



NDA 21-228\S-008

**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 January 13, 2005 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. This supplement provided a new proposed patient package insert (PPI).

We also acknowledge receipt of your submissions dated May 25 and June 30, 2005.

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 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-008.**" 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).

If you have any questions, call Jean Makie, M.S., R.D., Sr. Regulatory Project Manager, at 301-827-4260.

Sincerely,

*{See appended electronic signature page}*

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

Enclosure

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/s/

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Donna Griebel

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