DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville, MD 20857

ANDA 091289

Watson Laboratories, Inc. - Florida
Attention: Janet Vaughn
Director, Regulatory Affairs
4955 Orange Drive
Fort Lauderdale, FL 33314

Dear Madam:

This is in reference to your abbreviated new drug application (ANDA) received on March 2, 2009, and submitted pursuant to section 505(j) of the Federal Food, Drug, and Cosmetic Act (the Act), for Trospium Chloride Extended-release Capsules, 60 mg.

Reference is also made to your amendments dated June 2, July 14, and August 4, 2009; May 7, July 12 and 13, August 17, and September 10, 2010; February 1, July 15, September 1 and 16, November 15 and 18, 2011; and January 26, April 23 and 25, June 13, July 3 and 20, August 1, and September 4, 2012.

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 Trospium Chloride Extended-release Capsules, 60 mg, to be bioequivalent and, therefore, therapeutically equivalent to the reference listed drug (RLD), Sanctura XR Capsules, 60 mg, of Allergan, 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:

Dissolution Testing should be conducted in:

Medium: 0.1 N HCl, pH 1.1 for 2 hours; then adjust pH to 7.5 with addition of 200 mL of 0.1 N NaOH in 200 mM Phosphate Buffer

Volume: Acid Stage: 750 mL; Buffer Stage 950 mL

Apparatus: II (Paddle) with sinker
Speed: 50 rpm
Sampling: 2, 3, 4, 8, 12 and 16 hrs

Interim Specifications:

Time (Hours)	Amount Dissolved (%)
2	(b) (4)
3	
12	

The "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, Allergan's Sanctura XR Capsules, is subject to periods of patent protection. The following patents and 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
7,410,978 (the '978 patent)	February 1, 2025
7,759,359 (the '359 patent)	November 4, 2024
7,763,635 (the '635 patent)	November 4, 2024
7,781,448 (the '448 patent)	November 4, 2024
7,781,449 (the '449 patent)	November 4, 2024

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 Trospium Chloride Extended-release Capsules, 60 mg, under this ANDA. (Of the patents listed above, only the '978 patent was listed in the Orange Book when your ANDA was received; your paragraph IV certifications to the other patents were submitted in amendments to your ANDA.) You have notified the agency that Watson Laboratories, Inc.-Florida (Watson) complied with the requirements of section 505(j)(2)(B) of the Act, and that litigation was initiated against Watson for

infringement of the '978 patent within the statutory 45-day period in the United States District Court for the District of Delaware [Allergan, Inc., Allergan USA, Inc., Allergan Sales, LLC, Endo Pharmaceuticals Solutions Inc. and Supernus Pharmaceuticals, Inc. v. Watson Pharmaceuticals, Inc., Watson Laboratories, Inc.-Florida, and Watson Pharma, Inc., Civil Action No. 09-cv-00511]. You have also notified the agency that the court decided that the '978 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 Watson was the first ANDA applicant for Trospium Chloride Extended-release Capsules, 60 mg, to submit a substantially complete ANDA with a paragraph IV certification. Therefore, with this approval, Watson may be eligible for 180 days of generic drug exclusivity for Trospium Chloride Extended-release Capsules, 60 mg. This exclusivity, which is provided for under section 505(j)(5)(B)(iv) of the Act, would begin to run from the date of the commercial marketing identified in section 505(j)(5)(B)(iv). The agency notes that Watson 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) (forfeiture of exclusivity for failure to obtain tentative approval within 30 months). The agency is not, however, making a formal determination at this time of Watson’s eligibility for 180-day generic drug exclusivity. We will do so only if another paragraph IV applicant becomes eligible for full approval within 180 days after Watson begins commercial marketing of Trospium Chloride Extended-release Capsules, 60 mg. Please submit correspondence to this ANDA informing the agency of the date commercial marketing begins.

As of October 1, 2012, Watson Laboratories, Inc. – Florida (Watson) must pay fees in accordance with the Generic Drug User Fee Amendments of 2012 (Public Law 112-144, Title III). Because your ANDA was pending on October 1, 2012, your ANDA is now subject to a backlog fee. However, you will not be penalized until the backlog fee payment is overdue. The fee must be paid within 30 days of publication in the Federal Register (FR) of the amount of the backlog fee (e.g., to be published by October 31, 2012). If you do not pay the fee by the due date, statutory penalties take effect. At that time, FDA cannot receive any ANDAs or supplemental ANDAs from Watson or its affiliates, and Watson will be placed on a publically available arrears list until the fee is paid. In addition, your ANDA is now subject to facility fee(s). As noted above, you will not be penalized for

nonpayment of the facility fee(s) until the fee payment is overdue. The fee(s) must be paid by the date listed in the FR notice announcing the amount of the facility fee. If the facility fee is not paid by the due date, statutory penalties take effect. At that time, FDA will deem misbranded this ANDA product and all drug products manufactured at facilities that have not paid the appropriate fee. In addition, the facility(ies) that have not paid the fee will be placed on a publically available arrears list until the fee is paid or the facility(ies) are removed from the ANDA.

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
Office of Prescription Drug Promotion
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 Office of Prescription Drug Promotion with a completed Form FDA 2253 at the time of their initial use.

As soon as possible, but no later than 14 days from the date of this letter, submit, using the FDA automated drug registration and listing system (eLIST), the content of labeling [21 CFR

314.50(l)] in structured product labeling (SPL) format, as described at http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm, that is identical in content to the approved labeling (including the package insert, and any patient package insert and/or Medication Guide that may be required). Information on submitting SPL files using eLIST may be found in the guidance for industry titled “SPL Standard for Content of Labeling Technical Qs and As” at http://www.fda.gov/downloads/DrugsGuidanceComplianceRegulatoryInformation/Guidances/UCM072392.pdf. The SPL will be accessible via publicly available labeling repositories.

Sincerely yours,

{See appended electronic signature page}

Gregory P. Geba, M.D., M.P.H.
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

10/12/2012

Deputy Director, Office of Generic Drugs, for
Gregory P. Geba, M.D., M.P.H.