

**CENTER FOR DRUG EVALUATION AND  
RESEARCH**

*APPLICATION NUMBER:*

**21-228/S-001**

**ADMINISTRATIVE and CORRESPONDENCE  
DOCUMENTS**

**Division of Reproductive and Urologic Drug Products**

**Regulatory Project Manager Labeling Review**

**Application Number:** NDA 21-228, S-001

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

**Sponsor:** Pharmacia & Upjohn Company

**Material Reviewed:** Final Printed Labeling for business reply card

**Submission Dates:** April 13, 2001

**Receipt Dates:** April 16, 2001

**Background and Summary Description:**

On December 28, 2000, Pharmacia & Upjohn Company submitted a supplement requesting the approval of a business reply card, similar to that approved for Detrol. An Approvable letter was issued on April 6, 2001, requesting several changes (see below). The sponsor responded on April 13, 2001 that the recommended changes were acceptable, and submitted a copy of the final printed label in both printed and electronic formats.

**Review:**

The sponsor was asked on April 6, 2001, to submit final printed labeling revised as follows:

1. Delete the first sentence in the proposed business card, which reads “ \_\_\_\_\_  
\_\_\_\_\_”
2. The second sentence in the front side of the proposed business card should read as follows:  
“That is why we’d like to send you FREE information that can help you get the most from your treatment, plus answers to commonly asked questions about Detrol LA.”
3. Delete the phrase \_\_\_\_\_ in the third sentence in the front side of the proposed business card, so that this sentence reads as follows:  
“Just call 1-888-846-9061, visit our Web site at www.detrolla.com, or fill out the back of this coupon and mail it today.”
4. Delete the first line on the backside of the business card, which reads “ \_\_\_\_\_  
\_\_\_\_\_”

The business reply card submitted on April 13, 2001, included all the above recommendations.

**Conclusion:**

Recommend that an Approval Letter be issued for the business reply card, as submitted in the April 13, 2001 correspondence.

---

Evelyn R. Farinas, R.Ph., MGA

NDA 21-228/S-002  
RPM Review  
Page 2

Concurrence:

Rumble 4.18/Gierhart 4.18/Hirsch 4.18/Shames 4.19/Allen 4.20

**APPEARS THIS WAY  
ON ORIGINAL**

-----  
**This is a representation of an electronic record that was signed electronically and  
this page is the manifestation of the electronic signature.**  
-----

/s/  
-----

Evelyn Farinas  
4/26/01 08:28:33 AM  
CSO

Terri F. Rumble  
4/26/01 01:53:03 PM  
CSO  
I concur.

Brenda Gierhart  
4/30/01 06:39:23 PM  
MEDICAL OFFICER

Mark S. Hirsch  
5/2/01 01:17:48 PM  
MEDICAL OFFICER

Daniel A. Shames  
5/10/01 05:06:29 PM  
MEDICAL OFFICER

Susan Allen  
5/26/01 09:19:46 AM  
MEDICAL OFFICER

**APPEARS THIS WAY  
ON ORIGINAL**



NDA 21-228/S-001

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

Dear Mr. Shawaryn:

We acknowledge receipt on April 16, 2001 of your April 13, 2001 resubmission to your supplemental new drug application for Detrol LA (tolterodine extended release) capsules.

This resubmission contains a revised version of the proposed business reply card submitted in response to our April 06, 2001 action letter.

With this amendment, we have received a complete response to our April 06, 2001 action letter.

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  
4/16/01 04:28:43 PM

**APPEARS THIS WAY  
ON ORIGINAL**



/s/

-----  
Brenda Gierhart  
3/22/01 04:18:30 PM  
MEDICAL OFFICER

Mark S. Hirsch  
3/27/01 02:00:09 PM  
MEDICAL OFFICER

Daniel A. Shames  
3/28/01 03:27:17 PM  
MEDICAL OFFICER

**APPEARS THIS WAY  
ON ORIGINAL**

**Division of Reproductive and Urologic Drug Products – HFD 580**

**Regulatory Project Manager Labeling Review**

**Application Number:** NDA 21-228/S-001

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

**Sponsor:** Pharmacia & Upjohn Company

**Material Reviewed:** business reply card

**Submission Dates:** December 28, 2000

**Receipt Dates:** December 29, 2000

**Background and Summary Description:**

Pharmacia & Upjohn submitted a SLR with a business card for Detrol LA, similar to that approved for Detrol Tablets (NDA 20-771). This business card was omitted from the submission dated December 7, 2000 (NDA 21-228/S-012).

**Review:**

The proposed business card for Detrol LA was compared to the business card for Detrol Tablets, previously approved on March 25, 1998.

The following additions or word changes to the Detrol LA were noted when compared to the Detrol Tablet business card:

- “ \_\_\_\_\_ \” was added as the first sentence
- A proposal to s \_\_\_\_\_ s” to patients on therapy with Detrol LA
- An offer to “answer commonly-asked questions” rather than \_\_\_\_\_
- Directions on how to join \_\_\_\_\_
- Addition of a web site address
- Changes in the address and telephone number

**Conclusion:**

The addition of the initial : \_\_\_\_\_ ; do not allow for uniformity and consistency between the business cards of the two Pharmacia & Upjohn tolterodine products. The proposed Detrol LA business card does not list the \_\_\_\_\_ consists of. To avoid misleading patients, and maintain consistency between the Pharmacia & Upjohn tolterodine business cards, \_\_\_\_\_ should be deleted.

**Recommendations:**

Issue an approvable letter to sponsor with the above recommendations and comments.

---

Evelyn R. Farinas, R.Ph., MGA

Concurrence:

---

Terri Rumble, B.S.N.  
Chief Project Management Staff

---

Brenda Gierhart, M.D.  
Medical Officer

---

Mark Hirsch, M.D.  
Urology Team Leader

---

Daniel Shames, M.D.  
Deputy Director

---

Susan Allen, M.D., M.P.H.  
Director

**APPEARS THIS WAY  
ON ORIGINAL**

NDA 21-228, S-001  
RPM Review  
Page 3

Cc:  
Original NDA  
HFD-580  
HFD-580: Allen/Shames/Hirsch/Gierhart/Rumble

Drafted: erf/01.08.01  
Concurrence: Shames/Hirsch/Gierhart /Rumble 02.28.01  
Final:

**APPEARS THIS WAY  
ON ORIGINAL**

/s/

-----  
Evelyn Farinas  
3/12/01 08:27:04 AM  
CSO

pm label rewiw detrol LA business card

Brenda Gierhart  
3/16/01 07:00:59 AM  
MEDICAL OFFICER

Terri F. Rumble  
3/16/01 12:19:59 PM  
CSO

Mark S. Hirsch  
3/19/01 09:11:56 AM  
MEDICAL OFFICER

Daniel A. Shames  
3/19/01 12:41:09 PM  
MEDICAL OFFICER

Susan Allen  
3/20/01 10:53:10 AM  
MEDICAL OFFICER

**APPEARS THIS WAY  
ON ORIGINAL**



NDA 21-228/S-001

**PRIOR APPROVAL SUPPLEMENT**

Pharmacia & Upjohn Company  
Attention: Gregory Shawaryn  
Regulatory Manager, U.S. 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 LA (tolterodine extended release) capsules  
NDA Number:                    21-228  
Supplement Number:         S-001  
Date of Supplement:         December 28,2000  
Date of Receipt:                December 29, 2000

This supplement proposes the following change: inclusion of a business reply card in trade packages.

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 February 27, 2000 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:

---

Food and Drug Administration  
Rockville MD 20857

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,

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

**APPEARS THIS WAY  
ON ORIGINAL**

/s/

-----  
Terri F. Rumble  
1/2/01 04:47:33 PM

**APPEARS THIS WAY  
ON ORIGINAL**