CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

40310

BIOEQUIVALENCY REVIEW(S)

BIOEQUIVALENCY COMMENTS TO BE PROVIDED TO THE APPLICANT

ANDA:40-310 APPLICANT: Thames Pharamcal Co.

DRUG PRODUCT:Hydrocortisone Ointment USP, 2.5%

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

OFFICE OF GENERIC DRUGS

DIVISION OF BIOEQUIVALENCE

ANDA # 40-310 SPONSOR : Thames Pharmacal Company
DRUG & DOSAGE FORM : Hydrocortisone Ointment 2.5%

STRENGTH(s) : 2.5%
TYPE OF STUDY: SD SDF MULT X OTHER

STUDY SUMMARY : N/A

Formulation is acceptable, waiver is granted

PRIMARY REVIEWER : Jahnavi S. Kharidia BRANCH :3
INITIAL : /S/ DATE : 7/30/98

Team Leader : Barbara McDavit BRANCH : 3
INITIAL : /S/ DATE : 7/30/98

DIRECTOR
DIVISION OF BIOEQUIVALENCE
INITIAL : /S/ DATE : 8/17/98

DIRECTOR
OFFICE OF GENERIC DRUGS
INITIAL : _____ DATE :

Hydrocortisone Ointment USP
2.5%
ANDA # 40-310
Reviewer: Jahnavi S. Kharidia
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Thames Pharmacal Co. , Inc.
Ronkonkoma, NY
Submission Date:
April 17, 1998

Review of a Waiver Request

The firm has requested waiver of *in vivo* bioequivalence requirements for its Hydrocortisone Ointment USP, 2.5%, in accordance with 21 CFR 320.22 (c). Reference listed product is Dermik's Hytone® Ointment, 2.5%.

Comment

1. Hydrocortisone Ointment is AT rated in Orange Book. It is a pre-'62 drug product.

2. Formulation of the test product is shown in Table 1.

Table 1. Test Formulation **(Not to be released under FOI):**

Ingredients	Amount per gram
Hydrocortisone USP	2.5%
Mineral Oil, USP	%
White Petrolatum USP	%

3. The amount of each inactive ingredient is within the acceptable limit according to the Inactive Ingredient Guide (IIG, 1996).

4. Waiver is granted for the test product.

Recommendation

The Division of Bioequivalence agrees that the information submitted by Thames Pharmaceutical demonstrates that Hydrocortisone Ointment USP, 2.5%, falls under 21 CFR Section 320.22 (c) of the Bioavailability/ Bioequivalence Regulations. The waiver of *in vivo* bioequivalence study for Hydrocortisone

Ointment , 2.5% is granted. The test product, Thames' Hydrocortisone Ointment USP, 2.5%, is therefore deemed bioequivalent to Dermik's Hytone® Ointment, 2.5%.

/S/
Jahnavi S. Kharidia, Ph.D.
Division of Bioequivalence
Review Branch III

RD INITIALLED BY BDAVIT BMD 7/29/98
FT INITIALLED BY BDAVIT /S/ Date: 7/30/98

Concur: /S/ Date: 8/13/98
Dale P. Conner, Pharm.D.
Director
Division of Bioequivalence

cc: ANDA # 40-310 (original, duplicate), Kharidia, HFD-658, Drug File, Division File

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