DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 022030/S-006

SUPPLEMENT APPROVAL

Pfizer, Inc.
Attention: Ursula Campbell, Senior Director
Worldwide Regulatory Strategy
235 East 42nd St.
New York, NY 10017-5755

Dear Ms. Campbell:

Please refer to your Supplemental New Drug Application (sNDA) dated and received July 30, 2010, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Toviaz (fesoterodine fumarate), 4mg and 8mg extended release tablets.

We acknowledge receipt of your amendments dated October 8, 2010, March 31, April 11, and October 20, 2011.

This "Prior Approval" supplemental new drug application provides for revisions of the Package Insert in the following specific sections:

- WARNINGS AND PRECAUTIONS section, Concomitant Administration with CYP3A4 Inhibitors subsection,
- DRUG INTERACTIONS section, CYP3A4 Inhibitors and Warfarin subsections,
- CLINICAL PHARMACOLOGY section, Pharmacokinetics in Specific Populations – Renal Impairment and Hepatic Impairment subsections, Drug-Drug Interactions – CYP3A4 Inhibitors, CYP2D6 Inhibitors, and Warfarin subsections.
- HIGHLIGHTS section to correspond with the changes made in the Full Prescribing Information in WARNINGS AND PRECAUTIONS, DRUG INTERACTIONS, and USE IN SPECIFIC POPULATIONS subsections.

We have completed our review of this supplemental application, as amended. It is approved, effective on the date of this letter, for use as recommended in the enclosed, agreed-upon labeling text.

CONTENT OF LABELING

As soon as possible, but no later than 14 days from the date of this letter, submit the content of labeling [21 CFR 314.50(l)] in structured product labeling (SPL) format using the FDA automated drug registration and listing system (eLIST), as described at

http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm. Content of labeling must be identical to the enclosed labeling text for the package insert, with the addition of any labeling changes in pending "Changes Being Effected" (CBE) supplements, as well as annual reportable changes not included in the enclosed labeling.

Information on submitting SPL files using eLIST may be found in the guidance for industry titled "SPL Standard for Content of Labeling Technical Qs and As" at http://www.fda.gov/downloads/DrugsGuidanceComplianceRegulatoryInformation/Guidances/UCM072392.pdf.

The SPL will be accessible from publicly available labeling repositories.

Also within 14 days, amend all pending supplemental applications for this NDA, including CBE supplements for which FDA has not yet issued an action letter, with the content of labeling [21 CFR 314.50(l)(1)(i)] in MS Word format, that includes the changes approved in this supplemental application, as well as annual reportable changes and annotate each change. To facilitate review of your submission, provide a highlighted or marked-up copy that shows all changes, as well as a clean Microsoft Word version. The marked-up copy should provide appropriate annotations, including supplement number(s) and annual report date(s).

REPORTING REQUIREMENTS

We remind you that you must comply with reporting requirements for an approved NDA (21 CFR 314.80 and 314.81).

If you have any questions, please call Nenita Crisostomo, R.N., Regulatory Health Project Manager, at (301) 796-0875.

Sincerely,

{See appended electronic signature page}

Audrey Gassman, M.D.
Acting Deputy Director
Division of Reproductive and Urologic Products
Office of Drug Evaluation III
Center for Drug Evaluation and Research

ENCLOSURE(S):
Content of Labeling – Package Insert

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

/s/

AUDREY L GASSMAN
11/01/2011