

**CENTER FOR DRUG EVALUATION AND
RESEARCH**

APPLICATION NUMBER:

40310

ADMINISTRATIVE DOCUMENTS

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

ANDA Number: 40-310

Date of Submission: May 15, 1998

Applicant's Name: Thames Pharmacal Co., Inc.

Established Name: Hydrocortisone Ointment USP, 2.5%.

Labeling Deficiencies:

1. CONTAINER- 20 gm, 1 ounce, and 16 ounce.
 - i. Revise to include the statement "Keep away from eyes".
 - ii. Revise to include the statement " Keep tightly closed".
2. CARTON- 20 gm and 1 ounce.

SIDE PANEL

- i. Revise to include the phrase "Keep away from eyes"
 - ii. Revise to include "Keep tightly closed."
4. INSERT

This review is based upon the most recent package insert approved which was December 9, 1991, and which was a combination package insert for hydrocortisone 1% and 2.5% cream, lotion and ointment.

Please revise your labels and labeling, as instructed above, and submit in FPL or draft if you prefer.

Please note that we reserve 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.

/S/

—
Jerry Phillips
Director
Division of Labeling and Program Support
Office of Generic Drugs
Center for Drug Evaluation and Research