CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

22-030

APPROVAL LETTER

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 22-030

Pfizer, Inc
Attention: Alan McEmber
Director, Worldwide Regulatory
235 42nd Street
New York, NY 10017

Dear Mr. McEmber:

Please refer to your new drug application (NDA) dated March 17, 2006, received March 27, 2006, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Toviaz (fesoterodine fumarate) Tablets, 4 mg and 8 mg.

We acknowledge receipt of your submissions dated May 1, May 19, June 18, July 17, August 20, and October 7, 2008.

The May 1, 2008, submission constituted a complete response to our January 25, 2007, action letter.

This new drug application provides for the use of Toviaz (fesoterodine fumarate) Tablets, 4 mg and 8 mg, for the treatment of overactive bladder.

We have completed our review of this application, as amended. It is approved, effective on the date of this letter, for use as recommended in the content of labeling [21 CFR 314.50(1)] in structured product labeling (SPL) format submitted on October 20, 2008.

Your application for Toviaz was not referred to an FDA advisory committee because your product is a member of the class of antimuscarinic products used for the treatment of overactive bladder, including previously approved products, and your product did not pose unique concerns beyond those applicable to other members of this class.

CARTON AND IMMEDIATE CONTAINER LABELS

Submit final printed carton and container labels that are identical to those submitted on October 17, 2008, as soon as they are available, but no more than 30 days after they are printed. Please submit these labels electronically according to the guidance for industry titled *Providing Regulatory Submissions in Electronic Format – Human Pharmaceutical Product Applications and Related Submissions Using the eCTD Specifications (October 2005)*. Alternatively, you may submit 12 paper copies, with 6 of the copies individually mounted on heavy-weight paper or similar material. For administrative purposes, designate this submission "**Final Printed Carton and Container Labels for approved NDA 22-030.**" Approval of this submission by FDA is not required before the labeling is used.

Marketing the product with Final Product Labeling (FPL) that is not identical to the approved labeling text may render the product misbranded and an unapproved new drug.

REQUIRED PEDIATRIC ASSESSMENTS

Under the Pediatric Research Equity Act (PREA) (21 U.S.C. 355c), all applications for new active ingredients, new indications, new dosage forms, new dosing regimens, or new routes of administration are required to contain an assessment of the safety and effectiveness of the product for the claimed indication in pediatric patients unless this requirement is waived, deferred, or inapplicable.

We are waiving the pediatric study requirement for ages 0 months to 5 years, 11 months, because necessary studies are impossible or highly impracticable. This is because study endpoints are difficult to evaluate in this age group.

We are deferring submission of your pediatric study for ages 6 to 16 years, 11 months, for this application because this product is ready for approval for use in adults and the pediatric study has not been completed.

Your deferred pediatric study required by section 505B(a) of the Federal Food, Drug, and Cosmetic Act is a required postmarketing study. The status of this postmarketing study must be reported annually according to 21 CFR 314.81 and section 505B(a)(3)(B) of the Federal Food, Drug, and Cosmetic Act. This required study is listed below.

1. Deferred pediatric study under PREA for the treatment of overactive bladder in the subgroup of pediatric patients with neurologic disease ages 6 to 16 years, 11 months.

   Final Report Submission: January 31, 2012.

Submit the final study report to this NDA. For administrative purposes, all submissions related to this required pediatric postmarketing study must be clearly designated "**Required Pediatric Assessment.**"

PROMOTIONAL MATERIALS

You may request advisory comments on proposed introductory advertising and promotional labeling. To do so, submit, in triplicate, a cover letter requesting advisory comments, the proposed materials in draft or mock-up form with annotated references, and the package inserts to:

Food and Drug Administration
Center for Drug Evaluation and Research
Division of Drug Marketing, Advertising, and Communications
5901-B Ammendale Road
Beltsville, MD 20705-1266

As required under 21 CFR 314.81(b)(3)(i), you must submit final promotional materials, and the package inserts, at the time of initial dissemination or publication, accompanied by a Form FDA 2253. For instruction on completing the Form FDA 2253, see page 2 of the Form. For more information about submission of promotional materials to the Division of Drug Marketing, Advertising, and Communications (DDMAC), see www.fda.gov/cder/ddmac.

REPORTING REQUIREMENTS

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

LETTERS TO HEALTH CARE PROFESSIONALS

If you issue a letter communicating important safety related information about this drug product (i.e., a "Dear Health Care Professional" letter), we request that you submit an electronic copy of the letter to both this NDA and to the following address:

MedWatch
Food and Drug Administration
Suite 12B05
5600 Fishers Lane
Rockville, MD 20857

MEDWATCH-TO-MANUFACTURER PROGRAM

The MedWatch-to-Manufacturer Program provides manufacturers with copies of serious adverse event reports that are received directly by the FDA. New molecular entities and important new biologics qualify for inclusion for three years after approval. Your firm is eligible to receive copies of reports for this product. To participate in the program, please see the enrollment instructions and program description details at www.fda.gov/medwatch/report/mmp.htm.

If you have any questions, call Celia Peacock, MPH, RD, Regulatory Project Manager, at (301) 796-4154.

Sincerely,

{See appended electronic signature page}

Julie Beitz, M.D.
Director
Office of Drug Evaluation III
Center for Drug Evaluation and Research

Enclosure (PI, PPI, and Carton and Immediate Container Labels)

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

/s/

Julie Beitz
10/31/2008 10:46:57 AM