DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 20-076/S-027

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

Please refer to your supplemental new drug application dated June 29, 2004, received June 30, 2004, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Habitrol® (nicotine transdermal system)

We acknowledge receipt of your submissions dated August 2, 2004, and September 24, 2004.

This supplemental application proposes to eliminate the disposal tray.

We have completed our review of this application, as amended. This application is approved, effective on the date of this letter, for use as recommended in the agreed upon labeling text.

The final printed labeling (FPL) must be identical to the approved draft labeling (carton label, Self Help Guide submitted August 2, 2004, and the CD Script submitted September 24, 2004) and must be formatted in accordance with the requirements of 21 CFR 201.66.

Please submit the FPL electronically according to the guidance for industry titled Providing Regulatory Submissions in Electronic Format – NDA. For administrative purposes, this submission should be designated "FPL for approved supplement NDA 20-076/S-027." Approval of this submission by FDA is not required before the labeling is used.

If you issue a letter communicating important information about this drug product (i.e., a "Dear Health Care Professional" letter), we request that you submit a copy of the letter to this NDA and a copy to the following address:

MEDWATCH, HFD-410
FDA
5600 Fishers Lane
Rockville, MD 20857

We remind you that you must comply with reporting requirements for an approved NDA (21 CFR 314.80 and 314.81).

If you have any questions, call Laura Shay, Regulatory Project Manager, at (301) 827-2274.

Sincerely yours,

{See appended electronic signature page}

Charles Rosebraugh, M.D., M.P.H.
Deputy Director
Division of Over-the-Counter Drug Products
Office of Drug Evaluation V
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/

Curtis Rosebraugh

10/21/04 08:02:47 AM