CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

21-873

PROPRIETARY NAME REVIEW(S)

CONSULTATION RESPONSE
DIVISION OF MEDICATION ERRORS AND TECHNICAL SUPPORT
OFFICE OF DRUG SAFETY
(DMETS; HFD-420)

DATE RECEIVED: March 30, 2005 and April 14, 2005 **DOCUMENT DATE:** December 22, 2004	**DESIRED COMPLETION DATE:** June 1, 2005 **PDUFA DATE:** October 23, 2005	**ODS CONSULT #:** 04-0013-3 and 04-0013-4

TO: Daniel Shames, M.D.
Director, Division of Reproductive and Urologic Drug Products
HFD-580

THROUGH: Charlene Williamson
Project Manager, Division of Reproductive and Urologic Drug Products
HFD-580

PRODUCT NAME: **YAZ™** (Drospirenone and Ethinyl Estradiol Tablets) 3 mg/0.02 mg **NDA #:** 21-873	**SPONSOR:** Berlex Laboratories, Inc.

SAFETY EVALUATOR: Laura Pincock, Pharm.D.

RECOMMENDATIONS:

1. DMETS continues to not recommend the use of the proprietary name, "YAZ™".

2. DMETS recommends implementation of the label and labeling revisions outlined in the Section III of this review in order to minimize potential errors with the use of this product.

3. DDMAC finds the proprietary name, YAZ™, acceptable from a promotional perspective.

Denise P. Toyer, Pharm.D.
Deputy Director
Division of Medication Errors and Technical Support
Office of Drug Safety
Phone: (301) 827-3242 Fax: (301) 443-9664

Carol Holquist, R.Ph.
Director
Division of Medication Errors and Technical Support
Office of Drug Safety
Phone: (301) 827-3242 Fax: (301) 443-9664

Division of Medication Errors and Technical Support
Office of Drug Safety
HFD-420; Parklawn Rm. 6-34
Center for Drug Evaluation and Research

PROPRIETARY NAME REVIEW

DATE OF REVIEW: July 8, 2005

NDA #: 21-873

NAME OF DRUG: YAZ™
(Drospirenone and Ethinyl Estradiol Tablets)
3 mg/0.02 mg

NDA SPONSOR: Berlex Laboratories, Inc.

I. INTRODUCTION

This consult was written in response to a request from the Division of Reproductive and Urologic Drug Products (HFD-580), for reassessment of the proprietary name, YAZ™. In a review dated March 10, 2004 (ODS Consult #04-0013, NDA #21-676), DMETS recommended against the use of the proposed proprietary name, YAZ™. DMETS was concerned that the proprietary name YAZ™ could be misinterpreted as an abbreviation for the medication Yasmin. Misinterpretation of the proposed proprietary name YAZ™ would cause confusion and could result in medication errors. In a correspondence dated May 14, 2004, the sponsor submitted a request for reconsideration of the proposed name. Additionally, the sponsor submitted an independent analysis conducted by [redacted] in support of the proposed name YAZ™. In a review dated July 1, 2004 (ODS Consult #04-0013-2, NDA #21-676), DMETS reviewed and evaluated the [redacted] market research study for YAZ™ and concluded that the information provided had failed to provide persuasive evidence for DMETS to reverse its initial decision on the acceptability of the proprietary name YAZ™. Despite DMETS' concerns, the Division of Reproductive and Urologic Drug Products made the decision to accept the tradename YAZ™.

PRODUCT INFORMATION

YAZ™ is indicated for the prevention of pregnancy in women who elect to use an oral contraceptive. YAZ™ is also indicated for the treatment of symptoms of premenstrual dysphoric disorder (PMDD) in women who have no known contraindication to oral contraceptives and who desire contraception. The recommended dosage of YAZ™ is one tablet once daily without regard to meals. YAZ™ consists of 24 tablets of monophasic combined hormonal preparation plus 4 inert tablets. A patient should start YAZ™ either the first day of her menstrual period or the first Sunday after the onset of her menstrual period. YAZ™ will be supplied in packages of 3 blister packs. Each blister pack contains 28 tablets. The labeling contains a detailed package insert to be provided to the patient.

II. RISK ASSESSMENT:

The medication error staff of DMETS conducted a search of several standard published drug product reference texts[i,ii] as well as several FDA databases[iii] for existing drug names which sound-alike or look-alike to YAZ™ to a degree where potential confusion between drug names could occur under the usual clinical practice settings. A search of the electronic online version of the U.S. Patent and Trademark Office's Text and Image Database[iv] and the data provided by Thomson & Thomson's SAEGIS™ Online Service[v] were also conducted. An Expert Panel discussion was conducted to review all findings from the searches.

A. EXPERT PANEL DISCUSSION (EPD)

An Expert Panel discussion was held by DMETS to gather professional opinions on the safety of the proprietary name, YAZ™. Potential concerns regarding drug marketing and promotion related to the proposed name were also discussed. This group is composed of DMETS Medication Errors Prevention Staff and representation from the Division of Drug Marketing, Advertising, and Communications (DDMAC). The group relies on their clinical and other professional experiences and a number of standard references when making a decision on the acceptability of a proprietary name.

1. DDMAC has no objection to the use of the proprietary name, YAZ™.

2. The Expert Panel identified no additional names that were thought to have the potential for confusion with YAZ™.

B. PHONETIC ORTHOGRAPHIC COMPUTER ANALYSIS (POCA)

As part of the name similarity assessment, proposed names are evaluated via a phonetic/orthographic algorithm. The proposed proprietary name is converted into its phonemic representation before it runs though the phonetic algorithm. The phonetic search modules return a numeric score to the search engine based on the phonetic similarity to the input text. Likewise, an orthographic algorithm exists which operates in a similar fashion. All names considered having significant phonetic or orthographic similarities to YAZ™ were discussed by the Expert Panel (EPD).

C. SAFETY EVALUATOR RISK ASSESSMENT

In reviewing the proprietary name, YAZ™, no additional names were identified by the Expert Panel or the Independent Review. However, DMETS continues to be concerned that the proposed name could be misinterpreted as an abbreviation for the medication Yasmin. The proposed name looks

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[i] MICROMEDEX Integrated Index, 2005, MICROMEDEX, Inc., 6200 South Syracuse Way, Suite 300, Englewood, Colorado 80111-4740, which includes all products/databases within ChemKnowledge, DrugKnowledge, and RegsKnowledge Systems.

[ii] Facts and Comparisons, online version, Facts and Comparisons, St. Louis, MO.

[iii] AMF Decision Support System [DSS], the Division of Medication Errors and Technical Support proprietary name consultation requests, New Drug Approvals 1998-2005, and the electronic online version of the FDA Orange Book.

[iv] WWW location http://www.uspto.gov.

[v] Data provided by Thomson & Thomson's SAEGIS(tm) Online Service, available at www.thomson-thomson.com.

like a three letter abbreviation for something rather than a name itself. Therefore, healthcare professionals and patients may attempt to associate the name as an abbreviation for another medication. ———— , market research study, which DMETS reviewed in ODS Consult # 04-0013-2, showed that without prior knowledge of the product information (unaided research) 19 physicians and/or pharmacists (9.5%) associated the name YAZ™ with the proprietary name Yasmin. DMETS concluded that the —study failed to provide persuasive evidence for DMETS to reverse its initial decision (ODS Consult # 04-0013) on the acceptability of the proprietary name, YAZ™. In ODS Consults # 04-0013-3 and 04-0013-4, DMETS still does not recommend the use of the proprietary name, YAZ™.

III. LABELING, PACKAGING, AND SAFETY RELATED ISSUES

In review of the draft container labels, carton and package insert labeling of YAZ™, DMETS has attempted to focus on safety issues relating to possible medication errors and have identified the following areas of possible improvement, which might minimize potential user error.

APPEARS THIS WAY
ON ORIGINAL

IV. RECOMMENDATIONS:

A. DMETS continues to not recommend the use of the proprietary name, "YAZ™".

B. DMETS recommends implementation of the label and labeling revisions outlined in the Section III of this review in order to minimize potential errors with the use of this product.

C. DDMAC finds the proprietary name, YAZ™, acceptable from a promotional perspective.

DMETS would appreciate feedback of the final outcome of this consult. We are willing to meet with the Division for further discussion as well. If you have any questions concerning this review, please contact Diane Smith at 301-827-1998.

Laura Pincock, Pharm.D.
Safety Evaluator
Division of Medication Errors and Technical Support
Office of Drug Safety

Concur:

Linda Kim-Jung, Pharm.D.
Team Leader
Division of Medication Errors and Technical Support
Office of Drug Safety

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

/s/

Laura Pincock
8/18/2005 02:35:42 PM
DRUG SAFETY OFFICE REVIEWER

Carol Holquist
8/18/2005 02:38:42 PM
DRUG SAFETY OFFICE REVIEWER