DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 50-739/S-015
50-749/S-021

Abbott Laboratories
Attention: Laura L. Granitz
Manager, Global Pharmaceutical Regulatory Affairs
Dept. PA76/Bldg. AP30-1E
200 Abbott Park Road
Abbott Park, IL 60064-6157

Dear Ms. Garnitz:

Please refer to your supplemental new drug applications dated June 17, 2008, received June 18, 2008, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for OMNICEF® (cefdinir) capsules, 300 mg and OMNICEF® (cefdinir) oral suspension, 125 mg/5mL and 250 mg/5mL.

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

We also acknowledge receipt of your submissions amending these applications, dated August 6, 2008.

These "Changes Being Effected" supplemental new drug applications provide for updated labeling that incorporates all changes from previously approved supplemental applications, listed as follows:

1. NDA 50-739/S-013
2. NDA 50-739/S-014
3. NDA 50-749/S-017
4. NDA 50-749/S-018

We completed our review of these applications, as amended and they are approved, effective on the date of this letter, for use as recommended in the agreed-upon labeling text. As soon as possible, but no later than 14 days from the date of this letter, please submit the content of labeling [21 CFR 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 enclosed label submitted August 6, 2008. Upon receipt, we will transmit that version to the National Library of Medicine for public dissemination. For administrative purposes, designate this submissions "SPL for approved supplements NDA 50-739/S-015 and NDA 50-749/S-021."

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

Enclosure: Labeling submitted August 6, 2008

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
12/15/2008 10:42:06 AM