CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

75-502

ADMINISTRATIVE DOCUMENTS

APPROVAL PACAGE SUMMARY FOR 75-502

ANDA:75-502

FIRM: Altana Inc.

DRUG: Clotrimazole and Betamethasone Dipropionate

DOSAGE: Cream

STRENGTH: 1%/0.05%

CGMP STATEMENT/EIR UPDATE STATUS: EER is acceptable 5/10/01

BIO STUDY/BIOEQUIVALENCE: Bio is satisfactory 2/27/01

METHOD VALIDATION: The drug product is compendial.

STABILITY: The firm has provided 3 months satisfactory accelerated stability data at 40 C?75%RH for 15 g tube and 45 g tube for both lots #8077 and 8078. Also 24 months room temperature stability data at 25 C/60%RH for 15 mg and 45g for both lots #8077 and #8078.

LABELING REVIEW STATUS: Labeling is acceptable 6/4/01

STERILIZATION VALIDATION: N/A

BATCH SIZES: The firm has provided a copy of the exhibit batch lot #8077 using drug substances supplied by and for bioequvalence, Also, drug substance supplied by and P for stability. The maximum production batch is . The firm will be using the same drug substances suppliers', same process and same equipment.

COMMENTS: The application is approvable

REVIEWER: Nashed E. Nashed, Ph.D. DATE: 6/4/01

SUPERVISOR: Paul Schwartz, Ph.D. DATE: 6/4/01

PS 6/4/01

OFFICE OF GENERIC DRUGS
DIVISION OF BIOEQUIVALENCE

ANDA # 75-502 SPONSOR: Altana, Inc.

DRUG AND DOSAGE FORM : Clotrimazole and Betamethasone Dipropionate Cream, USP

STRENGTH: Clotrimazole, 1% and Betamethasone Dipropionate 0.05%

TYPES OF STUDIES: Pilot dose-response and pivotal in vivo bioequivalence vasoconstriction studies for the corticosteroid component, and a clinical study with respect to the clortrimazole component.

PILOT DOSE-RESPONSE STUDY SITE: ClinSites/LeeCoast Research Center, Inc., Fort Myers, FL

PIVOTAL VASOCONSTRICTION STUDY SITE: ClinSites/LeeCoast Research Center, Inc., Fort Myers, FL

CLINICAL STUDY SITE: Bailer Research, Inc., NJ

STUDY SUMMARY: The pilot dose-response study, pivotal in vivo bioequivalence vasoconstriction study for the corticosteroid component, and the clinical study on clortrimazole are acceptable.

DSI INSPECTION STATUS

Inspection needed: No	Inspection status:	Inspection results:
First Generic: No New facility _____ For cause _____ Other _____	Inspection requested: (date) Inspection completed: (date)	

PRIMARY REVIEWER : James Chaney BRANCH : I

INITIAL : JC DATE : 2/21/01

TEAM LEADER : Yih-Chain Huang BRANCH : I

INITIAL : YCH DATE : 2/26/2001

DIRECTOR, DIVISION OF BIOEQUIVALENCE : DALE P. CONNER, Pharm. D.

INITIAL : for DPC DATE : 2/27/2001

Attachment 1

Altana ANDA 75-502

MEDICAL OFFICER SUMMARY
October 14, 1999

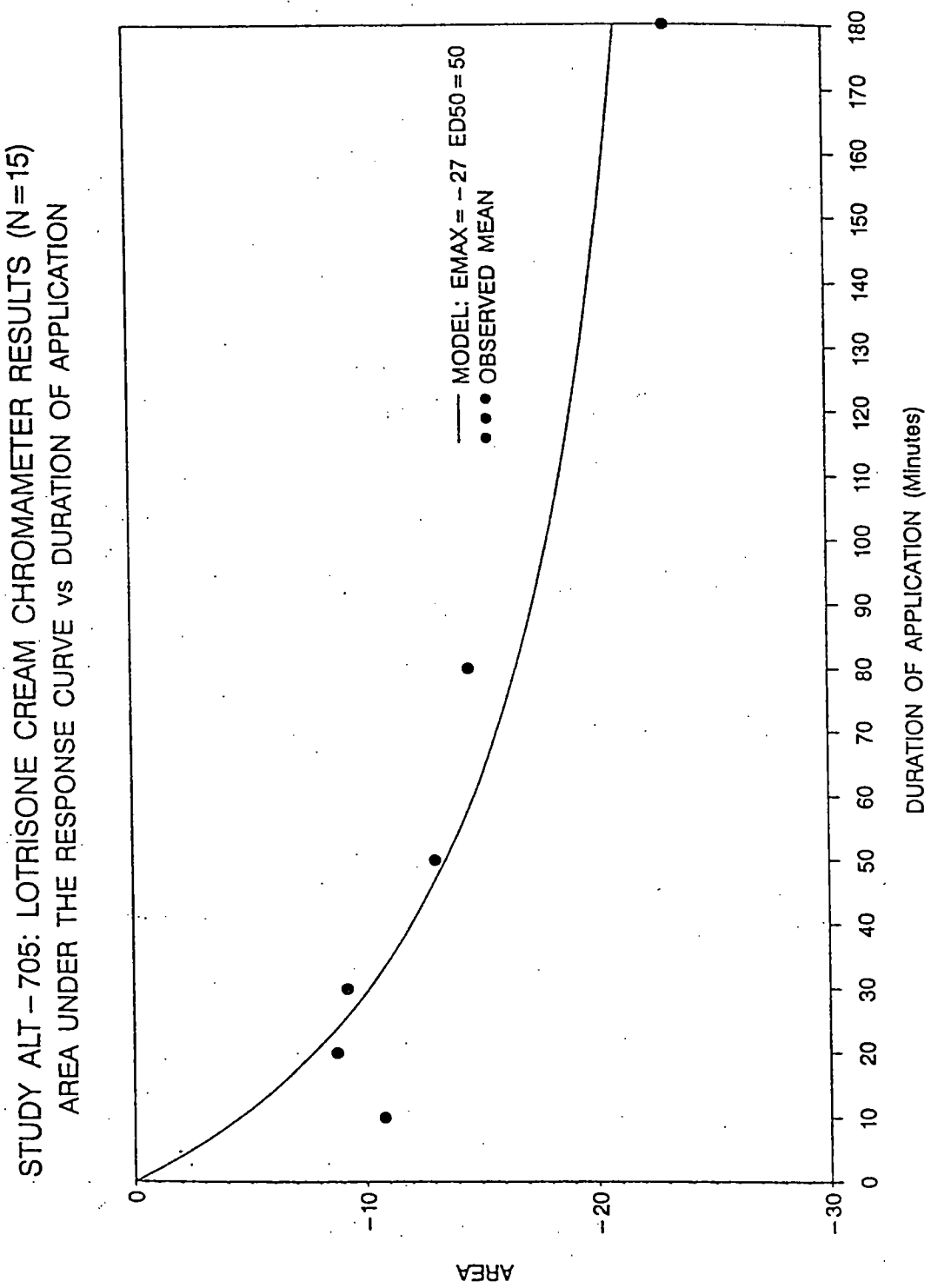
ANDA: 75-502
Drug Product: Clotrimazole, 1% and Betamethasone Dipropoinate, 0.05% Cream USP
Sponsor: Altana Inc.

The Statistician completed the review of this study and found that both active treatments, the generic and reference listed drug, were found to be efficacious when compared to placebo. The two active treatments were bioequivalent.

This study confirms the clinical bioequivalence of Altana's Clotrimazole, 1% and Betamethasone Dipropionate, 0.05% Cream USP and Schering Corporation's Lotrisone Cream.

Mary M. Fanning, M.D., Ph.D.
Associate Director for Medical Affairs
Office of Generic Drugs

Attachment 2
Altana ANDA 75-502



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Mary M. Fanning, M.D., Ph.D.
Associate Director for Medical Affairs
Office of Generic Drugs

REVIEW OF PROFESSIONAL LABELING
DIVISION OF LABELING AND PROGRAM SUPPORT
LABELING REVIEW BRANCH

ANDA Number: 75-502 Date of Submission: November 11, 1998 (Amendment)

Applicant's Name: Altana Inc.

Established Name: Clotrimazole and Betamethasone Dipropionate Cream USP, 1%/0.05% (base)

Labeling Deficiencies:

1. CONTAINER (15 g and 45 g)

   a. Include the product strength with the established name of your product. For example:

      CLOTRIMAZOLE AND
      BETAMETHASONE DIPROPIONATE
      CREAM USP, 1%/0.05% (base)

   b. Relocate "FOR DERMATOLOGIC USE ONLY. NOT FOR OPHTHALMIC USE." to the main display panel.

   c. In the "Each gram contains" statement:

      i. Delete use of the terminal zero (i.e., 10 mg rather than 10.0 mg).

      ii. Delete "USP".

      iii. Revise the ultimate sentence to read, Benzyl alcohol added as a preservative.

2. CARTON (15 g and 45 g)

   See CONTAINER comments (a) and (c).

3. INSERT

   a. DESCRIPTION

      i. See CONTAINER comments under (c).

      ii. Replace "empirical" with "molecular" in the second and fourth paragraphs.

iii. Subscript the "7" in the molecular formula for clotrimazole.

b. CLINICAL PHARMACOLOGY

Revise the ultimate sentence of paragraph 7 to read, …dressing of 0.5 mL…

c. PRECAUTIONS

i. Information for Patients

Replace "of" with "or" in the ultimate sentence of #2.

ii. Pediatric Use

Replace "children" with "pediatric patients".

iii. ADVERSE REACTIONS

Delete the colon following "cream" in the first paragraph.

Please revise your labels and labeling, as instructed above, and submit in final print.

Please note that the Agency reserves the right to request further changes in your labels and/or labeling based upon changes in the approved labeling of the listed drug or upon further review of the application prior to approval.

To facilitate review of your next submission, and in accordance with 21 CFR 314.94(a)(8)(iv), please provide a side-by-side comparison of your proposed labeling with your last submission with all differences annotated and explained.

John D. Grace for

Robert L. West, M.S., R.Ph.
Director
Division of Labeling and Program Support
Office of Generic Drugs
Center for Drug Evaluation and Research

ANDA 75-502

Altana Inc.
Attention: Virginia Carman
60 Baylis Road
Melville, NY 11747

DEC 8 1998

Dear Madam:

We acknowledge the receipt of your abbreviated new drug application submitted pursuant to Section 505(j) of the Federal Food, Drug and Cosmetic Act.

Reference is made to the telephone conversation dated November 30, 1998 and your correspondence dated November 30, 1998.

NAME OF DRUG: Clotrimazole and Betamethasone Dipropionate Cream USP, 1%/0.05% (base)

DATE OF APPLICATION: November 11, 1998

DATE (RECEIVED) ACCEPTABLE FOR FILING: November 12, 1998

We will correspond with you further after we have had the opportunity to review the application.

Please identify any communications concerning this application with the ANDA number shown above.

Should you have questions concerning this application, contact:

Joseph Buccine
Project Manager
(301) 827-5848

Sincerely yours,

Robert L. West, M.S., R.Ph.
Director
Division of Labeling and Program Support
Office of Generic Drugs
Center for Drug Evaluation and Research