

**CENTER FOR DRUG EVALUATION AND RESEARCH**

**Approval Package for:**

***APPLICATION NUMBER:***

**12-827/S014**

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

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

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

***Approval Date:*** July 13, 1977

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*APPLICATION NUMBER:*

**12-827/S014**

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*APPLICATION NUMBER:*  
**NDA 12-827/S014**

**APPROVAL LETTER**

NDA 12-827/S-014

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

JUL 13 1977

Gentlemen:

Reference is made to your supplemental new drug application of May 20, 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 an updating of the manufacturing and controls information.

We have completed the review of this supplemental application and it is approved. Our letter of December 17, 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/SCSO  
HFD-616  
HFL-10  
HFD-110/RJWalters/JFLangston/6/27/77/cto/7/11/77  
R/D init. by: RJTemple/6/28/77

APPROVED

*RJWalters*  
*7-12-77*  
*J Langston*  
*7/12/77*  
*R Temple 7/12/77*

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*APPLICATION NUMBER:*

**NDA 12-827/S014**

**CHEMISTRY REVIEW(S)**



1   Page(s) Withheld

Trade Secret / Confidential (b4)

Draft Labeling (b4)

Draft Labeling (b5)

Deliberative Process (b5)

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*APPLICATION NUMBER:*  
**NDA 12-827/S014**

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



NDA 12-827

A. H. Robins Company  
1407 Cummings Drive  
Richmond, Virginia 23220

JUN 1 1977

Gentlemen:

We acknowledge receipt of your supplemental application for the following:

Name of Drug: Robinul and Robinul Forte Tablets

NDA Number: 12-827

Supplement Number: S-014

Date of Supplement: May 20, 1977

Date of Receipt: May 23, 1977

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

cc: BLT-DO  
NDA Orig.  
HFD-110  
HFD-110/SCSO  
HFD-110/ALBrown/5/23/77/vh/5/25/77

SUPPLEMENT ACKNOWLEDGEMENT

Sincerely yours,

*THD 5/27/77*  
Thomas H. Davis  
Supervisory Consumer Safety Officer  
Division of Cardio-Renal  
Drug Products  
Bureau of Drugs

ORIGINAL

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

NDA NO. 12-827 REF. NO. S014  
NDA SUPPLEMENT FOR Cortisone

A-H-ROBINS

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

May 20, 1977

Re: NDA 12-827 ROBINUL (glycopyrrolate)  
and ROBINUL FORTE Tablets  
DESI 3265

Gentlemen:

Reference is made to the DESI Notice 3265 published in the Federal Register of Tuesday, March 22, 1977, reclassifying the less-than-effective indications for certain anticholinergic drugs.

Pursuant to the Notice, we are submitting in triplicate a supplement to our New Drug Application 12-827 providing for updating of the manufacturing, etc., for Robinul and Robinul Forte Tablets.

No stability data are included in the manufacturing section. Reference is made to your letter of February 18, 1976 approving the addition of a 5-year expiration date (S-011).

An Environmental Impact statement is included with this supplement.

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b(4)


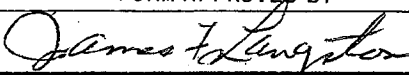
*Frances Arroe*

Mrs. Frances Arroe  
Staff Assistant  
Regulatory Affairs

ACTION: Label  
REVIEWER: [initials]  
DATE: 5/23/77

PJP

RECEIVED  
BUREAU OF DRUGS  
HFD-110  
MAY 23 1977

<b>NOTICE OF APPROVAL NEW DRUG APPLICATION OR SUPPLEMENT</b>		NDA NUMBER <b>12-827S-014</b>
		DATE APPROVAL LETTER ISSUED <b>JUL 13 1977</b>
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 <b>Robinul and Robinul Forte (glycopyrrolate)</b>		
DOSAGE FORM <b>Tablets</b>		HOW DISPENSED <input 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.)  <b>Glycopyrrolate 1 mg and 2 mg (Forte)</b>		
NAME OF APPLICANT (Include City and State) <b>A.H. Robins Company Richmond, Virginia 23220</b>		
PRINCIPAL INDICATION OR PHARMACOLOGICAL CATEGORY <b>Anticholinergic</b>		
COMPLETE FOR VETERINARY ONLY		
ANIMAL SPECIES FOR WHICH APPROVED		
COMPLETE FOR SUPPLEMENT ONLY		
CHANGE APPROVED TO PROVIDE FOR <b>Update of the manufacturing and controls information.</b>		
FORM PREPARED BY		
NAME <b>R.J. Wolters</b>		DATE <b>7/12/77</b>
FORM APPROVED BY		
NAME <b>J.F. Langston</b>		DATE <b>7/12/77</b>