DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

TRANSMITTED BY FACSIMILE

Mr. Vincent DeStefano
Associate Director, Regulatory Affairs
Novartis
560 Morris Avenue
Summit, New Jersey 07901-1312

RE: NDA#s 17-874, 20-501 Transderm Scop (scopolamine) Transdermal Therapeutic System
MACMIS# 10275

Dear Mr. DeStefano:

This letter notifies you that, through routine monitoring and surveillance, the Division of Drug Marketing, Advertising, and Communications (DDMAC) has identified a healthcare professional mailer for Transderm Scop (scopolamine) Transdermal Therapeutic System that is in violation of the Federal Food, Drug, and Cosmetic Act and applicable regulations. The mailer, entitled *Pharmacy Notice*, contains a one-page healthcare professional letter, brief summary, and a fact sheet. There are no identification numbers on these materials.

Specifically, DDMAC objects to the following:

1. The healthcare professional mailer lacks fair balance because there is no risk information in the body of the letter or the fact sheet. The brief summary is not adequate provision of the risk information that must be presented with prominence and readability that is reasonably comparable to the presentation of information relating to the effectiveness of the drug.

2. The claim that Transderm Scop is the longest lasting product for prevention of post operative nausea and vomiting is misleading because it is not substantiated by adequate and well-controlled comparative clinical trials.

3. The cost-effectiveness claim (e.g., "provide your surgical patients with a cost-effective, emesis-free surgical experience") is misleading because it is not substantiated. An index price of the product alone does not represent adequate evidence of cost-effectiveness.

Our records indicate that these promotional materials have not been submitted to DDMAC as stipulated in 21 CFR §314.81(b)(3)(i) that states that the sponsor shall submit all labeling and advertising at the time of initial dissemination.

To address these objections, DDMAC recommends that Novartis do the following:

1. Immediately discontinue the use of these mailers, as well as any other promotional material and practices with the same or similar messages.

2. Respond to this letter by September 14, 2001. Your response should include a statement of your intent to comply with the above, a list of all promotional materials with the same or similar issues, and your methods for discontinuing these promotional materials.

If you have any questions or comments, please contact Dr. Lisa Stockbridge 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. DDMAC reminds you that only written communications are considered official.

In all future correspondence regarding this particular matter, please refer to MACMIS ID #10275 in addition to the NDA number.

Sincerely,

{See appended electronic signature page}

Lisa L. Stockbridge, Ph.D.
Regulatory Review Officer
Division of Drug Marketing,
Advertising, and Communications

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

Lisa Stockbridge
8/31/01 09:34:06 AM

Dr. Geoffrey Ross
Director of Medical Affairs
Novartis Consumer Health
Enclosure

* Based on labeled dosing

Longest Lasting PONV Prevention[2] with

TRANSDERM SCŌP®

scopolamine 1.5mg

"The Nausea Prevention Patch"

Here is why TRANSDERM SCŌP® belongs on your pharmacy shelf...

- Up to 28 hours of PONV[1] prevention[2]
- One patch easily applied behind the ear preoperatively
- No redosing needed
- Just $0.19 per hour to prevent PONV[1] for up to 28 hours[3]
- Only $4.62 per patch[3]

TRANSDERM SCŌP® is indicated for prevention of nausea and vomiting associated with recovery from anesthesia and surgery

[1] PONV = Postoperative Nausea and Vomiting
[2] Based on Labeled Dosing
[3] *2000 Drug Topics® Red Book®.* Vol 20. No 4. Montvale, NJ: Medical Economics, Inc: 2001