DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 20-667/S-014
NDA 20-667/S-017
NDA 20-667/S-018

PRIOR APPROVAL SUPPLEMENT

Boehringer Ingelheim Pharmaceuticals, Inc.
Attention: Heidi C. Reidies, Director Drug Regulatory Affairs
900 Ridgebury Road, P. O. Box 368
Ridgefield, CT 06877

Dear Ms. Reidies:

Please refer to your supplemental new drug applications dated February 21, 2006, received February 22, 2006 (supplement 14), dated February 13, 2007, received February 15, 2007 (supplement 17), and dated May 31, 2007, and received June 5, 2007 (supplement 18), submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for MIRAPEX (pramipexole dihydrochloride) 0.125 mg, 0.25 mg, 0.5 mg, 1 mg, and 1.5 mg Tablets.

Supplements 14 and 17 provide for the addition of information regarding intense urges to gamble, increased sexual urges, and other intense urges in patients using medications to treat Parkinson's disease. Supplement 18 provides for the addition of information regarding melanoma to the PRECAUTIONS section of the package insert.

We also refer to the letter dated August 13, 2008, to the Division of Neurology Products, in which you agreed to add the following text to the Information for Patients subsection of the PRECAUTIONS section:

> "There have been reports of patients experiencing intense urges to gamble, increased sexual urges, and other intense urges and the inability to control these urges while taking one or more of the medications that increase central dopaminergic tone, that are generally used for the treatment of Parkinson's disease, including Mirapex. Although it is not proven that the medications caused these events, these urges were reported to have stopped in some cases when the dose was reduced or the medication was stopped. Prescribers should ask patients about the development of new or increased gambling urges, sexual urges or other urges while being treated with Mirapex. Patients should inform their physician if they experience new or increased gambling urges, increased sexual urges or other intense urges while taking Mirapex. Physicians should consider dose reduction or stopping the medication if a patient develops such urges while taking Mirapex."

We completed our review of these applications and they are approved, effective on the date of this letter, for use as recommended in the agreed-upon labeling text.

The final printed labeling (FPL) must be identical to the enclosed labeling (text for the package insert).

Please submit an electronic version of the FPL according to the guidance for industry titled *Providing Regulatory Submissions in Electronic Format - NDA*. 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. Individually mount 15 of the copies on heavy-weight paper or similar material. For administrative purposes, designate this submissions "**FPL for approved supplement NDA 20-667/S-014, S-017 and S-018**." Approval of this submission by FDA is not required before the labeling is used.

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
Food and Drug Administration
5515 Security Lane
HFD-001, Suite 5100
Rockville, MD 20852

We remind you that you must comply with reporting requirements for an approved NDA (21 CFR 314.80 and 314.81).

If you have any questions, call Beverly Conner, PharmD, Regulatory Management Officer, at (301) 796-1171.

Sincerely,

{See appended electronic signature page}

Russell Katz, M.D.
Director
Division of Neurology Products
Office of Drug Evaluation I
Center for Drug Evaluation and Research

Enclosed (labeling)

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

12/31/2008 08:18:34 AM