**DEPARTMENT OF HEALTH & HUMAN SERVICES**

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 17-577/S-033 and S-032
NDA 18-211/S-016 and S-014
NDA 20-897/S-009 and S-010

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

Dear Ms. Arbelaez:

Please refer to your supplemental new drug applications dated December 7, 2001, received December 7, 2001, submitted under section 505(b) pursuant to section 505(b)(1) of the Federal Food, Drug, and Cosmetic Act as follows:

| NDA Number | Supplement Number | Drug Product |
|---|---|---|
| 17-577 | S-033 and S-032 | DITROPAN® (oxybutynin chloride) Tablets |
| 18-211 | S-016 and S-014 | DITROPAN® (oxybutynin chloride) Syrup |
| 20-897 | S-009 and S-010 | DITROPAN® XL (oxybutynin chloride) Extended Release Tablets |

We acknowledge receipt of your "Response to Approvable Letter", submitted on October 16, 2002.

We also acknowledge receipt of your subsequent submissions dated March 12, 2002, February 28, March 13, March 14, March 31, April 3, April 4, April 7, April 9, and April 10, 2003 for NDA 17-577/S-033, NDA 18-211/S-016, and NDA 20-897/S-009.

Furthermore, we also acknowledge receipt of your submissions, which contained additional proposed labeling, dated July 2 and December 23, 2002, and March 5, March 13, March 31, April 3, April 4, April 7, April 9, and April 10, 2003 for NDA 17-577/S-032, NDA 18-211/S-014, and NDA 20-897/S-010.

These supplemental new drug applications provide for the use of DITROPAN® (oxybutynin chloride) Tablets, DITROPAN® (oxybutynin chloride) Syrup, and DITROPAN® XL (oxybutynin chloride) Extended Release Tablets for the treatment of overactive bladder in children aged six years of age and older.

We have completed the review of these applications, as amended, and have concluded that adequate information has been presented to demonstrate that the drug products are safe and effective for use as recommended in the attached labeling text. Accordingly, the applications are approved effective on the date of this letter.

The final printed labeling (FPL) must be identical to the submitted draft labeling (package inserts submitted for NDA 17-577/S-032 and S-033 on April 9, 2003; package inserts submitted for NDA 18-211/S-016 and S-014 on April 9, 2003; and package inserts submitted for NDA 20-897/S-009 and S-010 on April 3, 2003). Marketing the product with FPL that is not identical to the approved labeling text may render the product misbranded and an unapproved new drug.

Please submit 20 paper copies of the FPL for NDA 17-577, NDA 18-211, and NDA 20-897 as soon as it is available, in no case more than 30 days after it is printed. Please individually mount ten of the copies on heavy-weight paper or similar material.

Alternatively, you may submit the FPL electronically according to the guidance for industry titled *Providing Regulatory Submissions in Electronic Format - NDAs* (January 1999). For administrative purposes, this submission should be designated "FPL for approved NDA 17-577, NDA 18-211, and NDA 20-897", respectively. Approval of this submission by FDA is not required before the labeling is used.

In addition, please submit three copies of the introductory promotional materials that you propose to use for this product. All proposed materials should be submitted in draft or mock-up form, not final print. Please submit one copy to this Division and two copies of both the promotional materials and the package insert directly to:

Division of Drug Marketing, Advertising, and Communications, HFD-42
Food and Drug Administration
5600 Fishers Lane
Rockville, Maryland 20857

We remind you that you must comply with the requirements for an approved NDA set forth under 21 CFR 314.80 and 314.81.

If you have any questions, call Jean King, M.S., R.D., Regulatory Project Manager, at (301) 827-4260.

Sincerely,

*{See appended electronic signature page}*
Daniel Shames, M.D.
Division 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/

---

Daniel A. Shames

4/15/03 03:42:56 PM