050791_ORIG_APPROVAL_PKG

CENTER FOR DRUG EVALUATION AND RESEARCH

APPROVAL PACKAGE FOR:

APPLICATION NUMBER(S)

50-791

Trade Name: Myfortic

Generic Name(s): (mycophenolic acid)

Sponsor: Norvartis Pharmaceuticals Corporation

Agent:

Approval Date: February 27, 2004

Indication: Provides for prophylaxis of organ rejection in patients receiving allogeneic renal transplants, administered in combination with cyclosporine and corticosteroids

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50-791

Approval Letter(s)

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service
Food and Drug Administration
Rockville, MD 20857

NDA 50-791

Novartis Pharmaceuticals Corporation
Attention: M. Daniel Gordin, Ph.D.
Director, Drug Regulatory Affairs
One Health Plaza
East Hanover, NJ 07936-1080

Dear Dr. Gordin:

Please refer to your new drug application (NDA) dated April 30, 2003, received April 30, 2003, submitted pursuant to section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act for Myfortic® (mycophenolic acid) Delayed-Release Tablets, 180 mg and 360 mg.

We acknowledge receipt of your submissions dated:

June 16, 2003
June 20, 2003
August 28, 2003
October 8, 2003
November 26, 2003 (2)
December 2, 2003
December 4, 2003
December 8, 2003
December 11, 2003
December 17, 2003
January 9, 2004
January 13, 2004
February 13, 2004
February 18, 2004
February 19, 2004 (2)
February 23, 2004 (2)
February 25, 2004 (4)
February 26, 2004
February 27, 2004

This new drug application provides for the use of Myfortic® (mycophenolic acid) Delayed-Release Tablets for the prophylaxis of organ rejection in patients receiving allogeneic renal transplants, administered in combination with cyclosporine and corticosteroids.

We have completed our review of this application, as amended. It is approved, effective on the date of this letter, for use as recommended in the agreed-upon labeling text (enclosed).

The final printed labeling (FPL) must be identical to the submitted labeling (text for the package insert submitted February 27, 2004, immediate container and carton labels submitted February 27, 2004). Marketing the product with FPL that is not identical to the approved labeling text may render the product misbranded and an unapproved new drug.

Please submit an electronic version of the FPL according to the guidance for industry titled *Providing Regulatory Submissions in Electronic Format - NDA*. Alternatively, you may submit 20 paper copies of the FPL as soon as it is available but no more than 30 days after it is printed. Individually mount 15 of the copies on heavy-weight paper or similar material. For administrative purposes, designate this

submission "**FPL for approved NDA 50-791.**" Approval of this submission by FDA is not required before the labeling is used.
All applications for new active ingredients, new dosage forms, new indications, new routes of administration, and new dosing regimens are required to contain an assessment of the safety and effectiveness of the product in pediatric patients unless this requirement is waived or deferred. We note that you have fulfilled the pediatric study requirement for ages 11 to 16 years for this application. We are waiving the pediatric study requirement for ages 0 to 10 years for this application.

We remind you of your postmarketing study commitment in your submission dated February 25, 2004. This commitment is listed below.

1. Description of Commitment

   Conduct a prenatal-postnatal developmental toxicity study using mycophenolate sodium in pregnant female rats.

Protocol Submission:	by May 2004
Study Start:	by September 2004
Final Report Submission:	by September 2005

Submit clinical protocols to your IND for this product. Submit nonclinical and chemistry, manufacturing, and controls protocols and all study final reports to this NDA. In addition, under 21 CFR 314.81(b)(2)(vii) and 314.81(b)(2)(viii), you should include a status summary of the commitment in your annual report to this NDA. The status summary should include expected summary completion and final report submission dates, any changes in plans since the last annual report, and, for clinical studies, number of patients entered into each study. All submissions, including supplements, relating to this postmarketing study commitment must be prominently labeled "**Postmarketing Study Protocol**", "**Postmarketing Study Final Report**", or "**Postmarketing Study Correspondence.**"

In addition, submit three copies of the introductory promotional materials that you propose to use for this product. Submit all proposed materials in draft or mock-up form, not final print. Send one copy to the Division of Special Pathogen and Immunologic Drug Products and two copies of both the promotional materials and the package insert directly to:

Division of Drug Marketing, Advertising,
and Communications, HFD-42
Food and Drug Administration
5600 Fishers Lane
Rockville, MD 20857

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

We have not completed validation of the regulatory methods. However, we expect your continued cooperation to resolve any problems that may be identified.

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 Rebecca Saville, Pharm.D., Regulatory Project Manager, at (301) 827-2127.

Sincerely,

{See appended electronic signature page}

Renata Albrecht, M.D.
Director
Division of Special Pathogen and
Immunologic Drug Products
Office of Drug Evaluation IV
Center for Drug Evaluation and Research

Enclosure

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

/s/

Renata Albrecht
2/27/04 04:40:22 PM