CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

22-221

OTHER ACTION LETTER(s)

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration
Rockville, MD 20857

NDA 22-221

Akorn Inc.
Attention: Sam Boddapati, PhD
Vice President, Regulatory Affairs
2500 Millbrook Drive
Buffalo Grove, IL 60089

Dear Dr. Boddapati:

Please refer to your new drug application (NDA) dated June 29, 2007, received August 2, 2007, submitted under 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 July 17 and 20, and August 23, 2007, and February 27, March 4 and 12, April 11, (2) and May 5 and 7, 2008.

We completed our review of this application, as amended, and it is approvable. Before the application may be approved, however, it will be necessary for you to:

1. Provide information, either directly or by reference to a DMF, on the components and composition of the immediate container label, adhesive and printing ink.

2. Provide a completed comprehensive study of leachable and extractable substances from the immediate container, and from the label and secondary packaging, and provide a toxicological evaluation of the substances to determine safe exposure levels.

3. Propose a test and acceptance criterion in parts-per-million for any leachable substance above a level that is of toxicologic concern.

4. Provide data to indicate whether there is a difference in leachable substances for samples stored in both the horizontal and upright orientations with the preprinted shrink wrap.

5. Provide a revised amended Stability Protocol and Commitment to include a test and acceptance criterion for particulate matter, weight loss/gain and viscosity.

In addition, it will be necessary for you to submit revised labeling. We will continue to work with you on the content of that labeling after other portions of the application are acceptable. If additional information relating to the safety or effectiveness of this drug becomes available, additional revision of the labeling may be required.

When you respond to the above deficiencies, include a safety update as described at 21 CFR 314.50(d)(5)(vi)(b). The safety update should include data from all non-clinical and clinical studies of the drug under consideration regardless of indication, dosage form, or dose level.

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:

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

Within 10 days after the date of this letter, you are required to amend this application, notify us of your intent to file an amendment, or follow one of the other options under 21 CFR 314.110. If you do not follow one of these options, we will consider your lack of response a request to withdraw the application under 21 CFR 314.65. Any amendment should respond to all the deficiencies listed. We will not process a partial reply as a major amendment nor will the review clock be reactivated until all deficiencies have been addressed.

Under 21 CFR 314.102(d), you may request a meeting or telephone conference with this division to discuss what steps need to be taken before the application may be approved.

The drug product may not be legally marketed until you have been notified in writing that the application is approved.

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

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
6/2/2008 11:47:51 PM