DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

NDA 20-076/S-011

NOV 12 1999

Novartis Consumer Health, Inc.
Attention: Mr. Timothy R. Dring
Associate Director, Regulatory Affairs
560 Morris Avenue
Summit, New Jersey 07901-1312

Dear Mr. Dring:

Please refer to your supplemental new drug application dated December 3, 1998, received December 9, 1998, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Habitrol (nicotine transdermal system), 21, 14, and 7 mg/day patches.

Please also refer to the Agency approvable letters dated December 31, 1996 and June 2, 1999.

We acknowledge receipt of your submissions dated July 7 and November 5 and 11, 1999. Your submission of July 7, 1999 constituted a complete response to our June 2, 1999 action letter.

This supplemental new drug application provides for the over-the-counter (OTC) marketing of Habitrol (nicotine transdermal system), 21, 14, and 7 mg/day patches to adults (those who are at least 18 years of age) for use as an aid to stop smoking cigarettes. This age restriction is essential to the Agency's finding that this product is safe and effective for OTC use.

We have completed the review of this supplemental application, 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 labeling dated November 5, 1999. Accordingly, the supplemental new drug application is approved effective on the date of this letter.

The final printed labeling (FPL) must be identical to the labeling enclosed in the November 5, 1999 submission.

Please submit 20 copies of the FPL as soon as it is available, in no case more than 30 days after it is printed. Individually mount ten of the copies on heavy-weight paper or similar material. For administrative purposes, this submission should be designated "FPL for approved NDA 20-076/S-011." Approval of this submission by FDA is not required before the labeling is used.

We remind you of your Phase 4 commitments specified in your submission dated November 11, 1999. These commitments, along with any completion dates agreed upon, are listed below.

You have provided plans for marketing and surveillance designed to ensure that retailers and distributors of your products will only sell them to persons 18 years of age or older, and to include mechanisms, in addition to the proposed labeling, to ensure that the product cannot be sold in any manner or form that would allow a person to obtain the products without first presenting proof of lawful age.

Safety Surveillance:

You have committed to conduct safety surveillance to detect and investigate emergent patterns of misuse and/or abuse of OTC Habitrol, including

A. monitoring of standard, annual epidemiologic surveys of teenage drug abuse;
B. monitoring media and wire services;
C. evaluating all reports to determine if such cases represent a trend suggestive of a larger problem, and making a report of such a problem to FDA along with a proposal for remediation.

Marketing Restrictions and Compliance Surveillance:

You have also committed to marketing the Habitrol Patch in a manner which will ensure compliance with the approved labeling. The plan includes the following elements:

A. Targeting any advertisement to adult (≥18 years) smokers who are motivated to attempt smoking cessation.
B. Packaging of each patch in child-resistant pouches and of each carton in tamper-evident shrink-wrap, and including a disposal tray in each carton to restrict access to used patches by children or pets.
C. Restriction of distribution to retail pharmacies, food/grocery stores/supermarkets, mass merchandisers, and club warehouses, the majority of which will be equipped with UPC bar code scanners to assist in compliance with sales restrictions. The products will not be distributed to other channels, including convenience stores or vending machines.
D. Training of retailers will be provided regarding the marketing restrictions. Measures including random audits will be implemented to monitor retail distribution to detect any instances of product diversion or inappropriate sale. If, through the surveillance program, violations of the conditions of sale are identified the retailer will be retrained to bring the store into compliance, or distribution to the outlet in question will cease.
E. Encouraging retailers to shelve Habitrol in an appropriate area of the store to deter theft, and to program UPC codes to display a prompt to verify purchaser's age.
F. Not offering direct-to-consumer "trial size" or "sample" packs.
G. Making available a free smoking cessation program (toll-free phone number on labeling).

H. Making available a product information program for health care professionals.

As stated in your letter dated November 11, 1999, you agreed to revise the labeling for this drug product at the time of the next printing or within 180 days, whichever comes first, as follows:

1. Delete the statement, "This patch has not been studied in persons under 18 years of age."See D. 12, above and page 7 of the audio tape transcript.

2. In the self-help guide, move the chart on page 21 to page 22 to follow paragraph 2, so that the warnings are not separated.

3. Regarding the self-help guide, page 30, Your Daily Success Calendar, it is still unclear how the smoker (who smokes 10 or less cigarettes per day) can use this calendar. The instructions for the quit day (which day on the calendar), starting dose, and duration of use at that dose should be clearer.

4. Delete the phrases, "NEW NOW WITHOUT A PRESCRIPTION" and "FULL PRESCRIPTION STRENGTH" from all parts of the labeling after the first 6 months of OTC marketing.

Please be advised that, as of April 1, 1999, all applications for new active ingredients, new dosage forms, new indications, new routes of administration, and new dosing regimens are required to contain an assessment of the safety and effectiveness of the product in pediatric patients unless this requirement is waived or deferred (63 *FR* 66632). We are waiving the pediatric study requirement for this action on this application.

In addition, please submit three copies of the introductory promotional materials that you propose to use for this product. All proposed materials should be submitted in draft or mock-up form, not final print. Please submit one copy to this Division and two copies of both the promotional materials and the labeling directly to:

Division of Drug Marketing, Advertising, and Communications, HFD-40
Food and Drug Administration
5600 Fishers Lane
Rockville, Maryland 20857

If a letter communicating important information about this drug product (i.e., a "Dear Health Care Practitioner" 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

Please submit one market package of the drug product when it is available.

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

In line with Center for Drug Evaluation and Research policy, oversight of this application is being transferred to the Division of Over-the-Counter Drug Products. If you have any questions, contact Babette Merritt, Project Manager, at (301) 827-2222.

Sincerely yours,

MD

Charles Gabley, M.D.
Director
Division of Over-the-Counter Drug Products
Office of Drug Evaluation V
Center for Drug Evaluation and Research

Cynthia G. McCormick, M.D.
Director
Division of Anesthetic, Critical Care,
and Addiction Drug Products
Office of Drug Evaluation II
Center for Drug Evaluation and Research