DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 20-897/S-024

Ortho-McNeil-Janssen Pharmaceuticals, Inc.
Attention: Susan Nemeth, Ph.D.
Director, Regulatory Affairs
1000 U.S. Highway 202, P.O. Box 300
Raritan, NJ 08869-0602

Dear Dr. Nemeth:

Please refer to your supplemental new drug application, dated and received March 12, 2009, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for DITROPAN XL® (oxybutynin chloride, USP) Extended Release Tablets.

This "Prior Approval" supplemental new drug application provides for labeling changes requested in the January 23, 2009, Complete Response letter, wherein you were asked to add the term "QT interval prolongation" to the **ADVERSE REACTIONS** section, Postmarketing Surveillance subsection under *Cardiac Disorders*. In addition, this supplement provides for addition of the term "memory impairment" to the **ADVERSE REACTIONS,** Postmarketing Surveillance section, and revision of the company name in the **HOW SUPPLIED** section.

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

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(1)] in structured product labeling (SPL) format as described at Http://www.fda.gov/oc/datacouncil/spl.html that is identical to the enclosed labeling. Upon receipt, we will transmit that version to the National Library of Medicine for public dissemination. For administrative purposes, please designate these submissions, "SPL for approved NDA 20-897/S-024." The final printed labeling (FPL) must be identical to the enclosed labeling (text for the package insert).

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

MEDWATCH
Food and Drug Administration
Suite 12B05
5600 Fishers Lane
Rockville, MD 20857

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 Meredith Alpert, Regulatory Project Manager, at (301) 796-1218.

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: PI

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

/s/

George Benson
7/13/2009 01:39:27 PM