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APPLICATION NUMBER:

21-228 S006

APPROVAL LETTER



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-228/S-006

Pfizer Incorporated
Attention: Alan Traettino
Director, US Regulatory Affairs
235 East 42nd Street
New York, New York 10017

Dear Mr. Traettino:

Please refer to your supplemental new drug application dated October 10, 2003, received October 14, 2003, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Detrol LA[®] (tolterodine tartrate) 2 mg and 4 mg Extended Release capsules.

We also acknowledge receipt of your subsequent submissions dated February 13, March 16, April 1, April 8, and April 9, 2004, which contained additional proposed labeling.

This supplemental new drug application, "Submission of Pediatric Study Reports-Pediatric Exclusivity Determination Requested" provides pharmacodynamic, pharmacokinetic, safety, and efficacy data on the effects of Detrol LA[®], and proposed labeling for this product in response to a written request for pediatric studies in both neurologically impaired and neurologically normal children ranging in age from 3 months to 15 years.

We have completed our review of this supplemental new drug application, as amended. This application is approved effective on the date of this letter.

The final printed labeling (FPL) must be identical to the revised draft labeling submitted on April 9, 2004. Marketing this product with FPL that is not identical to the approved labeling text may render the product misbranded and unapproved.

Please submit the FPL electronically 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, in no case more than 30 days after it is printed. Please individually mount 15 of the copies on heavy-weight paper or similar material. For administrative purposes, this submission should be designated "FPL for approved supplement NDA 21-228/S-006." 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 Albert Perrine, RN, Regulatory Project Manager, at (301) 827-7511.

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

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/s/

Donna Griebel

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