DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 50-777/S-010

Astellas Pharma, Inc.
Attn.: Donald E. Baker, J.D.
Sr. Director, Regulatory Affairs
Parkway North Center
3 Parkway North
Deerfield, IL 60015-2548

Dear Dr. Baker:

Please refer to your supplemental new drug application dated January 28, 2005, received January 31, 2005, 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 a new product package size, a 5 gram tube, and for a change of (b)(4) supplier used in the manufacture of (b)(4) laminate tube head and shoulder sections by (b)(4) for all package sizes.

We completed our review of this application. This application is approved, effective on the date of this letter, for use as recommended in the agreed-upon labeling text.

The final printed labeling (FPL) must be identical to the submitted labeling (package insert submitted January 28, 2005, patient package insert submitted January 28, 2005, immediate container and carton labels submitted January 28, 2005). Note that you may, if you wish, revise the corporate name (only) on these materials to reflect your new "Astellas" name without further approval, as long as no other changes in format or content are made.

Please submit an electronic version of the FPL according to the guidance for industry titled *Providing Regulatory Submissions in Electronic Format - NDA*. Alternatively, you may submit 20 paper copies of the FPL as soon as it is available but no more than 30 days after it is printed. Individually mount 15 of the copies on heavy-weight paper or similar material. For administrative purposes, designate this submission "**FPL for approved supplement NDA 50-777/S-010**." Approval of this submission by FDA is not required before the labeling is used.

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 Mildred Wright, Regulatory Project Manager, at (301) 827-2020.

Sincerely,

{See appended electronic signature page}
Ramesh Sood, Ph.D.
Chemistry Team Leader for the Division of Dermatologic & Dental Drug Products, (HFD-540)
DNDC III, Office of New Drug Chemistry
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 Sood

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