CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION: NDA 50-674/S-012 & NDA 50-675/S-015

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	Included	Pending Completion	Not Prepared	Not Required
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Microbiology Review(s)	X			
Clinical Pharmacology Biopharmaceutics Review(s)	X			
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Administrative Document(s)	X			
Correspondence	X			

DEPARTMENT OF HEALTH AND HUMAN SERVICES **Public Health Service**

Center for Drug Evaluation and Research
Office of Training and Communication
Freedom of Information Staff HFD-205
5600 Fishers Lane 12 B 05
Rockville, Maryland 20857

January 26, 1999

In Response Refer to File : F98-29553

FDC Reports, Inc.
Attn.: Brittany Cady
5550 Friendship Blvd. Ste. One
Chevy Chase, MD 20815

Dear Ms. Cady:

This is in response to your request of November 24, 1998, in which you requested documents pertaining to the November 20, 1998 supplemental approval of Vantin, NDA 50-675. Your request was received in the Centers for Drug Evaluation and Research on November 24, 1998.

The documents you have requested are enclosed.

"In order to help reduce processing time and costs, certain material has been deleted from the record(s) furnished to you because a preliminary review of the record(s) indicated that the deleted information is not required to be publicly disclosed. If, however, you desire to review the deleted material, please make an additional request at the following address:

Food and Drug Administration
Freedom of Information Staff, HFI-35
5600 Fishers Lane
Rockville, MD 20857

Should the Agency then deny this information, you would have the right to appeal such denial. Any letter of denial will explain how to make this appeal." SMG 2460.7(3)

This concludes the response for the Center for Drug Evaluation and Research.

Charges of $82.90(Search $14.00, Review $58.00, Reproduction $10.90, Computer time $0.00) will be included in a monthly invoice. **DO NOT SEND ANY PAYMENT UNTIL YOU RECEIVE AN INVOICE.**

If there are any problems with this response, please notify us <u>in writing</u> of your specific problem(s). Please reference the above file number.

Sincerely,

Bernice Carter

Bernice Carter
Freedom of Information Officer
Office of Training and Communication
Freedom of Information Staff HFD-205
Direct Line 301 443-2244

+ **CENTER FOR DRUG EVALUATION AND RESEARCH**

Approval Package for:

Application Number: NDA 50-674/S-012 & NDA 50-675/S-015

Trade Name: Vantin Tablets/Oral Suspension

Generic Name:(cefpodoxime proxetil)

Sponsor:Pharmacia & Upjohn

Approval Date:November 20, 1998

Indication: Provides for the use of Vantin (cefpodoxime proxetil) Tablets and Vantin (cefpodoxime proxetil) Oral Suspension for the treatment of acute maxillary sinusitis

CENTER FOR DRUG EVALUATION AND RESEARCH

Application Number: NDA 50-674/S-012 & NDA 50-675/S-015

APPROVAL LETTER

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

NOV 20 1998

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,

/S/

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

Enclosure

cc:

Archival NDAs 50-674, 50-675
HFD-520/Div. Files
HFD-520/CSO/B. Duvall-Miller (w/label)
HFD-520/MO/H. Hamilton
HFD-520/Micro/F. Marsik
HFD-520/BioPharm/J. Zheng
HFD-520/Stats/J. Jiang
HF-2/MedWatch (with labeling)
HFD-002/ORM (with labeling)
HFD-104/ADRA (with labeling)
HFD-40/DDMAC (with labeling)
HFD-613/OGD (with labeling)
HFD-95/DDMS (with labeling)
HFD-830/DNDC Division Director
DISTRICT OFFICE

Concurrence only:

HFD-520/SCSO/J. Bona 11/20/98
HFD-520/SMO/J. Soreth 11/19/98
HFD-520/TLMicro/A. Sheldon 11/20/98
HFD-725/TLStats/D. Lin 11/19/98
HFD-520/DivDir/G. Chikami 11/20/98

Drafted by: bdm/November 19, 1998/M:\SUPPAP\50674.012
Initialed by:
final: 11/20/98

APPROVAL (AP)