



NDA 50-405/S-097

Advancis Pharmaceutical Corporation
Attention: Ms. Brenda Wolling
Associate Director, Regulatory Affairs
20425 Seneca Meadows Parkway
Germantown, MD 20876

Dear Ms. Wolling:

Please refer to your supplemental new drug application dated December 20, 2005, received December 21, 2005, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Keflex[®] (cephalexin) Capsules, 250 mg and 500 mg. This application is subject to the exemption provisions contained in section 125(d)(2) of Title I of the FDA Modernization Act of 1997.

This supplemental new drug application provides for information supporting the approval of two additional strengths of Keflex[®] capsules, 333 mg and 750 mg. Pursuant to this, the applicant has provided information on the manufacturing, packaging, stability, in vitro dissolution test data, and draft proposed labeling for Keflex[®]. In addition, the applicant requested that the Agency waive the requirement for the submission of evidence measuring the in vivo bioequivalence of the drug product.

We completed our review of this application and it is approved, effective on the date of this letter, for use as recommended in the agreed-upon labeling text, and with the minor editorial revisions listed below:

- In the **DOSAGE AND ADMINISTRATION/Adults** subsection, add the following statement as the second sentence:

“The 333 mg and 750 mg strengths should be administered such that the daily dose is within 1 to 4 grams per day.”

The final printed labeling (FPL) must be identical to, and include the revision listed, to the enclosed labeling. This revision is terms of the approval of this application.

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 supplement NDA 50-405/S-097.**" 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
WO 22, Room 4447
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

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 J. Christopher Davi, Regulatory Project Manager, at (301) 796-0702.

Sincerely,

{See appended electronic signature page}

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

Enclosure: Labeling submitted May 4, 2006

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

/s/

Lillian Gavrilovich
5/12/2006 01:00:17 PM
Signing for Dr. J. Soreth