

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER

ADMINISTRATIVE DOCUMENTS

ANDA APPROVAL SUMMARY

ANDA: 75-430	CHEMIST: Kathy P. Woodland	DATE: April 6, 1999
DRUG PRODUCT: Clobetasol Propionate Cream, 0.05% (Emollient)		
FIRM: Altana Inc.		
DOSAGE FORM: Cream (Emollient)	STRENGTH: 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: /s/		Signature of supervisor: /s/ 1/6/99

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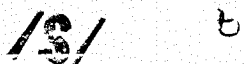
ADDENDUM TO THE REVIEW

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 ED₅₀ 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.


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

3/1/99
Date:

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

Date: 3/4/99

15120

RECORD OF TELEPHONE CONVERSATION

<p>Reference was made to the amendment dated 2/12/99.</p> <p>Following discussions with K.Woodland and P.Schwartz, I called the firm and requested the following addition information.</p> <p>1. Please explain the outlying stability value taken from the middle portion of the tube.</p> <p>2. Please identify the mean value referred to in the homogeneity spec of the mean.</p> <p>A t-amendment will follow.</p> <p>LECONS\75430.001</p>	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/	