CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER: 83232

MEDICAL REVIEW(S)

REVIEW OF ANDA AND RESUBMISSIONS

DATE COMPLETED: 3-26-74

ANDA #: 83-232

CO. NAME: Danbury Pharmacal, Inc.
131 West Street
Danbury, CT 06810

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

DATE OF SUBMISSION: 9-20-72 (ANDA) and resubmissions: 3-22-73 and 2-28-74

TYPE OF SUBMISSIONS: ANDA and Resubmissions

CLINICAL EVALUATION:

1. Review of Studies:

   A) The required bioavailability study has been submitted.

   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 FPL is satisfactory.

CONCLUSIONS:

1. The required bioavailability study (A) is submitted in the 2-28-74 submission.

2. The submitted FPL is satisfactory.

RECOMMENDATIONS:

1. Refer the submitted bioavailability study to DCR for evaluation.

2. Firm is to be notified about the approval of labeling.

/S/

J. Bacsanyi, M.D.

REVIEW OF AMENDMENT

DATE COMPLETED: 3-26-74

ANDA #: 83-232

CO. NAME: Danbury Pharmacal, Inc.
131 West Street
Danbury, CT 06810

NAME OF DRUG: Hydrochlorothiazide Tablets, 50 mg.

DATE OF SUBMISSION: 2-6-74

TYPE OF SUBMISSION: Amendment for a new distributor:

CLINICAL EVALUATION:

1. Review of Studies: None submitted - none required.

2. Review of Labeling:

   a. Container Labels: The submitted FPL is satisfactory.

   b. Package Insert: Not submitted in this submission. The distributor will apparently use the insert approved for Danbury.

CONCLUSION: The submitted distributor labeling for is satisfactory.

RECOMMENDATION: The firm is to be so informed.

/S/

J. Bacsanyi, M.D.