



NDA 50-739/S-010

NDA 50-749/S-013

Abbott Laboratories  
Attention: Mary Ellen Snyder  
Associate Director  
Global Pharmaceutical Regulatory Affairs  
200 Abbott Park Road  
Abbott Park, IL 60064-6157

Dear Ms. Snyder:

Please refer to your supplemental new drug applications dated February 4, 2005 received February 7, 2005, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for:

Omnicef (cefdinir) capsules, 300 mg (NDA 50-739)

Omnicef (cefdinir) powder for oral suspension, 125 mg/5ml (NDA 50-749)

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

These "Changes Being Effected in 30 days" supplemental new drug applications provide for revisions to the final printed package insert labeling to add the adverse event of "serum sickness" based on the analysis of post marketing reports.

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, and with the minor editorial revision listed below:

- The term "serum sickness-like reactions" should be used instead of "serum sickness" to describe the various adverse events possibly associated with cefdinir therapy.

The final printed labeling (FPL) must be identical, and include the minor editorial revision indicated, to the enclosed labeling. These revisions are terms of the approval of these applications.

Please submit an electronic version of the FPL according to the guidance for industry titled *Providing Regulatory Submissions in Electronic Format - NDA*. Alternatively, you may submit 20 paper copies of the FPL as soon as it is available but no more than 30 days after it is printed. Individually mount 15 of the copies on heavy-weight paper or similar material. For administrative purposes, designate these submissions "**FPL for approved supplement NDA 50-739/S-010 and 50-749/S-013.**" 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, HFD-410  
FDA  
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, Regulatory Project Manager, at (301) 827-2217.

Sincerely,

*{See appended electronic signature page}*

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

Enclosure: Labeling submitted on February 4, 2005

-----  
**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

7/19/05 02:35:33 PM