NDA 50-674/S-012
NDA 50-675/S-015

Pharmacia & Upjohn
Attention: Rebecca S. Tong
Regulatory Manager, Regulatory Affairs
7000 Portage Road
Kalamazoo, MI 49001-0199

Dear Ms. Tong:

Please refer to your supplemental new drug applications dated January 20, 1998, received January 22, 1998, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Vantin® (cefpodoxime proxetil) Tablets and Vantin® (cefpodoxime proxetil) Oral Suspension. We note that these applications are subject to the exemption provisions contained in section 125(d)(2) of Title I of the FDA Modernization Act of 1997.

We acknowledge receipt of your submissions dated June 1, 1998, November 5, 1998, and November 19, 1998.

These supplemental new drug applications provide for the use of Vantin® (cefpodoxime proxetil) Tablets and Vantin® (cefpodoxime proxetil) Oral Suspension for the treatment of acute maxillary sinusitis.

We have completed the review of these supplemental applications, as amended, and have concluded that adequate information has been presented to demonstrate that the drug products are safe and effective for use as recommended in the enclosed labeling text. Accordingly, these supplemental applications are approved effective on the date of this letter.

The final printed labeling (FPL) must be identical to the enclosed labeling (text for the package insert) and submitted draft labeling (package insert submitted November 19, 1998). Marketing the products with FPL that is not identical to the approved labeling text may render the products misbranded and unapproved new drugs.

Please submit 20 copies of the FPL as soon as it is available, in no case more than 30 days after it is printed to each application. Please individually mount ten of the copies on heavy-weight paper or similar material. For administrative purposes, these submissions should be designated "FPL for approved supplement NDA 50-674/S-012, 50-675/S-015." Approval of these submissions by FDA is not required before the labeling is used.

If a letter communicating important information about this drug product (i.e., a “Dear Health Care Practitioner” letter) is issued to physicians and others responsible for patient care, 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 the requirements for an approved NDA set forth under 21 CFR 314.80 and 314.81.

If you have any questions, contact Beth Duvall-Miller, Project Manager, at (301) 827-2125.

Sincerely yours,

Gary K. Chikami, M.D.
Director
Division of Anti-Infective Drug Products
Office of Drug Evaluation IV
Center for Drug Evaluation and Research

Enclosure