



Food and Drug Administration  
Rockville MD 20857

FEB 16 2001

**TRANSMITTED VIA FACSIMILE**

Donald E. Baker  
Senior Director, Regulatory Affairs  
Fujisawa Healthcare, Inc.  
Parkway North Center, Three Parkway North  
Deerfield, Illinois 60015-2548

Re: NDA 50-777  
Protopic (tacrolimus 0.03% and 0.1%) Ointment  
MACMIS# 9672

Dear Mr. Baker:

As part of its routine monitoring and surveillance program, the Division of Drug Marketing, Advertising, and Communications (DDMAC) has become aware of a journal advertisement (ad), disseminated by Fujisawa Healthcare, Inc. (Fujisawa), for Protopic that is in violation of the Federal Food, Drug and Cosmetic Act and applicable regulations. Specifically, DDMAC refers to the journal ad for Protopic that appears in the December 2000, issue of *Prevention Magazine*. The ad states, "Breakthrough research has finally uncovered a new kind of medicine for eczema. Made of a natural substance, this new treatment is steroid free." This ad represents that Fujisawa developed a new kind of medicine for eczema that is made from a natural substance and is steroid free. Fujisawa makes the only new kind of medicine for eczema that has these characteristics. Thus, the advertisement identifies the specific product without including the information that is required for an advertisement that makes claims about a product.

In order to address these objections, DDMAC recommends that Fujisawa take the following actions:

1. Immediately discontinue the use of this, and all other promotional materials for Protopic that contain the same or similar violations.
2. Provide to DDMAC, in writing, your intent to comply with #1 above. Your response should be received by March 2, 2001.
3. This response should include a list of all violative promotional materials and Fujisawa's method for discontinuing their use.

Donald E. Baker  
Fujisawa Healthcare, Inc.  
NDA 50-777

Page 2

If you have any questions or comments, please contact me by facsimile at (301) 594-6771, or at the Food and Drug Administration, Division of Drug Marketing, Advertising and Communications, HFD-42, Rm 17B-20, 5600 Fishers Lane, Rockville, MD 20857. We remind you that only written communications are considered official.

In all future correspondence regarding this particular matter, please refer to MACMIS ID #9672 in addition to the NDA number.

Sincerely,

**/s/** \_\_\_\_\_

Cheryl Y. Roberts, MS, JD  
Regulatory Review Officer  
Division of Drug Marketing,  
Advertising and Communications



**Fujisawa Healthcare, Inc.**

*A progress report:*

## New Hope for People with Eczema

### *What is eczema?*

Eczema (atopic dermatitis) is a common skin disease that causes itchiness, redness, and inflammation. It often begins in early childhood and can mean a lifetime of frustration and discomfort. Although the cause of eczema is unknown, scientists believe it's caused by an abnormal allergic response of the body's immune system. People with eczema often have other diseases such as asthma and hay fever.

### *Eczema treatment today*

For over 40 years, steroid creams and ointments have been the standard treatment for eczema. While these products can be effective, their side effects make them less than ideal for long-term use. Because eczema sufferers often need daily treatment, researchers have focused on finding a new solution that limits the risk of long-term side effects.

### *Scientific studies show promising results*

Breakthrough research has finally uncovered a new kind of medicine for eczema. Made from a natural substance, this new treatment is steroid free.

### *How to get more information*

If you or someone you know would like to receive information, including a free video titled *Inside Eczema*, call toll free 1-888-441-2442.