CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER: 83972

ADMINISTRATIVE/CORRESPONDENCE DOCUMENTS

NDA 83-972

AF _____

OCT 25 1973

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

Gentlemen:

Reference is made to your abbreviated new drug application dated August 30, 1973, submitted pursuant to Section 505(b) of the Federal Food, Drug, and Cosmetic Act for Hydrochlorothiazide Tablets, 25 mg. and 50 mg.

We have completed our review of this abbreviated new drug application. However, before we are able to reach a final conclusion, the following additional information is necessary:

1. Submit twelve copies of the final printed container labels and package insert. The labeling should be identical in content to the draft copy.

2. Include samples of the active ingredient, with the name of manufacturer and drug dosage forms, to expedite the handling of this application.

The bioavailability data is under review by our Division of Clinical Research.

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

/S/

NDA 83-972

SEP 26 1973

Barr Laboratories
Attention: Ms. Sandi Feldman
255 Livingston Street
Northvale, New Jersey 07647

Gentlemen:

We acknowledge the receipt of your abbreviated new drug application submitted pursuant to Section 505(b) of the Federal Food, Drug, and Cosmetic Act for the following:

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

DATE OF APPLICATION: August 30, 1973

DATE OF RECEIPT: September 10, 1973

We will correspond with you further after we have had the opportunity to review the application.

We would also like to call to your attention the Federal Register of March 15, 1973 (38 F.R. 7001) regulations establishing procedures for preparation of Environmental Impact Statements (Part 6 - Environmental Impact Considerations). Section 6.1(e) of these regulations requires that the applicant include an environmental impact analysis report as part of any new-drug application. Failure to submit an environmental impact analysis report is grounds for refusing to file or to approve an application (21 CFR 130.5(a)(8) or 130.12(a)(7)).

Please identify any communications concerning this application with the NDA number shown above.

Sincerely yours,

/S/

/S/

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

/S/

Page(s) 1

Contain Trade Secret, Commercial/Confidential Information and are not releasable.

Approvable ANDA's other than

83-972

MEMO RECORD	AVOID ERRORS PUT IT IN WRITING	DATE 80-3-13
FROM: R Wolters (thru Jack L. Meyer)		OFFICE BD-69
TO: Mr. Clifford G. Broker BD-340 Office of Compliance		DIVISION BD-300

SUBJECT: Collaborative draft(s)

SUMMARY

In connection with NDA 83-472 for Hydrochlorothiazide Tablets

The applicant Barr Laboratories
Northvale NJ 07647

AF

We acknowledge receipt on 9-26-73 of AMDT
dated 8-30-73
for
the above preparation

In accordance with the 2/27/73, directive, Office of Compliance a request is made for:

REQUESTED

☐ 1. Establishment inspection report on

☐ a. The applicant

☐ b. Others See below

☐ 2. Evaluation of compliance with CGMP

☑ 3. Recommendation for approval/disapproval of the application/supplement base on your evaluation of compliance ~~with~~ CGMP.

SIGNATURE /S/

DOCUMENT NUMBER 83-472

FD FORM 2034 (2/72)

83-710

ABBREVIATED NEW DRUG APPLICATION

BARR LABORATORIES, INC.
265 LIVINGSTON STREET
NORTHVALE, N.J. 07647
TELEPHONE (201) 767-1900

September 4, 1973

Marvin Seife, M.D., Director
Division of Actions Implementation
D.E.S.I. Project Office/Bureau of Drugs
Department of Health, Education and Welfare
Food and Drug Administration
5600 Fishers Lane
Rockville, Maryland 20852

Gentlemen:

Enclosed please find, in triplicate, an Abbreviated New Drug Application for Hydrochlorothiazide Tablets, 25 mg. and 50 mg., U.S.P.

You will note that we have submitted two (2) dosage strengths under one ANDA. Examination of the batch formulation and manufacturing records will indicate that both dosage strengths have a common formulation. The 25 mg. tablet run weight is 100 mg. with a yield of the 50 mg. tablet run weight is 200 mg. with a yield of tablets per batch.

Attached as Appendix "A" is the protocol for biological availability of Hydrochlorothiazide Tablets, U.S.P. We would appreciate your review and comments at the earliest possible time as we are most anxious to begin this study.

Sincerely,

BARR LABORATORIES, INC.

Sandi Feldman

Ms. Sandi Feldman, Director
Regulatory Affairs

SF/ew
Enclosures

ORIG NEW CORRES

BARR LABORATORIES, INC.
265 LIVINGSTON STREET
NORTHVALE, N.J. 07647
TELEPHONE (201) 767-1900

PERSONALLY SUBMITTED BY
Sandi Feldman
Reid by BAD
7-24-74

July 23, 1974

Marvin Seife, M.D., Director
Generic Drug Staff
Office Scientific Evaluation
Bureau of Drugs
Department of Health, Education & Welfare
Food and Drug Administration
5600 Fishers Lane
Rockville, Maryland 20852

Reference: ANDA #83-972
Hydrochlorothiazide Tablets, 25 mg. and 50 mg.

Gentlemen:

With reference to our telephone conversation of this date, below please find the information you requested in order to finish evaluating the above mentioned new drug application.

Batch numbers are assigned in the following manner: The first two (2)

Secondly, you requested the manufacturer of the active raw material used in Batch #3420028 which was submitted for our bioavailability study. The manufacturer is . The distributor of this manufacturer's material in the United States is

Trusting this information will enable you to finish evaluating the above mentioned application and looking forward to a prompt approval, I am

RECEIVED
JUL 24 1974
BUREAU OF DRUGS

Very truly yours,

BARR LABORATORIES, INC.

Sandi Feldman

Sandi Feldman, Director
Quality Assurance/Regulatory Affairs

SF/ew

ORIG NEW CORRES

BARR LABORATORIES, INC.
265 LIVINGSTON STREET
NORTHVALE, N.J. 07647
TELEPHONE (201) 767-1900

August 23, 1974

Generic Drug Staff
HFD 107
Department of Health, Education & Welfare
Food and Drug Administration
5600 Fishers Lane
Rockville, Maryland 20852

Reference: NDA #83-972

Gentlemen:

In connection with todays' discussion with Mr. Raymond McMurray, we are enclosing the following information which you requested.

Barr Laboratories bioavailability study on Hydrochlorothiazide 50 mg. tablets USP, was performed on our batch #340028. The Hydrochlorothiazide raw material used in this batch was manufactured by [illegible] This material was purchased through [illegible] stributor;

Should you require any additional information, please do not hesitate in contacting us.

Sincerely,

BARR LABORATORIES, INC.

Edwin A. Cohen
President

EAC:jag

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COVER LETTER MADE
FOR DUP ✓ TRIP ✓

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AUG 27 1974
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Rec'd 7/5 ORIG E

RESUBMISSION
NDA ORIG AMENDMENT

BARR LABORATORIES, INC.
265 LIVINGSTON STREET
NORTHVALE, N.J. 07647
TELEPHONE (201) 767-1900

July 2, 1974

Marvin Seife, M.D., Director
Generic Drug Staff/Bureau of Drugs
Office Scientific Evaluation
Department of Health, Education & Welfare
Food and Drug Administration
5600 Fishers Lane
Rockville, Maryland 20852

Re: Hydrochlorothiazide Tablets 25 mg. and 50 mg.
NDA #83-972

Gentlemen:

With reference to your letter dated June 17, 1974, we submit the following samples of Hydrochlorothiazide Tablets 25 mg, 50 mg., and raw material.

1. 4 X 2gm. Hydrochlorothiazide raw material lot no. R0479 used in the preparation of Hydrochlorothiazide Tablets 25 mg. Lot Number X-156 and Hydrochlorothiazide Tablets 50 mg., Lot Number 3420028. We are sorry to inform you that we do not have any more raw material available of Lot # R0479. In the event you can use a different lot of Hydrochlorothiazide raw material which will be used in our future manufacture, we will be glad to submit samples of satisfactory quantity.

2. 4 X 250 tablets Hydrochlorothiazide 50 mg. Lot Number #3420028 used in our bioavailability studies.

3. 4 X 1M of 50 mg. Hydrochlorothiazide tablets Lot No. 3420028 in finished package form.

4. 4 X 1M Hydrochlorothiazide 25 mg. tablets Lot No. X-156 in finished package form.

Please note that our company does not have pilot plan facilities and every batch is produced in our regular production facilities.

Attached also find analytical results of Hydrochlorothiazide raw material Lot No. R-0479, analytical record of Hydrochlorothiazide 25 mg. tablets, Lot Number X-156 and analytical record of Hydrochlorothiazide 50 mg. Tablets Lot No. 3420028.

We think the above information will answer completely your letter dated June 17, 1974.

RECEIVED JUL 8 1974 BUREAU OF DRUGS

Very truly yours,

BARR LABORATORIES, INC.

Athanasios P. Geronikos, Plant Manager

APG/ew: Enclosures

Samples Received in DRUG Rm

ORIG NEW CORRES

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ORIG

BARR LABORATORIES, INC.
265 LIVINGSTON STREET
NORTHVALE, N.J. 07647
TELEPHONE (201) 767-1900

PERSONALLY SUBMITTED BY
Sandi Feldman
Reidy BAO
6-21-74

June 19, 1974

Marvin Seife, M.D., Director
Generic Drug Staff/Bureau of Drugs
Office Scientific Evaluation
Department of Health, Education & Welfare
Food and Drug Administration
5600 Fishers Lane
Rockville, Maryland 20852

Reference: NDA 83-972
Hydrochlorothiazide Tablets, 25 mg. & 50 mg., USP

Gentlemen:

Reference is made to our letter of January 28, 1974 to your office concerning a manufacturing revision. I have not had any correspondence from you concerning this revision. As we are anxious to receive approval for this product, I have enclosed, in triplicate, this revision, in the event it has been misplaced or lost in the mail. I have also enclosed a copy of the covering letter.

Our bioavailability study was run on batch #3420028 which was manufactured using the revised procedure.

Please help me clear up this matter promptly.

Very truly yours,

BARR LABORATORIES, INC.

Sandi Feldman

Sandi Feldman, Director
Quality Assurance/Regulatory Affairs

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JUN 21 1974
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Enclosures

Original

BARR LABORATORIES, INC.
265 LIVINGSTON STREET
NORTHVALE, N.J. 07647
TELEPHONE (201) 767-1900

PERSONALLY SUBMITTED BY

ORIG NEW CORRES

May 15, 1974

Marvin Seife, M.D., Director
Drug Staff/Bureau of Drugs
Office Scientific Evaluation
Department of Health, Education & Welfare
Food and Drug Administration
5600 Fishers Lane
Rockville, Maryland 20852

Reference: NDA 83-972
Hydrochlorothiazide Tablets, 25 mg. & 50 mg., U.S.P.

Subject: Bioavailability Data

Gentlemen:

Enclosed, to be included in our pending ANDA on Hydrochlorothiazide, is data derived from a bioavailability study conducted by
The data is supplied in triplicate.

We would like to request an expedient review.

Thank you.

Sincerely,

BARR LABORATORIES, INC.

Sandi Feldman

Sandi Feldman, Director
Quality Assurance/Regulatory Affairs

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MAY 16 1974
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ORIG NEW CORRES

BARR LABORATORIES, INC.
265 LIVINGSTON STREET
NORTHVALE, N.J. 07647
TELEPHONE (201) 767-1900

April 15, 1974

Marvin Seife, M.D., Director
Generic Drug Staff/Bureau of Drugs
Office Scientific Evaluation
Department of Health, Education & Welfare
5600 Fishers Lane
Rockville, Maryland 20852

Reference: NDA 83-972
Hydrochlorothiazide Tablets, 25mg. & 50mg.

Gentlemen:

Enclosed to be included in our pending New Drug Application on Hydrochlorothiazide Tablets, U.S.P., 25mg. and 50mg., are twelve (12) final printed container labels and twelve (12) final printed package inserts which are identical in content to the draft copies submitted with our application for an Abbreviated New Drug Application.

Very truly yours,

BARR LABORATORIES, INC.

Sandi Feldman

Sandi Feldman, Director
Quality Assurance
Regulatory Affairs

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APR 19 1974
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