DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 20-771/S017
NDA 21-228/S010

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 supplemental new drug applications dated December 18, 2006, received December 19, 2006, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Detrol® (tolterodine tartrate), 1 and 2 mg tablets and Detrol® LA (tolterodine tartrate) extended release 2 and 4 mg capsules for the treatment of overactive bladder.

These Changes Being Effected (CBE) supplemental new drug applications contained revised package inserts (PIs) that address a request from the Division that you revise the Post-Marketing Surveillance sub-section of the ADVERSE EVENTS section. We also acknowledge the additional editorial and formatting changes that you have made.

We have completed our review of these applications. These applications are 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 that submitted in your December 18, 2006, submission.

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 these submissions "**FPL for approved supplement NDA 20-771/S-017**" and "**FPL for approved supplement NDA 21-228/S-010**", respectively. Approval of these submissions 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).

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}

Mark Hirsch, M.D.
Acting Deputy Director
Division of Reproductive and Urologic Products
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/

Mark S. Hirsch

3/16/2007 10:36:19 AM