DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 50-777/S-012

Astellas Pharma US, Inc.
Attention: Marcia Marconi
Vice President, Regulatory Affairs, Quality Assurance and Safety
Three Parkway North
Deefield, IL 60015-2548

Dear Ms. Marconi:

Please refer to your supplemental new drug application dated September 2, 2005, received September 6, 2005, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for PROTOPIC (tacrolimus) Ointment, 0.03% and 0.1%.

We reference our supplement request letter dated August 2, 2005.

We acknowledge receipt of your submissions dated September 9, October 13, 14 and 20, November 10 and 18 (2), 2005.

This supplemental new drug application provides for labeling revisions to communicate risks associated with use of PROTOPIC Ointment.

We completed our review of this application, as amended. 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 enclosed labeling (text for the package insert, and text for medication guide).

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 NDA50-777/S-012**." Approval of this submission by FDA is not required before the labeling is used.

We remind you that the enclosed labeling should be implemented at next printing but no later than June 1, 2006.

In addition, submit three copies of the introductory promotional materials that you propose to use for this product. Submit all proposed materials in draft or mock-up form, not final print. Send one copy to this division and two copies of both the promotional materials and the package insert directly to:

Food and Drug Administration
Center for Drug Evaluation and Research
Division of Drug Marketing, Advertising, and Communications
Food and Drug Administration
5901-B Ammendale Road
Beltsville, MD 20705-1266

When you issue the "Dear Health Care Professional" letter or any future letter communicating important information about this drug product, we request that you submit a copy of the letter to this NDA and a copy to the following address:

MEDWATCH
Food and Drug Administration
WO 22, Room 4447
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

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 Margo Owens, Regulatory Project Manager, at (301) 796-2110.

Sincerely,

{See appended electronic signature page}

Stanka Kukich, M.D.
Acting Director
Division of Dermatology and Dental Products
Office of Drug Evaluation III
Center for Drug Evaluation and Research

Enclosure

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

/s/

Stanka Kukich

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