**DEPARTMENT OF HEALTH & HUMAN SERVICES**

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 50-405/S-101

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

Dear Ms. Wolling:

Please refer to your supplemental new drug application dated March 20, 2008, received March 21, 2008 submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Keflex® Capsules (cephalexin, USP) 250, 333, 500 and 750 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 "Changes Being Effected" supplemental new drug application proposes changes to the Keflex® Capsule 500 mg bottle label.

We completed our review of this application and it is approved, effective on the date of this letter.

Submit final printed carton and container labels that are identical to the bottle labels submitted on March 20, 2008. Approval of this submission by FDA is not required before the bottle labels are 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
Suite 12B05
5600 Fishers Lane
Rockville, MD 20857

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

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

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/s/

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Kathrine Laessig
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