CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER: 20-771/S-004

CLINICAL PHARMACOLOGY BIOPHARMACEUTICS REVIEW

SEP 20 2000

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DEPARTMENT OF HEALTH AND HUMAN SERVICES PUBLIC HEALTH SERVICE FOOD AND DRUG ADMINISTRATION	Clinical Pharmacology & Biopharmaceutics (HFD 860/870/880) Tracking/Action Sheet for Formal/Informal Consults

From: **Dhruba J. Chatterjee, Ph.D.**	To: DOCUMENT ROOM (LOG-IN and LOG-OUT) **Please log-in this consult and review action for the specified IND/NDA submission**

DATE: **4/11/00**	NDA No.: **20-771** Supplement No: **S 004**	NDA No. **N/A**	DATE OF DOCUMENT **12/29/1999**	
NAME OF DRUG **Detrol (tolterodine tartarate)**		PRIORITY CONSIDERATION **S**	DATE OF FORMAL REVIEW **4/11/00**	

NAME OF THE SPONSOR: **Pharmacia and Upjohn**

TYPE OF SUBMISSION

CLINICAL PHARMACOLOGY/BIOPHARMACEUTICS RELATED ISSUE

- ☐ PRE-IND
- ☐ ANIMAL to HUMAN SCALING
- ☐ IN-VITRO METABOLISM
- ☐ PROTOCOL
- ☐ PHASE II PROTOCOL
- ☐ PHASE III PROTOCOL
- ☐ DOSING REGIMEN CONSULT
- ☐ PK/PD- POPPK ISSUES
- ☐ PHASE IV RELATED
- ☐ DISSOLUTION/IN-VITRO RELEASE
- ☐ BIOAVAILABILITY STUDIES
- ☐ IN-VIVO WAIVER REQUEST
- ☐ SUPAC RELATED
- ☐ CMC RELATED
- ☐ PROGRESS REPORT
- ☐ SCIENTIFIC INVESTIGATIONS
- ☐ MEETING PACKAGE (EOP2/Pre-NDA/CMC/Pharmacometrics/Others)
- ☐ FINAL PRINTED LABELING
- ☐ LABELING REVISION
- ☐ CORRESPONDENCE
- ☐ DRUG ADVERTISING
- ☐ ADVERSE REACTION REPORT
- ☐ ANNUAL REPORTS
- ☐ FAX SUBMISSION
- ☐ OTHER *(SPECIFY BELOW)*:

  Supplemental NDA

REVIEW ACTION

- ☐ NAI (No action indicated)
- ☐ E-mail comments to:

  ☐Medical ☐Chemist ☐Pharm-Tox ☐Micro ☐Pharmacometrics ☐Others

  (Check as appropriate and attach e-mail)
- ☐ Oral communication with

  Name: [ ]
- ☐ Comments communicated in meeting/Telecon. see meeting minutes dated:

  [ ]
- ☐ Formal Review/Memo (attached)
- ☐ See comments below
- ☐ See submission cover letter
- ☐ OTHER *(SPECIFY BELOW)*:

  [ ]

REVIEW COMMENT(S)

☒ **NEED TO BE COMMUNICATED TO THE SPONSOR** ☐ **HAVE BEEN COMMUNICATED TO THE SPONSOR**

COMMENTS/SPECIAL INSTRUCTIONS:

This supplemental NDA has no apparent PK/Biopharm issues. This was confirmed by the Medical Officer assigned to this NDA, Dr. Gierhart. Hence, no formal review of this S-NDA was conducted.

However, the sponsor is suggesting one minor change in the CLINICAL PHARMCOLOGY section of the label. In the third

SIGNATURE OF REVIEWER: ___ /S/	Date 9/20/00
SIGNATURE OF TEAM LEADER /S/	Date 9/20/00
CC.: HFD # 870; TL: Parekh; DD: Huang	Project Manager: _____ Date _____

MAR 11 2000 MAR 11 2000 D/F

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REVIEW ACTION

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  ☐Medical ☐Chemist ☐Pharm-Tox ☐Micro ☐Pharmacometrics ☐Others
  (Check as appropriate and attach e-mail)
- ☐ Oral communication with
  Name: [.]
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- ☐ Formal Review/Memo (attached)
- ☐ See comments below
- ☐ See submission cover letter
- ☐ OTHER *(SPECIFY BELOW)*:
  [ ]

REVIEW COMMENT(S)

☐ **NEED TO BE COMMUNICATED TO THE SPONSOR** ☐ **HAVE BEEN COMMUNICATED TO THE SPONSOR**

COMMENTS/SPECIAL INSTRUCTIONS:
This supplemental NDA has no apparent PK/Biopharm issues. This was confirmed by the Medical Officer assigned to this NDA, Brenda Gierhart. Hence, no formal review of this S-NDA was performed.

SIGNATURE OF REVIEWER: /S/ Date 4/11/00

SIGNATURE OF TEAM LEADER /S/ Date

CC.: HFD # 870; TL: Parekh; DD: Huang

Project Manager:
Date