



NDA 21083/S066

SUPPLEMENT APPROVAL

PF PRISM C.V.
c/o Pfizer, Inc.
Attention: Deneen Stewart, PhD
Director, Global Regulatory Affairs
500 Arcola Road
Collegeville, PA 19426

Dear Dr. Stewart:

Please refer to your supplemental new drug application (sNDA) dated and received May 2, 2019, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Rapamune (sirolimus) oral solution, 1 mg/mL.

This Prior Approval supplemental new drug application provides for revisions to the carton label to harmonize the contents with the text of the Instructions for Use section of the product labeling approved on April 5, 2019.

APPROVAL & LABELING

We have completed our review of this application. It is approved, effective on the date of this letter, for use as recommended in the enclosed agreed-upon carton label.

CARTON LABELING

Submit final printed carton label that is identical to the enclosed carton labeling, as soon as it is available, but no more than 30 days after it is printed. Please submit this labeling electronically according to the guidance for industry *Providing Regulatory Submissions in Electronic Format — Certain Human Pharmaceutical Product Applications and Related Submissions Using the eCTD Specifications*. For administrative purposes, designate this submission “**Final Printed Carton Labeling for approved NDA 21083/S066.**” 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
Acting Director
Division of Transplant and Ophthalmology
Products
Office of Antimicrobial Products
Center for Drug Evaluation and Research

ENCLOSURE: Carton Labeling

This is a representation of an electronic record that was signed electronically. Following this are manifestations of any and all electronic signatures for this electronic record.

/s/

OZLEM A BELEN
06/18/2019 01:57:41 PM