DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville, MD 20857

ANDA 77-724

Barr Laboratories, Inc.
Attention: Nicholas Tantillo
Sr. Director, Regulatory Affairs
223 Quaker Road
P.O. Box 2900
Pomona, NY 10970

Dear Sir:

This is in reference to your abbreviated new drug application (ANDA) dated May 26, 2005, submitted pursuant to section 505(j) of the Federal Food, Drug, and Cosmetic Act (the Act), for Pramipexole Dihydrochloride Tablets, 0.125 mg, 0.25 mg, 0.5 mg, 1 mg, and 1.5 mg.

Reference is made to the tentative approval letter issued by this office on October 29, 2007, and to your amendments dated October 28, and October 31, 2005, January 9, 2006, and September 4, and December 4, 2007.

We have completed the review of this ANDA and have concluded that the drug is safe and effective for use as recommended in the submitted labeling. Accordingly, the ANDA is approved, effective on the date of this letter. The Division of Bioequivalence has determined your Pramipexole Dihydrochloride Tablets, 0.125 mg, 0.25 mg, 0.5 mg, 1 mg, and 1.5 mg, to be bioequivalent and, therefore, therapeutically equivalent to the reference listed drug (RLD), Mirapex Tablets 0.125 mg, 0.25 mg, 0.5 mg, 1 mg, and 1.5 mg, respectively, of Boehringer Ingelheim. Your dissolution testing should be incorporated into the stability and quality control program using the same method proposed in your ANDA.

The RLD upon which you have based your ANDA, Mirapex Tablets of Boehringer Ingelheim, is subject to periods of patent protection. The following patents with their expiration dates are currently listed in the agency's publication titled Approved

Drug Products with Therapeutic Equivalence Evaluations (the "Orange Book") for this drug product:

U.S. Patent Number	Expiration Date
4,886,812 (the '812 patent)	March 25, 2011
6,001,861 (the '861 patent)	January 16, 2018
6,194,445 (the '445 patent)	January 16, 2018

With respect to the '861 and '445 patents, your ANDA contains statements under section 505(j)(2)(A)(viii) of the Act indicating that these are method of use patents, and that they do not claim any indication for which you are seeking approval under your ANDA.

With respect to the '812 patent, your ANDA contains a paragraph IV certification under section 505(j)(2)(A)(vii)(IV) of the Act stating that the '812 patent is invalid, unenforceable, or will not be infringed by your manufacture, use, or sale of Pramipexole Dihydrochloride Tablets, 0.125 mg, 0.25 mg, 0.5 mg, 1 mg, and 1.5 mg, under this ANDA. Section 505(j)(5)(B)(iii) of the Act provides that approval of an ANDA shall be made effective immediately, unless an action was brought against Barr Laboratories, Inc. (Barr) for infringement of the '812 patent that was the subject of the paragraph IV certification. This action must have been brought against Barr prior to the expiration of 45 days from the date the notice you provided under section 505 (j)(2)(B)(i) was received by the NDA/patent holder(s). You have notified the agency that Barr complied with the requirements of section 505(j)(2)(B) of the Act, and that litigation for infringement of the '812 patent was brought against Barr within the statutory 45-day period in the United States District Court for the District Court of Delaware [Boehringer Ingelheim Internation GmbH and Boehringer Ingelheim Pharmaceuticals, Inc. v. Barr Laboratories, Inc. and Barr Pharmaceuticals, Inc., Civil Action No. 05-700]. Although this litigation remains ongoing, the 30-month period identified in section 505(j)(5)(B)(iii) of the Act, during which time FDA was precluded from approving your ANDA, has expired.

With respect to 180-day generic drug exclusivity, the agency has determined that Barr was the first ANDA applicant to submit a substantially complete ANDA with a paragraph IV certification to the '812 patent. Therefore, with this approval, Barr is eligible for 180-days of generic drug exclusivity for Pramipexole Dihydrochloride Tablets, 0.125 mg, 0.25 mg, 0.5 mg, 1 mg, and 1.5 mg. This exclusivity, which is provided for under

section 505(j)(5)(B)(iv) of the Act, will begin to run from the date of the commercial marketing identified in section 505(j)(5)(B)(iv). Please submit correspondence to this ANDA informing the agency of the date the exclusivity begins to run.

Under section 506A of the Act, certain changes in the conditions described in this ANDA require an approved supplemental application before the change may be made.

Postmarketing reporting requirements for this ANDA are set forth in 21 CFR 314.80-81 and 314.98. The Office of Generic Drugs should be advised of any change in the marketing status of this drug.

Promotional materials may be submitted to FDA for comment prior to publication or dissemination. Please note that these submissions are voluntary. If you desire comments on proposed launch promotional materials with respect to compliance with applicable regulatory requirements, we recommend you submit, in draft or mock-up form, two copies of both the promotional materials and package insert directly to:

Food and Drug Administration
Center for Drug Evaluation and Research
Division of Drug Marketing, Advertising, and Communications
5901-B Ammendale Road
Beltsville, MD 20705

We call your attention to 21 CFR 314.81(b)(3) which requires that all promotional materials be submitted to the Division of Drug Marketing, Advertising, and Communications with a completed Form FDA 2253 at the time of their initial use.

Sincerely yours,

{See appended electronic signature page}

Gary Buehler
Director
Office of Generic Drugs
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/

Robert L. West
2/19/2008 07:11:26 AM
for Gary Buehler