CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER: 83-009

MEDICAL REVIEW(S)

REVIEW OF RESUBMISSION

DATE COMPLETED: 10-2-72

ANDA #: 83-009

F.R. DATE: 10-21-70

CO.NAME: Rowell Labs, Inc.
Baudette, Minn. 56623

NAME OF DRUG: Trade: Orasone Tablets, 1 mg., 5 mg., 10 mg., and 20 mg. Tabs
& (bottles of 100 and 1,000)
Generic: Prednisone

DATE OF SUBMISSION: 9-14-72

TYPE OF SUBMISSION: Resubmission

CLINICAL EVALUATION:

1. Review of Studies:

   A) Bioavailability studies are now deferred for this drug.
   B) Manufacturing data, ingredients will be reviewed by the chemist.
   C) The firm plans to continue marketing of their 10 mg. and 20 mg. size tablets without filing a full NDA.

2. Review of Labeling:

   Container label:
   No container labels were submitted. The firm promised to carry out the proposed revision at the time of the next printing.

   Package insert:
   The following revisions are recommended:
   1) The ADVERSE REACTIONS section should follow the PRECAUTIONS section.
   2) The general principles of steroid therapy should be reinserted right under the heading DOSAGE AND ADMINISTRATION.
   3) Correct spelling of the word "immune" in the ACTIONS section (2nd paragraph - line 2).

CONCLUSION:

   A) Revision of the package insert is necessary; this may be done at the time of the next printing.
   B) Manufacturing information will be reviewed by the chemist.

RECOMMENDATIONS:

   1) Request revision of labeling at the time of the next printing.
   2) Request a full NDA for the tablet sizes of 10 mg. and 20 mg.

/S/

J. Bacsanyi, M.D.

cc:
Dup BD-69

REVIEW OF ANDA

DATE COMPLETED: April 26, 1972 ANDA #: 80-009

F.R. DATE: Oct. 21, 1970

CO. NAME: Rowell Labs., Inc.
Baudette, Minn. 56623

NAME OF DRUG: Trade: Orasone Tablets, 1 mg., 5 mg., 10 mg., and 20 mg. Tabs. (bottles of 100 and 1,000)

Generic: Prednisone

DATE OF SUBMISSION: April 14, 1972

TYPE OF SUBMISSION: ANDA

CLINICAL EVALUATION:

1. Review of Studies:

1. Bioavailability studies are now deferred for this drug.
2. Manufacturing data, ingredients will be reviewed by the chemist.
3. The 10 mg. and 20 mg. dosage forms for this drug are not acceptable as there has never been any approval for these. These should be deleted from their product line.

2. Review of Labeling:

Container label: The FPL of all four tablet sizes is submitted. Delete the dosage information and substitute "Usual Dosage: See Package insert".

Package insert: Draft copy of the insert is submitted.

The following devisions are necessary:

1. In the section on INDICATIONS revise typography of sub-section #2.
2. In the section on DOSAGE AND ADMINISTRATION include the six paragraphs of general principles, preceeding the present dosage recommendations.

CONCLUSION: 1. Manufacturing information is to be reviewed by the chemist.
2. Revision of the container label and package insert is necessary.
3. 10 mg. and 20 mg. dosage forms must be discontinued.

RECOMMENDATIONS: 1. Revise labeling. 2. Copy of our labeling guidelines may be sent to the firm. 3. Inform firm regarding dosage forms.

cc:
Dup

/S/

J. Bacsanyi, M.D.

REVIEW OF RESUBMISSION

DATE COMPLETED: Dec. 5, 1972

ANDA #: 83-009

F.R. DATE: 10-21-70

CO. NAME: Rowell Labs, Inc.
Baudette, Minn. 56623

NAME OF DRUG: Trade: Orasone Tablets, 1 mg., 5 mg., 10 mg., and 20 mg. bottles of 100 and 1,000)

Generic: Prednisone

DATE OF SUBMISSION: Nov. 20 and Nov. 21, 1972

TYPE OF SUBMISSION: Letter (11-20-72) and Resubmission (11-21-72)

CLINICAL EVALUATION:

1. Review of Studies:

   a) Bioavailability studies are deferred for this drug at the present time.

   b) Manufacturing data will be evaluated by the chemist.

2. Review of Labeling:

   Container label: Was not submitted in this submission. A previous review (4-26-72) requested revision, with which the firm promised to comply.

   Package Insert:
   Draft copy of the revised insert is submitted. It is satisfactory now. The firm still keeps the 10 mg. and 20 mg. potencies listed in the HOW SUPPLIED section. In this regard, they have also initiated legal action (see letter of Nov. 20, 1972, by Pendergast).

CONCLUSION: The revised package insert is not satisfactory so long as the 10 and 20 mg. potencies are listed.

RECOMMENDATION: The firm is to be so notified.

/S/
J. Bacsanyi, M.D.

cc:
Dup

REVIEW OF RESUBMISSION

DATE COMPLETED: 1-2-74

ANDA #: 83-009

CO. NAME: Rowell Labs. Inc.
Bardette, MN 56623

NAME OF DRUG: Trade: Orasone Tablets, 1 mg. 5 mg. 10 mg. and 20 mg.
Generic: Prednisone

DATE OF SUBMISSION: 12-6-73

TYPE OF SUBMISSION: Resubmission - FPL

CLINICAL EVALUATION:

1. Review of Studies: None submitted - none required

2. Review of Labeling:

a. Container labels: The submitted FPL is satisfactor-.

b. Package insert: The submitted FPL is satisfactory

CONCLUSION: The submitted revised FPL is satisfactory from a medical standpoint.

RECOMMENDATION: The firm is to be so notified.

/S/

J. Bacsanyi, M.D.

cc:
Dup