DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
Rockville MD 20857

NDA 20-536/S-010

Pharmacia and Upjohn Company
Attention: Fred J. Frullo
Associate Director, Regulatory Affairs
100 Route 206 North
Peapack, New Jersey 07977

Dear Mr. Frullo:

Please refer to your supplemental new drug application dated December 21, 2001, received December 26, 2001, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Nicotrol Patch (15 mg nicotine transdermal system).

We acknowledge receipt of your submissions dated April 23 and April 26, 2002.

This supplemental new drug application provides revised labeling which incorporates the "Drug Facts" format.

We have completed the review of this supplemental application, as amended, and it is approved effective on the date of this letter.

The final printed labeling (FPL) must be identical to the submitted draft labeling (pouch labeling, Taking Action Handbook, Staying Smoke Free Handbook, and the Audiotape Script submitted April 23, 2002, and 7 and 14 patch Starter Kit and Refill cartons and Information and Instructions Leaflet submitted April 26, 2002) and must be formatted in accordance with the requirements of 21 CFR 201.66.

Please submit the copies of final printed labeling (FPL) electronically according to the guidance for industry titled *Providing Regulatory Submissions in Electronic Format - NDA* (January 1999). Alternatively, you may submit 20 paper copies of the FPL as soon as it is available but no 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 20-536/S-010. Approval of this submission by FDA is not required before the labeling is used.

The following minor editorial revisions should be incorporated in the final printed labeling and submitted to the NDA with the final printed labeling for this supplement.

1. Bold the word "more" in the statement, "For people who smoke **more** than 10 cigarettes a day" on the principal display panel (PDP).

2. Revise the directions in diagram 5 of the Information and Instructions Leaflet to include the direction to fold the sticky ends of the used patch together, to be consistent with the Drug Facts labeling. This statement does not have to be bolded.

3. Revise the directions in diagram 5 of the Information and Instructions Leaflet by combining bullets 7 and 8 under one bullet to read, "Stop using the patch at the end of 6 weeks. If you still feel the need to use the patch talk to your doctor."

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

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

If you have any questions, call Elaine Abraham, Project Manager, at (301) 827-2301.

Sincerely,

{See appended electronic signature page}

Linda M. Katz, M.D., M.P.H.
Deputy Director
Division of Over-the-Counter Drug Products
Office of Drug Evaluation V
Center for Drug Evaluation and Research

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

Linda Katz

7/23/02 02:03:44 PM