DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 210115/S-001
NDA 50708/S-048
NDA 50709/S-041

SUPPLEMENT APPROVALS

Astellas Pharma US, Inc.
Attention: Mary Jo Pritza, MPH, PharmD
Senior Director, Regulatory Affairs
1 Astellas Way
Northbrook, Illinois 60062

Dear Dr. Pritza:

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

NDA/Supplement No.	Product Name	Dosage Form /Strength	Date of Submission And Receipt
50708/S048	PROGRAF® (tacrolimus)	capsules, 0.5mg, 1mg, and 5mg	July 23, 2018
50709/S041	PROGRAF® (tacrolimus)	injection, 5mg/mL	July 23, 2018
210115/S001	PROGRAF® Granules (tacrolimus for oral suspension)	for oral suspension, 0.2mg and 1mg	July 23, 2018

In these supplemental applications, submitted as Changes Being Effected supplements to NDA 50708 with cross-references to NDA 50709 and NDA 210115, you amend the approved product labeling to:

- Add a new term to Section 6.2 of the prescribing information (PI) to describe calcineurin-inhibitor induced pain syndrome.

APPROVAL & LABELING

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

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 http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm. Content of labeling must be identical to the enclosed labeling (Prescribing Information), with the addition of any labeling changes in pending "Changes Being Effected" (CBE) supplements, as well as annual reportable changes not included in the enclosed labeling. If the content of labeling in SPL format initially submitted with this CBE-0 labeling supplement is identical to the attached approved labeling, an additional submission of content of labeling in SPL format is not required.

Information on submitting SPL files using eList may be found in the guidance for industry titled "SPL Standard for Content of Labeling Technical Qs and As" at http://www.fda.gov/downloads/DrugsGuidanceComplianceRegulatoryInformation/Guidances/UCM072392.pdf.

The SPL will be accessible from publicly available labeling repositories.

Also within 14 days, amend all pending supplemental applications that include labeling changes for this NDA, 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 this supplemental application, 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 an approved NDA (21 CFR 314.80 and 314.81).

If you have any questions, please call Wendy Streight, PhD, Regulatory Project Manager, at 301-796-1600.

Sincerely,

{See appended electronic signature page}

Renata Albrecht, MD
Director
Division of Transplant and Ophthalmology Products
Office of Antimicrobial Products
Center for Drug Evaluation and Research

ENCLOSURE:
Content of Labeling: Prescribing Information

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/

RENATA ALBRECHT
12/02/2018