



NDA 21083/S064  
NDA 21110/S083

## SUPPLEMENT APPROVAL

PF Prism C.V.  
Attention: Deneen Stewart, PhD  
Director, Worldwide Safety and Regulatory  
500 Arcola Road  
Collegeville, PA 19426

Dear Dr. Stewart:

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:

<b>NDA Number</b>	<b>Supplement</b>	<b>Product Name</b>	<b>Date of Submission and Receipt</b>
21083	064	Rapamune (sirolimus) Oral Solution, 1mg/mL	June 25, 2018
21110	083	Rapamune (sirolimus) Tablet, 0.5mg, 1mg, 2mg	June 25, 2018

These Prior Approval supplemental new drug applications provides for revisions to the package insert to comply with the Pregnancy and Lactation Labeling Rule (PLLR) format.

### **APPROVAL & LABELING**

We have completed our review of these applications, as amended. They are approved, effective on the date of this letter, for use as recommended in the enclosed agreed-upon labeling, which is identical to the labeling submitted on June 21, 2019.

### **CONTENT OF LABELING**

As soon as possible, but no later than 14 days from the date of this letter, submit the content of labeling [21 CFR 314.50(l)] in structured product labeling (SPL) format using the FDA automated drug registration and listing system (eLIST), as described at FDA.gov.<sup>1</sup> Content of labeling must be identical to the enclosed labeling text for the Prescribing Information, Instructions for Use and Medication Guide, with the addition of

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<sup>1</sup> <http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm>

any labeling changes in pending “Changes Being Effected” (CBE) supplements, as well as annual reportable changes not included in the enclosed labeling.

Information on submitting SPL files using eList may be found in the guidance for industry *SPL Standard for Content of Labeling Technical Qs and As*.<sup>2</sup> The SPL will be accessible from publicly available labeling repositories.

Also, within 14 days, amend all pending supplemental applications that include labeling changes for these NDAs, including CBE supplements for which FDA has not yet issued an action letter, with the content of labeling [21 CFR 314.50(l)(1)(i)] in Microsoft Word format, that includes the changes approved in these supplemental applications, as well as annual reportable changes. To facilitate review of your submission(s), provide a highlighted or marked-up copy that shows all changes, as well as a clean Microsoft Word version. The marked-up copy should provide appropriate annotations, including supplement number(s) and annual report date(s).

## **REPORTING REQUIREMENTS**

We remind you that you must comply with reporting requirements for approved NDAs (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(S): Content of Labeling

- Prescribing Information
- Medication Guide
- Instructions for Use

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<sup>2</sup> We update guidances periodically. For the most recent version of a guidance, check the FDA Guidance Documents Database <https://www.fda.gov/RegulatoryInformation/Guidances/default.htm>.

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**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.**  
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/s/  
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