



NDA 50-674/S-014  
50-675/S-017

Pfizer Global Pharmaceuticals, Inc.  
Attention: Mr. Priso Epale  
Regulatory Manager  
235 East 42<sup>nd</sup> Street  
New York, NY 10017

Dear Mr. Epale:

Please refer to your supplemental new drug applications dated April 26, 2007, received May 1, 2007, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for the following:

- NDA 50-674/S-014; Vantin (cefpodoxime proxetil) Tablets, 100 and 200 mg
- NDA 50-675/S-017; Vantin (cefpodoxime proxetil) Oral Suspension, 50 mg/5 mL and 100 mg/5 mL

These applications are subject to the exemption provisions contained in section 125(d)(2) of Title I of the FDA Modernization Act of 1997.

These "Changes Being Effected" supplemental new drug applications provide for revisions to the Vantin package insert, in the WARNINGS section as well as the PRECAUTIONS/Information for Patients subsection. These revisions were requested by the Agency in a letter to you dated October 27, 2006, and are associated with the potential risks of contracting *Clostridium difficile* associated disease (CDAD) as a result of antimicrobial therapy.

We completed our review of these applications and they are approved, effective on the date of this letter, for use as recommended in the agreed-upon labeling text, and with the minor editorial revisions included in the enclosed labeling.

The final printed labeling (FPL) must be identical, and include the minor editorial revisions indicated, to the enclosed labeling (i.e., with tracked additions and deletions accepted) submitted on April 26, 2007. These revisions are terms of the approval of these applications.

Please submit an electronic version of the FPL according to the guidance for industry titled *Providing Regulatory Submissions in Electronic Format - NDA*. For administrative purposes, designate these submissions "**FPL for approved supplements NDA 50-674/S-014 and NDA 50-675/S-017.**" Approval of these submissions 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  
5515 Security Lane  
HFD-001, Suite 5100  
Rockville, MD 20852

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

Sincerely,

*{See appended electronic signature page}*

Janice M. Soreth, MD  
Director  
Division of Anti-Infective and Ophthalmology Products  
Office of Antimicrobial Products  
Center for Drug Evaluation and Research

Enclosure: Labeling submitted on April 26, 2007

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/s/

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Janice Soreth

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