CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER: NDA 20-714

CORRESPONDENCE

D. MCNEAL

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

NDA 20-714

APR 15 1997

Pharmacia and Upjohn Company
7000 Portage Road
Kalamazoo, Michigan 49001

Attention: Raymond E. Dann, Ph.D.
Director, OTC Regulatory Affairs

Dear Dr. Dann:

Please refer to your new drug application submitted pursuant to section 505(b) of the Federal Food, Drug, Cosmetic Act for Nicotrol Inhaler (nicotine inhalation system), 10 mg.

During a conversation by telephone on March 19, 1997 between Beth Thielking of Pharmacia and Upjohn and Bonnie McNeal of this Division, an agreement was made to delay a meeting to discuss the development plans for the over-the-counter (OTC) marketing of the Nicotrol Inhaler, requested in your submission of January 24, 1997, until after the decision on the approvability of the product for prescription use. This decision will most likely be made on or before May 2, 1997, the User Fee Goal date.

If you have any questions, please contact Bonnie McNeal, Project Manager, at (301) 443-3741.

Sincerely,

Curtis Wright, M.D., M.P.H.
Acting Director
Division of Anesthetic, Critical Care and
Addiction Drug Products, HFD-170
Office of Drug Evaluation III
Center for Drug Evaluation and Research

cc:
Original NDA 20-714
HFD-170/Div. Files
HFD-170/CSO/B.McNeal
HFD-170/JLongmire/CWinchell/CWright

Drafted by: BmcNeal/March 21, 1997/n:cso/bonnie/n20714.gc
Initialed by: CMoody/4-14-97
final: sl/4-15-97

GENERAL CORRESPONDENCE

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

McNeal

Food and Drug Administration
Rockville MD 20857

NDA 20-714

MAY 15 1996

Pharmacia Inc.
Post Office Box 16529
Columbus, Ohio 43216-6529

Attention: Barbara L. Gunther
Manager, Regulatory Affairs

Dear Ms. Gunther:

We have received your new drug application (NDA) submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for the following:

Name of Drug Product: Nicotrol Inhaler (nicotine inhalation system), 10 mg/unit

Therapeutic Classification: Standard

Date of Application: May 1, 1996

Date of Receipt: May 2, 1996

Our Reference Number: 20-714

Unless we notify you within 60 days of our receipt date that the application is not sufficiently complete to permit a substantive review, this application will be filed under section 505(b) of the Act on July 1, 1996 in accordance with 21 CFR 314.101(a).

Should you have any questions, please contact:

Bonnie McNeal
Consumer Safety Officer
Telephone: (301) 443-3741

Please cite the NDA number listed above at the top of the first page of any communications concerning this application.

Sincerely yours,

Corinne P. Moody
Acting Chief, Project Management Staff
Division of Anesthetic, Critical Care and
Addiction Drug Products, HFD-170
Office of Drug Evaluation III
Center for Drug Evaluation and Research

cc:
Original NDA 20-714
HFD-170/Div. Files
HFD-170/CSO/B.McNeal
HFD-170/Longmire/Doddapaneni/Geyer/Ross/Permutt
DISTRICT OFFICE

drafted: Bmc/May 8, 1996/n20714.ack on N drive under Bonnie

R/D by: C.Moody/5-10-96
Final: S.Liu/5-14-96

ACKNOWLEDGEMENT (AC)