CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER: 83965

CHEMISTRY REVIEW(S)

CHEMIST'S REVIEW FOR ABBREVIATED NEW DRUG APPLICATION OR SUPPLEMENT

Federal Register Statement Date

NDA Number 83-965

AF Number

Name and Address of Applicant (City and State)

camall co
detroit, mi 48234

Original 9/11/[illegible]
Amendment
Supplement
Resubmission
Correspondance
Report
Other

Purpose of Amendment/Supplement

Date(s) of Submission

Pharmacological Category	Name of Drug	
diuretic	hydrochlorothiazide	
Dosage Form(s)	Potency (ies)	How Dispensed
oral	50 mgs	R_x ☒ OTC ☐
Environmental Impact Analysis Report submitted	Samples requested	Related IND/NDA/AF(s)

Labeling

as per HO (jbacsanyi)

Biologic Availability

requested protocol

Establishment Inspection

Components, Composition, Manufacturing and Controls

see below

Remarks

request:

Conclusion

rev w/f

gmillar /S/

.OR SUPPLEMENT

83-965

AE Number

me and Address of Applicant (City and State)

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detroit, MI 48234

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Report
Other

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amend

Date(s) of Submission(s)

as per letter

armacological Category	Name of Drug	
diuretic/ antihypertensive	hydrochlorothiazide	
sage Form(s)	Potency(ies)	How Dispensed
oral	50 mg.	R_x xx OTC
ckaging/Sterilization	Samples	Related IND/NDA/NF
submitted	to be requested + bic	

abeling

as per MD(jbacsanyi)

iologic Availability

approved. as per HFD-522 memo of 3/11/77.

stablishment Inspection

in compliance, as per HFD-322 memo of 12/14/76

mponents, Composition, Manufacturing and Controls

satisfactory

emarks

approved

/S/

omillar

OR SUPPLEMENT

83-965

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amend

Date(s) of Submission(s)

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armacological Category	Name of Drug	
diuretic/ antihypertensive	hydrochlorothiazide	
sage Form(s)	Potency(ies)	How Dispensed
oral	50 mg.	R_x xx OTC
ckaging/Sterilization	Samples	Related IND/NDA/MF
submitted	to be requested + bic	

abeling

as per MD(jbacsanyi)

iologic Availability

needed & requested

stablishment Inspection

requested 1/10/77

omponents, Composition, Manufacturing and Controls

as per letter to issue

emarks

rev w/f gmillar

/S/

CHEMIST'S REVIEW FOR ABBREVIATED NEW DRUG APPLICATION OR SUPPLEMENT

Federal Register Statement Date

NDA Number 83-965

AF Number

Name and Address of Applicant (City and State)

camall co
detroit, mi 48234

Original 9/11/73
Amendment
Supplement
Resubmission
Correspondance
Report
Other

Purpose of Amendment/Supplement

Date(s) of Submission(s)

Pharmacological Category	Name of Drug	How Dispensed
diuretic	hydrochlorothiazide	R_x X OTC
Dosage Form(s)	Potency (ies)	
oral	50 mgs	
Environmental Impact Analysis Report: submitted	Samples: requested	Related IND/NDA/NF(s)

Labeling

as per MO (jbacsanyi)

Biologic Availability

protocol accepted, as per 10/7/74 letter
request data

Establishment Inspection

re-requested

Components, Composition, Manufacturing and Controls

as per letter to issue

Remarks

Conclusion

rev w/f

/S/

CHEMIST'S REVIEW
(If necessary, continue any item on 8" x 10½" paper. Key continuation to item by number.)

1. ORGANIZATION	2. NDA NUMBER
HFD-530	83-965

3. NAME AND ADDRESS OF APPLICANT *(City and State)*
camall co.
detroit, MI 48234

4. DATE NDA APPROVED

5. IF PRIOR TO OCT 10, 1962, DATE APPROVED FOR EFFICACY

6. NAME OF DRUG	7. NONPROPRIETARY NAME	8. SUPPLEMENT NUMBER	8. SUPPLEMENT DATE
hydrochlorothiazide			

9. PURPOSE OF SUPPLEMENT
as per letter to issue
1/9 = distributors
2/6 = spec sheet FD&C yellow
2/18 = revised bottling & labeling sheets
2/24 = supplier =
3/31 = final reconciliation sheet

10. AMENDMENT DATE(s)

11. OTHER DATE *(Report, etc.)*

12. PHARMACOLOGICAL CATEGORY
diuretic

13. AF NUMBER
none

14. DOSAGE FORM
oral

15. HOW DISPENSED
☒ Rx ☐ OTC

16. RELATED IND/NDA/MF(s)

17. POTENCY(ies)
50 mg.

18. DRUG REGUIRES
☐ NDA ☒ ANDA

19. CHEMICAL NAME

20. RECORDS AND REPORTS

CURRENT		REVIEWED	
☐ YES	☐ NO	☐ YES	☐ NO

21. CHEMICAL FORMULA

22. REMARKS
bio protocol approved in 10/7/74 letter + additions
labeling needed
mfg = (a) samples (b) results (justify 3 yr expir date)
need commitment to submit reustls for first 5 prod batches

23. CONCLUSIONS
rev w/f

24. REVIEWER

NAME	SIGNA	DATE COMPLETED
gmillar	/S/	5/13/75

DISTRIBUTION ☒ ORIGINAL JACKET ☐ DUPLICATE JACKET ☐ REVIEWER

FORM FDH 2266 (11/73) PREVIOUS EDITION MAY BE USED UNTIL SUPPLY IS EXHAUSTED.

Enter evaluation or comments for each item. If necessary, continue on 8" x 10½" paper. Key continuation to item by number. Enter "NC" if no change or "NA" if not applicable.

NDA NUMBER 83-965

25. COMPONENTS AND COMPOSITION (6, 7)

satisfactory, as per submissions upto 3/31/75

26. FACILITIES AND PERSONNEL (8a,b)

NA

27. SYNTHESIS (8c)

1 = supplier

28. RAW MATERIAL CONTROLS (8d,e)
a. NEW DRUG SUBSTANCE

satisfactory

b. OTHER INGREDIENTS

completed +

29. OTHER FIRM(s) (8f)

does testing + qua;ity control for drug.

30. MANUFACTURING AND PROCESSING (8g,h,j,k)

satisfactory as per submissions upto & including 3/31
1/13 master formula sheet re-copied reperm 9/24/75

31. CONTAINER (8i)

amber plastic 1/13/

32. PACKAGING AND LABELING (8l,m)

NA

33. LABORATORY CONTROLS (In-Process and Finished Dosage Form) (8n)

dissolution

34. STABILITY (8p)

requested--lists 3 yr. expiration date

35. CONTROL NUMBERS (8c)

NA

36. SAMPLES AND RESULTS (9)

a. VALIDATION requested b. MARKET PACKAGE

37. LABELING (4)

requested(as per 10(j bacsanyi)

38. ESTABLISHMENT INSPECTION

in compliance, as per HFD-322 memo of9/27/74

39. RECALLS NA

FDH FORM 2266 (10/68)

Enter evaluation or comments for each item. If necessary, continue on 8" x 10½" paper. Key continuation to item by number. Enter "NC" if no change or "NA" if not applicable.

NDA NUMBER 83-965

25. COMPONENTS AND COMPOSITION (6, 7)

satisfactory, as per submissions upto 3/31/75

26. FACILITIES AND PERSONNEL (8a,b)

NA

27. SYNTHESIS (8c)

: = supplier

28. RAW MATERIAL CONTROLS (8d,e)

a. NEW DRUG SUBSTANCE

satisfactory

b. OTHER INGREDIENTS

completed +

29. OTHER FIRM(s) (8f)

does testing + quality control for drug.

30. MANUFACTURING AND PROCESSING (8g,h,j,k)

satisfactory as per submissions upto & including 3/31
1/13 master formula sheet

31. CONTAINER (8i)

amber plastic 1/13/

32. PACKAGING AND LABELING (8l,m)

NA

33. LABORATORY CONTROLS (In-Process and Finished Dosage Form) (8n)

dissolution

34. STABILITY (8p)

requested--lists 3 yr. expiration date

35. CONTROL NUMBERS (8c)

NA

36. SAMPLES AND RESULTS (9)

a. VALIDATION requested b. MARKET PACKAGE

37. LABELING (4)

requested(as per MO(j bacsanyi)

38. ESTABLISHMENT INSPECTION

in compliance, as per HFD-322 memo of9/27/74

39. RECALLS

NA

FDH FORM 2266 (10/68)

ame and Address of Applicant (City and State)

camall co.
detroit, MI 48234

AF Number

Original
Amendment
Supplement
Resubmission
Correspondance
Report
Other

urpose of Amendment/Supplement

amends

Date(s) of Submission(s)

as per letter

harmacological Category	Name of Drug	
diuretic/ antihypertensive	hydrochlorothiazide	
osage Form(s)	Potency(ies)	How Dispensed
oral	50 mg.	R_x XX OTC
ackaging/Sterilization	Samples	Related IND/NDA/MF
submitted	to be requested + bic	e

abeling

as per MD(jbacsanyi)

iologic Availability

needed & requested

stablishment Inspection

requested 1/10/77

omponents, Composition, Manufacturing and Controls

as per letter to issue

emarks

rev w/f gmillar

/S/

onclusion

EVIEWER DATE

CHEMIST'S REVIEW
(If necessary, continue any item on 8" x 10½" paper. Key continuation to item by number.)

1. ORGANIZATION: HFD-530	2. NDA NUMBER: 83-985
3. NAME AND ADDRESS OF APPLICANT *(City and State)*: camall co. detroit, MI 48234	4. DATE NDA APPROVED
	5. IF PRIOR TO OCT 10, 1962, DATE APPROVED FOR EFFICACY
6. NAME OF DRUG: hydrochlorothiazide	7. NONPROPRIETARY NAME
	8. SUPPLEMENT NUMBER / DATE
9. PURPOSE OF SUPPLEMENT: as per letter to issue 1/9 = distributors 2/6 = spec sheet FD&C yellow 2/18 = revised bottling & labeling sheets 2/24 = supplier 3/31 = final reconciliation sheet	10. AMENDMENT DATE(s): 9/23/75
	11. OTHER DATE *(Report, etc.)*
12. PHARMACOLOGICAL CATEGORY: diuretic	13. AF NUMBER: none
14. DOSAGE FORM: oral	15. HOW DISPENSED: ☒ Rx ☐ OTC
17. POTENCY*(ies)*: 50 mg.	18. DRUG REQUIRES: ☐ NDA ☒ ANDA
19. CHEMICAL NAME	20. RECORDS AND REPORTS: CURRENT ☐ YES ☐ NO; REVIEWED ☐ YES ☐ NO
	16. RELATED IND/NDA/MF(s)

21. CHEMICAL FORMULA

22. REMARKS

bio protocol approved in 10/7/74 letter + additions
labeling needed
mfg = (a) samples (b) results (justify 3 yr expir date)
need commitment to submit reustls for first 5 prod batches

23. CONCLUSIONS

rev w/f

24. REVIEWER

NAME	SIGNATURE	DATE COMPLETED
gmillar	/S/	11/3/75

DISTRIBUTION: ☒ ORIGINAL JACKET ☐ DUPLICATE JACKET ☐ REVIEWER

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CHEMIST'S REVIEW FOR
ABBREVIATED NEW DRUG APPLICATION
OR SUPPLEMENT

Federal Register Statement Date

83-965

AF Number

Name and Address of Applicant (City and State)

camall co.
detroit, MI 48234

Original
Amendment
Supplement
Resubmission
Correspondance
Report
Other

Purpose of Amendment/Supplement

amend(resubmission)

Date(s) of Submission(s)

undated rec'd 6/25/76

Pharmacological Category	Name of Drug	
diuretic/ antihypertensive	hydrochlorothiazide	
Dosage Form(s)	Potency(ies)	How Dispensed
oral	50	R_x xx OTC
Packaging/Sterilization	Samples	Related IND/NDA/MF
submitted	na	

Labeling

as per MO(jbacsanyi)

Biologic Availability

requested: protocl previously approved

Establishment Inspection

requested

Components, Composition, Manufacturing and Controls

as per letter to issue

Remarks

rev w/f

gmillar /S/

Conclusion

REVIEWER

DATE