
Attention: Nancy Yee  
Regulatory Affairs Specialist II  
555 Gateway Drive  
Napa, CA 94558

Dear Ms. Yee:

Please refer to your supplemental new drug application dated August 22, 2001, received August 23, 2001, submitted under the Federal Food, Drug, and Cosmetic Act for Quixin (levofloxacin ophthalmic solution) 0.5%.

This supplemental new drug application provides for revisions to the **CLINICAL PHARMACOLOGY** and the **INDICATIONS AND USAGE** section of the product package insert.

We have completed the review of this supplemental application, 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. Accordingly, the supplemental application is approved effective on the date of this letter.

The final printed labeling (FPL) must be identical to the enclosed labeling.

In addition, we recommend that a future labeling supplement include the following changes:

Please revise the **HOW SUPPLIED** section in order to include the container fill volume for each container size.

Please submit the copies of final printed labeling (FPL) electronically according to the guidance for industry titled *Providing Regulatory Submissions in Electronic Format - NDA* (January 1999). Alternatively, you may submit 20 paper copies of the FPL as soon as it is available but no 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 supplement NDA 21-199/S-002." Approval of this submission by FDA is not required before the labeling is used.

NDA 21-199/S-002

Page 2

If a letter communicating important information about this drug product (i.e., a "Dear Health Care Professional" letter) is issued to physicians and others responsible for patient care, we request that you submit a copy of the letter to this NDA and a copy to the following address:

MEDWATCH, HF-2  
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 Lori Goski, Project Manager, at (301) 827-2090.

Sincerely,

*{See appended electronic signature page}*

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

Enclosure

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**This is a representation of an electronic record that was signed electronically and  
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/s/

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Wiley Chambers  
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