DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville, MD 20857

ANDA 79-028

Watson Laboratories, Inc.
Attention: Christine M. Woods
Associate Director, R&D Regulatory Affairs
311 Bonnie Circle
Corona, CA 92880

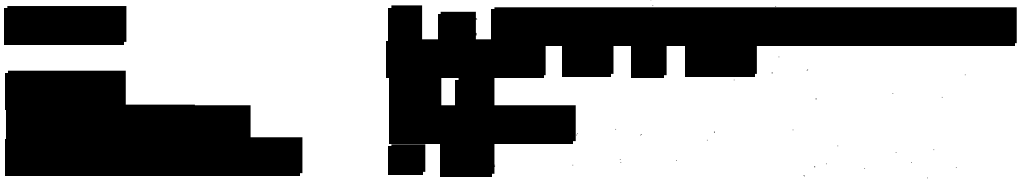
Dear Madam:

This is in reference to your abbreviated new drug application (ANDA) dated June 29, 2007, submitted pursuant to section 505(j) of the Federal Food, Drug, and Cosmetic Act (the Act), for Galantamine Hydrobromide Extended-release Capsules, 8 mg, 16 mg and 24 mg.

Reference is also made to your amendments dated August 13, and December 18, 2007; and April 11, July 11, July 25, September 5, September 11, September 24, October 27, and December 8, 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, 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:



[redacted]

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, Janssen's Razadyne ER, is subject to a period of unexpired patent protection. As noted in the agency's publication titled Approved Drug Products with Therapeutic Equivalence Evaluations (the "Orange Book"), U.S. Patent No. 7,160,559 (the '559 patent) is scheduled to expire on December 20, 2019.

Your ANDA contains a paragraph IV certification under section 505(j)(2)(A)(vii)(IV) of the Act stating that the '559 patent is invalid, unenforceable, or will not be infringed by your manufacture, use, or sale of Galantamine Hydrobromide Extended-release Capsules, 8 mg, 16 mg and 24 mg, under this ANDA. You have notified the agency that Watson Laboratories, Inc. (Watson) complied with the requirements of section 505(j)(2)(B) of the Act, and that no action for infringement of the '559 patent was brought against Watson within the statutory 45-day period, which action would have resulted in a 30-month stay of approval under section 505(j)(5)(B)(iii) of the Act. In addition, the 180-day generic drug exclusivity period for this drug product expired on December 14, 2008.

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 79-028"***.

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/

Gary Buehler
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