



ANDA 77-603

Mylan Pharmaceuticals Inc.
Attention: Ronald T. Groman
U.S. Agent for: Alphapharm Pty Ltd.
781 Chestnut Ridge Road
Morgantown, WV 26504-4310

Dear Sir:

This is in reference to your abbreviated new drug application (ANDA) dated February 18, 2005, submitted pursuant to section 505(j) of the Federal Food, Drug, and Cosmetic Act (the Act), for Galantamine Hydrobromide Tablets USP, 4 mg, 8 mg, and 12 mg.

Reference is also made to the tentative approval letter issued by this office on June 1, 2007, and your amendments dated October 24, 2005; March 7, May 20, July 8, August 11, and August 26, 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 Tablets USP, 4 mg, 8 mg, and 12 mg, to be bioequivalent and, therefore, therapeutically equivalent to the reference listed drug (RLD), Razadyne Tablets (formerly Reminyl Tablets) 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 application.

The RLD upon which you have based your ANDA, Janssen's Razadyne Tablets, 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>U.S. Patent Number</u> | <u>Expiration Date</u> |
|-----------------------------|------------------------|
| 4,663,318 (the '318 patent) | December 14, 2008 |
| 6,099,863 (the '863 patent) | June 6, 2017 |
| 6,358,527 (the '527 patent) | June 6, 2017 |

With respect to each of these patents, your ANDA contains paragraph IV certifications under section 505(j)(2)(A)(vii)(IV) of the Act stating that each patent is invalid, unenforceable, or will not be infringed by your manufacture, use, or sale of Galantamine Hydrobromine Tablets USP, 4 mg, 8 mg, and 12 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 Alphapharm Pty Ltd. (Alphapharm) for infringement of one or more of these patents that were the subjects of the paragraph IV certifications. You notified the agency that Alphapharm complied with the requirements of section 505(j)(2)(B) of the Act, and that litigation for infringement of the '318 patent was brought against Alphapharm within the statutory 45-day period in the United States District Court for the District of Delaware [Janssen Pharmaceutica N.V., Janssen, L.P., and Synaptech, Inc. v. Alphapharm Pty Ltd., Civil Action No. 05-420]. The Office of Generic Drugs is aware of an August 27, 2008, district court opinion in which the '318 patent was held invalid. In the absence of a court order or judgment finding in favor of the plaintiff, your ANDA is eligible for final approval based upon the expiration on August 28, 2008, of the 7½ year period identified in sections 505(j)(5)(F)(ii) and 505(j)(5)(B)(iii)¹ of the Act, during which time FDA was precluded from approving your ANDA.

With respect to 180-day generic drug exclusivity, we note that Alphapharm was one of the first ANDA applicants to submit a substantially complete ANDA for Galantamine Hydrobromide Tablets, USP with paragraph IV certifications to the '318, '863 and '527 patents. Therefore, with this approval, Alphapharm is eligible for 180 days of shared generic drug exclusivity for Galantamine Hydrobromide Tablets USP, 4 mg, 8 mg, and 12 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 commercial marketing identified in section 505(j)(5)(B)(iv).

¹ Because information on the '318 patent was submitted before August 18, 2003, this reference to section 505(j)(5)(B)(iii) is to that section of the Act as in effect prior to December 8, 2003, when the Medicare Prescription Drug, Improvement and Modernization Act (MMA) (Public Law 108-173) was enacted. See MMA § 1101(c)(3).

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.

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(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 77-603**".

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
8/28/2008 03:09:43 PM
Deputy Director, for Gary Buehler