



NDA 021595/S-007

SUPPLEMENT APPROVAL

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

Dear Dr. Richmond:

Please refer to your supplemental New Drug Application (NDA) dated and received December 1, 2010, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for SANCTURA[®] (trospium chloride) 20 mg tablets.

This prior approval supplement provides for the addition of the following changes to the SANCTURA[®] labeling as requested in the November 4, 2010, Prior Approval Supplement Request Letter:

1. The following paragraph should be added as a new **WARNINGS** section after the **CONTRAINDICATIONS** section.

WARNINGS:

Angioedema of the face, lips, tongue and/or larynx has been reported with trospium chloride. In one case, angioedema occurred after the first dose. Angioedema associated with upper airway swelling may be life threatening. If involvement of tongue, hypopharynx, or larynx occurs, trospium chloride should be promptly discontinued and appropriate therapy and or measures necessary to ensure a patent airway should be promptly provided.

2. Under **PRECAUTIONS, Information for Patients**, the following is to be a new first paragraph of the section:

Patients should be informed that trospium chloride may produce angioedema which could result in life-threatening airway obstruction. Patients should be advised to promptly discontinue trospium chloride and seek immediate medical attention if they experience edema of tongue, edema of laryngopharynx, or difficulty breathing.

CONTENT OF LABELING

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

As soon as possible, but no later than 14 days from the date of this letter, please submit the content of labeling [21 CFR 314.50(l)(1)(i)] in structured product labeling (SPL) format as described at <http://www.fda.gov/oc/datacouncil/spl.html> that is identical to the enclosed labeling (text for the package insert). For administrative purposes, please designate this submission “SPL for approved NDA 021595/S-007.”

PROMOTIONAL MATERIALS

You may request advisory comments on proposed introductory advertising and promotional labeling. To do so, submit, in triplicate, a cover letter requesting advisory comments, the proposed materials in draft or mock-up form with annotated references, and the package insert to:

Food and Drug Administration
Center for Drug Evaluation and Research
Division of Drug Marketing, Advertising, and Communications
5901-B Ammendale Road
Beltsville, MD 20705-1266

As required under 21 CFR 314.81(b)(3)(i), you must submit final promotional materials, and the package insert(s), at the time of initial dissemination or publication, accompanied by a Form FDA 2253. For instruction on completing the Form FDA 2253, see page 2 of the Form. For more information about submission of promotional materials to the Division of Drug Marketing, Advertising, and Communications (DDMAC), see <http://www.fda.gov/AboutFDA/CentersOffices/CDER/ucm090142.htm>.

LETTERS TO HEALTH CARE PROFESSIONALS

If you issue a letter communicating important safety related information about this drug product (i.e., a “Dear Health Care Professional” letter), we request that you submit an electronic copy of the letter to both this NDA and to the following address:

MedWatch
Food and Drug Administration
5600 Fishers Lane, Room 12B05
Rockville, MD 20857

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, call Eufrecina DeGuia, Senior Regulatory Health Project Manager, at (301) 796-0081.

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
01/31/2011