



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 20-771/S-019
NDA 21-228/S-012

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 March 14, 2008, received March 14, 2008, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Detrol[®] (tolterodine tartrate tablets), and Detrol[®] LA (tolterodine tartrate extended release capsules).

These "Changes Being Effected" supplemental new drug applications contained revisions to the PRECAUTIONS section of the package insert and additional language to the Patient Package Information. 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. We also acknowledge receipt of the enclosed labeling in SPL format. We will transmit this version to the National Library of Medicine for public dissemination.

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 Celia R. Peacock, MPH, RD, Regulatory Project Manager, at (301) 796-4154.

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

**This is a representation of an electronic record that was signed electronically and
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/s/

George Benson
9/11/2008 03:35:44 PM