



Food and Drug Administration
Rockville MD 20857

MAR 19 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 included one 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 these materials to be false or misleading under the Federal Food, Drug, and Cosmetic Act (Act) and regulations promulgated thereunder. Specific objections are described below.

Television Advertisement

The television advertisement is lacking in fair balance or otherwise misleading for a number of reasons related to the required presentation of risk information associated with the use of Nicotrol Inhaler. First, the risk information is not presented with a prominence reasonably comparable to the presentation of information about product efficacy. During the audio presentation of the risk information, there are six different visual presentations that distract attention from the presentation of the required risk information. This visual distraction interferes significantly with the audio presentation. In addition, the volume of the audio presentation decreases during presentation of the risk information.

Second, McNeil combines the "super" stating that Nicotrol must be used as part of a smoking cessation program with a background that makes it difficult to read.

Third, the advertisement depicts the person casually inhaling on the unit. Using the inhaler requires a concerted effort to draw nicotine from the unit, and depicting it as easy to inhale is false or misleading.

Finally, the disclosure relating to the component of the "adequate provision" procedure that directs viewers to their doctor or pharmacist for additional product information does not adequately convey this information. Simply recommending that the viewer "ask your doctor," undermines the purpose of this part the "adequate provision" procedure, which is to let the viewer know that there is additional product information that is available from different sources.

Website and Direct-to-Consumer Print Advertisement

The website and print advertisement state "[s]imply hold the inhaler between your fingers and draw on it...." This statement implies one simply draws on the inhaler as one would a cigarette to obtain the nicotine from the product. As noted above, using the inhaler requires a concerted effort to draw nicotine from the unit, and depicting it as easy to draw is false or misleading. Dissemination of promotional materials that convey false or misleading representations is a violation of the Act.

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 3, 1998, describing the steps that it has taken to ensure that the use of these materials have been suspended and to ensure that such violations will not occur again.

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.

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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