CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

22-030

CHEMISTRY REVIEW(S)

MEMORANDUM

Date: September 23, 2008

To: NDA 22-030

From: Elaine Morefield, Ph.D.
Division Director
Pre-marketing Assessment Division II
ONDQA

Subject: Tertiary review of ONDQA recommendation for NDA 22-030 Toviaz® (fesoteridine fumarate) Extended Release Tablets, by Pfizer, Inc.

NDA 22-030 is for Toviaz® (fesoteridine fumarate) extended release tablets for the treatment of overactive bladder with symptoms of urge urinary incontinence, urgency, and urinary frequency.

This NDA has provided sufficient CMC information to assure the identity, strength, purity, and quality of the drug product. All facilities involved are in compliance with cGMP, and labels have adequate information as required. Therefore, from a CMC perspective, this NDA is recommended for approval.

I have assessed the ONDQA review of NDA 22-030. I believe that there are adequate manufacturing procedures and controls for production of a quality product. I concur with the approval recommendation from a CMC perspective.

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/s/

Elaine Morefield
10/16/2008 04:18:18 PM
CHEMIST

NDA 22-030

TOVIAZ
(Fesoterodine fumarate)
{Trade name is not finalized}

Extended release tablets

Pfizer, Inc.

Division of Reproductive and Urologic Products

Rajiv Agarwal

DIVISION OF PRE-MARKETING DRUG QUALITY ASSESSMENT
(Branch III, Division II)

Chemistry Review Data Sheet

1. NDA # 22-030
2. REVIEW #: 2
3. REVIEW DATE: 10-AUG-2008
4. REVIEWER: Rajiv Agarwal
5. PREVIOUS DOCUMENTS:

Original	17-MAR-2006
Amendment	15-MAY-2006
Amendment	03-AUG-2006
Amendment	06-OCT-2006
Amendment	16-NOV-2006
Amendment	22-NOV-2006
Amendment	11-JAN-2007
CMC review # 1	19-JAN-2007
Approvable letter	25-JAN-2007

6. SUBMISSION(S) BEING REVIEWED:

Submission(s) Reviewed	Document Date
Complete Response	01-MAY-2008
Amendment	19-MAY-2008
Amendment	18-JUN-2008

7. NAME & ADDRESS OF APPLICANT:

Name: Pfizer, Inc.

Address: 235 East 42nd Street, New York, NY 10017

Representative: Alan McEmber, Director, Worldwide Regulatory

Telephone: 212-733-0081

8. DRUG PRODUCT NAME/CODE/TYPE:

a) Proprietary Name: TOVIAZ
b) Non-Proprietary Name (USAN): fesoterodine fumarate
c) Code Name/# (ONDQA only): SPM 907
d) Chem. Type/Submission Priority (ONDQA only):

- Chem. Type: 1
- Submission Priority: Standard

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