DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 20-897/S-013

Johnson & Johnson Pharmaceutical Research & Development, L.L.C.
Attention: Liliana Arbelaez
Associate Director, Regulatory Affairs
1125 Trenton-Harbourton Road
P.O. Box 200
Titusville, NJ 08560-0200

Dear Ms. Arbelaez:

Please refer to your supplemental new drug application dated September 2, 2003, received September 3, 2003, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Ditropan® XL (oxybutynin chloride) 5, 10, and 15 mg extended release tablets.

We also acknowledge receipt of your subsequent submissions dated February 25, March 30, and May 6, and June 17, 2004.

This supplemental new drug application provides for a change in the pharmacokinetics, precautions, adverse events, and dosage and administration sections of the currently approved label.

We have completed our review of this supplemental new drug application, as amended. This application is approved effective on the date of this letter, for use as recommended in the agreed upon labeling text.

The final printed labeling (FPL) must be identical to the revised draft labeling enclosed. Marketing this product with FPL that is not identical to the approved labeling text may render the product misbranded and unapproved.

Please submit the FPL electronically according to the guidance for industry titled Providing Regulatory Submissions in Electronic Format – NDA. Alternatively, you may submit 20 paper copies of the FPL as soon as it is available, in no case more than 30 days after it is printed. Please individually mount 15 of the copies on heavy-weight paper or similar material. For administrative purposes, this submission should be designated "FPL for approved supplement NDA 20-897/S-013." Approval of this submission by FDA is not required before the labeling is used.

All applications for new active ingredients, new dosage forms, new indications, new routes of administration, and new dosing regimens are required to contain and assessment of the safety and effectiveness of the product in pediatric patients unless this requirement is waived or deferred. We note that you have fulfilled the pediatric study requirement for this application.

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, HFD-410
FDA
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 Albert Perrine, Regulatory Project Manager, at (301) 827-7511.

Sincerely,

{See appended electronic signature page}

Donna Griebel, M.D.
Deputy Director,
Division of Reproductive and Urologic Drug 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/

Donna Griebel

6/30/04 11:40:05 AM