DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 21-222/S-013
NDA 21-222/S-016

SUPPLEMENT APPROVALS

Vansen Pharma
c/o Methapharm, Inc.
Attention: Irma Monaco, US Agent
Associate Director, Regulatory Affairs and Quality Assurance
11772 West Sample Road, #101
Coral Springs, FL 33065

Dear Ms. Monaco:

Please refer to your Supplemental New Drug Applications (sNDAs) dated February 6, 2008, received February 11, 2008 (S-013), and dated January 27, 2012, received January 30, 2012 (S-016), submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Spectracef (cefditoren pivoxil) 200mg and 400mg, Tablets.

We also acknowledge receipt of your amendments to these supplemental applications dated June 29 and October 21, 2011, and June 25, 2012 (S-013) and February 17, April 13, and July 13, 2012 (S-016).

The June 29, 2011, submission constituted a complete response to our July 28, 2010, action letter for S-013.

These supplemental applications provide for the following:

- **NDA 21-222/S-013:** Updates the *in vitro* susceptibility test interpretive criteria (i.e., breakpoints) listed in the package insert.

- **NDA 21-222/S-016:** Changes to the WARNINGS section and ADVERSE EVENTS, **POSTMARKETING EXPERIENCE** subsection of the package insert.

We have completed our review of these applications, as amended, and they are approved, effective on the date of this letter, for use as recommended in the agreed-upon labeling text.

CONTENT OF LABELING

As soon as possible, but no later than 14 days from the date of this letter, submit the content of labeling [21 CFR 314.50(l)] in structured product labeling (SPL) format using the FDA automated drug registration and listing system (eLIST), as described at

http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm. Content of labeling must be identical to, except with the revisions indicated in the references section, the enclosed labeling (text for the package insert) with the addition of any labeling changes in pending "Changes Being Effected" (CBE) supplements, as well as annual reportable changes not included in the enclosed labeling.

Information on submitting SPL files using eLIST may be found in the guidance for industry titled "SPL Standard for Content of Labeling Technical Qs and As" at http://www.fda.gov/downloads/DrugsGuidanceComplianceRegulatoryInformation/Guidances/UCM072392.pdf.

The SPL will be accessible via publicly available labeling repositories.

Also within 14 days, amend all pending supplemental applications for this NDA, including CBE supplements for which FDA has not yet issued an action letter, with the content of labeling [21 CFR 314.50(l)(1)(i)] in MS Word format, that includes the changes with the revisions indicated above approved in this supplemental application, as well as annual reportable changes, and annotate each change. To facilitate review of your submission, provide a highlighted or marked-up copy that shows all changes, as well as a clean Microsoft Word version. The marked-up copy should provide appropriate annotations, including supplement number(s) and annual report date(s).

REPORTING REQUIREMENTS

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, Senior Regulatory Project Manager, at (301) 796-0702.

Sincerely,

{See appended electronic signature page}
Sumathi Nambiar, MD, MPH
Deputy Director for Safety
Division of Anti-Infective Products
Office of Antimicrobial Products
Center for Drug Evaluation and Research

ENCLOSURE: Approved Labeling (with updated references)

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

/s/

SUMATHI NAMBIAR
08/06/2012