CENTER FOR DRUG EVALUATION AND RESEARCH

Approval Package for:

Application Number:74-579

Trade Name: Betamethasone Dipropionate Cream USP .05%

Generic Name: Betamethasone Dipropionate Cream USP .05%

Sponsor: Clay Park Labs Inc.

Approval Date: November 26, 1997

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

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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)				
Microbiology Review(s)	X			X
Clinical Pharmacology Biopharmaceutics Review(s)				X
Bioequivalence Review(s)	X			
Administrative/ Correspondence Document(s)	X			

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Application Number: 74-579

APPROVAL LETTER

ANDA 74-579

NOV 26 1997

Clay-Park Labs, Inc.
Attention: Gabriel Lebovic
1700 Bathgate Avenue
Bronx, NY 10457

Dear Sir:

This is in reference to your abbreviated new drug application dated December 1, 1994, submitted pursuant to Section 505(j) of the Federal Food, Drug, and Cosmetic Act, for Betamethasone Dipropionate Cream USP, 0.05% (base).

Reference is also made to your amendments dated September 12 and October 17, 1997.

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 Betamethasone Dipropionate Cream USP, 0.05% (base) to be bioequivalent and, therefore, therapeutically equivalent to the listed drug (Diprosone Cream, 0.05% of Schering Corporation).

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. 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-240). 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-240) with a completed Form FD-2253 at the time of their initial use.

Sincerely yours,

/S/

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