CENTER FOR DRUG EVALUATION AND RESEARCH

Approval Package for:

Application Number:83-972

Trade Name:Hydrochlorothiazide Tablets USP 25 &50mg

Generic Name: Hydrochlorothiazide Tablets USP 25 &50mg

Sponsor: Barr Laboratories Inc.

Approval Date: 10/3/74

INDICATION(s): Adjunctive therapy in edema associated with congestive heart failure, hepatic cirrhosis and corticosteroid and estrogen therapy.

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION: 83-972

CONTENTS

	Included	Pending Completion	Not Prepared	Not Required
Approval Letter	X			
Tenative Approval Letter				X
Approvable Letter				X
Printed Labeling	X			
Medical Review(s)	X			
Chemistry Review(s)	X			
EA/FONSI				X
Pharmacology Review(s)				X
Statistical Review(s)				
Microbiology Review(s)				X
Clinical Pharmacology Biopharmaceutics Review(s)				X
Bioequivalence Review(s)	X			
Administrative/ Correspondence Document(s)	X			

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Application Number: 83972

APPROVAL LETTER

NDA 83-972
AF 42-189

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

OCT 0 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.

We acknowledge receipt of your communications dated May 15, 1974, July 23, 1974 and August 23, 1974.

We have completed the review of this abbreviated new drug application and have concluded that the drug is safe and effective for use as recommended in the submitted labeling. Accordingly, the application is approved. The approved source of the active ingredient is

Any significant change in the conditions outlined in this abbreviated new drug application requires an approved supplemental application before the change may be made, except for changes made in conformance with other provisions of Section 314.8 of the new drug regulations.

This Administration should be advised of any change in the marketing status of this drug.

The enclosures summarize the conditions relating to the approval of this application.

Sincerely yours,

/S/

Paul A. Bryan, M.D.
Deputy Director for
Medical Activities
Office of Scientific Evaluation
Bureau of Drugs

1-94

rug Application

ORIG

NOTICE OF APPROVAL
NEW DRUG APPLICATION OR SUPPLEMENT

NDA NUMBER: 83-972

DATE APPROVAL LETTER ISSUED: OCT 3 1974

TO: Press Relations Staff *(PA-40)*

FROM:
- [X] Bureau of Drugs
- [ ] Bureau of Veterinary Medicine

ATTENTION

Forward original of this form for publication only after approval letter has been issued and the date of approval has been entered above.

TYPE OF APPLICATION
- [ ] ORIGINAL NDA
- [ ] SUPPLEMENT TO NDA
- [X] ABBREVIATED ORIGINAL NDA — ORIGINAL
- [ ] SUPPLEMENT TO ANDA

CATEGORY
- [X] HUMAN
- [ ] VETERINARY

TRADE NAME *(or other designated name)* AND ESTABLISHED OR NONPROPRIETARY NAME *(if any)* OF DRUG

Hydrochlorothiazide

DOSAGE FORM: **Tablet**

HOW DISPENSED
- [X] RX
- [ ] OTC

ACTIVE INGREDIENT(S) *(as declared on label. List by established or nonproprietary name(s) and include amount(s), if amount is declared on label.)*

Hydrochlorothiazide 25 mg. and 50 mg.

NAME OF APPLICANT *(Include City and State)*

Barr Laboratories, Inc.
Northvale, NJ 07647

PRINCIPAL INDICATION OR PHARMACOLOGICAL CATEGORY

Thiazide

COMPLETE FOR VETERINARY ONLY

ANIMAL SPECIES FOR WHICH APPROVED

COMPLETE FOR SUPPLEMENT ONLY

CHANGE APPROVED TO PROVIDE FOR

FORM PREPARED BY

NAME **J. Taylor** — J Taylor — DATE

FORM APPROVED BY

NAME **J. L. Meyer** — DATE

Form FD 1642 (4/73)

PREVIOUS EDITION MAY BE USED UNTIL SUPPLY IS EXHAUSTED.