CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

22-030

STATISTICAL REVIEW(S)

U.S. Department of Health and Human Services
Food and Drug Administration
Center for Drug Evaluation and Research
Office of Pharmacoepidemiology and Statistical Science
Office of Biostatistics

Statistical Review and Evaluation

CLINICAL STUDIES

NDA/Serial Number:	22-030
Drug Name:	Toviaz™ (Fesoterodine Fumarate)
Indication(s):	Treatment of Overactive Bladder.
Applicant:	Pfizer Global Pharmaceuticals.
Date (s):	Submitted: 5/02/2008
	PDUFA: 11/2/2008
Review Priority:	Standard
Biometrics Division:	Division of Biometrics III (HFD-725)
Statistical Reviewer:	Mahboob Sobhan, Ph.D. (HFD-725)
Medical Division:	Division of Reproductive and Urological Drug Products (HFD-580)
Clinical Team:	Mark Hirsch, M.D. (HFD-580)
	Harry Handlesman, M.D. (HFD-580)
Project Manager:	Ceilia Peacock (HFD-580)
Keywords:	NDA review, Clinical studies.

NDA 20-030: Toviaz®

Statistical Reviewer's comment

This submission pertains to revised labeling, in most part, the clinical pharmacology and adverse reactions section of the label. There was no new efficacy data submitted for our statistical review. We agreed with the revised efficacy results in the clinical trial section. From a statistical perspective, there are no further efficacy comments pertaining to this submission.

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/s/

Mahboob Sobhan
10/20/2008 04:36:11 PM
BIOMETRICS

STATISTICAL EVALUATION OF NEW NDAs - FILEABILITY

NDA:	22-030
Drug Name:	Fesoterodine
Sponsor:	Schwarz Pharma.
Indications:	Treatment of overactive bladder.
Medical Officer:	Suresh Kaul, M.D., HFD-580
Statistician:	Mahboob Sobhan, Ph.D., HFD-715
Project Manager:	Jean Makie
Submission Date:	3/17/2006
45 day Meeting Date:	5/10/2006

Two P3 controlled studies constitutes the main database to support the above indication. In addition, efficacy data from three ongoing open-label studies wee also submitted. The summary of the two P3 studies are as follows:

Brief Summary of Controlled Trials

Study	Site(s)	No. of Patients Randomized/ Treatments	Duration of Treatment	Endpoints (P-value*)
SP583	Europe, Australia, New Zealand, South Africa	Total: 1135 Placebo: 285 Feso 4mg: 272 Feso 8mg: 288 Tolt 4mg: 290	12 weeks	Co-primary: • Change in micturitions • Change in incontinence episodes Secondary • Change in urge incontinence • Volume voided • Health outcomes
S584	USA	Total: 836 Placebo: 274 Feso 4mg: 283 Feso 8mg: 279	12 weeks	Co-primary • Change in micturitions • Change in incontinence episodes Secondary • Change in urge incontinence • Volume voided • Health outcomes

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