

**CENTER FOR DRUG EVALUATION AND RESEARCH**

**Approval Package for:**

***APPLICATION NUMBER:***

**12-827/S015**

***Trade Name:*** Robinul & Robinul Forte Tablets

***Generic Name:*** (glycopyrrolate )

***Sponsor:*** A.H. Robins Company

***Approval Date:*** September 27, 1977

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*APPLICATION NUMBER:*

**12-827/S015**

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*APPLICATION NUMBER:*  
**NDA 12-827/S015**

**APPROVAL LETTER**

NDA 12-827/S-015

A. H. Robins Company  
Attention: Frances Aaroe  
1407 Cummings Drive  
Richmond, Virginia 23220

SEP 27 1977

Dear Mrs. Aaroe:

Reference is made to your supplemental new drug application of August 17, 1977, submitted pursuant to section 505(b) of the Federal Food, Drug, and Cosmetic Act for Robinul and Robinul Forte (glycopyrrolate) Tablets.

The supplemental application provides for the addition of the microbial limits test to the specifications for ~~1-7~~ and ~~1-8~~ b(4)

We have completed the review of this supplemental application and it is approved. Our letter of December 15, 1975, detailed the conditions relating to the approval of this application.

Sincerely yours,

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

cc: BLT-DO

Orig. NDA

HFD-110

HFD-110/CSO

HFD-616

HFL-10

HFD-110/RJWalters/JFLangston/9/13/77/vw/9/24/77

R/D init. by: RTemple/9/13/77

APPROVED

*J. Langston*  
9/26/77  
*R Temple*  
9/26/77

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**CHEMISTRY REVIEW(S)**

<b>CHEMIST'S REVIEW</b> <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 Richmond, Virginia 23220		4. AF NUMBER 16-375	
6. NAME OF DRUG Robinul Robinul Forte		7. NONPROPRIETARY NAME Glycopyrrolate	5. SUPPLEMENT (S) NUMBER(S) DATE(S) S-015 8-17-77
8. SUPPLEMENT(S) PROVIDES FOR: Provides for the updating of the specifications applied to <del>_____</del> and <del>_____</del> to include the USP microbial limits test.		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) Tablets	14. POTENCY (ies) 1 mg and 2 mg (Forte)		
15. CHEMICAL NAME AND STRUCTURE N.F. 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 The microbial limits test will be performed according to the U.S.P. procedures			
18. CONCLUSIONS AND RECOMMENDATIONS Approve supplement.			
19. REVIEWER			
NAME R.J. Wolters	SIGNATURE <i>R.J. Wolters</i> 9-26-77		DATE COMPLETED 9-13-77
DISTRIBUTION <input checked="" type="checkbox"/> ORIGINAL JACKET <input type="checkbox"/> REVIEWER <input type="checkbox"/> DIVISION FILE			

b(4)

SEP 27 1977

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**NDA 12-827/S015**

**ADMINISTRATIVE and CORRESPONDENCE**  
**DOCUMENTS**

ORIGINAL

A. H. Robins Company  
1407 Cummings Drive  
Richmond, Virginia 23220  
Telephone (804) 257-2000

NDA NO. 12-827 REF. NO. S015  
SUPPL FOR Controls

CS

**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

August 17, 1977

RE: NDA 12-827  
Robinul and Robinul Forte

Gentlemen:

This is a supplement to our New Drug Application for Robinul and Robinul Forte to provide for the updating of the raw material specifications for

ACTION:	<input type="checkbox"/>
REVIEWER:	<input type="checkbox"/>
DATE:	<input type="checkbox"/>

	<u>Robins Code</u>	<u>Ingredient</u>	<u>Date</u>
b(4)	_____	_____	April, 1977
b(4)	_____	_____	April, 1977

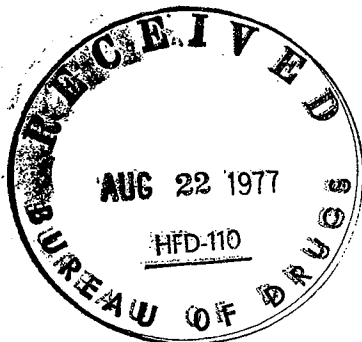
These have been updated to reflect microbiological testing.

Sincerely,

*Frances Aaroe*

(Mrs.) Frances Aaroe  
Staff Assistant  
Regulatory Affairs

mah





3 Page(s) Withheld

J Trade Secret / Confidential (b4)

       Draft Labeling (b4)

       Draft Labeling (b5)

       Deliberative Process (b5)

<b>NOTICE OF APPROVAL NEW DRUG APPLICATION OR SUPPLEMENT</b>		NDA NUMBER 12-827/S-015
		DATE APPROVAL LETTER ISSUED SEP 27 1977
TO:  Press Relations Staff (HFI-40)	FROM: <input checked="" type="checkbox"/> Bureau of Drugs  <input type="checkbox"/> Bureau of Veterinary Medicine	
ATTENTION Forward original of this form for publication only after approval letter has been issued and the date of approval has been entered above.		
TYPE OF APPLICATION <input type="checkbox"/> ORIGINAL NDA <input checked="" type="checkbox"/> SUPPLEMENT TO NDA <input type="checkbox"/> ABBREVIATED ORIGINAL NDA <input type="checkbox"/> SUPPLEMENT TO ANDA		CATEGORY <input checked="" type="checkbox"/> HUMAN <input type="checkbox"/> VETERINARY
TRADE NAME (or other designated name) AND ESTABLISHED OR NONPROPRIETARY NAME (if any) OF DRUG Robinul and Robinul Forte (glycopyrrolate)		
DOSAGE FORM Tablets	HOW DISPENSED <input checked="" type="checkbox"/> RX <input type="checkbox"/> 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.) Glycopyrrolate 1 mg and Forte 2 mg		
NAME OF APPLICANT (Include City and State) A.H. Robins Company Richmond, Virginia 23220		
PRINCIPAL INDICATION OR PHARMACOLOGICAL CATEGORY Anticholinergic		
COMPLETE FOR VETERINARY ONLY		
ANIMAL SPECIES FOR WHICH APPROVED		
COMPLETE FOR SUPPLEMENT ONLY		
CHANGE APPROVED TO PROVIDE FOR  Control Revision		
FORM PREPARED BY		
NAME R.J. Wolters	<i>R.J. Wolters</i>	DATE 9-26-77
FORM APPROVED BY		
NAME J.F. Langston	<i>James F. Langston</i>	DATE 9/26/77