DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville, MD 20857

ANDA 78-804

Barr Laboratories Inc.
Attention: Nicholas Tantillo
Senior Director, Regulatory Affairs
400 Chestnut Ridge Road
Woodcliff Lake, NJ 07677

Dear Sir:

This is in reference to your abbreviated new drug application (ANDA) dated January 31, 2007, submitted pursuant to section 505(j) of the Federal Food, Drug, and Cosmetic Act (the Act), for Aspirin and Dipyridamole Extended-release Capsules, 25 mg and 200 mg.

Reference is also made to your amendments dated May 30, August 10, and November 14, 2007; June 6, August 25, and August 26, 2008; and July 1, July 13, July 14, and July 20, 2009.

We have completed the review of this ANDA and have concluded that adequate information has been presented to demonstrate 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 Aspirin and Dipyridamole Extended-release Capsules, 25 mg and 200 mg, to be bioequivalent and, therefore, therapeutically equivalent to the reference listed drug (RLD), Aggrenox Extended-release Capsules, 25 mg/200 mg of Boehringer Ingelheim Pharmaceuticals, Inc.

Your dissolution testing should be incorporated into the stability and quality control program using the same method proposed in your ANDA. The "interim" dissolution specifications are as follows:

The dissolution testing for aspirin should be conducted in 900 mL of 0.05M acetate buffer, pH 4.5 at 37°C ± 0.5°C using USP apparatus I (basket) at 100 rpm. The test product should meet the following "interim" specification:

NLT (b) (4) (Q) of aspirin dissolved in 45 minutes.

The dissolution testing for dipyridamole should be conducted in 900 mL of 0.1N HCl for the 1st hour and 0.1M phosphate buffer, pH 5.5 thereafter at 37°C ± 0.5°C using USP apparatus I (basket) at 100 rpm. The test product should meet the following "interim" specifications:

Dipyridamole:

Time (hours)	Percent Dissolved
1	(b) (4)
2	(b) (4)
5	(b) (4)
7	NLT (b) (4)

These "interim" dissolution test(s) and tolerances should be finalized by submitting dissolution data from the first three production size batches. These data should be submitted as a "Special Supplement – Changes Being Effected" if there are no revisions to be made to the "interim" specifications, or if the final specifications are tighter than the "interim" specifications. In all other instances, the information should be submitted in the form of a Prior Approval Supplement.

The RLD upon which you have based your ANDA, Boehringer Ingelhein's Aggrenox Extended-release Capsules, 25 mg/200 mg, is subject to a period of patent protection. As noted in the agency's publication titled Approved Drug Products with Therapeutic Equivalence Evaluations (the "Orange Book"), U.S. Patent No. 6,015,577 (the '577 patent), is scheduled to expire on January 18, 2017.

Your ANDA contains a paragraph IV certification to the '577 patent under section 505(j)(2)(A)(vii)(IV) of the Act stating that the patent is invalid, unenforceable, or will not be infringed by your manufacture, use, or sale of Aspirin and Dipyridamole Extended-release Capsules, 25 mg and 200 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 listed '577 patent. You have notified the agency that Barr complied with the requirements of section

505(j)(2)(B) of the Act, and that litigation was initiated against Barr for infringement of the '577 patent in the United States District Court for the District of Delaware [Boehringer Ingelheim Pharma GMBH & CO. KG, DR. Karl Thomae GMBH, Boehringer Ingelheim International GMBH, and Boehringer Ingelheim Pharmaceuticals, Inc., v. Barr Laboratories, Inc. and Barr Pharmaceuticals, Inc., Civil Action No. 07-432 (GMS)]. You further notified the agency that this civil action was dismissed with prejudice on August 14, 2008. Therefore, under section 505(j)(5)(B)(iii) your ANDA is eligible for approval.

With respect to 180-day generic drug exclusivity for Aspirin and Dipyridamole Extended-release Capsules, 25 mg and 200 mg, Barr was the first ANDA applicant to submit a substantially complete ANDA for Aspirin and Dipyridamole Extended-release Capsules, 25 mg and 200 mg, with a paragraph IV certification to the '577 patent. Therefore, with this approval, Barr may be eligible for 180 days of generic drug exclusivity for Aspirin and Dipyridaole Extended-release Capsules, 25 mg and 200 mg. Generic drug exclusivity, which is provided for under section 505(j)(5)(B)(iv) of the Act, begins to run from the date of commercial marketing identified in section 505(j)(5)(B)(iv). Please submit correspondence to this ANDA informing the agency of the date commercial marketing begins. The agency notes that Barr failed to obtain tentative approval of this ANDA within 30 months after the date on which the ANDA was filed. See section 505(j)(5)(D)(i)(IV) of the Act. However, the agency is not making a formal determination at this time of Barr's eligibility for 180-day generic drug exclusivity. It will do so only if another applicant becomes eligible for approval within 180 days after Barr begins commercial marketing of Aspirin and Dipyridamole Extended-release Capsules, 25 mg and 200 mg.

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.

Please note that if FDA requires a Risk Evaluation & Mitigation Strategy (REMS) for a listed drug, an ANDA citing that listed drug also will be required to have a REMS. See section 505-1(i) of the Act.

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.

Within 14 days of the date of this letter, submit updated content of labeling [21 CFR 314.50(1)] in structured product labeling (SPL) format, as described at http://www.fda.gov/oc/datacouncil/spl.html, that is identical in content to the approved labeling. Upon receipt and verification, we will transmit that version to the National Library of Medicine for public dissemination. For administrative purposes, please designate this submission as ***"Miscellaneous Correspondence - SPL for Approved ANDA 78-804".***

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
08/14/2009
Deputy Director, for Gary Buehler