DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

AUG 31 2001

R. Bruce Dickson, Esq.
P. Susan Lively, Esq.
Paul, Hastings, Janofsky & Walker LLP
1299 Pennsylvania Avenue, N.W.
Washington, D.C. 20004-2400

Docket No. 01P-0122/CP1

Dear Mr. Dickson and Ms. Lively:

I am writing to inform you that the Food and Drug Administration (FDA) has not yet resolved the issues raised in your citizen petition on behalf of Pharmacia Consumer Healthcare dated March 7, 2001, asking the Agency to order Novartis Consumer Health, Inc. to revise the labeling for its prescription motion sickness product Transderm Scop to remove false or misleading statements comparing Transderm Scop with the oral dimenhydrinate (the active ingredient in Dramamine Original Formula).

FDA has been unable to reach a decision on your petition because it raises significant issues requiring extensive review and analysis by Agency officials. This interim response is provided in accordance with FDA regulations on citizen petitions (21 CFR 10.30(e)(2)). We will respond to your petition as soon as we have reached a decision on your request.

Sincerely yours,

Janet Woodcock, M.D.
Director
Center for Drug Evaluation and Research

01P-0122

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