DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

FOI

APR 6 1998

TRANSMITTED BY FACSIMILE

Vivian Chester
Vice President
Regulatory Affairs
McNeil Consumer Products Company
7050 Camp Hill Road
Fort Washington, PA 19034-2299

Re: NDA 20-714
Nicotrol Inhaler (nicotine inhalation system)
MACMIS File ID #6413

Dear Ms. Chester:

This letter is in reference McNeil Consumer Products Company's (McNeil) submission of promotional materials under cover of Form FDA 2253 for Nicotrol Inhaler (nicotine inhalation system). These materials were revised in response to DDMAC's letter dated March 19, 1998, objecting to the dissemination of false or misleading promotional materials. The revised materials included a 30-second television advertisement, photocopies of the information available on the product's website, and a direct-to-consumer print advertisement. The Division of Drug Marketing, Advertising, and Communications (DDMAC) regards the revised television commercial to be false or misleading under the Federal Food, Drug, and Cosmetic Act (Act) and regulations promulgated thereunder. Specific objections are described below.

Fair Balance

The television advertisement fails to sufficiently reveal material facts with respect to consequences that may result from the use of the drug in light of the representations made concerning the use of the Nicotrol Inhaler as recommended or suggested in the advertisement. The communication of important information related to limitations to the use of the drug is inadequate. Competing multiple visual backgrounds in the main viewing area distract the viewers' attention from the supers containing important information that the product is available "[b]y prescription only ..." and it "[m]ust be used as part of a smoking cessation program." These supers are presented in a relatively small size at the bottom of the screen. Because the important information in these supers is not reinforced in the accompanying oral presentation, a purely visual presentation should be

sufficiently prominent to attract attention to allow the viewer to process the information. These supers are insufficient to achieve their intended effect.

Furthermore, the advertisement does not adequately provide for the dissemination of the approved product labeling, or "adequate provision." The super that directs viewers to "product information in pharmacies and doctors' offices" is insufficient. The concept of this provision is to communicate information concerning the approved product labeling and to convey to patients that these health care providers are an important source of such product information. McNeil should encourage viewers to obtain additional product information from their doctor or pharmacist.

Website and Direct-to-Consumer Print Advertisement

DDMAC has no objections to the revisions instituted to correct the misleading representations that were present on the Website and in the direct-to-consumer print advertisement submitted previously.

McNeil should immediately discontinue the use of all promotional activities that convey or contain the allegedly violative claims or information identified in this letter until these allegations are resolved. McNeil should submit a written response to DDMAC on or before April 17, 1998, confirming that McNeil discontinued airing the television commercial as of April 3, 1998, as represented in a teleconference between McNeil and DDMAC on April 1, 1998.

If McNeil has any questions or comments, please contact the undersigned by facsimile at (301) 594-6771, or at the Food and Drug Administration, Division of Drug Marketing, Advertising and Communications, HFD-40, Rm 17B-20, 5600 Fishers Lane, Rockville, MD, 20857. DDMAC reminds McNeil that only written communications are considered official.

In all future correspondence regarding this matter, please refer to MACMIS ID #6413 in addition to the NDA number.

Sincerely,

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