CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER: 83972

CHEMISTRY REVIEW(S)

05-912

	7-26-72	None

Barr Laboratories, Inc.
265 Livingston Street
Northvale, New Jersey 07647

x

8-30-73

Antihypertensive	Hydrochlorothiazide	
Tablet	25 mg. and 50 mg.	Rx X OTC
Submitted	request	

Satisfactory (JTBascabyi)

[redacted]

Bio protocol under reviewed send to BD 220 10-1-73

Satisfactory BD 340 memo 9-4-73

Active ingredient and drug dosahe forms complies to USP specs.

Request FPl, samples and bio under review.

rev w/f

RJWolters 10-23-73

CHEMIST'S REVIEW FOR ABBREVIATED NEW DRUG APPLICATION OR SUPPLEMENT	Federal Register Statement Date	NDA Number 83-972 AF Number 42-189

Name and Address of Applicant (City and State)

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

Original
Amendment
Supplement
Resubmission XXX
Correspondance
Report
Other

Purpose of Amendment/Supplement

Date(s) of Submission(s)

July 23, 1974
August 23, 1974
May 15, 1974

Pharmacological Category	Name of Drug	
Thaizide	**Hydrochlorothiazide**	
Dosage Form(s) **Tablet**	Potency(ies) **25 mg. and 50 mg.**	How Dispensed R XXXXX OTC
Packaging/Sterilization **Satisfactory**	Samples **dosage** **Active and drug XXXXX form met specs confirmed orally by Jesse Roe of Dallas DO** written confirmation 9-30-74	Related IND/NDA/MF

Labeling

Satisfactory (JBacsanyi)

Biologic Availability

Data satisfactory (MSeife)

Establishment Inspection

Satisfacbory 9-4-73

Components, Composition, Manufacturing and Controls

Drug dosage form and active ingredient **tested to compendium specs.**

Remarks

none

XXXXXXXXXXXX Manufacurer of active:

Conclusion **Approve with above supplier of active.** **J. Taylor 9-10-74**

REVIEWER /S/ DATE

CHEMIST'S REVIEW FOR ANTIBIOTIC NEW DRUG APPLICATION OR SUPPLEMENT

Federal Register Statement Date

83-972

NF Number 42-189

Name and Address of Applicant (City and State)

Barr Laboratories, Inc.
Northvale, NJ 07647

Original
Amendment
Supplement
Resubmission xxx
Correspondence
Report
Other

Purpose of Amendment/Supplement

Samples and amended manufacturing process

Date(s) of Submission

June 19, 1974
July 2, 1974

Pharmacological Category	Name of Drug	How Dispensed
Thiazide	Hydrochlorothiazide	Rx [x] OTC [ ]
Dosage Form(s)	Potency (ies)	
Tablet	25 and 50 mg.	
Environmental Impact Analysis Report	Samples	Related IND/NDA/PMF(s)
Submitted	Recieved July 8, 1974 Requested shortest 7-19-74	

Labeling

Satisfactory ((JBacsanyi)

Biologic Availability

Protocol and study results found satisfactory. (Marvin Seife)

Establishment Inspection

Satisfactory 9-4-73

Components, Composition, Manufacturing and Controls

Drug dosage form and active ingredient tested to USP specs.

Remarks

1. Request identification of manufacturer of active ingredient.
2. Clarify discrepancy between batch number in bio study and lot number in submitted samples.

Conclusion

J Taylor 7-14-74 Rev w/f

/S/

CHEMIST'S REVIEW FOR ABBREVIATED NEW DRUG APPLICATION OR SUPPLEMENT

Federal Register Statement Date: 7-26-72

NDA Number 83-972

AE Number none

Name and Address of Applicant (City and State)

Barr Laboratories, Inc.
Northvale, NJ 07647

Original
Amendment
Supplement
Resubmission x
Correspondance
Report
Other

Purpose of Amendment/Supplement

FPL submission

Date(s) of Submission(s)

April 15, 1974

Pharmacological Category	Name of Drug	How Dispensed
Antihypertensive	**Hydrochlorothizide**	R_x XXX OTC
Dosage Form(s) **Tablet**	Potency(ies) **25 mg. and 50 mg.**	
Packaging **Satisfactory**	Samples **Requested**	Related IND/NDA/MF
Sterilization **NA**		

Labeling

Satisfactory (JBacsanyi)

Biologic Availability

Under review (protocol submitted) by DCR

Establishment Inspection

Satisfacotry BD-340 memo 9-4-73

Components, Composition, Manufacturing and Controls

Active ingredient and drug dosage form comply to USP.

Remarks

Ask firm to ~~withdraw names of two manufacturers/suppliers of active ingredient~~, to submit samples of identified active ingredient and drug dosage form with results of tests.

Conclusion Rev w/f

REVIEWER /S/ DATE 6-11-74