DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 11-525/S-017

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

Dear Dr. Boddapati:

Please refer to your supplemental new drug application dated December 27, 2004, received December 29, 2004, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for IC-GREEN (indocyanine green for injection, USP) Sterile.

We acknowledge receipt of your submissions dated March 22 and June 28, 2006. The submission dated March 22, 2006, constituted a complete response to our February 14, 2006, action letter.

This supplemental new drug application provides for changes to the package insert, immediate container and carton labeling.

We completed our review of this application. This application is approved, effective on the date of this letter, for use as recommended in the enclosed labeling text. The final printed labeling (FPL) must be identical to the enclosed labeling text for the package insert dated June 28, 2006, and to the carton and container labeling dated March 22, 2006.

The electronic labeling rule published December 11, 2003, (68 FR 69009) requires submission of labeling content in electronic format effective June 8, 2004. For additional information, consult the following guidances for industry regarding electronic submissions: *Providing Regulatory Submissions in Electronic Format - NDAs* (January 1999) and *Providing Regulatory Submissions in Electronic Format – Content of Labeling* (February 2004). The guidances specify that labeling to be submitted in *pdf* format. To assist in our review, we request that labeling also be submitted in MS Word format with proposed revisions clearly indicated, preferably in track changes. If formatted copies of all labeling pieces are submitted electronically, labeling does not need to be submitted in paper.

Please submit the FPL electronically according to the guidance for industry titled Providing Regulatory Submissions in Electronic Format – NDA. Approval of this submission by FDA is not required before the labeling is used.

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

MEDWATCH
Food and Drug Administration
5515 Security Lane
HFD-001, Suite 5100
Rockville, MD 20852

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 Gorski, Project Manager, at (301) 796-0722.

Sincerely,

{See appended electronic signature page}

Janice M. Soreth, M.D.
Director
Division of Anti-Infective and Ophthalmology Products, HFD-520
Office of Antimicrobial Products
Center for Drug Evaluation and Research

Enclosure

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

/s/

Janice Soreth

9/22/2006 10:41:58 AM