



NDA 20-771\S-014

APPROVAL LETTER

Pfizer Global Pharmaceuticals
Attention: Birming Wong
Senior Manager, U.S. Regulatory Affairs
235 East 42nd Street
New York, NY 10017

Dear Ms. Wong:

Please refer to your December 15, 2005 supplemental new drug application submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Detrol (tolterodine tartrate), 1 and 2 mg tablets. This supplement provided a revised package insert (PI) and a new patient package insert (PPI) in response to the Division's "Prior Approval Supplement Request" letter, dated October 20, 2005.

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

As indicated on the revised PI enclosed, we request one change to the proposed "PRECAUTIONS, Patients with Congenital or Acquired QT Prolongation" section of the labeling for Detrol. The final printed labeling (FPL) must be identical to the enclosed labeling (text for the PI and PPI).

Please submit an electronic version of the FPL 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 but no more than 30 days after it is printed. Individually mount 15 of the copies on heavy-weight paper or similar material. For administrative purposes, designate this submission "**FPL for approved supplement NDA 20-771/S-014.**" Approval of this submission by FDA is not required before the labeling is used.

We remind you that you must comply with reporting requirements for an approved NDA (21 CFR 314.80 and 314.81).

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If you have any questions, call Jean Makie, M.S., R.D., Sr. Regulatory Project Manager, at 301-796-0952.

Sincerely,

{See appended electronic signature page}

Daniel Shames, M.D., F.A.C.S.
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
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/s/

Daniel A. Shames
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