DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 20-076/S-029

Novartis Consumer Health, Inc.
Attention: Rich Cuprys
Global Head, Regulatory Affairs
200 Kimball Drive
Parsippany, NJ 07054-0622

Dear Mr. Cuprys:

Please refer to your supplemental new drug application dated January 23, 2006, received January 24, 2006, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Habitrol® (7, 14, and 21 mg nicotine transdermal system) patch.

This supplemental new drug application provides for removal of the self-help CD from all sizes of Habitrol packaging. This supplement also includes revisions to the labeling to reflect this change and to add an 800 number for consumers to order the CD upon request.

We have completed our review of this application. 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 self-help guide and carton labels submitted January 23, 2006, and must be formatted in accordance with the requirements of 21 CFR 201.66.

Please submit an electronic version of the FPL according to the guidance for industry titled *Providing Regulatory Submissions in Electronic Format - NDA.* Alternatively, you may submit 20 paper copies of the FPL as soon as it is available but no more than 30 days after it is printed. Individually mount 15 of the copies on heavy-weight paper or similar material. For administrative purposes, designate this submission "**FPL for approved supplement NDA 20-076/S-029**." 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
Food and Drug Administration
WO 22, Room 4447
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

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) 796-0994.

Sincerely,

{See appended electronic signature page}

Andrea Leonard-Segal, MD
Director
Division of Nonprescription Clinical Evaluation
Office of Nonprescription Products
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/

Andrea Segal

5/5/2006 10:54:49 AM