DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 17-577/S-034
NDA 18-211/S-017
NDA 20-897/S-018

Johnson & Johnson Pharmaceutical Research & Development, L.L.C.
Attention: Melissa Gannon
Associate Director, Regulatory Affairs
920 Route 202 South, P.O. Box 300
Raritan, NJ 08869

Dear Ms. Gannon:

Please refer to your supplemental new drug applications dated August 22, 2005, received August 23, 2005, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Ditropan® (oxybutynin chloride) Tablets 5 mg, Ditropan® (oxybutynin chloride) Syrup 5 mg/5 mL, and Ditropan XL® (oxybutynin chloride) Extended Release Tablets 5 mg, 10 mg, and 15 mg.

We acknowledge receipt of your submissions dated March 2, 2006 (NDAs 17-577, 18-211, and 20-897), May 23, 2006 (NDAs 17-577, 18-211, and 20-897), November 1, 2006 (NDAs 17-577, 18-211 and 20-897), July 10, 2007 (NDAs 17-577, 18-211 and 20-897), October 17, 2007 (NDAs 17-577, 18-211 and 20-897), October 22, 2007 (NDA 18-211), and November 29, 2007 (NDA 20-897).

Your submissions of October 17, 2007 (NDAs 17-577 and 20-897), and October 22, 2007 (NDA 18-211), constituted a complete response to our February 23, 2006, action letter.

All three of these supplemental new drug applications provide for the following changes to the Package Insert: Addition of a new precaution concerning central nervous system effects in the **PRECAUTIONS** section and revision of the **ADVERSE REACTIONS** section. In addition, the supplemental new drug application for Ditropan XL also provides for changes in the **DOSAGE AND ADMINISTRATION** section and the **Drug Interactions** subsection of the **PRECAUTIONS** section.

We have completed our review of these applications, as amended. These applications are approved, effective on the date of this letter, for use as recommended in the agreed-upon labeling text and with the following minor editorial revision indicated in the enclosed labeling: The last word of the **Geriatric Use** subsection of the **PRECAUTIONS** section for the Ditropan XL Package Insert is corrected from "Gender" to "Geriatric."

Within 14 days of the date of this letter, submit content of labeling [21 CFR 314.50(l)] in structured product labeling (SPL) format, as described at http://www.fda.gov/oc/datacouncil/spl.html, that is identical in content to the enclosed labeling. Upon receipt and verification, we will transmit that version to the National Library of Medicine for public dissemination.

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
5515 Security Lane
HFD-001, Suite 5100
Rockville, MD 20852

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 Karl Stiller, Regulatory Project Manager, at (301) 796-1993.

Sincerely,

{See appended electronic signature page}

Scott Monroe, M.D.
Director
Division of Reproductive and Urologic Products
Office of Drug Evaluation III
Center for Drug Evaluation and Research

Enclosure

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

/s/

Scott Monroe

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