CENTER FOR DRUG EVALUATION AND RESEARCH

Approval Package for:

APPLICATION NUMBER:

20-771/S-009

Trade Name: Detrol 1 and 2 mg

Generic Name: tolterodine tartrate tablets

Sponsor: Pharmacia & Upjohn Company

Approval Date: 07/20/2001

Indications: For the treatment of overactive bladder with symptoms of urge urinary incontinence, urgency and frequency.

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APPLICATION NUMBER:

20-771/S-009

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APPLICATION NUMBER:

20-771/S-009

APPROVAL LETTER

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

NDA 20-771/S-009

Pharmacia & Upjohn Company
Attention: Gregory G. Shawaryn
Regulatory Manager, Regulatory Affairs
7000 Portage Road
Kalamazoo, MI 49001

Dear Mr. Shawaryn:

Please refer to your supplemental new drug application dated March 19, 2001, received March 21, 2001, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Detrol (tolterodine tartrate) tablets.

This supplemental new drug application provides for alternate packaging materials for the 1 mg and 2 mg strength tablets. The proposed alternate packaging systems are: 1) 60 count [ ] HDPE bottles, 2) 500 count [ ] HDPE bottles.

We have completed the review of this supplemental application, and it is approved.

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, call Evelyn R. Farinas, R.Ph., M.G.A., Regulatory Project Manager, at (301) 827-4260.

Sincerely,

{See appended electronic signature page}

Moo-Jhong Rhee, Ph.D.
Chemistry Team Leader, for the
Division of Reproductive and Urologic Drug Products, (HFD-580)
DNDC II, Office of New Drug Chemistry
Center for Drug Evaluation and Research

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/s/

Moo-Jhong Rhee
7/20/01 09:44:42 AM

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APPLICATION NUMBER:

20-771/S-009

CHEMISTRY REVIEW(S)

CHEMIST REVIEW
OF **SUPPLEMENT**

1. **ORGANIZATION:** DRUDP HFD-580
2. **NDA NUMBER:** 20-771/SCP-009
3. **SUPPLEMENT NUMBERS/DATES:**
   Letterdate: 19-MAR-2001
   Stampdate: 21-MAR-2001
4. **AMENDMENTS/REPORTS/DATES:**
   Letterdate:
   Stampdate:
5. **RECEIVED BY CHEMIST:** 23-MAR-2001

6. **APPLICANT NAME AND ADDRESS:**
   Pharmacia & Upjohn Co.
   7000 Portage Road
   Kalamazoo, MI 49001

7. **NAME OF DRUG:**
   Detrol

8. **NONPROPRIETARY NAME:**
   Tolterodine tartrate tablets

9. **CHEMICAL NAME/STRUCTURE:**
   (R)-N,N-Diisopropyl-3-(2-hydroxy-5-methylphenyl)-3-phenylpropanamine L-hydrogen tartrate

   see USP Dictionary of Drug Names for structure

10. **DOSAGE FORM(S):**
    Tablets

11. **POTENCY:**
    1 mg, 2 mg

12. **PHARMACOLOGICAL CATEGORY:**
    Treatment of overactive bladder with symptoms of frequency, urgency, urge incontinence or any combination of these symptoms.

13. **HOW DISPENSED:**
    RX

14. **RECORDS & REPORTS CURRENT:**
    Yes

15. **RELATED IND/NDA/DMF:**
    none

16. **SUPPLEMENT PROVIDES FOR:**
    Alternate packaging materials for the 1 mg and 2 mg strength tablets. The proposed alternate packaging systems are: 1) 60 count[ ] HDPE bottles, 2) 500 count[ ] HDPE bottles[ ]
    [ ]

17. COMMENTS

The current approved packaging configurations are: 1) 60 count [ ] HDPE bottles, [ ] [ ] 3) 500 count [ ] HDPE bottles, [ ] [ ] The sponsor proposes to package the drug product tablets in different size HDPE bottles from an alternate vendor [ ]. The DMFs for the packaging components have been reviewed and found to be acceptable for the storage of oral solid dosage forms.

18. CONCLUSIONS AND RECOMMENDATIONS:

This Prior Approval Supplement may be approved. **Issue an approval letter.**

19. REVIEWER NAME	**SIGNATURE**	**DATE COMPLETED**
David T. Lin, Ph.D. Review Chemist		12-JUL-2001

cc: Original: NDA 20-771/SCP-009
HFD-580/Division File
HFD-580/EFarinas
HFD-580/MRhee/DLin

INIT by MJ Rhee

Filename: S20771.009 (doc)

Redacted 7 page(s)

of trade secret and/or

confidential commercial

information from

Chemistry Review

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/s/

David T. Lin
7/16/01 01:02:15 PM
CHEMIST
Supplement for new packaging materials.

Moo-Jhong Rhee
7/16/01 03:02:50 PM
CHEMIST
I concur

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

20-771/S-009

ADMINISTRATIVE and CORRESPONDENCE DOCUMENTS

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

NDA 20-771/S-009

PRIOR APPROVAL SUPPLEMENT

Pharmacia & Upjohn Company
Attention: Gregory Shawaryn
Regulatory Manager, Regulatory Affairs
7000 Portage Road
Kalamazoo, MI 49001-0199

Dear Mr. Shawaryn:

We have received your supplemental drug application submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for the following:

Name of Drug Product: Detrol (tolterodine tartrate) Tablets

NDA Number: 20-771

Supplement Number: S-009

Date of Supplement: March 19, 2001

Date of Receipt: March 21, 2001

This supplement proposes the following changes: alternate packaging materials for the 1 mg and 2 mg tablets to include [ ] 60 count bottles, [ ] 500 count bottles [ ] [ ]

Unless we notify you within 60 days of our receipt date that the application is not sufficiently complete to permit a substantive review, this application will be filed under section 505(b) of the Act on May 20, 2001 in accordance with 21 CFR 314.101(a). If the application is filed, the primary user fee goal date will be July 19, 2001 and the secondary user fee goal date will be September 17, 2001.

Please cite the application number listed above at the top of the first page of any communications concerning this application. All communications concerning this supplemental application should be addressed as follows:

U.S. Postal/Courier/Overnight Mail:

Food and Drug Administration
Center for Drug Evaluation and Research
Division of Reproductive and Urologic Drug Products, HFD-580
Attention: Document Room
5600 Fishers Lane
Rockville, Maryland 20857

If you have any questions, call Evelyn R. Farinas, R.Ph., M.G.A., Regulatory Project Manager, at (301) 827-4260.

Sincerely,

{See appended electronic signature page}

Terri Rumble
Chief, Project Management Staff
Division of Reproductive and Urologic Drug Products
Office of Drug Evaluation III
Center for Drug Evaluation and Research

/s/

Terri F. Rumble
3/23/01 01:44:37 PM