CENTER FOR DRUG EVALUATION AND RESEARCH

Approval Package for:

Application Number: 83-009

Trade Name: Orasone (Prednisone) Tablets 1, 5, 10, 20 mg

Generic Name: Orasone (Prednisone) Tablets 1, 5, 10, 20 mg

Sponsor: Rowell Laboratories Inc.

Approval Date: January 29, 1974

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

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APPLICATION: 83-009

CONTENTS

	Included	Pending Completion	Not Prepared	Not Required
Approval Letter	X			
Tenative 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 Biopharmaceutics Review(s)				X
Bioequivalence Review(s)	X			
Administrative/ Correspondence Document(s)	X			

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Application Number: 83-009

APPROVAL LETTER

NDA 83-009

AF 20-333

JAN 29 1974

Rowell Laboratories, Incorporated
Attention: Dr. Ben E. Greenwell
Baudette, Minnesota 56623

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 Orasone (prednisone) Tablets, 1, 5, 10 and 20 mg.

Reference is also made to your communication dated December 6, 1973, enclosing 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 130.9 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.

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

Sincerely yours,

/S/ 1/25/74

Paul A. Bryan, M.D.
Deputy Director for
Medical Activities
Office of Scientific Evaluation
Bureau of Drugs

cc: MIN-DO
Dup
HFD-107 HFD-8
HFD-106 HFD-310
JBacsanyi/JLMeye /S/ 1/24/74 [illegible]-9-74/
jmb/1-17-74 1-23-74
R/D init by: JLmeyer/mseiffe/1-14-74
APPROVAL /S/ 1/24/74

Enclosures: Conditions of Approval of a New Drug Application
Records and Reports Requirement

/S/ 1/25/74