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050749_origapp_package

CENTER FOR DRUG EVALUATION AND RESEARCH

Approval Package for:

APPLICATION NUMBER:

50-739

50-749

Trade Name: Omnicef (capsules)
Omnicef (oral suspension)

Generic Name: (cefdinir)

Sponsor: Parke-Davis

Approval Date: December 4, 1997

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APPLICATION NUMBER:

50-739

50-749

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APPLICATION NUMBER:

50-739

50-749

APPROVAL LETTER

NDA 50-739

NDA 50-749

DEC 4 1997

Parke-Davis

Attention: Drusilla Scott, Ph.D.

Director, Worldwide Regulatory Affairs

2800 Plymouth Road

Ann Arbor, MI 48105

Dear Dr. Scott:

Please refer to your new drug applications dated September 3, 1996 (NDA 50-739) and December 30, 1996 (NDA 50-749), received September 4, 1996 and December 31, 1996 respectively, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Omnicef (cefdinir) Capsules and Powder for Oral Suspension. We note that these products are subject to the exception provisions of Section 125 (2) of Title 1 of the FDA Modernization Act of 1997.

We acknowledge receipt of your submissions dated September 24, November 13, December 16, and December 31, 1996; and January 31, February 21, March 10, March 31, April 25, May 6, May 9, June 2, June 11, June 23, June 30, July 1, July 7, July 8, July 9, July 21, July 22, August 8, August 14, August 27, August 29, September 10, September 18, September 29, October 7, October 16, October 20, October 27, November 7, November 18, November 25, and December 3, 1997. The original User Fee goal date for these applications was September 4, 1997 (NDA 50-739) and December 31, 1997 (NDA 50-749). Your submission of June 23, 1997 extended the User Fee goal date for NDA 50-739 to December 4, 1997.

These new drug applications provide for treatment of patients with community-acquired pneumonia, acute exacerbations of chronic bronchitis, acute bacterial otitis media, acute maxillary sinusitis, pharyngitis/tonsillitis, and uncomplicated skin and skin structure infections.

We have completed the review of these applications, including the submitted draft labeling, 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 marked-up draft labeling. Accordingly, these applications are approved effective on the date of this letter.

The final printed labeling (FPL) must be identical to the enclosed marked-up draft labeling. Marketing the products with FPL that is not identical to this draft labeling 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. Please individually mount ten of the copies on heavy-weight paper or similar material. For administrative purposes, this submission should be designated "FINAL".

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NDA 50-749

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PRINTED LABELING" for approved NDA's 50-739, 50-749. Approval of this submission by FDA is not required before the labeling is used.

Should additional information relating to the safety and effectiveness of the drugs become available, revision of that labeling may be required.

We remind you of your Phase 4 commitments specified in your submissions dated October 20 and December 3, 1997. These commitments, along with any completion dates agreed upon, are listed below.

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Protocols, data, and final reports should be submitted to your IND for these products and a copy of the cover letters sent to these NDA's. Should an IND not be required to meet your Phase 4 commitments, please submit protocol, data, and final reports to these NDA's as correspondences. In addition, we request under 21 CFR 314.81(b)(2)(vii) that you include in your annual report to these applications, a status summary of each commitment. The status summary should include the number of patients entered in each study, expected completion and submission dates, and any changes in plans since the last annual report. For administrative purposes, all submissions, including labeling supplements, relating to these Phase 4 commitments must be clearly designated "Phase 4 Commitments."

In addition, please submit three copies of the introductory promotional material that you propose to use for these products. All proposed materials should be submitted in draft or mock-up form, not final print. Please submit one copy to the Division of Anti-Infective Drug Products and two copies of both the promotional material and the package inserts directly to:

Food and Drug Administration
Division of Drug Marketing, Advertising and Communications,
HFD-40
5600 Fishers Lane
Rockville, Maryland 20857

Please submit one market package of the drug product when it is available.

We remind you that you must comply with the requirements for an approved NDA set forth under 21 CFR 314.80 and 314.81.

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If you have any questions, please contact Beth Duvall-Miller, Project Manager, at (301) 827-2120.

Sincerely yours,



David Feigal, M.D., M.P.H.
Acting Office Director
Office of Drug Evaluation IV
Center for Drug Evaluation and Research

ENCLOSURES