DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 50-777/S-014

Astellas Pharma US, Inc.
Attention: Eva Essig, Ph. D.
Senior Director, Regulatory Affairs
Three Parkway North
Deerfield, IL 60015

Dear Dr. Essig:

Please refer to your supplemental new drug application dated July 2, 2008, received July 3, 2008, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Protopic® (tacrolimus) Ointment, 0.03% and 0.1%.

This "Changes Being Effected in 30 days" supplemental new drug application provides for the addition of Astellas Toyama Co., Ltd., Toyama, Japan, as an alternate manufacturing site for the drug product filled in laminate tubes.

We have completed our review of this application. It is approved, effective on the date of this letter, for use identical to the submitted labeling on July 2, 2008.

CONTENT OF LABELING

As soon as possible, but no later than 14 days from the date of this letter, please submit the content of labeling [21 CFR 314.50(l)] in structured product labeling (SPL) format as described at http://www.fda.gov/oc/datacouncil/spl.html that is identical to the submitted labeling on July 2, 2008. Upon receipt, we will transmit that version to the National Library of Medicine for public dissemination. For administrative purposes, please designate this submission, "**SPL for approved NDA 50-777/S-014**."

CARTON AND IMMEDIATE CONTAINER LABELS

Submit final printed carton and container labels that are identical to the submitted carton and immediate container labels as soon as they are available, but no more than 30 days after they are printed. Please submit these labels electronically according to the guidance for industry titled *Providing Regulatory Submissions in Electronic Format – Human Pharmaceutical Product Applications and Related Submissions Using the eCTD Specifications (October 2005)*. Alternatively, you may submit 12 paper copies, with 6 of the copies individually mounted on heavy-weight paper or similar material. For administrative purposes, designate this submission "**Final Printed Carton and Container Labels for approved NDA 50-777/S-014**." Approval of this submission by FDA is not required before the labeling is used.

Marketing the product(s) with FPL that is not identical to the approved labeling text may render the product misbranded and an unapproved new drug.

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 Swati Patwardhan, Regulatory Project Manager, at (301) 796-4085.

Sincerely,

{See appended electronic signature page}

James D. Vidra, Ph.D.
Branch Chief
Branch VII, Division of Post-Marketing Evaluation
Office of New Drug Quality Assessment
Center for Drug Evaluation and Research

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

/s/

Ramesh Raghavachari
12/31/2008 01:20:36 PM
Signed for Dr. James D. Vidra