CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

21-228/S-001

APPROVABLE LETTER

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

NDA 21-228/S-001

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

Dear Mr. Shawaryn:

Please refer to your supplemental new drug application dated December 28, 2000, received December 29, 2000, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Detrol LA (tolterodine extended release) capsules.

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

We have completed the review of this application, as amended, and it is approvable. Before this application may be approved, however, it will be necessary for you to submit final printed labeling revised as follows:

1. Delete the first sentence in the proposed business card, which reads "[redacted]

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 "[redacted]' 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 [redacted]

In addition, all previous revisions as reflected in the most recently approved labeling must be included. To facilitate review of your submission, please provide a highlighted or marked-up copy that shows the changes that are being made.

Please submit the copies of final printed labeling (FPL) electronically according to the guidance for industry titled Providing Regulatory Submissions in Electronic Format - NDA (January 1999). Alternatively, you may submit 20 paper copies of the FPL, ten of which individually mounted on heavy weight paper or similar material.

If additional information relating to the safety or effectiveness of this drug becomes available, revision of the labeling may be required.

Within 10 days after the date of this letter, you are required to amend the supplemental application, notify us of your intent to file an amendment, or follow one of your other options under 21 CFR 314.110. In the absence of any such action FDA may proceed to withdraw the application. Any amendment should respond to all the deficiencies listed. We will not process a partial reply as a major amendment nor will the review clock be reactivated until all deficiencies have been addressed.

This product may be considered to be misbranded under the Federal Food, Drug, and Cosmetic Act if it is marketed with this/these change(s) prior to approval of this supplemental application.

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}

Susan Allen, M.D., M.P.H.
Director
Division of Reproductive and Urologic Drug Products
Office of Drug Evaluation III
Center for Drug Evaluation and Research

APPEARS THIS WAY
ON ORIGINAL

/s/

Susan Allen
4/6/01 08:18:16 AM

APPEARS THIS WAY
ON ORIGINAL