



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
Rockville, MD 20857

NDA 20-076/S-025

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

Dear Mr. DeStefano:

Please refer to your supplemental new drug application(s) submitted August 11, 2003, received August 12, 2003, under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Habitrol® (nicotine transdermal system).

We also refer to your amendment dated October 17, 2003, and December 17, 2003.

This supplemental application provides for minor changes to the carton label.

We 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 submitted labeling (carton labels submitted December 17, 2003), 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. Alternatively, you may submit 20 paper copies of the FPL as soon as it is available, in no case more than 30 days after it is printed. Please individually mount ten of the copies on heavy-weight paper or similar material. For administrative purposes, this submission should be designated "FPL for approved supplement NDA 20-076/S-025." 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

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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, Laura Shay, Regulatory Project Manager, at (301) 827-2274.

Sincerely,

*{See appended electronic signature page}*

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

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/s/

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Curtis Rosebraugh  
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