

**CENTER FOR DRUG EVALUATION AND
RESEARCH**

APPLICATION NUMBER:

21-735

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: 21-735
SERIAL NUMBER: 000
DATE RECEIVED BY CENTER: 11/25/03
PRODUCT: Terconazole Vaginal Cream 0.8%
INTENDED CLINICAL POPULATION: Vulvovaginal Candidiasis
SPONSOR: Altana Inc,
60 Baylis Road, Melville, New York 11747
DOCUMENTS REVIEWED: Vol. 1
REVIEW DIVISION: Division of Special Pathogen and
Immunologic Drug Products (HFD-590)
PHARM/TOX REVIEWER: Owen G McMaster, PhD
PHARM/TOX SUPERVISOR: Steve Hundley, PhD (Acting)
DIVISION DIRECTOR: Renata Albrecht, MD
PROJECT MANAGER: Yon Yu
Review to Division File System (DFS): 10/01/04

INTRODUCTION AND DRUG HISTORY

Terconazole is a triazole antifungal with the chemical name *cis*-1-p[[2-(2,4-Dichlorophenyl)-2-(1*H*-1,2,4-triazol-1-ylmethyl)-1,3-dioxolan-4-yl]methoxy]phenyl]-4-isopropylpiperazine. The formulation of the vaginal cream is essentially identical to that of an approved product Terazol® (see Table 1, below).

Table 1. Components of terconazole vaginal cream 0.8% compared to Terazol vaginal cream 0.8%

	Function	Terconazole vaginal cream (%)	Terazol®3 vaginal cream 0.8% (%)
Terconazole	Antifungal	0.8	0.8
Butylated hydroxyanisole NF			
Cetyl alcohol NF			
Isopropyl Myristate			
Polysorbate 60 NF			
Polysorbate 80 NF			
Propylene glycol USP			
Stearyl alcohol NF			
Purified water USP			

The sponsor initially submitted this NDA to the Office of Generic Drugs in order to get a generic designation. Review of the data showed that the drug performed better than the approved comparator drug. The Office of Generic Drugs therefore refused to file the drug and referred them to the Division of Special Pathogens.

No new Pharmacology or Toxicology data was submitted with this NDA and the sponsor refers us to NDA 19-964 and the label for Terazol® for information.

EXECUTIVE SUMMARY

I. Recommendations

A. Recommendation on approvability.

There is no information in this submission that would preclude the approval of Terconazole Vaginal Cream for the treatment of vulvovaginal candidiasis,

B. Recommendation for nonclinical studies

No additional nonclinical studies are indicated at this time.

C. Recommendations on labeling

Information in the label of the reference product (Terazol) provides adequate preclinical information to the doctor and patient that will be using this product.

OVERALL CONCLUSIONS AND RECOMMENDATIONS

Terconazole 0.8% vaginal cream is essentially identical to the approved reference product Terazol® vaginal cream 0.8%. There is no information in this submission that would preclude the approval of Terconazole Vaginal Cream for the treatment of vulvovaginal candidiasis.

Owen McMaster, PhD
Pharmacology/Toxicology Reviewer
Division of Special Pathogen and Immunologic Drug Products
HFD-590

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/s/

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10/1/04 11:10:12 AM
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