CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

21698

CLINICAL PHARMACOLOGY AND BIOPHARMACEUTICS REVIEW(S)

DEPARTMENT OF HEALTH AND HUMAN SERVICES PUBLIC HEALTH SERVICE FOOD AND DRUG ADMINISTRATION	**Clinical Pharmacology & Biopharmaceutics (HFD 870)** **Tracking/Action Sheet for Formal/Informal Consults**

From: **Tien-Mien Chen, Ph.D. (HFD-870)**			**To: DOCUMENT ROOM (LOG-IN and LOG-OUT)** **Please log-in this consult and review action for the specified IND/NDA submission**	
DATE: 06/10/04	IND No.: Serial No.:	NDA No. 21-698	DATE OF DOCUMENT **10/31/03** (N-000) and **05/06/04** (N-000, BL)	
NAME OF DRUG **[Zantac 150;** **ranitidine 150 mg Tablet]**	PRIORITY CONSIDERATION		Date of informal/Formal Consult: 12/09/03	

NAME OF THE SPONSOR: **[Pfizer]**

TYPE OF SUBMISSION

CLINICAL PHARMACOLOGY/BIOPHARMACEUTICS RELATED ISSUE

- ☐ PRE-IND
- ☐ ANIMAL to HUMAN SCALING
- ☐ IN-VITRO METABOLISM
- ☐ PROTOCOL
- ☐ PHASE II PROTOCOL
- ☐ PHASE III PROTOCOL
- ☐ DOSING REGIMEN CONSULT
- ☐ PK/PD- POPPK ISSUES
- ☐ PHASE IV RELATED
- ☐ DISSOLUTION/IN-VITRO RELEASE
- ☐ BIOAVAILABILITY STUDIES
- ☐ IN-VIVO WAIVER REQUEST
- ☐ SUPAC RELATED
- ☐ CMC RELATED
- ☐ PROGRESS REPORT
- ☐ SCIENTIFIC INVESTIGATIONS
- ☐ MEETING PACKAGE (EOP2/Pre-NDA/CMC/Pharmacometrics/Others)
- ☐ FINAL PRINTED LABELING
- ☐ LABELING REVISION
- ☐ CORRESPONDENCE
- ☐ DRUG ADVERTISING
- ☐ ADVERSE REACTION REPORT
- ☐ ANNUAL REPORTS
- ☐ FAX SUBMISSION
- ☒ OTHER *(SPECIFY BELOW)*: [Rx to OTC switch]

REVIEW ACTION

- ☐ NAI (No action indicated)
- ☐ E-mail comments to:
  ☐Medical ☐Chemist ☐Pharm-Tox ☐Micro ☐Pharmacometrics ☐Others
  (Check as appropriate and attach e-mail)
- ☐ Oral communication with
  Name: [ ]
- ☐ Comments communicated in meeting/Telecon. see meeting minutes dated: [ ]
- ☐ Formal Review/Memo (attached)
- ☒ • See comments below
- ☐ • See submission cover letter
- ☐ OTHER *(SPECIFY BELOW)*: [ ]

REVIEW COMMENT(S)

☐ **NEED TO BE COMMUNICATED TO THE SPONSOR** ☐ **HAVE BEEN COMMUNICATED TO THE SPONSOR**

COMMENTS/SPECIAL INSTRUCTIONS:

[X] Zantac 300 and 150 (ranitidine 300 and 150 mg) oral tablets have been on the market for prescription use under NDA 18-703 since 1983 . Zantac 75 (ranitidine 75 mg) under NDA 20-520 has been on the market for over the counter (OTC) use since 12/19/95 for **1)** relief of heartburn associated with acid ingestion and sour stomach and **2)** prevention of heartburn associated with acid ingestion and sour stomach brought on by certain foods and beverages. For the purpose of prevention of heartburn, Zantac 75 is to be given **30-60 min before** eating or drinking. The ownership of Zantac 75 was transferred from GlaxoSmithKline (GSK) to Pfizer on 01/01/99.

In October, 2000, Pfizer further obtained rights for future OTC use of Zantac 150 from GSK. On 10/31/03, Pfizer submitted NDA 21-698 for Zantac 150 for OTC use for **1)** treatment of heartburn and **2)** prevention of heartburn

On 05/06/04, the sponsor submitted revised version of proposed labeling.

Five clinical trials (two trials support the treatment of heartburn and three support the prevention of heartburn) along with literature data were submitted in support of the application. No new pharmacokinetic data was submitted to support this NDA. This review will focus only on the sponsor's proposed labeling revisions.

RECOMMENDATION:

4 Page(s) Withheld

_____ Trade Secret / Confidential

✓ Draft Labeling

_____ Deliberative Process

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

/s/

Tien-Mien Chen
6/10/04 10:30:28 AM
BIOPHARMACEUTICS

Suresh Doddapaneni
6/10/04 12:05:03 PM
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