CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

22-030

OTHER REVIEW(S)

Department of Health and Human Services
Public Health Service
Food and Drug Administration
Center for Drug Evaluation and Research
Office of Surveillance and Epidemiology

Date:	October 14, 2008
To:	Scott Monroe, M.D., Director **Division of Reproductive & Urologic Products**
Through:	Jodi Duckhorn, M.A. Team Leader **Patient Labeling and Education Team** **Division of Risk Management**
From:	Nancy Carothers, BA, RN Patient Product Information Specialist **Patient Labeling and Education Team** **Division of Risk Management**
Subject:	Review of Patient Labeling for TOVIAZ™ (Patient Package Insert), #2
Drug Name(s):	TOVIAZ™ (fesoterodine fumarate, extended release tablets)
Application Type/Number:	NDA 22-030
Applicant/sponsor:	Pfizer
OSE RCM #:	2008-810

RESPONSE TO SPONSOR'S REVISIONS TO THE PPI:

Please see our response the sponsor's revision of the TOVIAZ PPI:

1. If the sponsor [redacted] we recommend the term "doctor." One term should be used consistently throughout the PPI. We recommend against the term "healthcare professional" as it is not generally understood.
2. We defer to the Review Division on the question of whether TOVIAZ inhibits or induces enzymes involved in the metabolism of other drugs.
3. We recommend retaining the bullet, '[redacted] [doctor] may give you a lower dose if you have certain medical conditions such as severe kidney problems." The PI states in three sections (Phamacokinetics in Special Populations, Dosage and Administration, and Precautions) that TOVIAZ is not recommended for patients with severe renal insufficiency at doses higher than 4 mg. This bullet provides additional safety information concerning the patient's medical condition (severe renal insufficiency) and the recommended dosing of TOVIAZ. It is important for these patients to understand clearly that a higher dose is not recommended, especially if their renal problems change from less serious to more serious during their course of treatment with TOVIAZ.
4. [redacted] b(4)
5. We agree with listing "constipation" as one of the most common side effects.
6. [redacted] b(4)
7. The statement, "Safely throw away TOVIAZ that is out of date or no longer needed" [redacted] Again, we generally recommend following the Medication Guide regulations as much as possible for consistency across all patient labeling.

MATERIAL REVIEWED FOR THIS RESPONSE:

- **TOVIAZ™** PI submitted by the Sponsor on May 1, 2008 and further revised by the reviewing division on September 4, 2008
- **TOVIAZ™** PPI submitted by the Sponsor on May 1, 2008 and further revised by the reviewing division on September 9, 2008

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

/s/

Nancy B Carothers
10/14/2008 02:36:42 PM
DRUG SAFETY OFFICE REVIEWER

Jodi Duckhorn
10/14/2008 03:05:40 PM
DRUG SAFETY OFFICE REVIEWER

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Pediatric and Maternal Health Staff
Office of New Drugs
Center for Drug Evaluation and Research
Food and Drug Administration
Silver Spring, MD 20993
Tel 301-796-0700
FAX 301-796-9744

Maternal Health Team Review

Date: September 8, 2008 **Date Consulted:** June 27, 2008

From: Richardae Araojo, Pharm.D.
Regulatory Reviewer, Maternal Health Team (MHT)
Pediatric and Maternal Health Staff

Tammie Brent, RN, MSN
Regulatory Reviewer, Maternal Health Team (MHT)
Pediatric and Maternal Health Staff

Through: Karen Feibus, MD
Team Leader, Maternal Health Team (MHT)
Pediatric and Maternal Health Staff

Lisa Mathis, MD
Associate Director, Pediatric and Maternal Health Staff

To: Division of Reproductive and Urologic Products (DRUP)

Drug: Toviaz (fesoterodine fumarate) tablets; NDA 22-030

Subject: Pregnancy and Nursing Mothers labeling

Materials Reviewed: Pregnancy and Nursing Mothers subsections of Toviaz labeling.

Consult Question: This request is for a labeling consult for NDA 22-030. Please review the Pregnancy and Nursing Mothers subsections of labeling.

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