DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 22-221 **NDA APPROVAL**

Akorn Inc.
Attention: Sam Boddapati, PhD
Vice President, Regulatory Affairs
1925 West Field Court
Lake Forest, IL 60045

Dear Dr. Boddapati:

Please refer to your new drug application (NDA) dated June 29, 2007, received August 2, 2007, submitted pursuant to section 505(b) of the Federal Food, Drug, and Cosmetic Act for Akten™ (lidocaine hydrochloride ophthalmic gel), 3.5%.

We acknowledge receipt of your submissions dated June 6, 13 and 26, August 8 and 29, and September 16, 22 and 29, 2008.

The August 8, 2008, submission constituted a complete response to our June 2, 2008, action letter.

This new drug application provides for the use of Akten™ (lidocaine hydrochloride ophthalmic gel), 3.5% for ocular surface anesthesia during ophthalmologic procedures.

We have completed our review of this application, as amended. It is approved, effective on the date of this letter, for use as recommended in the content of labeling [21 CFR 314.50(1)] in structured product labeling (SPL) format submitted on September 29, 2008.

We acknowledge your August 29, 2008, submission containing final printed carton and container labels.

Marketing the product(s) with FPL that is not identical to the approved labeling text may render the product misbranded and an unapproved new drug.

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 note that the assessment of safety and effectiveness of this product in pediatric patients has been completed.

You may request advisory comments on proposed introductory advertising and promotional labeling. To do so, submit, in triplicate, a cover letter requesting advisory comments, the proposed materials in draft or mock-up form with annotated references, and the package insert(s) to:

Food and Drug Administration
Center for Drug Evaluation and Research
Division of Drug Marketing, Advertising, and Communications
5901-B Ammendale Road
Beltsville, MD 20705-1266

As required under 21 CFR 314.81(b)(3)(i), you must submit final promotional materials, and the package insert(s), at the time of initial dissemination or publication, accompanied by a Form FDA 2253. For instruction on completing the Form FDA 2253, see page 2 of the Form. For more information about submission of promotional materials to the Division of Drug Marketing, Advertising, and Communications (DDMAC), see www.fda.gov/cder/ddmac.

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

MedWatch
Food and Drug Administration
Suite 12B05
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 Jane A. Dean, RN, MSN, Regulatory Health Project Manager, at (301) 796-1202.

Sincerely,

{See appended electronic signature page}

Wiley A. Chambers, MD
Acting Director
Division of Anti-Infective and Ophthalmology Products
Office of Antimicrobial Products
Center for Drug Evaluation and Research

Enclosure: Content of labeling

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

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