

**CENTER FOR DRUG EVALUATION AND
RESEARCH**

APPLICATION NUMBER:

21-228/S-003

**ADMINISTRATIVE and CORRESPONDENCE
DOCUMENTS**

06-DEC-2001

FDA CDER EES
ESTABLISHMENT EVALUATION REQUEST
SUMMARY REPORT

Page 1 of 1

Application: NDA 21228/003 Priority: 3S Org Code: 580
Stamp: 13-NOV-2001 Regulatory Due: 13-MAY-2002 Action Goal: District Goal: 08-APR-2002
Applicant: PHARMACIA AND UPJOHN Brand Name: DETROL LA
7000 PORTAGE RD Established Name:
KALAMAZOO, MI 49001 Generic Name: TOLTERODINE PROLONGED
RELEASE 2/4MG CAPS
Dosage Form: EXC (EXTENDED RELEASE CAPSULI
Strength: 2MG AND 4MG

FDA Contacts: E. FARINAS (HFD-580) 301-827-4260 , Project Manager
S. TRAN (HFD-580) 301-827-4260 , Review Chemist
M. RHEE (HFD-580) 301-827-4237 , Team Leader

Overall Recommendation:

ACCEPTABLE on 05-DEC-2001 by J. D AMBROGIO(HFD-324)301-827-0062

Establishment: _____ DMF No:
_____ AADA No:
_____ ;

Profile: CTR OAI Status: NONE Responsibilities: FINISHED DOSAGE PACKAGER
Last Milestone: OC RECOMMENDATION
Milestone Date: 05-DEC-2001
Decision: ACCEPTABLE
Reason: BASED ON PROFILE

APPEARS THIS WAY
ON ORIGINAL

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/s/

Suong Tran
12/12/01 09:02:09 AM
CHEMIST

paper sign-off: 12/11

Moo-Jhong Rhee
12/12/01 11:40:46 AM
CHEMIST
I concur

**APPEARS THIS WAY
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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

NDA 21-228/S-003

CBE-30 SUPPLEMENT

Pharmacia & Upjohn
Attention: James Balun
Regulatory Manager
7000 Portage Road
Kalamazoo, MI 49001-0199

Dear Mr. Balun:

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-L-tartrate) Capsules

NDA Number: 21-228

Supplement Number: S-003

Date of Supplement: November 7, 2001

Date of Receipt: November 13, 2001

This supplemental application, submitted as a "Supplement - Changes Being Effected in 30 days" supplement, proposes the following change: addition of an alternate site for performance of primary packaging and labeling of the drug product.

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 January 12, 2002 in accordance with 21 CFR 314.101(a). If the application is filed, the user fee goal date will be May 13, 2002.

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, 17B20
5600 Fishers Lane
Rockville, Maryland 20857

NDA 21-228/S-003

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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/

Terri F. Rumble
11/16/01 01:30:57 PM

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