**DEPARTMENT OF HEALTH & HUMAN SERVICES**

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-228\S-007 **APPROVAL LETTER**

Pfizer Global Pharmaceuticals
Attention: Naumann Chaudry, Pharm.D.
Senior Manager, U.S. Regulatory Affairs
235 East 42nd Street
New York, NY 10017

Dear Dr. Chaudry:

Please refer to your December 20, 2004, supplemental new drug application submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Detrol® LA (tolterodine tartrate), 2 and 4 mg extended release capsules.

We acknowledge receipt of your submissions dated January 26, March 15 and 29, May 11, June 21, September 13 and 22, 2005.

This supplemental new drug application provides the results of a study and proposed revisions to the package insert.

We completed our review of this application, as amended. This application is 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 the enclosed labeling (text for the package insert and text for the patient package insert).

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 21-228/S-007**." 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, call Jean Makie, M.S., R.D., Sr. Project Manager, at 301-796-0952.

Sincerely,

*{See appended electronic signature page}*

Daniel Shames, M.D., FACS
Director
Division of Reproductive and Urologic Drug Products
Office of Drug Evaluation III
Center for Drug Evaluation and Research

Enclosure

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

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/s/

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Daniel A. Shames

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