CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

22-186

OTHER ACTION LETTER(s)

(Do Not Release)

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
Rockville, MD 20857

Not Approval Letter

NDA 22-186

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

Dear Dr. Boddapati:

Please refer to your new drug application (NDA) dated April 5, 2007, received April 6, 2007, submitted pursuant to section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act for AK-Fluor® (fluorescein sodium injection), 10% and 25%.

We acknowledge receipt of your submissions dated April 26 (2), May 11 (2), July 6, and August 8, and 21, 2007.

We completed our review of this application, as amended, and it is not approvable. FDA inspection of the ——————— and Akorn, Inc., Decatur, IL, manufacturing facilities revealed significant deviations from the Current Good Manufacturing Practice (cGMP) regulations. Before the application may be approved, it will be necessary for the methods to be used in, and the facilities and controls used for, the manufacture, processing, packing, and holding of the drug substance and the drug product to comply with cGMP. b(4)

In addition, the methods to be used in, and the facilities and controls used for, the manufacture, processing, packing, or holding of the drug product are inadequate to preserve its quality, purity, and stability. Specifically,

1. b(4)

b(4)

2 Page(s) Withheld

✓ Trade Secret / Confidential (b4)

_____ Draft Labeling (b4)

_____ Draft Labeling (b5)

_____ Deliberative Process (b5)

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5. b(4)

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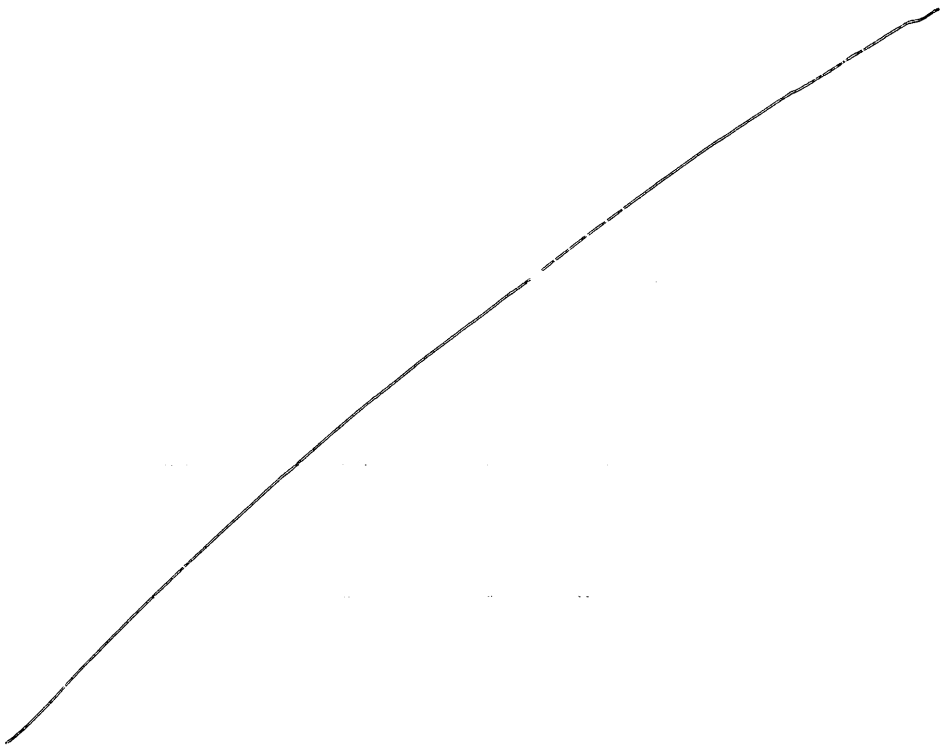

Attached is a preliminary draft revised label. We will continue to work with you on labeling.

If additional information relating to the safety or effectiveness of this drug becomes available, 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.

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 your 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 products may not be legally marketed until you have been notified in writing that the application is approved.

If you have any questions, call Alison Rodgers, Regulatory Project Manager, at (301) 796-0797.

Sincerely,

{See appended electronic signature page}

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

Enclosure – Labeling

4 Page(s) Withheld

_____ Trade Secret / Confidential (b4)

✓ Draft Labeling (b4)

_____ Draft Labeling (b5)

_____ Deliberative Process (b5)

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/s/

Wiley Chambers
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