# CENTER FOR DRUG EVALUATION AND RESEARCH

**Approval Package for:**

**Application Number: 020667**

**Trade Name: MIRAPEX**

**Generic Name: PRAMIPEXOLE DIHYDROCHLORIDE**

**Sponsor: PHARMACIA & UPJOHN, INC**

**Approval Date: 07/01/97**

**INDICATION(s): PROVIDES FOR THE TREATMENT OF THE SIGNS AND SYMPTOMS OF IDIOPATHIC PARKINSON'S DISEASE.**

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## APPLICATION: 020667

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| | Included | Pending Completion | Not Prepared | Not Required |
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| Approval Letter | X | | | |
| Tenative Approval Letter | | | | X |
| Approvable Letter | | | | X |
| Final Printed Labeling | | X | | |
| Medical Review(s) | X | | | |
| Chemistry Review(s) | X | | | |
| EA/FONSI | X | | | |
| Pharmacology Review(s) | X | | | |
| Statistical Review(s) | X | | | |
| Microbiology Review(s) | | | | X |
| Clinical Pharmacology Biopharmaceutics Review(s) | X | | | |
| Bioequivalence Review(s) | | | | X |
| Administrative Document(s)/ Correspondence | X | | | |

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**Application Number: 020667**

## APPROVAL LETTER

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

Registered Mail
Return Receipt Requested

NDA 20-667

JUL 1 1997

Pharmacia & Upjohn, Inc.
Attention: Ms. Julianna Stewart
Regulatory Affairs Department
7000 Portage Road
Kalamazoo, MI 49001-0199



Dear Ms. Stewart:

Please refer to your new drug application dated December 26, 1995, and your January 7, 1997 resubmission received January 10, 1997, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Mirapex, (pramipexole dihydrochloride), tablets, 0.125 mg, 0.25 mg, 1.0 mg, 1.25 mg, and 1.5 mg.

We also refer to an Agency Approvable letter dated December 23, 1996, and we acknowledge receipt of your submissions dated:

| | | |
|---|---|---|
| January 6, 1997 | January 8, 1997 | January 10, 1997 |
| January 24, 1997 | January 27, 1997 | February 5, 1997 |
| February 10, 1997 | February 11, 1997 | March 6, 1997 |
| June 12, 1997 | June 17, 1997 | |

The User Fee goal date for this application is July 10, 1997.

This new drug application provides for the treatment of the signs and symptoms of idiopathic Parkinson's Disease.

We have completed the review of this application, as amended, 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 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 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 20-667. 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.

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 Teresa Wheelous, R.Ph., Regulatory Management Officer, at (301) 594-2850.

Sincerely yours,

APPEARS THIS WAY
ON ORIGINAL

/S/

Robert Temple, M.D.
Director
Office of Drug Evaluation I
Center for Drug Evaluation and Research

ENCLOSURE

APPEARS THIS WAY
ON ORIGINAL

FINAL PRINTED LABELING HAS NOT BEEN SUBMITTED TO THE FDA.

DRAFT LABELING IS NO LONGER BEING SUPPLIED SO AS TO ENSURE ONLY CORRECT AND CURRENT INFORMATION IS DISSEMINATED TO THE PUBLIC.