DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 204096/S-001

SUPPLEMENT APPROVAL

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

Dear Dr. Pritza:

Please refer to your Supplemental New Drug Application (sNDA) dated August 14, 2013, received August 15, 2013, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Astagraf XL® (tacrolimus extended-release capsules).

This "Changes Being Effected" supplemental new drug application provides for changes to the carton and immediate container labels as follows:

1. For all Carton and Container Labels, the established name was increased in prominence to at least half that of the proprietary name pursuant to 21 CFR 201.10(g)(2) and the size of the middle four numbers of the national drug code (NDC) number was reduced.

2. For Bottle Labels, the colored box around the text "Note: Astagraf XL capsules are not filled to maximum capsule capacity. Capsule contains labeled amount." was deleted.

APPROVAL & LABELING

We have completed our review of this supplemental new drug application, as amended. This supplement is approved.

CARTON AND IMMEDIATE CONTAINER LABELS

We acknowledge your August 14, 2013, submission containing final printed carton and container labels.

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, MA, Senior 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(S):
Carton and Container 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
02/11/2014