

**CENTER FOR DRUG EVALUATION AND
RESEARCH**

APPLICATION NUMBER:

22-045

**CLINICAL PHARMACOLOGY AND
BIOPHARMACEUTICS REVIEW(S)**

DEPARTMENT OF HEALTH AND
HUMAN SERVICES
PUBLIC HEALTH SERVICE
FOOD AND DRUG ADMINISTRATION

Clinical Pharmacology
Tracking/Action Sheet for Formal/Informal Consults

From: Sue-Chih Lee, Ph.D.

To: DOCUMENT ROOM (LOG-IN and LOG-OUT)
Please log-in this consult and review action for the specified
IND/NDA submission

DATE: 12/18/06

IND No.:
Serial No.:

NDA No.
22-045

Document ID:

DATE OF DOCUMENT
3/24/06

NAME OF DRUG
YAZ

PRIORITY CONSIDERATION
Standard

Document Type and
Sequence No.:

Date of informal/Formal
Consult:

NAME OF THE SPONSOR: Berlex

TYPE OF SUBMISSION

CLINICAL PHARMACOLOGY/BIOPHARMACEUTICS ASSIGNMENT

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

REVIEW ACTION

NAI (No action indicated)

- | | | |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <input checked="" type="checkbox"/> E-mail comments to:
<input checked="" type="checkbox"/> Medical <input type="checkbox"/> Chemist <input type="checkbox"/> Pharm-Tox
<input type="checkbox"/> Micro <input type="checkbox"/> Pharmacometrics <input checked="" type="checkbox"/> Others
(Check as appropriate and attach e-mail)
Millie Wright (Project Manager,
HFD-540) | <input type="checkbox"/> Oral communication with
Name: []
<input type="checkbox"/> Comments communicated in
meeting/Telecon. see meeting minutes
dated: [] | <input type="checkbox"/> Formal Review/Memo (attached)
<input type="checkbox"/> See comments below
<input type="checkbox"/> See submission cover letter
<input type="checkbox"/> OTHER (SPECIFY BELOW):
[] |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|

REVIEW COMMENT(S)

NEED TO BE COMMUNICATED TO THE SPONSOR

HAVE BEEN COMMUNICATED TO THE SPONSOR

COMMENTS/SPECIAL INSTRUCTIONS:

The following drug-drug interaction information should be added to the YAZ label. This comment has been communicated to the clinical division.

SIGNATURE OF REVIEWER: Sue-Chih Lee

Date: 12/18/06

SIGNATURE OF ACTING TEAM LEADER: Abimbola
Adebowale

Date:

CC.: HFD # []; TL: []; DD: [] CDR;

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

/s/

Sue Chih Lee
12/20/2006 12:11:45 PM
BIOPHARMACEUTICS

Abi Adebawale
12/20/2006 01:59:16 PM
BIOPHARMACEUTICS