DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville, MD 20857

ANDA 78-189

Barr Laboratories, Inc.
Attention: Nicholas Tantillo
Senior Director, Regulatory Affairs
225 Summit Avenue
Montvale, NJ 07645

Dear Sir:

This is in reference to your abbreviated new drug application (ANDA) dated March 1, 2006, submitted pursuant to section 505(j) of the Federal Food, Drug, and Cosmetic Act (the Act), for Galantamine Hydrobromide Extended-release Capsules, Eq. 8 mg, 16 mg and 24 mg.

This letter corrects our approval letter dated September 15, 2008. That letter incorrectly made reference to the '559 patent in the first paragraph of page 3. This letter will be backdated to the date of the original approval date of September 15, 2008.

Reference is also made to your amendments dated September 18, and October 17, 2006; September 27, 2007; and February 12, May 2, June 2, June 19, and July 16, August 20, August 27, and September 2, 2008.

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 Galantamine Hydrobromide Extended-release Capsules, Eq. 8 mg, 16 mg and 24 mg, to be bioequivalent and, therefore, therapeutically equivalent to the reference listed drug (RLD), Razadyne ER of Janssen Pharmaceutica Products, L.P. (Janssen).

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:

Medium:	50 mM potassium dihydrogen phosphate buffer,pH 6.5
Volume:	900 mL
USP Apparatus:	II (paddle)
Rotational Speed:	50 rpm

The test product should meet the following specifications:

1 hour	(b) (4)
2 hours	(b) (4)
4 hours	(b) (4)
12 hours	NLT (b)

The “interim” dissolution test(s) and tolerances should be finalized by submitting dissolution data for the first three production size batches. Data should be submitted as a Special Supplement – Changes Being Effected when there are no revisions to the “interim” specifications or when 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, Janssens’s Razadyne ER, is subject to periods of patent protection. As noted in the agency's publication titled Approved Drug Products with Therapeutic Equivalence Evaluations (the “Orange Book”), U.S. Patent Nos. 4,663,318 (the '318 patent) and 7,160,559 (the '559 patent) are scheduled to expire on December 14, 2008, and December 20, 2019, respectively.

With respect to both patents, your ANDA contains paragraph IV certifications under section 505(j)(2)(A)(vii)(IV) of the Act stating that the patents are invalid, unenforceable, or will not be infringed by your manufacture, use, or sale of Galantamine Hydrobromide Extended-release Capsules, Eq. 8 mg, 16 mg and 24 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 is brought against Barr Laboratories, Inc. (Barr) for infringement of one or more of the patents that were the subjects of the paragraph IV certifications. 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 litigation for infringement of the ‘318 patent was

brought against Barr in the United States District Court for the District of New Jersey [Janssen Pharmaceutica N.V., Janssen, L.P., Ortho-McNeil Neurologics, Inc., and Sunnaptech, Inc., v. Barr Laboratories, Inc. and Barr Pharmaceuticals, Inc., Civil Action No. 2:06-cv-03008-JAP-MCA]. Litigation for infringement of the '559 patent was also brought against Barr in the United States District Court for the District of New Jersey [Janssen, L.P., Pharmaceutica N.V., and Ortho-McNeil Neurologics, Inc., v. Barr Laboratories, Inc. and Barr Pharmaceuticals, Inc., Civil Action No. 07-1515(JAP)]. You have also notified the agency that the court decided that the '318 patent is invalid, unenforceable, or not infringed; therefore, under section 505(j)(5)(B)(iii) your ANDA is eligible for approval.

With respect to 180-day generic drug exclusivity, we note that Barr was the first ANDA applicant to submit a substantially complete ANDA with a paragraph IV certification to '318 and '559 patents. Therefore, with this approval, Barr is eligible for 180-days of generic drug exclusivity for Galantamine Hydrobromide Extended-release Capsules, Eq. 8 mg, 16 mg and 24 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.

We 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(s) 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 78-189".***

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
9/15/2008 02:57:26 PM
Deputy Director, for Gary Buehler