DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 17-874/S-035

Novartis Consumer Health, Inc.
Attn: Vincent DeStefano
Associate Director, Regulatory Affairs
200 Kimball Drive
Parsippany, NJ 07054-0622

Dear Mr. DeStefano:

Please refer to your supplemental new drug application dated July 10, 2006, received July 12, 2006, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Transderm Scop® (scopolamine) Transdermal Therapeutic System, 1.5 mg.

We acknowledge receipt of your submission dated September 08, 2006.

This "Changes Being Effected" supplemental new drug application provides for changes to the label in the following manner:

a. To add the following paragraph to the package insert (PI) and patient package insert (PPI):

> "Skin burns have been reported at the patch site in several patients wearing an aluminized transdermal system during a magnetic resonance imaging scan (MRI). Because Transderm Scōp® contains aluminum, it is recommended to remove the system before undergoing an MRI."

b. To add the following sentence to the carton and pouch:

> "To avoid possible burns, remove Transderm Scōp® before undergoing an MRI (magnetic resonance imaging) procedure."

We completed our review of this supplemental new drug application, and it is approved, effective on the date of this letter, for use as recommended in the final printed labeling (FPL) submitted on July 10, 2006.

Submit content of labeling [21 CFR 314.50(l)] in structured product labeling (SPL) format, as described at http://www.fda.gov/oc/datacouncil/spl.html, that is identical in content to the submitted labeling dated July 10, 2006. Upon receipt and verification, we will transmit that version to the National Library of Medicine for posting on the DailyMed website.

In addition, submit three copies of the introductory promotional materials that you propose to use for this product. Submit all proposed materials in draft or mock-up form, not final print. Send one copy to this division and two copies of both the promotional materials and the package insert directly to:

Food and Drug Administration
Center for Drug Evaluation and Research
Division of Drug Marketing, Advertising, and Communications
5901-B Ammendale Road
Beltsville, MD 20705-1266

We remind you that you must comply with the requirements for an approved NDA set forth under 21 CFR 314.80 and 314.81.

If you have any questions, call Giuseppe Randazzo, Regulatory Project Manager, at (301) 796-0980.

Sincerely,

{See appended electronic signature page}

Joyce Korvick, M.D., M.P.H.
Deputy Director
Division of Gastroenterology Products
Office of Drug Evaluation III
Center for Drug Evaluation and Research

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

/s/

Joyce Korvick

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