DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

FOI

Food and Drug Administration
Rockville MD 20857

JUN 5 1998

TRANSMITTED VIA FACSIMILE

David L. Silberstein
Manager, Drug Regulatory Affairs
Westwood-Squibb Pharmaceuticals
100 Forest Avenue
Buffalo, NY 14213-1091

RE: NDA# 20-273
Dovonex (calcipotriene ointment) 0.005%
MACMIS ID #6395

Dear Mr. Silberstein:

Reference is made to Westwood-Squibb Pharmaceuticals' (WWS) submission of promotional materials under cover of FDA Forms 2253 dated January 29, 1997, (sales aid, Cor-7714), May 2, 1997, (journal advertisements, WWD 5402, WWD5404, WWD5405), and a September 1, 1997, (sales aid C-2766), for Dovonex (calcipotriene) Ointment, 0.005%. The Division of Drug Marketing, Advertising and Communication (DDMAC) has reviewed these materials and finds that they are in violation of the Federal Food, Drug and Cosmetic Act and its implementing regulations. Specifically, DDMAC has identified the following violations:

Unapproved Use

The statement
and the use of the reference study,

is misleading because it suggests that Dovonex ointment is useful in than has been demonstrated by substantial evidence. For example, Dovonex ointment is indicated only for the treatment of moderate plaque psoriasis in adults.

Misleading Efficacy Claims

The headline "Don't your patients deserve a vacation from psoriasis," with the 12 month calendar graphic, is misleading because it implies, without clinical evidence, that patients will be psoriasis free for 12 months with Dovonex treatment. However, the

"Clinical Studies" section of the approved product labeling states only that after 8 weeks of twice daily Dovonex, 70% of patients showed at least marked improvement (only 11.3% showed complete clearing).

In addition, the statements in the sales aids, "In 8 week studies, 70% of patients gained control over psoriasis with marked or better improvement" are misleading because they overstate the product's efficacy by omitting important contextual information. For example, after 8 weeks of twice daily Dovonex, 70% of patients showed at least marked improvement; of these patients, only 11.3% showed complete clearing. DDMAC refers WWS to similar issues discussed in letters to WWS dated September 11 and October 21, 1996.

Maintenance of Therapeutic Effect Claims

The claims of "...ongoing therapeutic effect after stopping treatment" are misleading because they are not supported by substantial evidence. The claims suggest that Dovonex provides therapeutic activity for up to 12 weeks after discontinuation of the therapy. However, the data on file referenced by WWS in support of these claims and submitted for review at DDMAC's request do not constitute substantial evidence.

Fair Balance

The journal ads are misleading because they fail to provide any information regarding side effects and other risk information. Dovonex may cause irritation of lesions and surrounding uninvolved skin, and should not be used on the face. Adverse events in the extended studies included skin irritation in approximately 25% of patients and worsening of psoriasis in approximately 10% of patients. Further, burning, itching, and skin irritation occurred in approximately 10 to 15% of patients in controlled clinical trials.

DDMAC requests that WWS take the following actions:

1. Immediately discontinue the use of these and all other promotional materials for Dovonex that contain the same or similar violations.

2. Provide to DDMAC, in writing, WWS' intent to comply with #1 above. Your response should be received by June 19, 1998.

If WWS has any questions or comments, please contact me by facsimile (301) 594-6771, or by written communication at the Food and Drug Administration, Division of Drug Marketing, Advertising and Communications, 5600 Fishers Lane, HFD-40, Rm. 17B-20, Rockville, MD 20857.

In all future correspondence regarding this matter, please refer to the MACMIS ID# 6395, in addition to the NDA number.

Sincerely,

Jean E. Raymond, P.A.
Regulatory Review Officer
Division of Drug Marketing,
Advertising and Communications