DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-222/S-003

Purdue Pharmaceutical Products, L.P.
Attention: Robert Kessler, Ph.D.
Director, Worldwide Regulatory Affairs
One Stamford Forum
Stamford, CT 06901-3431

Dear Dr. Kessler:

Please refer to your supplemental new drug application dated August 7, 2003, received August 11, 2003, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Spectracef® (cefditoren pivoxil) Tablets.

We acknowledge receipt of your submission dated August 29, 2003.

This supplemental application, submitted as a "Supplement - Changes Being Effected in 30 days" supplement, proposes the following change to be in compliance with the systemic antibacterial drug products labeling regulations as found in 21 CFR 201.24 and to add five adverse reactions to the **ADVERSE EVENTS** section of the label.

We have 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 the enclosed labeling (text for the package insert dated August 7, 2003).

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 21-222/S-003." 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 LT Raquel Peat, Regulatory Health 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

Enclosure: Labeling

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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