DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 022103/S-003

SUPPLEMENT APPROVAL

Allergan, Inc.
Attention: Terri Richmond, Ph.D., M.Sc.
Specialist, Global Regulatory Affairs
2525 Dupont Dr., P.O. Box 19534
Irvine, CA 92623-9534

Dear Dr. Richmond:

Please refer to your Supplemental New Drug Application (sNDA) dated and received September 30, 2010, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for SANCTURA XR (trospium chloride), 60 mg tablets.

We acknowledge receipt of your amendments dated December 3, 2010, March 11, May 13, and September 8, 2011.

This "Prior Approval" supplemental new drug application provides for the following changes to the package insert:

- Reinstatement of the previously approved wording in the Pharmacokinetic section, Hepatic Insufficiency subsection following an independent audit of Study IP631-007 by (b) (4) in order to address the validity of the data from that study.
- Revisions to the PRECAUTIONS section,
    1) Drug Interactions section from Study MA-SXR-09-002, a drug-drug interaction study with metformin.
    2) Carcinogenesis, Mutagenesis, Impairment of Fertility, Pregnancy: Teratogenic Effects, Pregnancy C subsections: alignment of labeling for all products of the same drug class and to be consistent with SANCTURA label.
- Minor editorial changes to align the SANCTURA XR label with the SANCTURA label, and to correct grammatical and formatting errors.

We have completed our review of this supplemental application, as amended. It is approved, effective on the date of this letter, for use as recommended in the enclosed, agreed-upon labeling text.

CONTENT OF LABELING

As soon as possible, but no later than 14 days from the date of this letter, submit the content of labeling [21 CFR 314.50(l)] in structured product labeling (SPL) format using the FDA automated drug registration and listing system (eLIST), as described at http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm. Content of labeling must be identical to the enclosed text for the package insert with the addition of any labeling changes in pending "Changes Being Effected" (CBE) supplements, as well as annual reportable changes not included in the enclosed labeling.

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 from publicly available labeling repositories.

Also within 14 days, amend all pending supplemental applications for this NDA, including CBE supplements for which FDA has not yet issued an action letter, with the content of labeling [21 CFR 314.50(l)(1)(i)] in MS Word format, that includes the changes approved in this supplemental application, as well as annual reportable changes and annotate each change. To facilitate review of your submission, provide a highlighted or marked-up copy that shows all changes, as well as a clean Microsoft Word version. The marked-up copy should provide appropriate annotations, including supplement number(s) and annual report date(s).

REPORTING REQUIREMENTS

We remind you that you must comply with reporting requirements for an approved NDA (21 CFR 314.80 and 314.81).

If you have any questions, please call Nenita Crisostomo, R.N., Regulatory Health Project Manager, at (301) 796-0875.

Sincerely,

{See appended electronic signature page}

George Benson, M.D.
Deputy Director
Division of Reproductive and Urologic Products
Office of Drug Evaluation III
Center for Drug Evaluation and Research

ENCLOSURE:
Content of Labeling

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

GEORGE S BENSON
09/14/2011