CENTER FOR DRUG EVALUATION AND RESEARCH

Approval Package for:

Application Number:83-965

Trade Name: Hydrochlorothiazide Tablets 50mg

Generic Name: Hydrochlorothiazide Tablets 50mg

Sponsor: Camall Co.

Approval Date: 3/21/77

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: 83-965

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			

CENTER FOR DRUG EVALUATION AND RESEARCH

Application Number: 83965

APPROVAL LETTER

NDA 83-965

Camall Company
Attention: Mr. Eugene M. Schmall
11401 East 7 Mile Road
Detroit, MI 48234

MAR 21 1977

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, 50 mg.

We acknowledge receipt of your communication dated February 21, 1977, enclosing bioavailability data.

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.

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,

/S/

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

Application

NOTICE OF APPROVAL
NEW DRUG APPLICATION OR SUPPLEMENT

NDA NUMBER: 83-965

DATE APPROVAL LETTER ISSUED: MAR 21 1977

TO: Press Relations Staff (HFI-40)

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

ATTENTION

Forward original of this form for publication only after approval has been entered above.

TYPE OF APPLICATION

ORIGINAL ABBREVIATED

- [ ] ORIGINAL NDA
- [ ] SUPPLEMENT TO NDA
- [ ] ABBREVIATED ANTIBIOTIC DRUG APPLICATION
- [ ] ABBREVIATED NEW ANIMAL DRUG APPLICATION
- [ ] SUPPLEMENT TO ABBREVIATED ANDA

CATEGORY
- [XX] HUMAN
- [ ] VETERINARY

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

hydrochlorothiazide tablets

DOSAGE FORM: oral

HOW DISPENSED
- [XX] 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,
50 mg.

NAME OF APPLICANT *(Include City and State)*

Camall Co.
Detroit, MI 48234

PRINCIPAL INDICATION OR PHARMACOLOGICAL CATEGORY

diuretic

COMPLETE FOR VETERINARY ONLY

ANIMAL SPECIES FOR WHICH APPROVED

COMPLETE FOR SUPPLEMENT ONLY

CHANGE APPROVED TO PROVIDE FOR

FORM PREPARED BY

NAME: [illegible] DATE:

FORM APPROVED BY

NAME: DATE:

NOTICE OF APPROVAL
NEW DRUG APPLICATION OR SUPPLEMENT

NDA NUMBER: 83-965

DATE APPROVAL LETTER ISSUED: MAR 21 1977

TO: Press Relations Staff (HFI-40)

FROM:
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TYPE OF APPLICATION
- [ ] ORIGINAL NDA
- [ ] SUPPLEMENT TO NDA
- [XX] ABBREVIATED ORIGINAL ANDA
- [ ] SUPPLEMENT TO ANDA

CATEGORY
- [XX] HUMAN
- [ ] VETERINARY

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

DOSAGE FORM: oral

HOW DISPENSED
- [XX] 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,
50 mg.

NAME OF APPLICANT *(Include City and State)*

Camall Co.
Detroit, MI 48234

PRINCIPAL INDICATION OR PHARMACOLOGICAL CATEGORY: diuretic

COMPLETE FOR VETERINARY ONLY

ANIMAL SPECIES FOR WHICH APPROVED

COMPLETE FOR SUPPLEMENT ONLY

CHANGE APPROVED TO PROVIDE FOR

FORM PREPARED BY

NAME: [illegible] DATE: 3/18/77

FORM APPROVED BY

NAME DATE