



Fujisawa Healthcare, Inc.
Donald E. Baker, J.D.
Senior Director, Regulatory Affairs
Three Parkway North
Deerfield, Illinois 60015-2548
Tel. (847) 317-8872 Telefax (847) 317-7286
www.fujisawa.com
E-Mail: don_baker@fujisawa.com

January 27, 2005

Jan N. Johannessen, Ph.D.
Senior Science Policy Analyst
FDA, Office of Science and Health Coordination
5600 Fishers Lane, Room 14C-06, HF33
Rockville, MD 20857

Re: NDA 50-777
Protopic (tacrolimus) Ointment, 0.03% and 0.1%
Background Package for February 15, 2005
Pediatric Advisory Committee

Dear Dr. Johannessen:

Pursuant to your request, Fujisawa Healthcare, Inc. (FHI) is hereby submitting 50 copies of a background package for the upcoming FDA Pediatric Advisory Committee meeting scheduled for February 15, 2005. This background information document provides general information relevant to atopic dermatitis, treatment options and a risk-benefit evaluation of Protopic ointment and summarizes the current status of continued surveillance efforts by Fujisawa.

This background package is available for public disclosure without redaction. An electronic copy of this background package (in Microsoft Word) has also been submitted to you today via e-mail.

Should you require any additional information or have any questions regarding this document, please do not hesitate to contact the undersigned at (847) 317-8872 or Marcia Marconi at (847) 317-8898.

Sincerely,

Donald E. Baker, JD
Senior Director, Regulatory Affairs

cc: Mary Jean Kozma-Fornaro, Supervisor, Project Management Staff
(HFD-540), FDA (cover letter only)