DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 20-771/S-011

Pharmacia & Upjohn Company
Attention: Tara Feehan
Manager, US Regulatory Affairs
235 East 42nd Street
New York, New York 10017

Dear Ms. Feehan:

Please refer to your supplemental new drug application dated August 20, 2002 received August 21, 2002 submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Detrol® (tolterodine tartrate) 1 mg and 2 mg tablets.

We are also in receipt of your submission dated September 25, 2003 received on September 26, 2003, wherein the "Changes Being Effected" Labeling Supplement provides for the addition of angioedema, palpitations, and minor editorial changes to the "Postmarketing Surveillance" section of the package insert (PI).

We have completed our review of this supplemental application and it is approved, effective on the date of this letter. Other than the approved revisions identified in this letter, the final printed label (FPL) must be identical to the labeling submission dated July 30, 2003.

Please submit the updated final printed labeling (FPL), with the aforementioned approved revisions, 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 20-771/S-011." Approval of this submission by FDA is not required before the labeling is used.

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, please call, Jean Makie, R.D., MS, Regulatory Project Manager, at (301) 872-4260.

Sincerely,

{See appended electronic signature page}

Daniel Shames, M.D.
Director
Division of Reproductive and Urologic Drug Products (HFD-580)
Office of Drug Evaluation III
Center for Drug Evaluation and Research

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

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