CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER: 83607

CHEMISTRY REVIEW(S)

Name and Address of Applicant (City and State) richlyn laboratories, inc phila [illegible] 19124	AP Number 83-607 Original Amendment Supplement Resubmission Correspondance Report Other
Purpose of Amendment/Supplement distributor supplements	Date(s) of Submission as per letter

Pharmacological Category	Name of Drug	
diuretic/ antihypertensive	hydrochlorothiazide	
Dosage Form(s) oral	Potency(ies) 50 mg.	How Dispensed R_x xxx OTC
Packaging/Sterilization [illegible]	Samples na	Related IND/NDA/MF

Labeling

as per NO(jabsonyi)

Biologic Availability

approved, as per HFD-522 memo of 8/3/77 for 83-607
50 mg. potency

Establishment Inspection

in compliance as per HFD-32[illegible] memo of 3/30/77

Components, Composition, Manufacturing and Controls

satisfactory

Remarks

approves gaillar

Conclusion

REVIEWER DATE

NEW SUPPLEMENT

Name and Address of Applicant (City and State)
richlyn laboratories, inc
phila, pa. 19124

Original ____
Amendment ____
Supplement ____
Other ____

Name of Drug: hydrochlorthiazine

Nonproprietary Name:

Purpose of Supplement:

Date(s) of Submission:
8/26/73
1/22/74(three+1/28/74

Pharmacological Category: diuretic

How Dispensed: R_x ☒ O.T.C. ☐

Dosage Form(s): tablet

Potency (ies): 25 & 50 mg.

AF Number: 23-724

Related IND/NDA/MF:

Satisfactory ☐ Labeling
Date Due as per MO's review (jbacsanyi)

Satisfactory ☐ Components, Composition, Manufacturing and Controls
Date Due as per comments in letter of 9/17/73

Satisfactory ☐ Biologic Availability
Date Due as per comments in letter of [illegible]
Is data on current formulation? YES ☐ NO ☐

Satisfactory ☐ Probably or Possibly Effective Indications (if in labeling)
Date data Due

Establishment Inspection: nc

Recalls:

Is relabeling of drug in commercial channels required? YES ☐ No ☐
If so, what level?

Remarks

1. re-request mfg infor, as per letter of 9/17/73
2. request + bio data, as per comments of 8/24/73

Conclusions

rev w/f

/s/

[illegible]

CHEMIST'S REVIEW FOR
ABBREVIATED NEW DRUG APPLICATION
OR SUPPLEMENT

Statement Date

NDA Number 72-724

Name and Address of Applicant (City and State)
richlyn laboratories, inc.
phila, pa 19124

Original
Amendment
Supplement
Resubmission
Correspondance
Report
Other

Purpose of Amendment/Supplement
rugby labs as distrobutor

Date(s) of Submission(s)
10/30/+11/2+11/9/73
2/6/74

Pharmacological Category	Name of Drug	How Dispensed
diuretic	hydrochlorthiazide	R_x ☐ XX OTC ☐
Dosage Form(s) tablets	Potency (ies) 25 & 50 mgs	
Environmental Impact Analysis Report nc	Samples holding until info re bio study is submitted	Related IND/NDA/NF(s)

Labeling
as per mo (jbacsanyi)

Biologic Availability
under review by DCR

Establishment Inspection
nc

Components, Composition, Manufacturing and Controls
as per letters of 9/17 + 12/26/73

Remarks

Conclusion
rev w/f

S

NEW DRUG APPLICATION
OR SUPPLEMENT

Statement Date

AF Number 28-72

Original
Amendment
Supplement
Resubmission
Correspondance
Report
Other

Name and Address of Applicant (City and State)
richlyn laboratories, inc.
phila, pa 19124

Purpose of Amendment/Supplement
rugby labs as distrobutor

Date(s) of Submission(s)
10/30/+11/2+11/9/73
2/6/74 + 2/11/+ 3/4/73
withdrawn 5/13/74

Pharmacological Category	Name of Drug	How Dispensed
diuretic	hydrochlorthiazide	R_x XX OTC
Dosage Form(s)	Potency (ies)	
tablets	25 & 50 mgs	
Environmental Impact Analysis Report	Samples	Related IND/NDA/NF(s)
nc	holding until info re bio study is submitted	

Labeling
as per mo (jbacsanyi)

Biologic Availability
under review by DCR

Establishment Inspection
nc

Components, Composition, Manufacturing and Controls
as per letter 2/26/73

Remarks

Conclusion
rev w/f

/s/
gvillar

Name and Address of Applicant (City and State)
richlyn laboratories, inc.
phila, pa 19124

Original
Amendment
Supplement
Resubmission
Correspondence
Report
Other

Purpose of Amendment/Supplement
distributors = mfg info

Date(s) of Submission
1/21/74
2/13(two)+3/[illegible]
undated(rec'd 3/[illegible]
3/15/25 &undated rec'd

Pharmacological Category	Name of Drug	Dosage Form(s)	Potency (ies)	How Dispensed
diuretic	hydrochlorthiazide	tablets	50 mgs	R_x ☐ OTC ☐

Environmental Impact Analysis Report	Samples	Related IND, NDA(s)
nc	holding until info re bio study is submitted	

Labeling
as per NDA (Amendment)

Biologic Availability
disapproved, as per 4/15/74 letter to NDA 83-607

Establishment Inspection
nc

Components, Composition, Manufacturing and Controls
as per letters through 4/5/74

Remarks
as per issuing letter

Conclusion
rev w/f

/S/

Name and Address of Applicant (City and State)
richlyn laboratories, inc.
phila, pa 19124

Original
Amendment
Supplement
Resubmission
Correspondence
Report
Other

Type of Amendment/Supplement
distributors = mfg info

Date(s) of Document
1/21/74
2/13(two)+3/[illegible]
undated(rec'd [illegible]
3/15/25 &undated rec'd
5/16/74

Pharmacological Category	Name of Drug	How Dispensed
diuretic	hydrochlorthiazide	Rx ☐ XX OTC ☐
Dosage Form(s)	Potency (ies)	
tablets	50 mgs	
Environmental Impact Analysis Report	Samples	Related IND/NDA(s)
nc	holding until info re bio study is submitted	

Labeling
as per ltr (undated)

Biologic Availability
disapproved, as per 4/15/74 letter to NDA 03-607

Establishment Inspection
nc

Components, Composition, Manufacturing and Controls
as per letters through 4/5/74

Labels
as per issuing letter

Conclusion
rev w/f

/S/
[illegible]

Applicant | Statement date

83-607
NF Number

Name and Address of Applicant (City and State)
richlyn laboratories, inc.
phila, pa 19124

Original
Amendment
Supplement
Resubmission
Correspondence
Report
Other

Purpose of Submission/Supplement
distributors = mfg info

Date(s) of Submission
1/21/74
2/13(two)+3/13[illegible]
undated(rec'd 3[illegible]
3/15/25 &undated(re2[illegible]

Pharmacological Category	Name of Drug	How Dispensed
diuretic	hydrochlorthiazide	R_x ☐ XX OTC ☐
Dosage Form(s)	Potency (ies)	
tablets	50 mgs	
Environmental Impact Analysis Report	Samples	Related IND/NDA(s)
nc	holding until info re bio study is submitted	

Labeling
as per mo (jbacsanyi)

Biologic Availability
disapproved, as per 4/15/74 letter to NDA 83-607

Establishment Inspection
nc

Components, Composition, Manufacturing and Controls
as per letters through 4/5/74

Remarks
as per issuing letter

Conclusion
rev w/f

/S/

Name and Address of Applicant (City and State)
richlyn laboratories, inc.
phila, pa 19124

Original 83-607
Amendment
Supplement
Resubmission
Correspondence
Report
Other

Purpose of Amendment/Supplement
distributors = mfg info

Date(s) of Submission
1/21/74
2/13(two)+3/13 [illegible]
undated(rec'd [illegible]
3/15/25 &undated
5/16/74
8/7+8/22/74

Pharmacological Category	Name of Drug	How Dispensed
diuretic	hydrochlorthiazide	Rx ☐ XX OTC ☐
Dosage Form(s)	Potency (ies)	
tablets	50 mgs	
Environmental Impact Analysis Report	Samples	Related IND/NDA(s)
nc	holding until info re bio study is submitted	

Labeling
as per nc (Unchanged)

Biologic Availability
disapproved, as per 4/15/74 letter to NDA 83-607

Establishment Inspection
nc

Components, Composition, Manufacturing and Controls
as per letters through 4/5/74

Comments
as per issuing letter

Conclusion
rev w/f

/S/
[illegible]

Name of Applicant	83-607 NDA Number
Address of Applicant (City and State) mc ine laboratories, inc. phila, pa 19124	Original Amendment Supplement Resubmission Correspondence Report Other
Proprietary Name/Supplement distributors = mfg info	Date(s) of Submission 1/21/74 2/13(two)+3/13[illegible] undated(rec'd [illegible] 3/15/25 &undated(r 4/5/74
Pharmacological Category diuretic	Name of Drug hydrochlorthiazide
Dosage Form(s) tablets	Potency (ies) 50 mgs
How Dispensed R_x ☐ XX OTC ☐
Comparative Bioavailability Data? nc	Samples holding until info re bio study is submitted
Related IND/NDA(s)

Labeling

as per mc (jbacsanyi)

Bioavailability

disapproved, as per 4/15/74 letter to NDA 83-607

Recommendation on Inspection

nc

Chemistry, Components, Composition, Manufacturing and Controls

as per letters through 4/5/74

Summary

as per issuing letter

/S/

Signature

[illegible]

[illegible] (City and State)		
[illegible] Laboratories, Inc. Phila, Pa 19124		Original [illegible] — Amendment — Supplement — Resubmission — Correspondence — Report — Other —
[illegible]	distributors = mfg info	Date(s) of [illegible]: 1/21/74; 2/13(t...)-3[illegible]; undated(rec [illegible]); 3/15/23 [illegible]; 11/5/74 as per letter [illegible]
Pharmacological Category: diuretic	Name of Drug: hydrochlorthiazide	
Dosage Form(s): tablets	Potency (ies): 50 mgs	How Dispensed: Rx ☐ OTC ☐
[illegible] Impact Analysis: nc	Samples: holding until info re bio study is submitted	Related [illegible]

[illegible]

as per mo (jbacsanyi)

Biologic Availability

disapproved, as per 4/15/74 letter to NDA 83-807

[illegible] Inspection

nc

[illegible], Composition, Manufacturing and Controls

as per letters through 4/5/74

Remarks

as per issuing letter

Rev w/l /S/ [illegible]

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	83-607

3. NAME AND ADDRESS OF APPLICANT *(City and State)*
Richlyn Labs, Inc
Phila, PA 19124

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
~~XXXXXXXXX~~ amendments
2/13/75 = distributor
3/21/75 = updated mfg cards(dated in 1975 rather than previous one of 1973--in original submission)

10. AMENDMENT DATE(s)

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

12. PHARMACOLOGICAL CATEGORY
diuretic

13. AF NUMBER
28-724

16. RELATED IND/NDA/MF(s)

14. DOSAGE FORM	15. HOW DISPENSED	18. DRUG REGUIRES
oral	☒ Rx ☐ OTC	☐ NDA ☒ ANDA

17. POTENCY(ies)
50 mg

19. CHEMICAL NAME

20. RECORDS AND REPORTS

CURRENT		REVIEWED	
☐ YES	☐ NO	☐ YES	☐ NO

21. CHEMICAL FORMULA

22. REMARKS
bio study disapproved in 4/15/74 letter
firm containues to update with
(1) additional distributors & (2) mfg info,

23. CONCLUSIONS
rev w/f
request that firm NOT submit additional information until it completes taht part pertaining to bio availability

24. REVIEWER

NAME	SIGNATURE	DATE COMPLETED
gmillar	/S/ 5/22/75	5/13/75

DISTRIBUTION ☒ ORIGINAL JACKET ☐ DUPLICATE JACKET ☐ REVIEWER

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

CHEMIST'S REVIEW FOR [redacted] NEW DRUG APPLICATION OR SUPPLEMENT

Federal Register Statement Date

NDA Number 83-607

AE Number 28-724

Name and Address of Applicant (City and State)

richlyn labs, inc
phila, pa 19124

Original ____
Amendment ____
Supplement ____
Resubmission ____
Correspondance ____
Report ____
Other ____

Purpose of Amendment/Supplement

dist amends

Date(s) of Submission

as per letter

Pharmacological Category	Name of Drug	How Dispensed
anti diuretic	hydrochlorothiazide	R_x zz OTC
Dosage Form(s)	Potency(ies)	Related IND/NDA/NF
oral	50 mg.	
Packaging/Sterilization	Samples	
na	na	

Labeling

as per MO(jbacsanyi)

Biologic Availability

disapproved = 4/15/74 letter

Establishment Inspection

NC

Components, Composition, Manufacturing and Controls

NC

Remarks

as per letter

Conclusion rev def

[redacted] [S]

OR SUPPLEMENT

AF Number 28-724

Name and Address of Applicant (City and State)

richlyn labs, inc
phila, pa 19124

Original
Amendment
Supplement
Resubmission
Correspondance
Report
Other

Purpose of Amendment/Supplement

dist amends

Date(s) of Submission

as per letter

Pharmacological Category	Name of Drug	How Dispensed
anti diuretic	hydrochlorothiazide	R_x zz OTC
Dosage Form(s)	Potency(ies)	
oral	50 mg.	
Packaging/Sterilization	Samples	Related IND/NDA/NF
na	na	

Labeling

as per MO(jbacsanyi)

Biologic Availability

disapproved = 4/15/74 letter

Establishment Inspection

NC

Components, Composition, Manufacturing and Controls

NC

Remarks

as per letter

/S/..

Conclusion rev def

REVIEWED gmillar

OR SUPPLEMENT

83-607
AF Number

Name and Address of Applicant (City and State)

richlyn laboratories, inc
Phila, PA 19124

Original
Amendment
Supplement
Resubmission
Correspondance
Report
Other

Purpose of Amendment/Supplement

amend

Date(s) of Submission(s)

as per letter

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

Labeling

as per HO(jabsanyi)

Biologic Availability

approved, as per HFD-522 memo of 5/3/77 for 83-607
50 mg. potency

Establishment Inspection

in compliance as per HFD-322 memo of 3/30/77

Components, Composition, Manufacturing and Controls

satisfactory

Remarks

approved

cuillar
/S/

Conclusion

REVIEWER

DATE

ABBREVIATED NEW DRUG APPLICATION OR SUPPLEMENT | Statement Date | SUPPLEMENT ☐

Name & Address of Applicant (City & State)
richlyn labs, inc
phila, pa. 19124

NDA Number 83-607

Supplement Date and Number

Name of Drug | Nonproprietary Name
hydrochlorthiazide

Amendment Date(s)
4/11+4/16/73

Purpose of Supplement

Other Date(s)

Pharmacological Category
diuretic

How Dispensed
℞ [XX] O.T.C. ☐

AF Number 28-724

Related IND/NDA/NF(s)

Dosage Form(s)
tablet

Potency (ies)
25 & 50 mg.

Satisfactory ☐ Labeling
Date Due _____ as per MO(jbacsanyi)

Satisfactory ☐ Components, Composition, Manufacturing and Controls
Date Due _____ see below .

Satisfactory ☐ Biologic Availability
Date Due _____ protocol reviewed by DCR and comments to firm on 4/25/73
Is data on current formulation? YES ☐ NO ☐

Satisfactory ☐ Probably or Possibly Effective Indications (if in labeling)
Date Data Due _____

Establishment Inspection
as per BD-340 memo of 4/26/73
• requested 3/7/73
= requested 5/16/73

Recalls

If relabeling of drug in commercial channels required? YES ☐ NO ☐
If so, what level:

Remarks
request: 1. revised distributor's labels
2. mfg
3. certifications from testing labs + methods
4. samples
remind firm that protocol was commented upon
tell firm that environmental impact statement will be commented upon later
give firm comments of BD-340 regarding evalution of current GMP .

Conclusions
rev w/f

gmillar /s/

REVIEWER: SIGNATURE: DATE:

ABBREVIATED NEW DRUG APPLICATION OR SUPPLEMENT	Federal Register Statement Date	NDA Number 83-607
		AP Number 28-724

Name and Address of Applicant (City and State)		
richlyn labs, inc. phila, pa 19124		Original Amendment Supplement Report Other
Nature of Supplement		Date(s) of Submission(s) 6/14+7/19 = mfg 5/14/+5/17+5/21+5/29 6/5+6/22+8/20/73 undated (recd 7/16+7/30/
Established Name of Drug hydrochlorthiazide	Pharmacological Category diuretic	
Dosage Form(s) tablets	Potency (ies) requested 6/18/73	How Dispensed Rx xx OTC
Clinical Pharmacology Report submitted 4/11/73	Samples requested 6/18/73	Related IND, NDA(s)

Labeling

as per mo(jbacsanyi)

Chemistry, Composition, Manufacturing and Controls

firm does not comply with requests of 6/18/73
re-request the same information

Microbiology

protocol reviewed; comments to firm on 4/25/73

Recommended Disposition

richlyn = in compliance, as per bd-340 memo of 6/27/73

Bioavailability

re-request info, as per letter of 6/18/73
note; daylin proposes unit of use labeling

rev w/f

/S/

Reviewer gmillar 7/31/73

Date

ABBREVIATED NEW DRUG APPLICATION OR SUPPLEMENT | Statement Date | 83-607

Name and Address of Applicant (City and State)
richlyn laboratories, inc
phila, pa. 19124

Original ____
Amendment ____
Supplement ____
Other ____

Name of Drug: hydrochlorthiazine

Nonproprietary Name:

Purpose of Supplement:

Date(s) of Submission(s): 8/24/73

Pharmacological Category: diuretic

How Dispensed: R_x ☒ ZZ O.T.C. ☐

Dosage Form(s): tablet

Potency (ies): 25 & 50 mg.

AF Number: 28-724

Related IND/NDA/MF:

Satisfactory ☐ Labeling
Date Due as per MO's review (jbacsanyi)

Satisfactory ☐ Components, Composition, Manufacturing and Controls
Date Due as per comments in letter of 9/17/73

Satisfactory ☐ Biologic Availability
Date Due as per comments in letter of 8/24/73
Is data on current formulation? YES ☐ NO ☐

Satisfactory ☐ Probably or Possibly Effective Indications (if in labeling)
Date data Due

Establishment Inspection: nc

Recalls:

Is relabeling of drug in commercial channels required? YES ☐ No ☐
If so, what level?

Remarks

1. re-request mfg infor, as per letter of 9/17/73
2. request + bio data, as per comments of 8/24/73

Conclusions

rev w/f

/S/
gmillar

ABBREVIATED NEW DRUG APPLICATION OR SUPPLEMENT | Statement Date | 83-607

Name and Address of Applicant (City and State)
richlyn laboratories, inc
phila, pa. 19124

Original ____
Amendment ____
Supplement ____
Other ____

Name of Drug	Nonproprietary Name
	hydrochlorthiazine

Purpose of Supplement

Date(s) of Submission
8/24/73
9/24+10/8+11+22/73

Pharmacological Category	How Dispensed
diuretic	R_x ☒ ZZ O.T.C. ☐

Dosage Form(s)	Potency (ies)
tablet	25 & 50 mg.

AF Number 28-724
Related IND/NDA/MF

Satisfactory ☐ Labeling
Date Due as per MO's review (jbacsanyi)

Satisfactory ☐ Components, Composition, Manufacturing and Controls
Date Due as per comments in letter of 9/17/73

Satisfactory ☐ Biologic Availability
Date Due ____
Is data on current formulation? YES ☐ NO ☐ 10/11/73 data to be sent to DCR

Satisfactory ☐ Probably or Possibly Effective Indications (if in labeling)
Date data Due ____

Establishment Inspection	Recalls
nc	

Is relabeling of drug in commercial channels required? YES ☐ No ☐
If so, what level?

Remarks

1. re-request mfg infor, as per letter of 9/17/73
bio data to DCR
other comments, as per letter

NB: samples arrived

Conclusions

rev w/f

gmillar 1/3/74

ABBREVIATED NEW DRUG APPLICATION OR SUPPLEMENT | Statement Date | 83-607

Name and Address of Applicant (City and State)
richlyn laboratories, inc
phila, pa. 19124

Original ____
Amendment ____
Supplement ____
Other ____

Name of Drug	Nonproprietary Name
	hydrochlorthiazine

Purpose of Supplement

Date(s) of Submission
8/24/73
9/24+10/8+11+22/73
10/25/73

Pharmacological Category	How Dispensed
diuretic	R_x ☒ O.T.C. ☐

Dosage Form(s)	Potency (ies)
tablet	25 & 50 mg.

AF Number 28-724

Related IND/NDA/MF

Satisfactory ☐ Labeling
Date Due as per MO's review (jbacsanyi)

Satisfactory ☐ Components, Composition, Manufacturing and Controls
Date Due as per comments in letter of 9/17/73

Satisfactory ☐ Biologic Availability
Date Due ____
Is data on current formulation? YES ☐ NO ☐ 10/11/73 data to be sent to DCR

Satisfactory ☐ Probably or Possibly Effective Indications (if in labeling)
Date data Due ____

Establishment Inspection	Recalls
nc	

Is relabeling of drug in commercial channels required? YES ☐ No ☐
If so, what level?

Remarks

1. re-request mfg infor, as per letter of 9/17/73
bio data to DCR
other comments, as per letter

NB: samples arrived

Conclusions

rev w/f

gmillar

CHEMIST'S REVIEW FOR ABBREVIATED NEW DRUG APPLICATION OR SUPPLEMENT

Federal Register Statement Date

NDA Number 83-607

AF Number 28-724

nd Address of Applicant (City and State)
richlyn laboratories, inc.
phila, pa 19124

Original
Amendment
Supplement
Resubmission
Correspondance
Report
Other

Purpose of Amendment/Supplement

Date(s) of Submission(s)
10/30/+11/2+11/9/73

Pharmacological Category	Name of Drug	
diuretic	hydrochlorthiazide	
Dosage Form(s)	Potency (ies)	How Dispensed
tablets	25 & 50 mgs	R_x ☐ XX OTC ☐
Environmental Impact Analysis Report nc	Samples holding until info re bio study is submitted	Related IND/NDA/MF(s)

Labeling

as per mo (jbacsanyi)

Biologic Availability

under review by DCR

Establishment Inspection

nc

Components, Composition, Manufacturing and Controls

as per letters of 9/17 + 12/26/73

Remarks

Conclusion

rev w/f

/S/

REVIEWER

gmTllar

DATE

ABBREVIATED NEW DRUG APPLICATION OR SUPPLEMENT	Statement Date	83-607 AF Number 28-724

e and Address of Applicant (City and State)		
richlyn labs, inc phila, pa 19124		Original Amendment Supplement Resubmission Correspondance Report Other
Purpose of Amendment/Supplement dist amends bio study		Date(s) of Submission(s) as per letter 5/6/77
Pharmacological Category anti diuretic	Name of Drug hydrochlorothiazide	
Dosage Form(s) oral	Potency(ies) 50 mg.	How Dispensed R_x zz OTC
Packaging/Sterilization na	Samples na	Related IND/NDA/NF

Labeling
re-requested

Biologic Availability
approved, as per HFD-522 memo of 5/3/77

Establishment Inspection
requested

Components, Composition, Manufacturing and Controls
as per letter to issue

Remarks
rev w/f, gmillar

/S/

Conclusion

REVIEWER DATE