DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
Rockville MD 20857

NDA 20-076/S-021

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

Dear Mr. DeStefano:

Please refer to your supplemental new drug application dated January 29, 2002, received January 30, 2002, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Habitrol (21 mg, 14 mg, and 7 mg nicotine transdermal system).

This Changes Being Effected supplemental new drug application provides for revised final printed labeling which incorporates the current pregnancy/breast-feeding warning, as requested in FDA's correspondence of August 17, 2001.

We have completed the review of this supplemental application 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 (carton and pouch labeling, self-help guide, and compact disc submitted January 29, 2002). Accordingly, the supplemental application is approved effective on the date of this letter.

The following minor editorial revisions should be made to the 21 mg, 14 mg, and 7 mg Drug Facts carton labeling at the time of the next printing and noted in the following annual report.

1. Under ***Warnings***, **Ask a doctor before use if you have**, delete the period at the end of the sentence in the third bulleted statement.

2. Under ***Directions***, delete the period at the end of the sentence in the second bulleted statement.

3. Under ***Inactive ingredients***, delete the period after "copolymer".

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 Elaine Abraham, Project Manager, at (301) 827-2301.

Sincerely,

{See appended electronic signature page}

Linda M. Katz, 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/

Charles Ganley
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