CENTER FOR DRUG EVALUATION AND RESEARCH

Approval Package for:

Application Number: 75-042

Trade Name: Hydrocortisone Valerate Cream 0.2%

Generic Name: Hydrocortisone Valerate Cream 0.2%

Sponsor: Taro Pharmaceuticals

Approval Date: 8/25/98

INDICATION(s): ..for the relief of the inflammatory and pruritic manifestations of the corticosteroid-responsive dermatoses.

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APPLICATION: 75-042

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	Included	Pending Completion	Not Prepared	Not Required
Approval Letter	X			
Tenative Approval Letter				X
Approvable Letter				X
Printed Labeling	X			
Medical Review(s)				
Chemistry Review(s)	X			
EA/FONSI				X
Pharmacology Review(s)				X
Statistical Review(s)				X
Microbiology Review(s)				X
Clinical Pharmacology Biopharmaceutics Review(s)				X
Bioequivalence Review(s)	X			
Administrative/ Correspondence Document(s)	X			

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Application Number 75042

APPROVAL LETTER

ANDA 75-042

AUG 25 1998

Taro Pharmaceuticals USA, Inc.
Attention: Lorraine W. Sachs
U.S. Agent for: Taro Pharmaceuticals, Inc.
5 Skyline Drive
Hawthorne, NY 10532

Dear Madam:

This is in reference to your abbreviated new drug application dated December 23, 1996, submitted pursuant to Section 505(j) of the Federal Food, Drug, and Cosmetic Act, for Hydrocortisone Valerate Cream USP, 0.2%.

Reference is also made to your amendments dated June 18 and November 7, 1997; and March 30, April 16, May 11, June 15, June 16, July 30, and August 19, 1998.

We have completed the review of this abbreviated application and have concluded that the drug is safe and effective for use as recommended in the submitted labeling. Accordingly, the application is approved. The Division of Bioequivalence has determined your Hydrocortisone Valerate Cream USP, 0.2%, to be bioequivalent and, therefore, therapeutically equivalent to the listed drug (Westcort® Cream, 0.2%, of Westwood Squibb Pharmaceuticals, Inc.).

Under 21 CFR 314.70, certain changes in the conditions described in this abbreviated application require an approved supplemental application before the change may be made.

Post-marketing reporting requirements for this abbreviated application are set forth in 21 CFR 314.80-81 and 314.98. The Office of Generic Drugs should be advised of any change in the marketing status of this drug.

We request that you submit, in duplicate, any proposed advertising or promotional copy which you intend to use in your initial advertising or promotional campaigns. Please submit all proposed materials in draft or mock-up form, not final print. Submit both copies together with a copy of the proposed or final printed labeling to the Division of Drug Marketing, Advertising, and Communications (HFD-40). Please do not use Form FD-2253

(Transmittal of Advertisements and Promotional Labeling for Drugs for Human Use) for this initial submission.

We call your attention to 21 CFR 314.81(b)(3) which requires that materials for any subsequent advertising or promotional campaign be submitted to our Division of Drug Marketing, Advertising, and Communications (HFD-40) with a completed Form FD-2253 at the time of their initial use.

Sincerely yours,

Douglas L. Sporn
Director
Office of Generic Drugs
Center for Drug Evaluation and Research