DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 20-667/S-008

Pharmacia & Upjohn
Attention: Roma Thomas
Regulatory Manager
7000 Portage Road
Kalamazoo, MI 49001

Dear Ms. Thomas:

Please refer to your supplemental new drug application dated July 2, 2002, received August 6, 2002 submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Mirapex (pramipexole dihydrochloride) 0.125, 0.25, 1.0, 1.25, 1.5 mg Tablets.

This supplemental new drug application provides for a labeling revision that adds language about findings in a pigmented rat study.

We have completed our review of this supplemental new drug application, and it is approved, effective on the date of this letter, for use as recommended in the final printed labeling (FPL) submitted on July 2, 2002.

If you issue a letter communicating important information about this drug product (i.e., a "Dear Health Care Professional" letter), 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, contact Teresa Wheelous, R.Ph., Regulatory Management Officer, at (301) 594-2850.

Sincerely,

Russell Katz, M.D.
Acting Director
Division of Neuropharmacological Drug Products
Office of Drug Evaluation I
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/

Russell Katz
5/6/03 08:29:27 AM