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# 10972

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 professional journal advertisement (ID 0928-00) for Transderm Scop (scopolamine) Transdermal Therapeutic System that is misleading and thus in violation of the Federal Food, Drug, and Cosmetic Act and applicable regulations.

Specifically, DDMAC objects to the following:

Your journal advertisement is misleading because it promotes an unapproved dosing regimen for Transderm Scop. The journal advertisement is entitled, "Long Lasting Prevention of PONV" (post operative nausea and vomiting), and in the second bulleted statement instructs physicians to "apply patch behind ear 1 to 4 hours prior to surgery."

This dosing regimen is inconsistent with the instructions in the Dosage and Administration section of the approved product labeling (PI). The PI states that, to prevent post-operative nausea and vomiting, the Transderm Scop patch should be applied the evening before scheduled surgery, except in the case of cesarean section (for cesarean section, the patch should be applied 1 hour prior to surgery to minimize the drug exposure to the newborn). Furthermore, although it appears that there is some circulating scopolamine at 4 hours or even sooner, the Clinical Pharmacology section of the PI indicates that peak levels are not obtained, on average, until 24 hours.

FDA's determination of the appropriate dosing and dosage regimen for an indicated use of a drug is often based on a complex balance of factors related to the efficacy of the product, adverse event and toxicity risks, and considerations of administration. FDA is not aware of any data to support the dosing recommendation in the ad. Because peak levels of scopalamine are not obtained, on average, until 24 hours after administration, applying the patch just 4 hours before surgery will likely decrease the expected effectiveness of Transderm Scop.

Additionally, our records indicate that this advertisement was not submitted to DDMAC. FDA regulations at 21 CFR §314.81(b)(3)(i) require that sponsors submit all advertising at the time of initial publication.

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

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

2. Respond to this letter within 10 days. 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. 8B-45, 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 #10972 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
12/3/02 10:54:29 AM

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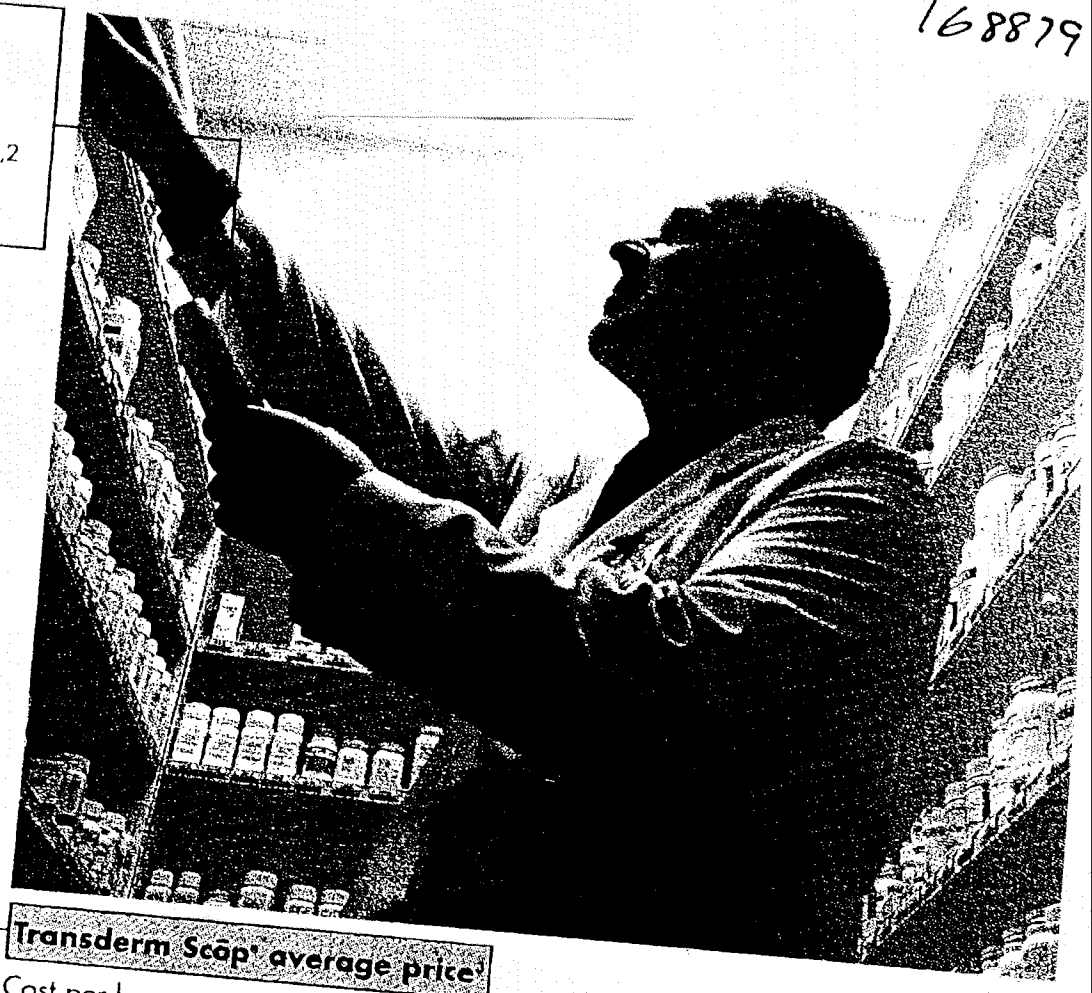
Long Lasting Prevention of PONV*†[1,2]



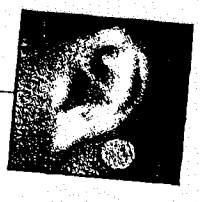
Transderm Scōp® average price[3]

Cost per hour
$0.19

Cost per 24 hours
$4.62

- Just $0.19 per hour to prevent PONV for 24 hours
- Convenient and easy — apply patch behind ear 1 to 4 hours prior to surgery
- Most frequently reported adverse events were dry mouth (29%) and dizziness (12%)[1]

Stock Transderm Scōp in your pharmacy. Now available in convenient 24-patch Multipack — NDC0067-4346-24.



TRANSDERM SCŌP®
scopolamine 1.5 mg "THE NAUSEA PREVENTION PATCH"

*Based on labeled frequency of dosing.
†PONV=postoperative nausea and vomiting.

Available by prescription only, Transderm Scōp should not be prescribed for children, or for patients with glaucoma, difficulty in urinating, or an allergy to scopolamine or other belladonna alkaloids. Exercise special care when prescribing Transderm Scōp for the elderly. In postoperative nausea and vomiting clinical studies, the most commonly reported adverse events were dry mouth (29%) and dizziness (12%). While using this product, one should not drive, operate dangerous machinery, or do other things that require alertness. One should not use alcohol.

Please see accompanying Brief Summary of complete Prescribing Information.

To learn more about Transderm Scōp, visit www.transdermscop.com

References: 1. Transderm Scōp [package insert]. Summit, NJ: Novartis Consumer Health Inc. **2.** *Physicians' Desk Reference®*. 54th ed. Montvale, NJ: Medical Economics Inc; 2000. **3.** *2000 Drug Topics Red Book®*. Vol 20. No 4. Montvale, NJ: Medical Economics, Inc; 2001.

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