

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER: 84-655

MEDICAL REVIEW(S)

REVIEW OF RESUBMISSION

DATE COMPLETED: 11-25-75

ANDA #: 84-655

FR DATE: 10-16-71

CO. NAME & ADDRESS:
The Central Pharmacal Co.
Seymour, IN 47274

NAME OF DRUG: Trade: "Prednicen-M"

Generic: Prednisone Tablets 5 mg

DATE OF SUBMISSION: 10-30-75

TYPE OF SUBMISSION: Resubmission (reply to FDA Letter 6-9-75)

CLINICAL EVALUATION:

1. Review of Studies: Pertinent data is to be reviewed by the chemist
Bioavailability Requirement: Required
2. Review of Labeling:
 - (a) Container Labels: Satisfactory
8 tablets Professional Samples Bottles of 100, 1,000
 - (b) Insert Labeling: Satisfactory
July 75

CONCLUSION: Labeling is satisfactory for the safe and effective use of this product

RECOMMENDATIONS: The firm is to be so notified

cc:

/S/
V. V. Karusaitis, M.D.

REVIEW OF ANDA

DATE COMPLETED: 4-9-75

ANDA #: 84-655

F.R. DATE: 10-16-71

CO. NAME: The Central Pharmacal Co.
Seymour, IN 47274

NAME OF DRUG: Trade: "Prednicen-M"
Generic: Prednisone 5 mg.

DATE OF SUBMISSION: 2-27-75

TYPE OF SUBMISSION: ANDA

CLINICAL EVALUATION:

1. Review of Studies: Pertinent data is to be reviewed by the chemist.
Bioavailability requirement: Deferred

2. Review of Labeling:

a. Container labels: Unsatisfactory 5 mg. tablets
Bottles of 8 : 100 : 1,000

Delete "5 mg. to 20 mg. per day, given in divided doses "
Consult package insert for full information ; is adequate.

b. Insert labeling: Satisfactory

Description: Add some description of Prednisone (may be done at next printing).

CONCLUSION: Labeling is satisfactory for insert labeling.
Unsatisfactory for container labels as noted above.

RECOMMENDATION: The firm is to be so notified.

cc:
Dup

/S/
V.V. Karusaitis, M.D.