CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION: NDA 20-771

CONTENTS

	Included	Pending Completion	Not Prepared	Not Required
Approval Letter	X			
Tenative Approval Letter				
Approvable Letter				
Final Printed Labeling		X		
Medical Review(s)	X			
Chemistry Review(s)	X			
EA/FONSI				
Pharmacology Review(s)	X			
Statistical Review(s)	X			
Microbiology Review(s)				
Clinical Pharmacology Biopharmaceutics Review(s)	X			
Bioequivalence Review(s)				
Administrative Document(s)	X			
Correspondence	X			

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Approval Package for:

Application Number: NDA 20-771

Trade Name: DETROL 1 & 2 MG TABLETS

Generic Name:(tolterodine L-tartrate)

Sponsor: Pharmacia & Upjohn Company

Approval Date: March 25, 1998

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Application Number:NDA 20-771

APPROVAL LETTER

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

NDA 20-771

MAR 25 1998

Pharmacia & Upjohn Co.
Attention: Susan M. Mondabaugh, Ph.D.
Director, U.S. Regulatory Affairs
Unit 0635-298-113
7000 Portage Road
Kalamazoo, Michigan 49001

Dear Dr. Mondabaugh:

Please refer to your new drug application dated March 24, 1997, received March 25, 1997, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for DETROL™ (tolterodine tartrate tablets).

We acknowledge receipt of your submissions dated April 14, 17, and 22, July 9 and 24, August 8, 12, and 29, September 12, October 31, November 18(2) and 24, and December 5, 23, and 31(2), 1997; and January 16, 27, 28, and 29(2), February 9, 11(2), 19, 24, and 25, and March 4, 6, 11, 12, 13, 19, 20, 24 and 25, 1998. The User Fee goal date for this application is March 25, 1998.

This new drug application provides for the use of Detrol Tablets for the treatment of patients with an overactive bladder with symptoms of urinary frequency, urgency, or urge incontinence.

We have completed the review of this application, as amended, and have concluded that adequate information has been presented to demonstrate that the drug product is safe and effective for use as recommended in the draft labeling. Accordingly, the application is approved effective on the date of this letter.

The final printed labeling (FPL) must be identical to the draft labeling in the submissions dated February 25, 1998 (carton and container labels), March 6, 1998 (sample tray for blisters), and March 25, 1998 (physician package insert). Marketing the product with FPL that is not identical to this draft labeling may render the product misbranded and an unapproved new drug.

Please submit 20 copies of the FPL as soon as it is available, in no case more than 30 days after it is printed. Please individually mount ten of the copies on heavy-weight paper or similar material. For administrative purposes, this submission should be designated "FINAL PRINTED LABELING" for approved NDA 20-771. Approval of this submission by FDA is not required before the labeling is used.

We remind you of the Phase 4 commitment specified in your March 12, 1998, submission to conduct a

Protocol, data, and final reports should be submitted to your IND for this product and a copy of the cover letter sent to this NDA. In addition, under 21 CFR 314.81(b)(2)(vii), we request that you include a status summary of each commitment in your annual report to this application. The status summary should include the number of patients entered in the study, expected completion and submission dates, and any changes in plans since the last annual report. For administrative purposes, all submissions, including labeling supplements, relating to this Phase 4 commitment should be clearly designated "Phase 4 Commitment."

In addition, please submit three copies of the introductory promotional material that you propose to use for this product. All proposed materials should be submitted in draft or mock-up form, not final print. Please submit one copy to the Division of Reproductive and Urologic Drug Products and two copies of both the promotional material and the package insert directly to:

Food and Drug Administration
Division of Drug Marketing, Advertising and Communications, HFD-40
5600 Fishers Lane
Rockville, Maryland 20857

Validation of the regulatory methods has not been completed. At the present time, it is the policy of the Center not to withhold approval because the methods are being validated. Nevertheless, we expect your continued cooperation to resolve any problems that may be identified.

Please submit one market package of the drug product when it is available.

We remind you that you must comply with the requirements for an approved NDA set forth under 21 CFR 314.80 and 314.81.

If you have any questions, please contact Alvis Dunson, Project Manager, at (301) 827-4260.

Sincerely,

James Bilstad, M.D.
Director
Office of Drug Evaluation II
Center for Drug Evaluation and Research