



NDA 50-749/S-010

Abbott Laboratories
Attention: MaryClare DeLuca
GPRC Project Manager
D-491/Bldg. AP30-1E
200 Abbott Park Road
Abbott Park, IL 60064-6157

Dear Ms. DeLuca:

Please refer to your supplemental new drug application dated March 26, 2004 received March 29, 2004, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Omnicel[®] (cefdinir) for Oral Suspension. We note that this application is subject to the exemption provisions contained in section 125(d)(2) of Title I of the FDA Modernization Act of 1997.

We acknowledge receipt of your submissions dated and July 21, 27, and 28, 2004.

This supplemental new drug application provides for changes regarding a 250 mg/5 mL dosage strength extension line.

We completed our review of this application, as amended. This application is 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 submitted labeling (package insert, immediate container and carton labels submitted March 26, 2004 (Nos. 3769, 3771, 615), with changes as agreed-upon in the teleconference held on July 23, and 26, 2004 and the submissions of July 27, and 28, 2004.

Please submit the FPL electronically 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, in no case more than 30 days after it is printed. Please individually mount 15 of the copies on heavy-weight paper or similar material. For administrative purposes, this submission should be designated "FPL for approved supplement NDA 50-749/S-010" Approval of this submission 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 Mr. J. Christopher Davi, Regulatory Project Manager, at (301) 827-2125.

Sincerely,

{See appended electronic signature page}

Janice M. Soreth, M. D.
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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