DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

JUL 10 1997

TRANSMITTED VIA FACSIMILE

Timothy R. Dring
Assistant Director, Regulatory Affairs
Novartis Consumer Health, Inc.
581 Main Street
Woodbridge, NJ 07095

Re: NDA 20-076
Habitrol (Nicotine transdermal system)
MACMIS File ID #5594

Dear Mr. Dring:

This letter is in reference to Novartis Consumer Health, Inc.'s (Novartis) submission, dated April 4, 1997, of promotional materials under cover of FDA Form 2253 for Habitrol (nicotine transdermal system). This submission included two "Dear Doctor" letters and a "Dear Pharmacist" concerning the benefits of prescription Habitrol in smoking cessation efforts. The Division of Drug Marketing, Advertising, and Communications (DDMAC) regards these letters to be lacking in fair balance or misleading under the Federal Food, Drug, and Cosmetic Act and the regulations promulgated thereunder.

DDMAC's specific objection is that these letters fail to present a fair balance between information relating to the side effects and contraindications and information relating to the effectiveness of the drug. These letters present the benefits of Habitrol in smoking cessation. However, Novartis fails to present the most frequently observed adverse events associated with the use of this drug or that nicotine from any source may be toxic and addictive. Therefore, these letters are misleading.

Novartis should immediately suspend all promotional activities and materials that convey or contain the allegedly violative claims or information identified in this letter until these allegations are resolved. Novartis should submit a written response to DDMAC on or before July 25, 1997, describing the steps that it has taken to ensure that these activities and the use of these materials have been suspended.

Novartis should address any correspondence or additional questions to the undersigned at the Division of Drug Marketing, Advertising, and Communications, HFD-40, Rm 17 B-17, 5600 Fishers Lane, Rockville, Maryland 20857. DDMAC reminds Novartis that only written communications are considered official.

In all future correspondence regarding this matter, please refer to MACMIS ID #5594, in addition to the NDA number.

Sincerely,

Stephen W. Sherman
Regulatory Review Officer
Division of Drug Marketing,
Advertising, and Communications