



NDA 17-874/S-018/S-027

Novartis Consumer Health, Inc.
Attention: Vincent De Stefano
Associate Director, Regulatory Affairs
560 Morris Avenue
Summit, NJ 07901-1312

Dear Mr. De Stefano:

Please refer to your supplemental new drug applications dated June 14, 1988 (S-018) and June 28, 1994 (S-027) submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Transderm Scop® (scopolamine), 1.5mg Transdermal Therapeutic System.

We acknowledge receipt of your submission dated March 21, 2001.

We note that supplement #027 was submitted to both this Division and the Division of Anesthetic, Critical Care, and Addiction Drug Products. We further acknowledge that this supplement was approved by the Division of Anesthetic, Critical Care, and Addiction Drug Products on October 27, 1997.

Please note that supplement #027 will supercede supplement #018. Therefore, we will not review supplement #018, but it will be retained in our files.

We have completed the review of supplement #027, as amended, and have concluded that adequate information has been presented to demonstrate that the drug product is safe and effective for use as recommended in the submitted final printed labeling. Accordingly, this supplemental application is approved effective on the date of this letter.

If a letter communicating important information about this drug product (i.e., a "Dear Health Care Professional" letter) is issued to physicians and others responsible for patient care, we request that you submit a copy of the letter to this NDA and a copy to the following address:

MEDWATCH, HF-2
FDA
5600 Fishers Lane
Rockville, MD 20857

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 Melaine Shin, R.Ph., Regulatory Project Manager, at (301) 594-5793.

Sincerely,

{See appended electronic signature page}

Russell Katz, M.D.
Director
Division of Neuropharmacological Drug Products
Office of Drug Evaluation I
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/

Russell Katz
7/26/01 10:51:01 AM