DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 204096/S-003
NDA 204096/S-004

SUPPLEMENT APPROVAL

Astellas Pharma US, Inc.
Attention: Mary Jo Pritza, M.P.H., Pharm.D.
Director, Regulatory Affairs
1 Astellas Way
Northbrook, IL 60062

Dear Dr. Pritza:

Please refer to your Supplemental New Drug Application (sNDA dated June 18, 2015, received June 18, 2015 and Supplemental New Drug Application (sNDA) dated August 21, 2015, received August 21, 2015, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Astagraf XL (tacrolimus extended-release capsules). We also refer to your amendment dated December 14, 2015.

The June 18, 2015, "Changes Being Effected" supplemental new drug application S-003 proposes to add language to section **7 DRUG INTERACTIONS/Table 6** of the package insert that addresses a potential drug interaction between tacrolimus and herbal products containing schisandra. The August 21, 2015, "Prior Approval" supplemental new drug application S-004 proposes to incorporate changes in labeling to make it consistent with the recommendations in recent Guidance(s) for Industry documents regarding physician labeling rule (PLR) labeling.

APPROVAL & LABELING

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

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 (text for the package insert), 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.

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 includes 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 MS Word format, that includes the changes approved in this supplemental application, as well as annual reportable changes and annotate each change. To facilitate review of your submission, 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, call Jacquelyn Smith, M.A., Senior Regulatory Project Manager, at (301) 796-1600.

Sincerely,

{See appended electronic signature page}

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

ENCLOSURE(S):
Content of Labeling

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

RENATA ALBRECHT
12/16/2015