

CENTER FOR DRUG EVALUATION AND RESEARCH

Approval Package for:

APPLICATION NUMBER:

12-827/S017

Trade Name: Robinul & Robinul Forte Tablets

Generic Name: (glycopyrrolate)

Sponsor: A.H. Robins Company

Approval Date: February 22, 1979

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APPLICATION NUMBER:

12-827/S017

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APPLICATION NUMBER:
NDA 12-827/S017

APPROVAL LETTER

NDA 12-827/S-017

FEB 22 1979

A. H. Robins Company
Attention: Frances Aaroe
1211 Sherwood Avenue
Richmond, Virginia 23220

Dear Mrs. Aaroe:

Please refer to your supplemental new drug application of July 10, 1978, submitted pursuant to section 505(b) of the Federal Food, Drug, and Cosmetic Act for Robinul and Robinul Forte (glycopyrrolate) Tablets.

Reference is also made to your communication dated December 1, 1978, amending the supplement.

The supplemental application provides for revised specifications and testing procedures for the drug products.

We have completed the review of this supplemental application as amended and it is approved. Our letter of December 17, 1975, detailed the conditions relating to the approval of this application.

Sincerely yours,

Robert Temple, M.D.
Director
Division of Cardio-Renal
Drug Products
Bureau of Drugs

cc: BLT-DO

Orig NDA

HFD-110

HFD-616

HFD-110/CSO

HFD-110/RJWalters/1/29/79/cto/2/14/79

R/D init. by: JLangston/1/30/79

RTemple/1/30/79

APPROVED

B. Walters 2-14-79
J. Langston MS 2/14/79

**CENTER FOR DRUG EVALUATION AND
RESEARCH**

APPLICATION NUMBER:
NDA 12-827/S017

APPROVABLE LETTER

14.1

NDA 12-827/S-017
12-950/S-017

A. H. Robins Company
Attention: Frances Aaroe
1211 Sherwood Avenue
Richmond, Virginia 23220

SEP 28 1978

Dear Ms. Aaroe:

Reference is made to your supplemental applications of July 10, 1978, submitted pursuant to section 505(b) of the Federal Food, Drug, and Cosmetic Act for Robinul and Robinul Forte (glycopyrrolate) Tablets (NDA 12-827) and Robinul-PH and Robinul-PH Forte (glycopyrrolate and phenobarbital) Tablets (NDA 12-950).

The supplemental applications provide for revised specifications and testing procedures for the drug products.

We have completed our review of these supplemental applications. However, before we are able to reach a final conclusion the following additional information is necessary:

~~_____~~

b(4)

We note that the NF XIV includes these tests for glycopyrrolate tablets.

Please submit the above information promptly.

Sincerely yours,

Robert Temple, M.D.
Director
Division of Cardio-Renal
Drug Products
Bureau of Drugs

cc: BLT-DO
Orig. NDA
HFD-110
HFD-110/CSO
HFD-110/RJWalters/cto/9/26/78
R/D init. by: JLangston/9/25/78
RTemple/9/25/78

*R/Walters
9/28/78*

REVIEW/WAITING FIRM

*J. Langston
9/25/78*

RTemple 9/28/78

**CENTER FOR DRUG EVALUATION AND
RESEARCH**

APPLICATION NUMBER:

NDA 12-827/S017

CHEMISTRY REVIEW(S)

CHEMIST'S REVIEW <i>(If necessary, continue any item on 8" x 10 1/2" paper. Key continuation to item by number.)</i>		1. ORGANIZATION HFD-110	2. NDA NUMBER 12-827
3. NAME AND ADDRESS OF APPLICANT (City and State) A.H. Robins and Company 1211 Sherwood Avenue Richmond, Virginia 23220		4. AF NUMBER 16-375	
		5. SUPPLEMENT (S) NUMBER(S) DATE(S) S-017 7-10-78	
6. NAME OF DRUG Robinul Robinul Forte	7. NONPROPRIETARY NAME Glycopyrrolate		9. AMENDMENTS AND OTHER (Reports, etc.) DATES
8. SUPPLEMENT(S) PROVIDES FOR: Revised product specifications and testing procedures.			
10. PHARMACOLOGICAL CATEGORY Anticholinergic	11. HOW DISPENSED <input checked="" type="checkbox"/> RX <input type="checkbox"/> OTC		12. RELATED IND/NDA/DMF(S)
13. DOSAGE FORM (S) Tablet	14. POTENCY (ies) 1 mg and 2 mg (Forte)		
15. CHEMICAL NAME AND STRUCTURE NF XIV		16. RECORDS AND REPORTS	
		CURRENT <input checked="" type="checkbox"/> YES <input type="checkbox"/> NO REVIEWED <input checked="" type="checkbox"/> YES <input type="checkbox"/> NO	
17. COMMENTS _____ _____ _____ _____ will be submitted when available.			
18. CONCLUSIONS AND RECOMMENDATIONS Approve supplement. cc: Orig. NDA 12-827 HFD-110 HFD-110/CSO HFD-110/RWolters/1/29/79 F/T:jp/2/14/79			
19. REVIEWER			
NAME R.J. Wolters	SIGNATURE <i>RJ Wolters</i> 2-14-79		DATE COMPLETED 1-29-79
DISTRIBUTION <input checked="" type="checkbox"/> ORIGINAL JACKET <input type="checkbox"/> REVIEWER <input type="checkbox"/> DIVISION FILE			

CHEMIST'S REVIEW <i>(If necessary, continue any item on 8" x 10 1/2" paper. Key continuation to item by number.)</i>		1. ORGANIZATION HFD-110	2. NDA NUMBER 12-827
3. NAME AND ADDRESS OF APPLICANT (City and State) A. H. Robins Company 1211 Sherwood Avenue Richmond, Virginia 23220		4. AF NUMBER 16-375	
		5. SUPPLEMENT (S) NUMBER(S) DATE(S)	
6. NAME OF DRUG Robinul and Robinul Forte	7. NONPROPRIETARY NAME Glycopyrrolate	S-017	7/10/78
8. SUPPLEMENT(S) PROVIDES FOR: Revised product specifications and testing procedures.		9. AMENDMENTS AND OTHER (Reports, etc.) DATES	
10. PHARMACOLOGICAL CATEGORY Anticholinergic	11. HOW DISPENSED <input checked="" type="checkbox"/> RX <input type="checkbox"/> OTC	12. RELATED IND/NDA/DMF(S)	
13. DOSAGE FORM (S) Tablet	14. POTENCY (ies) 1 mg and 2 mg (Forte)	16. RECORDS AND REPORTS	
15. CHEMICAL NAME AND STRUCTURE NF XIV		CURRENT <input checked="" type="checkbox"/> YES <input type="checkbox"/> NO	
		REVIEWED <input checked="" type="checkbox"/> YES <input type="checkbox"/> NO	
17. COMMENTS			
1. Weight specifications have been _____ b(4)			
2. _____ b(4)			
3. _____ b(4)			
4. Made editorial changes in the content uniformity procedures. _____ b(4)			
18. CONCLUSIONS AND RECOMMENDATIONS			
rev. w/f			
SEP 28 1978			
19. REVIEWER			
NAME R. J. Wolters	SIGNATURE <i>R. J. Wolters</i> 9/12/78	DATE COMPLETED 9/22/78	
DISTRIBUTION	<input checked="" type="checkbox"/> ORIGINAL JACKET	<input type="checkbox"/> REVIEWER	<input type="checkbox"/> DIVISION FILE

14.1

MEMORANDUM OF TELEPHONE CONVERSATION

Between: Frances Aaroe
A. H. Robins

and

Natalia Morgenstern

DEC 14 1978

Subject: _____

~~(b)(4)~~ 12-827, Robinul Tablets

~~_____~~

b(4)

Natalia Morgenstern 10/31/78
Natalia Morgenstern

cc:
Orig. NDA
HFD-110
HFD-110/CSO
HFD-110/NAMorgenstern/10/8/78/10/30/78/cto/10/11/78/10/31/78

**CENTER FOR DRUG EVALUATION AND
RESEARCH**

APPLICATION NUMBER:
NDA 12-827/S017

ADMINISTRATIVE and CORRESPONDENCE
DOCUMENTS

NDA 12-827

A. H. Robins Company
Research Laboratories
Attention: Frances Aaroe, Manager
1211 Sherwood Avenue
Richmond, Virginia 23220

DEC 7 1978

Dear Ms. Aaroe:

We acknowledge receipt of your resubmitted supplemental application for the following:

Name of Drug: Robinul (glycopyrrolate) Tablets

NDA Number: 12-827

Supplement Number: S-017

Date of Resubmitted Supplement: December 1, 1978

Date of Receipt: December 5, 1978

All communications concerning this NDA should be addressed as follows:

Bureau of Drugs HFD-110
Attention: DOCUMENT CONTROL ROOM #16B-30
5600 Fishers Lane
Rockville, Maryland 20857

Sincerely yours,

THD 12/7/78
Thomas H. Davis
Supervisory Consumer Safety Officer
Division of Cardio-Renal
Drug Products
Bureau of Drugs

cc: BET-DO
NDA Orig.
HFD-110
HFD-110/CSO
HFD-110/ALBrown/12/7/78/cto/12/7/78

RESUBMITTED SUPPLEMENT
ACKNOWLEDGEMENT

141

NDA 12-827

JUL 19 1978

A. H. Robins Company
Research Laboratories
Attention: Frances Aaroe
1211 Sherwood Avenue
Richmond, Virginia 23220

Dear Ms. Aaroe:

We acknowledge receipt of your supplemental application for the following:

Name of Drug: Robinul Tablets

NDA Number: 12-827

Supplement Number: S017

Date of Supplement: 7-10-78

Date of Receipt: 7-13-78

All communications concerning this NDA should be addressed as follows:

Bureau of Drugs HFD-110
Attention: DOCUMENT CONTROL ROOM #16B-30
5600 Fishers Lane
Rockville, Maryland 20857

Sincerely yours,

THD 7/19/78
Thomas H. Davis
Supervisory Consumer Safety Officer
Division of Cardio-Renal
Drug Products
Bureau of Drugs

cc: BLT-DO
NDA Orig.
HFD-110
HFD-110/CSO
HFD-110/ALBrown/c1/7/19/78

SHIPPI MFMENT ACKNOWLEDGEMENT

ORIGINAL

A. H. Robins Company
Research Laboratories
1211 Sherwood Ave.
Richmond, Virginia 23220
Telephone (804) 257-2361

RESUBMISSION

RS

A-H-ROBINS

Division of Cardio-Renal
Drug Products
Bureau of Drugs, HFD #110
Document Control Room 16B-30
5600 Fishers Lane
Rockville, Maryland 20857

December 1, 1978

Re: NDA 12-827/S-017
Robinul (glycopyrrolate)
Tablets

Gentlemen:

Reference is made to your letter of September 28, 1978 regarding Supplement 017 which provided product specifications for Robinul (glycopyrrolate) Tablets, NDA 12-827.

b(4)

You requested a definition _____

b(4)

~~_____~~
~~_____~~
~~_____~~

b(4)

Please refer to the attached study conducted by statistician James E. Duarte, Quality Assurance.

_____ will be submitted when available.

b(4)

b(4)

Sincerely yours,

Frances Aaroe

Frances Aaroe, Manager
Domestic Regulatory Affairs

dwm



/ Page(s) Withheld

 Trade Secret / Confidential (b4)

 Draft Labeling (b4)

 Draft Labeling (b5)

 Deliberative Process (b5)

Withheld Track Number: Administrative- 12-827
5017

NDA NO. 12-827 REF. NO. 5017
NDA SUPPL FOR Controls

A. H. Robins Company
Research Laboratories
1211 Sherwood Ave.
Richmond, Virginia 23220
Telephone (804) 257-2661

CS

ORIGINAL

A-H-ROBINS

Division of Cardio-Renal
Drug Products
Bureau of Drugs, HFD #110
Document Control Room 16B-30
5600 Fishers Lane
Rockville, Maryland 20857

July 10, 1978

Re: NDA 12-827
Robinul Tablets

Gentlemen:

Reference is made to our New Drug Application for Robinul and Robinul Forte tablets.

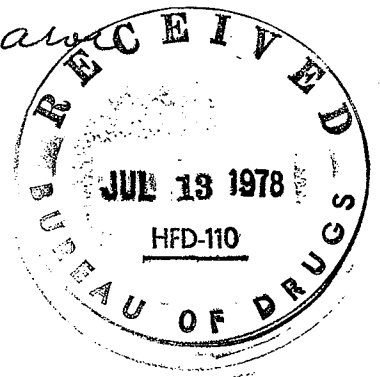
The Product Specifications and Test Procedures have been revised. The previously approved specifications dated July, 1976, were approved July 13, 1977 (S-014). The following revisions have been made in the new ones dated April, 1978:

1. Weight specifications on page 3 have been narrowed \leftarrow $\%.$ b(4)
2. ~~_____~~ b(4)
3. ~~_____~~ b(4)
4. ~~_____~~ b(4)

Your incorporation of these revisions in our New Drug Application would be appreciated.

Sincerely,

Frances Aaroe
Frances Aaroe
Staff Assistant
Regulatory Affairs



pjp

15 Page(s) Withheld

Trade Secret / Confidential (b4)

Draft Labeling (b4)

Draft Labeling (b5)

Deliberative Process (b5)

Withheld Track Number: Administrative-12-827
5017