DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 20-771/S-022

Pfizer Global Research and Development
Attention: Birming Wong
Director, U.S. Regulatory Affairs
235 East 42nd Street
New York, NY 10017

Dear Ms. Wong:

Please refer to your supplemental new drug application dated and received October 9, 2008, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Detrol® (tolterodine tartrate) tablets.

We also refer to your email communication on April 6, 2009, conveying your agreement to the recommended labeling changes by the Division of Risk Management (DRISK) which were provided to you on April 6, 2009.

This "Changes Being Effected" supplemental new drug application provides for changes to the Patient Package Insert.

We completed our review of this application and it is approved, effective on the date of this letter, for use as recommended in the enclosed labeling text (Physician Insert (PI) and Patient Package Insert (PPI).

As soon as possible, but no later than 14 days from the date of this letter, please submit the content of labeling [21 CFR 314.50(l)] in structured product labeling (SPL) format as described at http://www.fda.gov/oc/datacouncil/spl.html that is identical to the enclosed labeling (text for the patient package insert). Upon receipt, we will transmit that version to the National Library of Medicine for public dissemination. For administrative purposes, please designate this submission, "SPL for approved NDA 20-771/S-022."

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
Food and Drug Administration
Suite 12B05
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 Meredith Alpert, Regulatory Project Manager, at (301) 796-1218.

Sincerely,

{See appended electronic signature page}

George Benson, M.D.
Deputy Director
Division of Reproductive and Urologic Products
Office of Drug Evaluation III
Center for Drug Evaluation and Research

Enclosure PI and PPI

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

George Benson
4/8/2009 04:43:59 PM