

**CENTER FOR DRUG EVALUATION AND
RESEARCH**

APPLICATION NUMBER:

50-809

APPROVAL LETTER



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 50-809

Sicor Pharmaceuticals, Inc.
Attention: Sonia Hernandez
Manager, Regulatory Affairs
19 Hughes
Irvine, CA 92618

Dear Ms Hernandez:

Please refer to your new drug application (NDA) dated July 29, 2005, received August 2, 2005, submitted pursuant to section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act for azithromycin for injection.

This application is subject to the exemption provisions in section 125(d)(2) of Title I of the FDA Modernization Act of 1997.

We acknowledge receipt of your submissions dated June 16, August 8, September 15, December 8, December 12 and December 19, 2006.

The June 16, 2006 submission constituted a complete response to our June 2, 2006 action letter.

This new drug application provides for the use of azithromycin for injection for pelvic inflammatory disease and community acquired pneumonia.

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

The final printed labeling (FPL) must be identical to the enclosed labeling dated December 19, 2006, immediate container and carton labels dated June 16, 2006. Marketing the product with FPL that is not identical to the approved labeling text may render the product misbranded and an unapproved new drug.

Submit content of labeling [21CFR 314.50(1)] in structured product labeling (SPL) format, as described at <http://www.fda.gov/oc/datacouncil/spl.html>, that is identical to the submitted labeling text dated December 18, 2006. Upon receipt and verification, we will transmit that version to the National Library of Medicine for posting on the DailyMed website.

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 50-809." **Approval of this submission by FDA is not required before the labeling is used.**

If you choose to use a proprietary name for this product, the name and its use in the labels must conform to the specifications under 21 CFR 201.10 and 201.15. We recommend that you submit any proprietary name to the Agency for our review prior to its implementation.

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 deferring submission of your pediatric studies until December 31, 2009.

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Your deferred pediatric studies required under section 2 of the Pediatric Research Equity Act (PREA) are considered required postmarketing study commitments. The status of this postmarketing study shall be reported annually according to 21 CFR 314.81. This commitment is listed below.

Deferred pediatric study under PREA for the treatment of community acquired pneumonia and pelvic inflammatory disease in pediatric patients.

Final Report Submission: December 31, 2009.

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 the Division of Anti-Infective and Ophthalmology Products 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

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 Carmen DeBellas, Regulatory Project Manager, at 301-796-1203.

Sincerely,

{See appended electronic signature page}

Janice M. Soreth, MD
Division Director
Division of Anti-Infective and Ophthalmology Products
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

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