CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER _____

ADMINISTRATIVE DOCUMENTS

ANDA APPROVAL SUMMARY

ANDA:	CHEMIST:	DATE:
75-430	Kathy P. Woodland	April 6, 1999

DRUG PRODUCT:
Clobetasol Propionate Cream, 0.05% (Emollient)

FIRM:
Altana Inc.

DOSAGE FORM:	STRENGTH:
Cream (Emollient)	0.05%

cGMP:
Satisfactory October 1998

BIO:
Satisfactory, March 1999

VALIDATION - *(Description of dosage form same as firm's):*
Method Validation was found satisfactory, March 8, 1999.

STABILITY:
The containers in the stability studies are identical to those in the container section.

LABELING:
Approved by L Golson on February 19, 1999

STERILIZATION VALIDATION *(If applicable)*:
N/A

SIZE OF BIO BATCH *(Firm's source of NDS ok?)*:

SIZE OF STABILITY BATCHES *(If different from bio batch, were they Manufactured via the same process?)*:
Same as bio batch.

PROPOSED PRODUCTION BATCH - MANUFACTURING PROCESS THE SAME?:
The proposed production batch size is

Signature of chemist:	Signature of supervisor:
/S/	/S/ 4/6/99

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ADDENDUM TO THE REVIEW

Comments

1. The applicant has conducted a pilot and a pivotal dose-response study as per the OGD 1995 Guidance for Industry: Topical Dermatologic Corticosteroids: *In Vivo* Bioequivalence.

2. The clobetasol population ED_{50} of 19 minutes, determined for Temovate E® 0.05% in the pilot study, is consistent with previously reported values.

Recommendations

1. The in vivo bioequivalence study conducted by Altana Inc., on its Clobetasol Propionate Emollient Cream USP, 0.05% (Lot #B156) comparing it to the reference product, Temovate E® (Lot #7J370) has been found acceptable to the Division of Bioequivalence. The results of the pivotal vasoconstrictor study demonstrate that Altana's Clobetasol Propionate Emollient Cream USP, 0.05% is bioequivalent to the reference product, Temovate E®, 0.05%, manufactured by Glaxo Wellcome.

2. The firm should be informed of the above recommendation.

/S/

Barbara M. Davit, Ph.D.
Team Leader, Review Branch III
Division of Bioequivalence

Date: 3/1/99

Concur: /S/

Dale P. Conner, Pharm.D.
Director
Division of Bioequivalence

Date: 3/4/99

NDA 20-730

RECORD OF TELEPHONE CONVERSATION

Reference was made to the amendment dated 2/12/99.

Following discussions with K.Woodland and P.Schwartz, I called the firm and requested the following addition information.

1. Please explain the outlying stability value aken from the middle portion of the tube.

2. Please identify the mean value referred to in the homogeneity spec of f the mean.

A t-amendment will follow.

LECONS\75430.001

DATE 3/17/99

ANDA 75430

TELECON

INITIATED BY FDA

PRODUCT NAME
Clobetasol

FIRM NAME
Altana

NAME AND TITLE OF PERSON WITH WHOM CONVERSATION WAS HELD
Virginia Carmen

TELEPHONE NUMBER
516 454 7677

SIGNATURE
Joseph Buccine
/S/