



NDA 017577/S-037

**SUPPLEMENT APPROVAL**

Janssen Pharmaceuticals, Inc.  
Attention: Susan Nemeth, Ph.D.  
Director, Regulatory Affairs  
920 Route 202 South, P.O. Box 300  
Raritan, NJ 08869

Dear Dr. Nemeth:

Please refer to your Supplemental New Drug Applications (sNDAs) submitted and received September 12, 2011, under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for DITROPAN<sup>®</sup> (oxybutynin chloride) tablets, 5 mg.

This "Prior Approval" supplemental new drug application provides for updated protein binding information in the CLINICAL PHARMACOLOGY section of the Package Insert.

We have completed our review of this supplemental application and 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, 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 Effectuated" (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 Project Manager, at (301) 796-0875.

Sincerely,

*{See appended electronic signature page}*

Audrey Gassman, M.D.  
Acting Deputy Director  
Division of Reproductive and Urologic Products  
Office of Drug Evaluation III  
Center for Drug Evaluation and Research

ENCLOSURES:  
Content of Labeling

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**This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.**  
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/s/  
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AUDREY L GASSMAN  
12/15/2011