DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 50-405/S-099

MiddleBrook Pharmaceuticals, Inc.
Attention: Brenda L. Wolling
Director of Regulatory Affairs
20425 Seneca Meadows Parkway
Germantown, MD 20876

Dear Ms. Wolling:

Please refer to your supplemental new drug application dated, March 13, 2007, received March 14, 2007, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Keflex® Capsules (cephalexin USP), 250, 333, 500, and 750 milligrams.

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 "Changes Being Effected" supplemental new drug application provides for revisions to the **WARNINGS** and **PRECAUTIONS/Information for Patients** sections of the package insert to include information on *Clostridium difficile* associated disease (CDAD).

We have completed our review of this application. It is approved, effective on the date of this letter, for use as recommended in the content of labeling [21 CFR 314.50(1)] in structured product labeling (SPL) format submitted on March 13, 2007.

We note that your March 13, 2007 submissions include final printed labeling (FPL) for your package inserts. You are responsible for assuring that the wording in this printed labeling is identical to that of the approved content of labeling in the structured product labeling (SPL) format.

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

Sincerely,
{See appended electronic signature page}

Katherine A. Laessig, MD
Deputy Director
Division of Anti-Infective and Ophthalmology Products
Office of Antimicrobial Products
Center for Drug Evaluation and Research

Enclosure: Labeling submitted on March 13, 2007

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

/s/

Kathrine Laessig
5/21/2008 10:27:08 AM