

**CENTER FOR DRUG EVALUATION AND  
RESEARCH**

*APPLICATION NUMBER:*

**21-228/S-002**

**ADMINISTRATIVE and CORRESPONDENCE  
DOCUMENTS**



NDA 21-228/S-002

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

Dear Mr. Shawaryn:

We acknowledge receipt of your October 15, 2001, submission containing final printed labeling in response to our September 21, 2001, letter approving your supplemental new drug application for Detrol® LA (tolterodine tartrate extended release capsules).

We have reviewed the labeling that you submitted in accordance with our September 21, 200, letter and we find it acceptable.

If you have any questions, call Evelyn R. Farinas, Regulatory Project Manager, at 301-827-4260.

Sincerely,

*{See appended electronic signature page}*

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

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/s/

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Terri F. Rumble  
12/18/01 04:50:47 PM  
for Daniel Shames

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**Division of Reproductive and Urologic Drug Products**

**Regulatory Project Manager Review**

**Application Number:** NDA 21-228/S-002

**Name of Drug:** Detrol® LA (tolterodine extended release capsules)

**Sponsor:** Pharmacia & Upjohn

**Material Reviewed:**

**FPL for Approved NDA 21-228/S-002**

- Package Insert

**Submission Date:** October 15, 2001

**Receipt Date:** October 16, 2001

**Background and Summary Description:** Final Printed Labeling for approved NDA 21-228/S-002.

**Review:**

The submitted FPL is identical to the September 21, 2001, approved labeling.

**Conclusions:**

An Acknowledge and Retain Letter will be issued for this FA submission containing FPL.

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Jeanine A. Best, M.S.N., R.N.  
Senior Regulatory Associate

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/s/

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Jeanine Best  
12/13/01 10:35:47 AM  
CSO

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NDA 21-228/S-002

**CBE-0 SUPPLEMENT**

Pharmacia & Upjohn  
Attention: Greg Shawaryn  
Regulatory Manager, Regulatory Affairs  
7000 Portage Road  
Kalamazoo, MI

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 LA (tolterodine tartrate) extended release capsules

NDA Number: 21-228

Supplement Number: S-002

Date of Supplement: July 6, 2001

Date of Receipt: July 6, 2001

This supplemental application, submitted as a "Supplement - Changes Being Effected" supplement, proposes the following changes: revisions to the package insert to strengthen the safety information and minor editorial changes.

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 September 3, 2001 in accordance with 21 CFR 314.101(a).

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: Division 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

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/s/

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Jeanine Best  
7/13/01 08:51:49 AM  
Signing for T. Rumble

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