DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 021083/S-050
NDA 021110/S-060

SUPPLEMENTS APPROVAL
RELEASE REMS REQUIREMENT

Wyeth Pharmaceuticals, Inc.
Attention: Ms. Sharon Pfleger, M.S.
Manager, Worldwide Regulatory Strategy
P.O. Box 8299
Philadelphia, PA 19101-8299

Dear Ms. Pfleger:

Please refer to your supplemental new drug applications, dated and received on May 11, 2011, and submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Rapamune® (sirolimus) Oral Solution, 1mg/mL (NDA 21-083), and Rapamune® (sirolimus) Tablets, 1 mg, 2 mg, and 5 mg (NDA 21-110).

We acknowledge receipt of your risk evaluation and mitigation strategy (REMS) assessment dated May 26, 2011.

These supplemental new drug applications propose elimination of the requirement for the approved Rapamune® (sirolimus) Oral Solution and Tablets REMS.

We have completed our review of these supplemental applications. They are approved, effective on the date of this letter.

RISK EVALUATION AND MITIGATION STRATEGY REQUIREMENTS

The REMS for Rapamune® (sirolimus) Oral Solution and Tablets was originally approved on November 23, 2010. The REMS consists of a Medication Guide and a timetable for submission of assessments of the REMS.

You propose that FDA no longer require a REMS for Rapamune® (sirolimus).

We have determined that maintaining the Medication Guide as part of the approved labeling is adequate to address the serious and significant public health concern and meets the standard in 21 CFR 208.1. Therefore, it is no longer necessary to include the Medication Guide as an element of the approved REMS to ensure that the benefits of Rapamune® (sirolimus) outweigh its risks, and a REMS for Rapamune® (sirolimus) is no longer required.

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We remind you that the Medication Guide will continue to be part of the approved labeling in accordance with 21 CFR 208.

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

Sincerely,

{See appended electronic signature page}

Ozlem Belen, M.D., MPH
Division Director for Safety
Division of Transplant and Ophthalmic Products
Office of Antimicrobial Products
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/

OZLEM A BELEN
06/06/2011