CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER: 83972

MEDICAL REVIEW(S)

NDA 83-972
AF: None

Barr Laboratories, Inc.
Attention: Ms. Sandi Feldman
265 Livingston Street
Northvale, NJ 07647

JUN 17 1974

Gentlemen:

Reference is made to your abbreviated new drug application, submitted pursuant to Section 505(b) of the Federal Food, Drug, and Cosmetic Act, for Hydrochlorothiazide Tablets, 25 mg. and 50 mg.

We acknowledge receipt of your communication dated April 15, 1974, which contained printed labeling.

We also acknowledge receipt of a sample for one dosage form of the drug (50 mg. tablets, Batch No.: 3420028).

We have completed our review of this abbreviated new drug application and have the following comment:

> Submit samples of the active ingredient and drug dosage forms. It is suggested that Item 9 of the New Drug Application, FD Form 356H, be used as a guide in submitting samples.

Please let us have your response promptly.

Sincerely yours,

/S/

Marvin Seife, M.D.
Director
Generic Drug Staff
Office of Scientific Evaluation
Bureau of Drugs

6/74

NDA 83-972
AF 42-189

Barr Laboratories, Inc.
Attention: Ms. Sandi Feldman
265 Livingston Street
Northvale, NJ 07647

JUL 2 3 1974

Gentlemen:

Reference is made to your abbreviated new drug application submitted pursuant to Section 505(b) of the Federal Food, Drug, and Cosmetic Act for Hydrochlorothiazide Tablets, 25 mg. and 50 mg.

Reference is also made to your communication of June 19, 1974, which contained a revised manufacturing procedure.

We acknowledge receipt of your communication dated July 2, 1974, which included samples.

We have completed the review of this abbreviated new drug application and have the following comments:

1. Clarify how the lot numbers and/or batch numbers are assigned to the 25 mg. and 50 mg. tablets.

2. Identify the manufacturer of the hydrochlorothiazide raw material used in the manufacture of the tablets employed in the biologic availability study.

Please let us have your response promptly.

Sincerely yours,

/S/

Marvin Seife, M.D.
Director
Generic Drug Staff
Office of Scientific Evaluation
Bureau of Drugs

REVIEW OF ANDA

DATE COMPLETED: 10-2-73 ANDA #: 83-972

CO. NAME: Barr Laboratories
265 Livingston St.
Northvale, NJ 07647

NAME OF DRUG: Hydrochlorothiazide Tablets, 25 mg. and 50 mg.

DATE OF SUBMISSION: 9-4-73

TYPE OF SUBMISSION: ANDA

CLINICAL EVALUATION:

1. Review of Studies:

   a) Bioavailability studies are required for this drug. A proposed protocol for such a study has been submitted.

   b) Manufacturing data, ingredients, etc. will be evaluated by the chemist.

2. Review of Labeling:

   a) Container labels: Draft copies of the submitted labels are satisfactory

   b) Package insert: The submitted draft copy is satisfactory

CONCLUSIONS:

1. A protocol for the required bioavailability study is submitted.
2. The submitted draft labeling is satisfactory

RECOMMENDATIONS:

1. Refer the submitted bioavailability protocol to DCR for evaluation.
2. Request FPL.

/S/

J. Bacsanyi, M.D.

REVIEW OF RESUBMISSION

DATE COMPLETED: 5-28-74

ANDA #: 83-972

CO. NAME: Barr Laboratories
265 Livingston St.
Northvale, NJ 07647

NAME OF DRUG: Hydrochlorothiazide Tablets, 25 mg. and 50 mg.

DATE OF SUBMISSION: 4-15-74

TYPE OF SUBMISSION: Resubmission - FPL

CLINICAL EVALUATION:

1. Review of Studies:

- The submitted bioavailability protocol is under evaluation by DCR.

2. Review of Labeling:

   a. Container Labels: The submitted FPL is satisfactory.

   b. Package Insert: The submitted FPL is satisfactory.

CONCLUSIONS: The submitted FPL is satisfactory.

RECOMMENDATION: The firm is to be so notified.

/S/

J. Bacsanyi, M.D.