

**CENTER FOR DRUG EVALUATION AND  
RESEARCH**

*APPLICATION NUMBER:*

**22-045**

**PHARMACOLOGY REVIEW**



DEPARTMENT OF HEALTH AND HUMAN SERVICES  
PUBLIC HEALTH SERVICE  
FOOD AND DRUG ADMINISTRATION  
CENTER FOR DRUG EVALUATION AND RESEARCH

## PHARMACOLOGY/TOXICOLOGY REVIEW AND EVALUATION

NDA NUMBER: 22-045  
SERIAL NUMBER: 000  
DATE RECEIVED BY CENTER: 24-MAR-2006  
PRODUCT: YAZ tablets  
INTENDED CLINICAL POPULATION: Female acne patients who choose to use oral  
contraceptives  
SPONSOR: Berlex  
DOCUMENTS REVIEWED: All  
REVIEW DIVISION: Division of Dermatology and Dental Drug  
Products (HFD-540)  
PHARM/TOX REVIEWER: Norman A. See, Ph.D.  
PHARM/TOX SUPERVISOR: Paul Brown, Ph.D.  
DIVISION DIRECTOR: Susan Walker, M.D.  
PROJECT MANAGER: Mildred Wright

Date of review submission to Division File System (DFS): 04-OCT-2006

## ***EXECUTIVE SUMMARY***

### **I. Recommendations**

- A. Recommendation on approvability: The product is approvable with respect to nonclinical concerns.
- B. Recommendation for nonclinical studies: None.
- C. Recommendations on labeling: The labeling currently associated with NDA 21-676 is acceptable with respect to nonclinical issues that are associated with NDA 22-045, including the "Pregnancy Category" and "Carcinogenesis, Mutagenesis, and Impairment of Fertility" portions of the label.

### **II. Summary of nonclinical findings**

- A. Brief overview of nonclinical findings: Please see Pharmacology reviews associated with NDA 21-676.
- B. Pharmacologic activity: Please see Pharmacology reviews associated with NDA 21-676.
- C. Nonclinical safety issues relevant to clinical use: Please see Pharmacology reviews associated with NDA 21-676.

## **OVERALL CONCLUSIONS AND RECOMMENDATIONS**

Conclusions: NDA 21-676 was approved on 16-MAR-2006 for the indication of oral contraception. NDA 22-045 is a supplemental application ("efficacy supplement") that was submitted to add to NDA 21-676 the indication of " \_\_\_\_\_"

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\_\_\_\_\_ The drug product, conditions of use, and patient population (healthy young women who may have acne) associated with NDA 22-045 are identical to those associated with NDA 21-676. Therefore, the nonclinical database associated with the approved NDA 21-676 adequately addresses the nonclinical issues associated with NDA 22-045. Note that the sponsor of NDA 21-676 also submitted NDA 22-045, and has the right to reference the data in NDA 21-676.

Unresolved toxicology issues (if any): Please see Pharmacology reviews associated with NDA 21-676.

Recommendations: None.

Suggested labeling: Please see Pharmacology reviews associated with NDA 21-676, and the approved label of NDA 21-676.

Signatures (optional):

Reviewer Signature \_\_\_\_\_

Supervisor Signature \_\_\_\_\_ Concurrence Yes \_\_\_ No \_\_\_

**APPENDIX/ATTACHMENTS**

**APPEARS THIS WAY  
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/s/

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Norman See  
10/4/2006 10:36:10 AM  
PHARMACOLOGIST

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