DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 50-739/S-007
NDA 50-749/S-009

Abbott Laboratories
Attention: MaryClare DeLuca
GPRA Project Manager
200 Abbott Park Road
D491, AP30-1E
Abbott Park, IL 60064-6157

Dear Ms. DeLuca:

Please refer to your new drug applications (NDA) dated February 3, 2004, received February 7, 2004, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Omnicef®(cefdinir) capsules (NDA 50-739), and Omnicef® for 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 *"Changes Being Effected"* supplements provide for revisions to the package insert to address the requirements of the Final Labeling Rule for Systemic Antibacterial Drug Products Intended for Human Use (68 FR 6062, February 6, 2003).

We completed our review of these applications, and they are approved, effective on the date of this letter for use as recommended in the submitted final printed labeling.

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) 827-2125.

Sincerely,

{See appended electronic signature page}

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

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

/s/

Janice Soreth

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