



NDA 21-222/S-001

TAP Pharmaceutical Products, Inc.
Attention: Sandra Anderson
Regulatory Product Manager
675 North Field Drive
Lake Forest, IL 60045

Dear Ms. Anderson:

Please refer to your supplemental new drug application dated October 31, 2001, received November 2, 2001, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Spectracef™ (cefditoren pivoxil) Tablets.

We acknowledge receipt of your submissions dated November 13, December 17, 2001, March 28, April 18, May 23, June 7, July 9, July 11, July 19, and August 21, 2002.

This supplemental new drug application provides for the use of Spectracef™ (cefditoren pivoxil) Tablets for the treatment of community-acquired pneumonia in adults.

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).

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 ten 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-001." Approval of this submission by FDA is not required before the labeling is used.

All applications for new active ingredients, new dosage forms, new indications, new routes of administration, and new dosing regimens must contain an assessment of the safety and effectiveness of the product in pediatric patients unless this requirement is waived or deferred (21 CFR 314.55).

Based on the information submitted, we conclude the following:

For community-acquired pneumonia, we are waiving the pediatric study requirement for this action for this application for patients under 12 years of age.

In addition, submit three copies of the introductory promotional materials that you propose to use for this product. Submit all proposed materials in draft or mock-up form, not final print. Send one copy the Division of Anti-Infective Drug Products and two copies of both the promotional materials and the package insert directly to:

Division of Drug Marketing, Advertising, and Communications, HFD-42
Food and Drug Administration
5600 Fishers Lane
Rockville, MD 20857

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, HF-2
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 Beth Duvall-Miller, 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

**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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