DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-083/S-026
NDA 21-110/S-035

Wyeth Pharmaceuticals, Inc.
Attention: David K. Ellis, Ph.D.
Assistant Vice President, Global Regulatory Affairs
P.O. Box 8299
Philadelphia, PA 19101-8299

Dear Dr. Ellis:

Please refer to your New Drug Applications submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for the following:

NDA Number	Name of Drug Product	Supplement Number	Date of Supplement	Date of Receipt
21-083	Rapamune® (sirolimus) Oral Solution, 1 mg/mL	S-026	November 16, 2006	November 16, 2006
21-110	Rapamune® (sirolimus) Tablets, 1 mg, 2 mg, and 5 mg	S-035	November 16, 2006	November 16, 2006

These supplemental applications provide for the addition of a new subsection titled "*Angioedema*" regarding the concomitant use of sirolimus and angiotensin-converting enzyme inhibitors. The new subsection reads as follows:

> ***Angioedema***
> Rapamune® has been associated with the development of angioedema. The concomitant use of Rapamune® with other drugs known to cause angioedema, such as ACE-inhibitors, may increase the risk of developing angioedema.

This new subsection will be located in the **PRECAUTIONS** section of the package insert, following the ***Calcineurin inhibitor-induced hemolytic uremic syndrome*** subsection.

We completed our review of these applications and they are approved, effective on the date of this letter, for use as recommended in the package insert submitted on November 16, 2006.

Submit revised content of labeling [21 CFR 314.50(l)] in structured product labeling (SPL) format as described at http://www.fda.gov/oc/datacouncil/spl.html, that is identical in content to the enclosed labeling text. Upon receipt and verification, we will transmit that version to the National Library of Medicine for posting on the DailyMed website.

If you issue a letter communicating important information about this drug product (i.e., a "Dear Health Care Professional" letter), we request that you submit a copy of the letter to this NDA and a copy to the following address:

MEDWATCH
Food and Drug Administration
WO 22, Room 4447
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

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 Hyun Son, Pharm. D., Regulatory Project Manager, at (301) 796-1600.

Sincerely,

{See appended electronic signature page}

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

Enclosure: Package Insert

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

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