



NDA 21560/S-009

**SUPPLEMENT APPROVAL
RELEASE REMS REQUIREMENT**

Novartis Pharmaceuticals Corporation
Attention: Mr. Ronald G. Van Valen
Director, Drug Regulatory Affairs
One Health Plaza
East Hanover, NJ 07936-1080

Dear Mr. Van Valen:

Please refer to your Supplemental New Drug Application (sNDA) dated and received April 27, 2012, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Zortress[®] (everolimus) Tablets, 0.25 mg, 0.5 mg, and 0.75 mg.

We also acknowledge receipt of your risk evaluation and mitigation strategy (REMS) assessment dated October 20, 2011.

This supplemental new drug application proposes to eliminate the requirement for the approved Zortress[®] (everolimus) REMS.

RISK EVALUATION AND MITIGATION STRATEGY REQUIREMENTS

The REMS for Zortress[®] (everolimus) was originally approved on April 10, 2010, and the most recent REMS modification was approved on November 21, 2011. The REMS consists of a communication plan and a timetable for submission of assessments of the REMS.

You propose that FDA no longer require a REMS for Zortress[®] (everolimus).

Because the assessment demonstrates that the communication plan has been completed and has met its goals, we have determined that it is no longer necessary to include it as an element of the approved REMS to ensure that the benefits of the drug outweigh the risks.

Therefore, we agree with your proposal, and a REMS for Zortress[®] (everolimus) is no longer required.

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., Safety Regulatory Project Manager, at (301) 796-1939.

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

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
05/02/2012