DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 020897/S-033

SUPPLEMENT APPROVAL

Janssen Research & Development, LLC
Attention: Susan Nemeth, Ph.D.
Director, Global Regulatory Affairs – Established Products
1000 U.S. Route 202
Raritan, New Jersey 08869-0602

Dear Dr. Nemeth:

Please refer to your Supplemental New Drug Application (sNDA) dated and received August 4, 2015, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for DITROPAN XL® (oxybutynin chloride) Extended Release Tablets for oral use.

We acknowledge receipt of your amendments dated October 30, 2014, and February 13, 2015.

This "Prior Approval" supplemental new drug application proposes revisions to the following sections of the Package Insert to include new language regarding Parkinson's disease, autonomic neuropathy, and the potential interaction with intestinal prokinetic agents:

1. WARNINGS AND PRECAUTIONS
    - Addition of the following statement under Subsection 5.2: "DITROPAN XL should be used with caution in patients with Parkinson's disease due to the risk of aggravation of symptoms."
    - Addition of new Subsection 5.4 Worsening of Symptoms of Decreased Gastrointestinal Motility in Patients with Autonomic Neuropathy with the following statement: DITROPAN XL should be used with caution in patients with autonomic neuropathy due to the risk of aggravation of symptoms of decreased gastrointestinal motility.
2. DRUG INTERACTIONS
    - Addition of the following statement: Anticholinergic agents may also antagonize the effects of prokinetic agents, such as metoclopramide.
3. HIGHLIGHTS OF PRESCRIBING INFORMATION
    - WARNINGS AND PRECAUTIONS – Addition of the new proposed language regarding Parkinson's disease and autonomic neuropathy

- ADVERSE REACTIONS – Revision of the list of adverse reactions to correspond with the adverse reactions shown in Table 1 in Section 6.

4. EDITORIAL CHANGES

APPROVAL & LABELING

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 and with the minor editorial revision listed below and as indicated in the enclosed labeling.

- In HIGHLIGHTS, under WARNINGS AND PRECAUTIONS, 3rd bullet, add *"inhibitors"* after *"cholinesterase"*.

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 labeling 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 via 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 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, call Nenita Crisostomo, R.N., Regulatory Health Project Manager, at (301) 796-0875.

Sincerely,

{See appended electronic signature page}

Hylton V, Joffe, M.D., M.M.Sc.
Director
Division of Bone, 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/

HYLTON V JOFFE
02/27/2015