

**CENTER FOR DRUG EVALUATION AND
RESEARCH**

APPLICATION NUMBER:

21-571

APPROVAL LETTER(S)



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-571

Santen Incorporated
Attention: Nancy S. Yee
Manager, Regulatory Affairs
555 Gateway Drive
Napa, California 94558

Dear Ms. Yee:

Please refer to your new drug application (NDA) dated April 30, 2003, received May 1, 2003, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Iquix (levofloxacin ophthalmic solution), 1.5%.

We acknowledge receipt of your submissions dated June 27 and 30; July 2, 3, 17 and 23; August 22 and 29; September 17; October 1, 7 and 28; November 11; and December 9, 2003; and February 12, 19, 23, and 25, 2004.

This new drug application provides for the use of Iquix (levofloxacin ophthalmic solution), 1.5% for the treatment of corneal ulcers caused by susceptible strains of bacteria.

We completed our review of this application, as amended. It is approved, effective on the date of this letter, for use in the attached agreed-upon labeling text.

The final printed labeling (FPL) must be identical to the enclosed labeling text for the package insert dated February 25, 2004, and immediate container and carton labels dated April 30, 2003. 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 an electronic version of the FPL according to the guidance for industry titled *Providing Regulatory Submissions in Electronic Format - NDA*. 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. Individually mount 15 of the copies on heavy-weight paper or similar material. For administrative purposes, designate this submission "**FPL for approved NDA 21-571.**" Approval of this submission by FDA is not required before the labeling is used.

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. We are waiving the pediatric study requirement for this application.

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

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

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 Lori M. Gorski, 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, HFD-550
Office of Drug Evaluation V
Center for Drug Evaluation and Research

Enclosure

APPEARS THIS WAY
ON ORIGINAL

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

/s/

Wiley Chambers
3/1/04 02:01:04 PM

APPEARS THIS WAY
ON ORIGINAL