

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER: 83965

MEDICAL REVIEW(S)

REVIEW OF AMENDMENT RESUBMISSION

DATE COMPLETED: 7-8-76

ANDA#: 83-965

CO. NAME: Camall Company
ADDRESS: Detroit, MI 48234

NAME OF DRUG: Trade:
and Hydrochlorothiazide Tablets, 50 mg.
Generic:

DATE OF SUBMISSION: Undated

TYPE OF SUBMISSION: Amendment-Resubmission

CLINICAL EVALUATION:

1. Review of Studies:

- a) A bioavailability protocol has been approved.
- b) The submitted manufacturing information will be evaluated by the Chemist

2. Review of Labeling:

- a) Container Labels: The submitted FPL is satisfactory
- b) Package Insert: The submitted draft is satisfactory

CONCLUSION: The submitted labeling is satisfactory

RECOMMENDATIONS: Request FPL

/S/
J. Bacsanyi, M.D.

REVIEW OF ANDA

DATE COMPLETED: 9-26-73

ANDA #: 83-965

CO. NAME: Camall Co.
11401 E. 7 Mile Rd.
Detroit, MI 48234

NAME OF DRUG: Hydrochlorothiazide Tablets, 50 mg, (bottles of
100 and 1,000)

DATE OF SUBMISSION: 9-11-73

TYPE OF SUBMISSION: ANDA

CLINICAL EVALUATION:

1. Review of Studies:

- a. Bioavailability studies are required for this drug. However, no protocol was submitted.
- b. The submitted manufacturing information will be evaluated by the chemist.

2. Review of Labeling:

- a. Container labels: The submitted draft labels are satisfactory.
- b. Package insert: The submitted draft copy is satisfactory.

CONCLUSION: 1. No protocol was submitted for the required bio-availability study.
2. The submitted draft labeling is acceptable from a medical standpoint.

RECOMMENDATION: Request submission of a bioavailability protocol
Request FPL.

/S/

J. Bacsanyi, MJD.

REVIEW OF RESUBMISSION

DATE COMPLETED: 4-18-75

ANDA #: 83-965

CO. NAME: Camall Company
11401 E. 7 Mile Rd.
Detroit, MI 48234

NAME OF DRUG: Trade & Generic: Hydrochlorothiazide Tablets, 50 mg.

DATE OF SUBMISSION: 1-9-75; 2-6-75; 2-18-75; 2-24-75 and 3-31-75

TYPE OF SUBMISSION: Resubmission

CLINICAL EVALUATION:

1. Review of Studies:

- A) A Bioavailability protocol has already been submitted, evaluated and approved.
- B) The submitted manufacturing information will be evaluated by the chemist.

2. Review of Labeling:

Container labels:

FPL is submitted for the following distributors:

- 1.
- 2.
- 3.
- 4.
- 5.
- 6.

All these labels and Camall's own label are satisfactory. However, no distributor statements were submitted.

CONCLUSION:

The submitted FPL for the containers is satisfactory. No distributor statements were submitted and no FPL for the insert was provided.

RECOMMENDATIONS:

- 1. Request submission of FPL for the insert.
- 2. Request submission of distributor statements.

4-22-75

/S/
J. Bacsanyi, M.D.