CENTER FOR DRUG EVALUATION AND RESEARCH

Application Number: NDA 20-714

APPROVAL LETTER

McNeal

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

NDA 20-714

MAY 2 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 (NDA) dated May 1, 1996, received May 2, 1996, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Nicotrol Inhaler (nicotine inhalation system), 10 mg/cartridge (4 mg delivered).

We acknowledge receipt of your submissions dated June 5, June 7, June 24, September 6, November 6, and December 5, 1996; January 13, January 29, March 7, March 20, March 24, March 26, April 7, April 15, April 24, April 29, April 30 and May 1, 1997. The User Fee goal date for this application is May 2, 1997.

This new drug application provides for a new nicotine replacement product as an aid to smoking cessation.

We have completed the review of this application, including the submitted draft labeling, and have concluded that adequate information has been presented to demonstrate that the drug product is safe and effective for use as recommended in the enclosed marked-up draft labeling. Accordingly, the application is approved effective on the date of this letter.

The final printed labeling (FPL) must be identical to the enclosed marked-up draft labeling. Marketing the product with FPL that is not identical to this draft labeling may render the product misbranded and an unapproved new drug.

Please submit 20 copies of the FPL as soon as it is available, in no case 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 "FINAL PRINTED LABELING" for approved NDA 20-714. Approval of this submission by FDA is not required before the labeling is used.

Should additional information relating to the safety and effectiveness of the drug become available, revision of that labeling may be required.

We remind you of your Phase 4 commitments specified in your submission dated May 1, 1997. These commitments, along with any completion dates agreed upon, are listed below.

Protocols, data, and final reports should be submitted to your IND for this product and a copy of the cover letter sent to this NDA. Should an IND not be required to meet your Phase 4 commitments, please submit protocol, data, and final reports to this NDA as correspondences. In addition, we request under 21 CFR 314.81(b)(2)(vii) that you include in your annual report to this application, a status summary of each commitment. The status summary should include the number of patients entered in each study, expected completion and submission dates, and any changes in plans since the last annual report. For administrative purposes, all submissions, including labeling supplements, relating to these Phase 4 commitments must be clearly designated "Phase 4 Commitments."

In addition, please submit three copies of the introductory promotional material that you propose to use for this product. All proposed materials should be submitted in draft or mock-up form, not final print. Please submit one copy to this Division and two copies of both the promotional material and the package insert directly to:

Food and Drug Administration
Division of Drug Marketing, Advertising and Communications,
HFD-40
5600 Fishers Lane
Rockville, Maryland 20857

Validation of the regulatory methods has not been completed. At the present time, it is the policy of the Center not to withhold approval because the methods are being validated. Nevertheless, we expect your continued cooperation to resolve any problems that may be identified.

Please submit one market package of the drug product when it is available.

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, 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

ENCLOSURE

cc:
Original NDA 20-714
HFD-170/Div. files
HFD-170/CSO/B.McNeal
HFD-170/JLongmire/DKramer/CLi
HFD-170/SDoddapaneni/HGeyer
HFD-170/JRoss/TPermutt/CMoody/CWinchell/CWright
HFD-002/ORM (with labeling)
HFD-103/Office Director
HFD-101/L.Carter
HFD-820/ONDC Division Director
DISTRICT OFFICE
HF-2/Medwatch (with labeling)
HFD-92/DDM-DIAB (with labeling)
HFD-40/DDMAC (with labeling)
HFD-613/OGD (with labeling)
HFD-735/DPE (with labeling) - for all NDAs and supplements for adverse reaction changes.
HFI-20/Press Office (with labeling)
HFD-021/ACS (with labeling)

Final Draft Init. by:
Supervisory CSO _____
Supervisory MO _____
Supervisory Chem _____
Supervisory Pharm _____
Supervisory PK _____
Supervisory Stat. _____

Drafted by: BmcNeal/May 1, 1997/n:cso/Bonnie/n20714.apr
Initialed by:
final:

APPROVAL (AP) [with Phase 4 Commitments]