CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER: 83965

CHEMISTRY REVIEW(S)

Federal Register CHRIST'S REVIEW FOR Statement Date APERIN'IATED HEW DRUG APPLICATION OR SUPPLEMENT AF Number 9/11/77 Original Name and Address of Applicant (City and State) Amendment camall co Supplement detroit, mi 48234 Resubmission Correspondance Report Other Jurpose of Amendment/Supplement Date(s) of Submission. Pharmacological Category Name of Drug diuretic hydrochlorothiazide Dosage Form(s) Potency (ies) How Dispensed $-R_{\mathbf{x}}$ oral 50 mgs OTC Environmental Impact Analysis Samples Related IID/IDA/IF(s) Report submitted requested Labeling as per :10 (jbacsanyi) Biologic Availability requested protocol Establishment Inspection Components, Composition, Manufacturing and Controls see below. Remarks request:

rev w/f

Conclusion

>>*

NDA Number

33-965

iologic Availability

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

mponents, Composition, Manufacturing and Controls satisfactory

lemarks.

androved

omillar

requested 1/10/77

omponents, Composition, Manufacturing and Controls

as per letter to issue

emarks

rev w/f

gmillar

/S/

CHEMIST'S REVIEW FOR ABBREWIATED NEW DRUG APPLICATION OR SUPPLEMENT

Federal Register Statement Date NDA Number 83-965

OR SUPPLEMENT		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 diuretic	Name of Drug hydrochlorothiazide		
Dosage Form(s) oral	Potency (ies) 50 mgs	How Dispensed R _X	
Environmental Impact Analysis Report submitted	Samples requested	Related InD/iDA/MF(s)	
Tabeling as pe	er MO (jbacsanyi)		
Biologic Availability proto reque	ocol accepted, as per 10/7/76est data	4 letter	
Establishment Inspection re-re	equested		
Components, composition, Panufac as pe	turing and Controls r. letter to issue		
Recerks			

Camall CO. detroit, MI 48234 6. NAME OF DRUG 4. DATE NDA A 5. IF PRIOR TO DATE APPRIE	3-965
camall co. detroit, MI 48234 5. If PRIOR TO DATE APPRIES FICACY 7. NONPROPRIETARY NAME hydrochlorothiazide 8. Supplementary Name	-905
detroit, MI 48234 5. NAME OF DRUG 7. NONPROPRIETARY NAME hydrochlorothiazide 8. Supplementary Su	PPROVED
hydrochlorothiazide 8. Supe	OCT 10, 196
hydrochlorothiazide 8. SUPF	
· 지원하다 하는 학교에는 보냈는 이번 글로로 그리고 있다. 그는 이번 이번 지지 않는데 한 보다 나는 바로 바로 하는 것으로 없는 INUMBER	LEMENT
하는 그들은 하는 것이 가장 살아가 들는 하는 그로는 것 때문에 가장 주민은 사람들은 가장 하는 가는 가는 하는 것 같다.	DATE
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 2. PHARMÁCOLOGICAL CATEGORY	
라는 말을 만든 것으로 보는 1000년 1일 전략 1000년 1000년 1200년	
this programmer and the state of the state o	none
I. DOSAGE FORM 15. HOW DISPENSED	D/NDA/MF(4
oral □ orc	
7. POTENCY(iee) 18. DRUG REGUIRES DNDA ZZANDA	
, CHEMICAL NAME 20. RECORDS AND REPORTS	
20 RECORDS AND REPORTS CURRENT REVIEWED	
는 돈을 보고 말이 하는 것이 보고 있다면 보는 것이 되는 것이 없는 것이 되는 것이 되었다면 하는 말을 보는 수도 있다고 싶다는 것이다.	
. CHEMICAL FORMULA	e) tches
REMARKS bio protocol approved in 10/7/74 letter + additions labeling needed mfg = (a) samples (b) results (justify 3 yr expir data need commitment to submit reustls for first 5 prod ba	e) tches
bio protocol approved in 10/7/74 letter + additions labeling needed mfg = (a) samples (b) results (justify 3 yr expir dat need commitment to submit reustls for first 5 prod ba	e) tches
Dio protocol approved in 10/7/74 letter + additions labeling needed mfg = (a) samples (b) results (justify 3 yr expir data need commitment to submit reustls for first 5 prod base).	e) tches
REMARKS bio protocol approved in 10/7/74 letter + additions labeling needed mfg = (a) samples (b) results (justify 3 yr expir data need commitment to submit reustls for first 5 prod ba CONCLUSIONS rev w/f	tches
REMARKS bio protocol approved in 10/7/74 letter + additions labeling needed mfg = (a) samples (b) results (justify 3 yr expir dat need commitment to submit reustls for first 5 prod ba CONCLUSIONS REVIEWER	tches

Key continuation to item by number. Enter **NC** if no change or **NA** if not applicable. 5. COMPONENTS AND COMPOSITION (6, 7)	83-965
satisfactory, as per submissions upto 3/31/75	
. FACILITIES AND PERSONNEL (84,6)	
· SYNTHESIS (gc)	
역사 사람 사람들 사람들 어린 사람들은 사람들이 하는 사람들이 얼마를 받았다.	
ι = supplier	
. RAW MATERIAL CONTROLS (84.0)	
a. NEW DRUG SUBSTANCE	
satisfactory	
사용하다 하는 것도 되었다. 1982년 - 1일 전 1982년 - 1	
b. OTHER INGREDIENTS	
completed +	
OTHER FIRM(a) (81)	
12. 2. 2. 2. 2. 2. 2. 2. 2. 2. 2. 2. 2. 2	
does testing + জ্ua;ity cont	rol for drug.
MANUFACTURING AND PROCESSING (8g,h,j,k)	an da basa da basa da basa da basa da An esta esta da basa d
satisfactory as per submissions upto & includin	g 3/31
1/13 mistrome that re-copied reprin	9/21/75
CONTAINER (8i)	
amber plastic /j;3/	
PACKAGING AND LABELING (81,m)	
LABORATORY CONTROLS (In-Process and Finished Dosage Form) (8n)	
dżsssłużżon	
STABILITY (8P)	
requestedlists 3 yr. expiration date	
CONTROL NUMBERS (8C)	
SAMPLES AND RESULTS (9)	
	adyllic gruppali
LABELING (4)	
요. 그는 물리 경우 전문 경험을 돌아가 되었다. 그 그 그 말을 다 되는 사람들은 물리 화장을 보고 살을 때 모든 것이다. 그는 그 그는 그는 그를 다 살아 없다는 것이다.	
requested(as per :10(j bacsanyi)	
ESTABLISHMENT INSPECTION	
in compliance, as per HFD-322 memo of9/27/74 RECALLS NA	

	o Item by number. Enter **NC** if no change or **NA** if not applicable. 83-965
S	atisfactory, as per submissions upto 3/31/75
26. FACILITIES AND	DPERSONNEL (84,6)
27. SYNTHESIS (8c)	사용 마스트 보고 있는 보고 가능한 가는 것이 되었다. 그 사용 가는 가는 가는 보고 있는 것이 되었다. 그는 것이 되었다. 그는 것이 되었는데 보고 있는 것이 되었다. 그는 것이 있는 것이 없는 한 사용 하는 사용 사용 보고 있는 것이 되었다. 그런 것이 되었다. 그는 것이
	; = supplier
28. RAW MATERIAL (a. NEW DRUG SU	CONTROLS (8d,0) IBSTANCE
S	atisfactory
b. OTHER INGRE	Ompleted +
29. OTHER FIRM(*) (
	does testing + quality control for drug.
O MANUFACTURING	G AND PROCESSING (84,h,j,k)
Sa	atisfactory as per submissions upto & including 3/31 1/13 mast formal sheet
31. CONTAINER (81) All	nber plastic //3/
32. PACKAGING AND	LABELING (81,m)
NA	
	NTROLS (In-Process and Finished Dosage Form) (8n)
34. STABILITY (8P)	
re	questedlists 3 yr. expiration date -
35. CONTROL NUMBE	RS (8C)
NA	님들은 아이들 전에 되었다. 한 시간 전에 가르는 경험을 받는 것으로 되었다. 그는 것으로 되는 것으로 되었다. 그는 것으로 되었다. 하는 것으로 하는 것으로 하는 것으로 하는 것으로 하는 것으로 되었다. 그는 것은 것으로 하는 것으로 되었다. 것으로 되었다. 것으로 되었다. 것으로 되었다. 것으로 되었다. 것으로 되었다. 것으로 기
6. SAMPLES AND RES	Abraga elemente in inche le mente in ente il importi le le de le discrete de la circa de la circa de la circa d SULTS (9)
a. VALIDATIONE	quested b. MARKET PACKAGE
77. LABELING (4)	
red	quested(as per MO(j bacsanyi)
B. ESTABLISHMENT I	<u>~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~</u>
in	compliance, as per HFD-322 memo of9/27/74
99. RECALLS NA	

		LAE Number	
ame and Address of Applicant (City and State) camall co.' detroit, HI 48234		Original Amendment Supplement Resubmission Correspondance Report Other	
urpose of Amendment/Supplement amends		Date(s) of Submission(s) as per letter	
harmacological Category diuretic/ antihypertensive	Name of Drug hydrochlorothiazide		
osage Form(s) oral	Potency(ies) 50 mg.	How Dispensed	
ackaging/Sterilization sibmitted	Samples to be requested + bic	OIC Related IND/NDA/MF	
iologic Availability	(jbacsany1) needed & requested		
stablishment Inspection			
	requested 1/10/77		
omponents, Composition, Manuf	facturing and Controls as per letter to issue		
emarks			
	rev w/f gmillar	/ S /	
onclusion			
EVIEWER	DATE	살다. 프로그리트 로르 등을 받는 것이 없고 있는데 없다. 하고 하고 있는데 말로 보고를 했다. 그는 것으로 보고 있다.	

Kev continu	MIST'S REVIEW nue any item on 8" x 1014" paper.	I I I I I I I I I I I I I I I I I I I	2. NDA NUMBER
	SS OF APPLICANT (City and Stat	HFD-530	÷3−955
			4. DATE NDA APPROVED
	camall co.		5 IF PRIOR TO OCT 10
	detroit, MI 48234		5. IF PRIOR TO OCT 10. DATE APPROVED FOR EFFICACY
6. NAME OF DRUG	7. NON	PROPRIETARY NAME	
	hydrochlorothiazid		8. SUPPLEMENT
			NUMBER DATE
A BUDBAR			
9. PURPOSE OF SUPP	LEMENT THE RESERVE	Parkaga pinggang panggang baraga.	10. AMENDMENT DATE(3)
170	as per letter to i	ssue	1/23/75
1/9 = 01 $2/6 = cn$	stributors		
2/0 - Sp 2/12 = r	ec sheet FD&C yellow revised bottling & la		11 OTHER DATE (D.
2/24 = s	upplier =		11. OTHER DATE (Report, e
3/31 = f	inal reconciliation	na n	
12. PHARMACOLOGICA	L CATEGORY		13. AF NUMBER
	diuretic		none
4. DOSAGE FORM			16. RELATED IND/NDA/ME
oral		15. HOW DISPENSED	
		—————————————————————————————————————	
7. POTENCY (ies)		18. DRUG REGUIRES	
	50 mg.	□ NDA ZZ ANDA	
. CHEMICAL NAME		20. RECODS	AND REPORTS
		CURRENT	REVIEWED
REMARKS	bio protocol approv		
	laboling monday	ed in 10/7/74 letter -	additions -
	mfg = (a) samples (i	n) results (justify 2	
	mfg = (a) samples (i		
	mfg = (a) samples (i	n) results (justify 2	
	mfg = (a) samples (i	n) results (justify 2	
	mfg = (a) samples (i	n) results (justify 2	
CONCLUSIONS	mfg = (a) samples (i	n) results (justify 2	
CONCLUSIONS	mfg = (a) samples (i need commitment to	n) results (justify 2	
CONCLUSIONS	mfg = (a) samples (i	n) results (justify 2	
CONCLUSIONS	mfg = (a) samples (i need commitment to	n) results (justify 2	
CONCLUSIONS	mfg = (a) samples (i need commitment to	n) results (justify 2	
CONCLUSIONS	mfg = (a) samples (i need commitment to	n) results (justify 2	
CONCLUSIONS	mfg = (a) samples (i need commitment to	n) results (justify 2	
CONCLUSIONS	mfg = (a) samples (i need commitment to	n) results (justify 2	
	mfg = (a) samples (i need commitment to : rev w/f	n) results (justify 2	
ME	mfg = (a) samples (i need commitment to : rev w/f	b) results (justify 3 submit reustls for fin	yr expir date) st 5 prod batches
	mfg = (a) samples (i need commitment to : rev w/f	b) results (justify 3 submit reustls for fin	yr expir date) st 5 prod batches

OR SUPPLEMENT	ON Statement pace	83-965
		AF Number
ame Address of Applicant	(City and State)	Original
	Amendment	
camal1 co	Supplement	
detroit, MI 48234		Resubmission
		Correspondance
		Report
		Other
urpose of Amendment/Supplement		Date(s) of Submission(s)
amend(resu	ubmission) ,	undated rec'd 6/25/76
harmacological Category	Name of Drug	*****
diuretic/	hydrochlorothiazide	
antihypertensive		
osage Form(s)	Potency(ies)	How Dispensed
oral	50	R _X xx
		발표 남동 슬름을 ^^ 교육을 불 경을 다음다.
		OTC
ackaging/Sterilization submitted	Samples na	Related IND/NDA/MF
as per	MO(jbacsanyi)	
liologic Availability reques	ted: protocl previously approve	
stablishment Inspection	'equested	
Components, Composition, Manua	acturing and Controls	
	s per letter to issue	
lemarks		
	rev w/f gm	/S/ millar
Conclusion		

DATE

REVIEWER