CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

22-030

PHARMACOLOGY REVIEW(S)

Division of Reproductive and Urologic Products
Center for Drug Evaluation and Research

Date:	September 24, 2008
Reviewer:	Lynnda Reid, Ph.D. Supervisory Pharmacologist
NDA #/SS#/date:	22-030 (N000) May 1, 2008
Sponsor:	Pfizer
Drug Product:	Fesoterodine fumarate (Toviaz®)
Indication:	Overactive bladder
RE:	MHT Labeling Consult

Introduction: This NDA was originally filed on March 17, 2006. It received an approvable action pending satisfactory inspection of the manufacturing facility on January 25, 2007. Labeling negotiations were, for the most part, completed at that time. The submission received on May 1, 2008 contained the Sponsor's final proposed label. A consult was sent to the Maternal Health Team (MHT) on June 27, 2008. The DRUP Pharm/Tox team filed their completed reviews with recommended pregnancy labeling on September 16, 2008. On September 19, 2008, the Division received the MHT review of the Pregnancy section containing labeling recommendations in non-PLR and PLR formats.

The Toviaz labeling agreed to by the Sponsor and DRUP is consistent with other antimuscarinic drug labels. The reproductive and developmental findings for fesoterodine are similar to all other antimuscarinic products. The recommended changes proposed by the MHT would make the Toviaz label significantly different than the other drugs of this class and may unfairly penalize it. In addition, the recommended division of the nonclinical data into summary and detailed observations is considered cumbersome and confusing in the non-PLR labeling format.

Regulatory Action: We recommend that the labeling format proposed by the Sponsor be retained. At the time this label is converted from non-PLR to PLR formatting, we will incorporate the recommended changes as appropriate.

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

/s/

Lynnda Reid
9/25/2008 02:58:16 PM
PHARMACOLOGIST

DEPARTMENT OF HEALTH AND HUMAN SERVICES
PUBLIC HEALTH SERVICE
FOOD AND DRUG ADMINISTRATION
CENTER FOR DRUG EVALUATION AND RESEARCH

PHARMACOLOGY/TOXICOLOGY REVIEW AND EVALUATION

NDA NUMBER:	22-030
SERIAL NUMBER:	010
DATE RECEIVED BY CENTER:	01 May 2008
PRODUCT:	Fesoterodine
INTENDED CLINICAL POPULATION:	Men and women with overactive bladder with symptoms of urinary urgency, frequency and/or urge incontinence
SPONSOR:	Schwartz Pharma
DOCUMENTS REVIEWED:	Electronic File
REVIEW DIVISION:	Division of Reproductive and Urologic Products
PHARM/TOX REVIEWER:	Laurie McLeod-Flynn, Ph.D., D.A.B.T.
PHARM/TOX SUPERVISOR:	Lynnda Reid, Ph.D.
DIVISION DIRECTOR:	Scott Monroe, M.D.
PROJECT MANAGER:	Celia Peacock, MPH, RD

Date of review submission to Division File System (DFS): 09/11/08

TABLE OF CONTENTS

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