

**CENTER FOR DRUG EVALUATION AND
RESEARCH**

APPLICATION NUMBER:

21-735

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

CLINICAL PHARMACOLOGY / BIOPHARMACEUTICS REVIEW

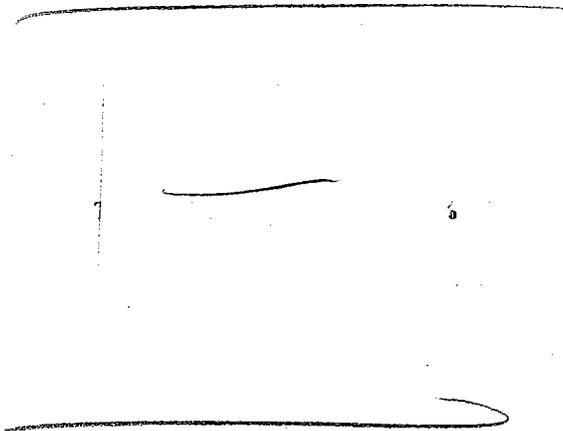
NDA:	21-735 (N-000)
Submission Date:	25 November 2003
Drug Product:	Terconazole Vaginal Cream, 0.8%
Trade Name:	N/A
Sponsor:	Altana, Inc.
Submission Type:	505(b)(2) NDA
Indication:	Vulvovaginal Candidiasis
OCPB Reviewer:	Gerlie C. De Los Reyes, Ph.D.
Team Leader:	Philip M. Colangelo, Pharm.D., Ph.D.

I. Executive Summary:

On 31 July 2003, the sponsor submitted the findings of their completed therapeutic bioequivalence (BE) study to the Office of Generic Drugs (OGD) for review. OGD refused to file the product as a 505(j) submission because the therapeutic BE study showed that the sponsor's terconazole vaginal cream offers a slight improvement over the reference listed drug (RLD), Terazol® 7 vaginal cream, 0.8%, with a confidence interval of 102-124%, outside the 80-120% acceptance criteria. The proposed commercial formulation is qualitatively and quantitatively identical to the RLD in terms of active ingredient, dosage form and route of administration. All inactive ingredient amounts conform to ranges as listed in the Inactive Ingredients Database.

This 505(b)(2) NDA submission does not include Clinical Pharmacology and Biopharmaceutics study findings to review. Thus, the following review only addresses any additional revisions and/or comments for the proposed labeling for Terconazole Vaginal Cream, 0.8%.

II. Proposed Labeling (Version: 01 Jan 2004):



3 Page(s) Withheld

 § 552(b)(4) Trade Secret / Confidential

X § 552(b)(4) Draft Labeling

 § 552(b)(5) 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/

Gerlie De Los Reyes
7/30/04 01:56:25 PM
BIOPHARMACEUTICS

Phil: You signed on the hard copy (after 7/6/04).

Phil Colangelo
8/17/04 03:51:51 PM
BIOPHARMACEUTICS