DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 21083/S-054
NDA 21110/S-068

SUPPLEMENT APPROVAL

Wyeth Pharmaceuticals, Inc.,
a subsidiary of Pfizer, Inc.
Attention: Nhu Debi Tran, Pharm.D.
Director, Worldwide Regulatory Strategy
PO Box 8299
Philadelphia, PA 19101-8299

Dear Dr. Tran:

Please refer to your Supplemental New Drug Applications (sNDAs) submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) as follows:

NDA Number	Supplement Number	Name of Drug Product	Submission date	Receipt date
021083	S-054	Rapamune® (sirolimus) Oral Solution, 1 mg/mL	March 18, 2013	March 18, 2013
021110	S-068	Rapamune® (sirolimus) Tablets, 1 mg, 2 mg, and 5 mg	March 18, 2013	March 18, 2013

These "Prior Approval" supplemental new drug applications provide for revisions to the carton and container labels for Rapamune as well as for the Amber Oral Syringe included in the Rapamune Oral Solution kit.

We have completed our review of these applications. They are approved, effective on the date of this letter, for use as recommended in the agreed-upon labeling text.

CARTON AND IMMEDIATE CONTAINER LABELS

Submit final printed carton and container labels that are identical to the enclosed carton and immediate container labels as soon as they are available, but no more than 30 days after they are printed.

Please submit these labels electronically according to the guidance for industry titled "Providing Regulatory Submissions in Electronic Format – Human Pharmaceutical Product Applications and Related Submissions Using the eCTD Specifications (June 2008)." Alternatively, you may submit 12 paper copies, with 6 of the copies individually mounted on heavy-weight paper or

similar material. For administrative purposes, designate this submission "**Product Correspondence – Final Printed Carton and Container Labels for approved NDA 21083/S-054 and NDA 21110/S-068**." Approval of this submission by FDA is not required before the labeling is used.

REPORTING REQUIREMENTS

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 Judit Milstein, Chief, Project Management Staff, at 301-796-0763.

Sincerely,

{See appended electronic signature page}

Ozlem Belen, MD, MPH
Deputy Director for Safety
Division of Transplant and Ophthalmology Products
Office of Antimicrobial Products
Center for Drug Evaluation and Research

ENCLOSURE: Carton and Container Labels
Amber Oral Syringe

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

/s/

OZLEM A BELEN
05/30/2013