



NDA 21-110/S-003

Wyeth Pharmaceuticals
Attention: Randall B. Brenner
Senior Manager, Worldwide Regulatory Affairs
P.O. Box 8299
Philadelphia, PA 19101-8299

Dear Mr. Brenner:

Please refer to your supplemental new drug application dated March 21, 2001, received March 26, 2002, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Rapamune[®] (sirolimus) Tablets.

We acknowledge receipt of your submissions dated October 4, 2001; April 19, 2002; and August 21, 2002.

Your submission of April 19, 2002, constituted a complete response to our September 26, 2001 action letter.

This supplemental new drug application provides for a 2-mg strength of Rapamune[®] Tablets.

We have completed the review of this application, as amended, and have concluded that adequate information has been presented to demonstrate that the drug product is safe and effective for use as recommended in the agreed upon labeling text. Accordingly, the application is approved effective on the date of this letter.

The final printed labeling (FPL) must be identical to the submitted labeling (package insert submitted April 19, 2002, immediate container and carton labels submitted March 21, 2001). In addition, all previous revisions as reflected in the most recently approved package insert must be included.

Please submit 20 paper 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 mount individually ten of the copies on heavy-weight paper or similar material. Alternatively, you may submit the FPL electronically according to the guidance for industry titled Providing Regulatory Submissions in Electronic Format – NDAs (January 1999). For administrative purposes, this submission should be designated "FPL for approved supplement NDA 21-110/S-003." Approval of this submission 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

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.

If you have any questions, call Matthew A. Bacho, Regulatory Project Manager, at (301) 827-2127.

Sincerely,

{See appended electronic signature page}

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

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

/s/

Edward Cox

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For Renata Albrecht, M.D.; NDA 21-110/S-003