

**CENTER FOR DRUG EVALUATION AND RESEARCH**

**Approval Package for:**

**Application Number: 84-655**

**Trade Name: Prednicen-M (Prednisone) Tablets 5mg**

**Generic Name: Prednicen-M (Prednisone) Tablets 5mg**

**Sponsor: The Central Pharmacal Company**

**Approval Date: December 9, 1975**

**INDICATION(s): Endocrine Disorders, Rheumatic Disorders, Collagen Diseases, Dermatologic Diseases, Allergic States, Ophthalmic Diseases, Respiratory Diseases, Hematologic Disorders, Neoplastic Diseases, Edematous States. (See labeling for specific indications--to numerous to list)**

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**APPLICATION: 84-655**

## CONTENTS

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

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**Application Number: 84-655**

**APPROVAL LETTER**

NDA 84-655

DEC 09 1975

The Central Pharmacal Company  
Attention: Mr. Kenneth D. Montgomery  
116-128 East Third Street  
Seymour, IN 47274

Gentlemen:

Reference is made to your abbreviated new drug application submitted pursuant to Section 505(b) of the Federal Food, Drug, and Cosmetic Act for Prednicen-M (Prednisone) Tablets, 5 mg.

Reference is also made to your communication dated October 30, 1975, enclosing manufacturing information, an environmental impact analysis report and final printed labeling.

We have completed the review of this abbreviated new drug application and have concluded that the drug is safe and effective for use as recommended in the submitted labeling. Accordingly, the application is approved.

Any significant change in the conditions outlined in this abbreviated new drug application, requires an approved supplemental application before the change may be made, except for changes made in conformance with other provisions of Section 314.8 of the new drug regulations.

This Administration should be advised of any change in the marketing status of this drug.

The requirement for adequate data to assure the biologic availability is being deferred at the present time. However, our action in approving this application is based upon an understanding that if this requirement is reinstated you will perform the appropriate procedures.

Promotion of a product marketed under an abbreviated new drug application must not convey the impression that the product is a new entity.

The enclosures summarize the conditions relating to the approval of this application.

DET-DO

Dup

HFD-614, HFD-616

VVKarusaitis/JLMeyer/CMSmith

R/D init. JMeyer/MSeife 12-8-75

final typing/cjb/12-8-75

approved

Sincerely yours

Marvin Seife, M.D.

Director

Division of Generic Drug Monographs

Office of Drug Monographs

Bureau of Drugs

Enclosures:

Conditions of Approval of a New Drug Application

Records and Reports Requirements