DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 50-777 / S-006

Fujisawa Healthcare, Inc.
Attention: Donald E. Baker, J.D.
Sr. Director, Regulatory Affairs
Three Parkway North
Deerfield, IL 60015-2548

Dear Mr. Baker:

Please refer to your supplemental new drug application dated September 5, 2003, received September 8, 2003, and the amendment dated October 17, 2003, received October 20, 2003, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for PROTOPIC® (tacrolimus) Ointment, 0.03% and 0.1%.

This prior approval supplemental new drug application provides for a new package size, 2 gram physician's samples packaged in tubes supplied by(b)(4)---------- for PROTOPIC ® (tacrolimus) Ointment, 0.03% and 0.1%, and for the discontinuation of the 3 gram physician's sample package size.

We have 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 in the enclosed labeling.

The final printed labeling (FPL) must be identical to the immediate container labels submitted September 5, 2003, and the package insert submitted October 17, 2003.

Please submit the FPL electronically 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, in no case more than 30 days after it is printed. Please individually mount ten of the copies on heavy-weight paper or similar material. For administrative purposes, this submission should be designated "FPL for approved supplement NDA 50-777/S-006." Approval of this submission by FDA is not required before the labeling is used.

We remind you that you must comply with the requirements for an approved NDA set forth in 21 CFR 314.80 and 314.81.

If you have any questions, call Mary Jean Kozma-Fornaro, Supervisory Regulatory Project Manager, at (301) 827-2020.

Sincerely,

{See appended electronic signature page}

Wilson H. DeCamp, 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

Enclosure

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

/s/

Wilson H. DeCamp
12/23/03 07:27:10 AM
approved