CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

75391

BIOEQUIVALENCY REVIEW(S)

OFFICE OF GENERIC DRUGS
DIVISION OF BIOEQUIVALENCE

DRUG NAME: Clobetasol Propionate Topical Solution, 0.05%
ANDA #: 75-391
SPONSOR: Altana Inc.
DOSAGE FORM: Topical Solution **STRENGTH:** 0.05%
TYPE OF STUDY: N/A
STUDY SITE: N/A

Waiver request for Clobetasol Propionate Topical Solution, 0.05%

Compositions of the test and reference products are similar. Waiver request for the test product is granted per 21 CFR 320.22(b)(3).

DISSOLUTION: N/A

PRIMARY REVIEWER: Nhan L. Tran, Ph.D. **BRANCH:** II

INITIAL: NLT DATE: 10/14/98

BRANCH CHIEF: Shriniwas Nerurkar, Ph.D. **BRANCH:** II

INITIAL: /S/ DATE: 10/14/1998

DIRECTOR, DIVISION OF BIOEQUIVALENCE: Dale Conner, Pharm.D.

INITIAL: DPC DATE: 10/19/98

14 Draft

BIOEQUIVALENCY COMMENTS

ANDA:75-391 APPLICANT: Altana Inc.

DRUG PRODUCT: Clobetasol Propionate Topical Solution, 0.05%

The Division of Bioequivalence has completed its review and has no further questions at this time.

Please note that the bioequivalency comments provided in this communication are preliminary. These comments are subject to revision after review of the entire application, upon consideration of the chemistry, manufacturing and controls, microbiology, labeling, or other scientific or regulatory issues. Please be advised that these reviews may result in the need for additional bioequivalency information and/or studies, or may result in a conclusion that the proposed formulation is not approvable.

Sincerely yours,

/S/

Dale Conner, Pharm. D.
Director, Division of Bioequivalence
Office of Generic Drugs
Center for Drug Evaluation and Research

Clobetasol Propionate
0.05% Topical Solution
ANDA # 75-391
Reviewer: Nhan L. Tran

Altana Inc.
Melville, NY
Submission Date:
May 27, 1998

REVIEW OF A WAIVER REQUEST

Clobetasol propionate topical solution 0.05% is a corticosteroid, and it is indicated for short-term topical treatment of inflammatory and pruritic manifestations of moderate to severe corticosteroid-responsive dermatoses of the scalp.
The firm is requesting a waiver of the in-vivo bioequivalence requirements for their Clobetasol propionate topical solution 0.05%. The waiver request is based upon comparable formulation to the reference product Temovate[R] manufactured by Glaxo-Wellcome.

Comments:

1. The product meets the criteria for waiver of the in vivo bioequivalence study requirements set forth in CFR 320.22b(3)(I)(ii)(iii).
   a. The test product is a solution intended solely for application to the skin.
   b. It contains an active ingredient in the same concentration and dosage form as a drug product that is subject to an approved full new drug application.
   c. It contains no inactive ingredient or other change in formulation from the drug product that is the subject of the approved full new drug application that may significantly affect absorption of the active moiety.

2. The comparative formulations for the 0.05% Topical Solution is presented in Table 1.

Table 1. Comparative formulations for the reference and test Clobetasol propionate topical solutions.

0.05% Topical Solution	Reference	Test
Clobetasol Propionate	0.05%	0.05%
Carbomer 934P	%	%
Isopropyl Alcohol	39.3%	39.3%
Sodium hydroxide	adjust for pH	adjust for pH
Purified Water	q.s.	q.s.

Comment

The firm indicates that the amount of carbomer 934P in the reference product is %. However, the correct amount should be %. The test product therefore contains % higher concentration of carbomer which is a thickening agent and this is within the % window for Q/Q.

Recommendation:

The Division of Bioequivalence agrees that the information submitted by Altana Inc., demonstrates that Clobetasol propionate topical solution; 0.05% falls under 21 CFR Section 320.22(b)(3)(I)(ii)(iii) of the Bioavailability/Bioequivalence Regulations. The waiver of in vivo bioequivalence study for the 0.05% topical solution of the test product is granted. From the bioequivalence point of view, the Division of Bioequivalence deems the test formulation to be bioequivalent to Temovate[R] manufactured by Glaxo-Wellcome.

Nhan L. Tran /S/ 10/14/98
Review Branch II

RD INITIALED SNERURKAR
FT INITIALED SNERURKAR /S/ Date 10/14/98

Concur: /S/ Date 10/19/98
Dale P. Conner, Pharm D.
Director, Division of Bioequivalence

ANDA #75-391 (original, duplicate), HFD-655 (Tran, Nerurkar), Drug File, Division File.