DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 50-739/S-013
50-749/S-017

Abbott Laboratories
Attention: Mary Konkowski
Manager, Global Pharmaceutical Regulatory Affairs
Department RA76/Bldg. AP30-1E
200 Abbott Park Road
Abbott Park, IL 60064-6157

Dear Ms. Konkowski:

Please refer to your new drug applications (NDAs) dated December 18, 2006, received December 19, 2006, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for OMNICEF® (cefdinir) capsules (NDA 50-739), and OMNICEF® oral suspension (NDA 50-749).

These applications are subject to the exemption provisions in section 125(d)(2) of Title I of the FDA Modernization Act of 1997.

These supplemental drug applications propose changes to the PRECAUTIONS – Postmarketing sections of the package inserts based on Abbott's routine post marketing safety surveillance program.

We completed our review of these applications and they are 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/patient package insert submitted on December 18, 2006.

Please submit an electronic version of the FPL according to the guidance for industry titled *Providing Regulatory Submissions in Electronic Format - NDA.* For administrative purposes, designate these submissions "**FPL for approved NDAs 50-739/S-013 and 50-749/S-017**." Approval of these submissions 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, MS, Regulatory Project Manager at (301) 796-0702.

Sincerely,

{See appended electronic signature page}

John J. Alexander, MD, MPH
Medical Team Leader
Division of Anti-Infective and Ophthalmology Products
Office of Antimicrobial Products
Center for Drug Evaluation and Research

Enclosure: Labeling submitted on December 18, 2006

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

/s/

John Alexander
6/15/2007 04:28:54 PM
Acting Director, for Dr. Soreth