CENTER FOR DRUG EVALUATION AND RESEARCH

Approval Package for:

Application Number:83-607

Trade Name:Hydrochlorothiazide Tablets USP 50mg

Generic Name: Hydrochlorothiazide Tablets USP 50mg

Sponsor: Richlyn Labs. Inc.

Approval Date: 8/19/77

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

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APPLICATION: 83-607

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:

APPROVAL LETTER

AUG 19 --

NDA 83-607/S-012

Richlyn Laboratories, Inc.
Attention: Mr. Louis P. Cecchini
Castor & Kensington Avenues
Philadelphia, PA 19124

Gentlemen:

Reference is made to your supplement dated June 30, 1977 regarding your abbreviated new drug application submitted pursuant to Section 505(b) of the Federal Food, Drug, and Cosmetic Act for Hydrochlorothiazide Tablets, 50 mg.

The supplemental application provides for you to label 1000 tablet containers with a label showing the distributor to be:

and the trade name to be:

We have completed the review of this supplemental application and it is approved. Our letter of June 6, 1977 detailed the conditions relating to the approval of this application.

Promotion of a product marketed under an abbreviated new drug application must not convey the impression that the product is a new entity.

We are enclosing with the copy of this letter to the distributor the conditions relating to the approval of this application.

Marvin Seife, M.D.
Director
Division of Generic Drug Monographs
Office of Drug Monographs
Bureau of Drugs

NOTICE OF APPROVAL
NEW DRUG APPLICATION OR SUPPLEMENT

NDA NUMBER: 83-607

DATE APPROVAL LETTER ISSUED:

TO: Press Relations Staff (HFI-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
- [ ] ABBREVIATED ORIGINAL NDA
- [ ] SUPPLEMENT TO ABBREVIATED NDA

CATEGORY
- [ ] HUMAN
- [ ] VETERINARY

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

DOSAGE FORM:

HOW DISPENSED
- [ ] 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.)*

m hydrochlorothiazide, 50 mg.

NAME OF APPLICANT *(Include City and State)*

Richlyn Laboratories, Inc.
Phila, PA 19124

PRINCIPAL INDICATION OR PHARMACOLOGICAL CATEGORY:
diuretic/antihypertensive

COMPLETE FOR VETERINARY ONLY

ANIMAL SPECIES FOR WHICH APPROVED:

COMPLETE FOR SUPPLEMENT ONLY

CHANGE APPROVED TO PROVIDE FOR:

distributors

FORM PREPARED BY

NAME: [illegible]

DATE:

FORM APPROVED BY

NAME: [illegible]

DATE:

FORM FD 1642 (2/75) PREVIOUS EDITION MAY BE USED UNTIL SUPPLY IS EXHAUSTED.

JUN 6 197

NDA 83-607

Richlyn Laboratories, Inc.
Attention: Mr. E.W. Rebollo
Castor & Kensington Avenues
Philadelphia, PA 19124

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, 60 mg.

We acknowledge receipt of your communication dated May 10, 1977, amending the application.

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.

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.

We note that you had provided for distributors. That material is NOT covered by this approval. If you elect to so distribute, that material should be re-submitted as supplements to this application.

Promotion of a product marketed under an abbreviated new drug application must not convey the impression that the product is a new entity.

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

Sincerely yours,

Marvin Seife, M.D.
Director
Division of Generic Drug Monographs
Office of Drug Monographs
Bureau of Drugs

cc: PHI-DO 6/3/77
Dup
HFD-614 HFD-616 JMeyer 6/3/77
RBarzilai/JMeyer/GMillar 6-1-77
R/D init. JMeyer/MSeife 6-2-77
Final typing/wlb/6-2-77
Approval 6/3/77

Enclosures:
Conditions of Approval of a New Drug Application
Records and Reports Requirement

NOTICE OF APPROVAL
NEW DRUG APPLICATION OR SUPPLEMENT

NDA NUMBER: 83-607

DATE APPROVAL LETTER ISSUED: JAN 6 1977

TO: Press Relations Staff (HFI-40)

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

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ORIGINAL ABBREVIATED

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- [ ] SUPPLEMENT TO ANDA

CATEGORY
- [ ] HUMAN
- [ ] VETERINARY

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

DOSAGE FORM

HOW DISPENSED
- [ ] 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.)*

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m 50 mg.

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COMPLETE FOR SUPPLEMENT ONLY

CHANGE APPROVED TO PROVIDE FOR

FORM PREPARED BY

NAME: [illegible]

DATE

FORM APPROVED BY

NAME: [illegible]

DATE

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