CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER: 84-655

CHEMISTRY REVIEW(S)

CHEMIST'S REVIEW FOR NEW DRUG APPLICATION OR SUPPLEMENT	Federal Register Statement Date	NDA Number 84-655 84-655

Name and Address of Applicant (City and State)	AE Number
The Central Pharmacal Company Seymour, Indiana	Original XXXXXX Amendment Supplement Resubmission Correspondence Report Other
Purpose of Amendment/Supplement	Date(s) of Submission(s) 10/30/75

Pharmacological Category	Name of Drug	
adrenocortical steroid	Prednicen-M (Prednisone)	
Dosage Form(s)	**Potency(ies)**	**How Dispensed**
Tablet	5 mg	Rx OTC
Packaging/Sterilization	**Samples**	**Related IND/NDA/MF**

Labeling

Satisfactory per VVKarusaitis

Biologic Availability

Deferred

Establishment Inspection

In compliance @ memo fr HDD- 6/20/75

Components, Composition, Manufacturing and Controls

satisfactory

Remarks

/S/ 12/8/75

Recommendation approval CMSmith

OR SUPPLEMENT

84-655

AF Number

Name and Address of Applicant (City and State)

The Central Pharmacal Co
116-128 E. 3rd St,
Seymour, Ind. 47274

Original XXXXX
Amendment
Supplement
Resubmission
Correspondance
Report
Other

Purpose of Amendment/Supplement

Date(s) of Submission(s)

April 27, 1975

Pharmacological Category	Name of Drug	
Adrenocortical steroid	Prenisone Tn: Prednicen-M	
Dosage Form(s)	Potency(ies)	How Dispensed
tablet	5 mg.	R_x OTC
Packaging/Sterilization	Samples	Related IND/NDA/NF

Labeling Unsatisfactory per VVKarusaitis, to be revised.

Biologic Availability Deferred

Establishment Inspection EIR requested 4/4/75, pending.

Components, Composition, Manufacturing and Controls Unsatisfactory, request made for actual specs and tests performed on all ingredients and dosage form.

Remarks Request also made for Environmental Impact statement and revised FPL.

Conclusion Rev w/ f

REVIEWER CMSmith

DATE /S/ 6-6-75

Page(s) 11

Contain Trade Secret, Commercial/Confidential Information and are not releasable.

FULL LIST OF COMPONENTS OF PREDNICEN-M TABLETS

Page(s) 2

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