DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-222/S-012

Cornerstone BioPharma
Attention: Brian Dickson, MD
Chief Medical Officer
2000 Regency Parkway
Suite 225
Cary, NC 27518

Dear Dr. Dickson:

Please refer to your supplemental new drug application dated January 21, 2008, received January 22, 2008, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for SPECTRACEF® (cefditoren pivoxil) tablets, 200 mg.

We also acknowledge receipt of your amendments to this application dated March 6, 2008, April 24, 2008, and May 29, 2008.

This supplemental new drug application provides for a 400 mg strength tablet of SPECTRACEF® (equivalent to two 200 mg tablets). We have completed our review of this application and it is approved, for the 400 mg strength tablet, effective on the date of this letter, for use as recommended in the agreed-upon labeling text, with the minor editorial revisions listed below:

The addition of the 400 mg strength in the opening statement of the DESCRIPTION section as follows:

> SPECTRACEF® (cefditoren pivoxil) tablets contain 200 mg <u>or 400 mg</u> of cefditoren as cefditoren pivoxil and the following inactive ingredients:

In addition, the following verbiage in the HOW SUPPLIED section of the package insert should be deleted:

> ~~SPECTRACEF® (cefditoren pivoxil) tablets containing cefditoren pivoxil equivalent to 200 mg of cefditoren are available as white, elliptical, film-coated tablets imprinted with CBP 200 in blue. These tablets are available in a multi-dose tamper-evident container as follows:~~
>
> ~~**NDC** 10122-801-60 Bottles of 60~~
> ~~10122-801-02 Samples~~
>
> ~~Store at 25°C (77°F); excursions permitted to 15°-30°C (59°-86°F). [See USP Controlled Room Temperature.] Protect from light and moisture.~~
>
> ~~Dispense in a tight, light-resistant container.~~

And replaced with:

SPECTRACEF® (cefditoren pivoxil) tablets containing cefditoren pivoxil equivalent to 200 mg or 400 mg of cefditoren are available as white, elliptical, film-coated tablets imprinted with "CBP 200" or "CBP 400" in blue. These tablets are available in a multi-dose tamper-evident container, or as the 1-count blister package (Physician Sample), as follows:

- NDC 10122-802-60: 400 mg 60 count bottles. SPECTRACEF tablets containing cefditoren pivoxil equivalent to 400 mg of cefditoren are available as white, elliptical, film-coated tablets imprinted with "CBP 400" in blue.
- NDC 10122-802-20: 400 mg 20 count bottles. SPECTRACEF tablets containing cefditoren pivoxil equivalent to 400 mg of cefditoren are available as white, elliptical, film-coated tablets imprinted with "CBP 400" in blue.
- NDC 10122-802-02: 400 mg 1 count blister. SPECTRACEF tablets containing cefditoren pivoxil equivalent to 400 mg of cefditoren are available as white, elliptical, film-coated tablets imprinted with "CBP 400" in blue.
- NDC 10122-801-60: 200 mg 60 count bottles. SPECTRACEF tablets containing cefditoren pivoxil equivalent to 200 mg of cefditoren are available as white, elliptical, film-coated tablets imprinted with "CBP 200" in blue.

Storage
Store at 25°C (77°F); excursions permitted to 15°-30°C (59°-86°F). [See USP Controlled Room Temperature.] Protect from light and moisture. Dispense in a tight, light-resistant container.

As soon as possible, but no later than 14 days from the date of this letter, please submit the content of labeling [21 CFR 314.50(1)] in structured product labeling (SPL) format as described at http://www.fda.gov/oc/datacouncil/spl.html that is identical to, except for including revisions, to the enclosed label submitted July 15, 2008. These revisions are terms of the approval of this application. For administrative purposes, designate this submissions "SPL for approved supplement NDA 21-222/S-012." 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
Food and Drug Administration
Suite 12B05
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, MS, Regulatory Project Manager, at (301) 796-0702.

Sincerely,

{See appended electronic signature page}

Katherine A. Laessig, MD
Deputy Division Director
Division of Anti-Infective and Ophthalmology Products
Office of Antimicrobial Products
Center for Drug Evaluation and Research

Enclosure: Revised labeling submitted July 15, 2008

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

/s/

Kathrine Laessig
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