



NDA 50-777 / S-004

Fujisawa Healthcare, 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 December 20, 2002, received December 23, 2002, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for PROTOPIC® (tacrolimus ointment) Ointment, 0.03% and 0.1% (w/w).

We acknowledge receipt of your submission dated February 28, 2003.

This supplemental new drug application provides for a new 100 gram package size for PROTOPIC® (tacrolimus ointment) Ointment, 0.03% and 0.1%.

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 and with the minor editorial revisions indicated in the enclosed labeling.

The final printed labeling (FPL) must be identical to the immediate container labels submitted December 20, 2002. These revisions are terms of the approval of this application.

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-004." Approval of this submission by FDA is not required before the labeling is used.

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:

Division of Drug Marketing, Advertising, and Communications, HFD-42
Food and Drug Administration
5600 Fishers Lane
Rockville, MD 20857

If you issue a letter communicating important information about this drug product (i.e., a “Dear Health Care Professional” letter), we request that you submit a copy of the letter to this NDA and a copy to the following address:

MEDWATCH, HF-2
FDA
5600 Fishers Lane
Rockville, MD 20857

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 A. Wright, 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/

Steve Hathaway
4/18/03 03:43:14 PM

Wilson H. DeCamp
4/18/03 03:48:10 PM
approved