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

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

12-827/S014

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Reviews / Information Included in this NDA Review.

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CENTER FOR DRUG EVALUATION AND RESEARCH

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/RJWolters/JFLangston/6/27/77/cto/7/11/77
R/D init. by: RJTemple/6/28/77

APPROVED

RJWolters 7-12-77
JFLangston 7/12/77
RJTemple 7/12/77

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

NDA 12-827/S014

CHEMISTRY REVIEW(S)

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-110	12-827

3. NAME AND ADDRESS OF APPLICANT *(City and State)*

A.H. Robins Company
Richmond, Virginia 23220

4. AF NUMBER: 16-375

5. SUPPLEMENT (S)

NUMBER(S)	DATE(S)
S-014	5/20/77

6. NAME OF DRUG	7. NONPROPRIETARY NAME
Robinul and Robinul Forte.	Glycopyrrolate

8. SUPPLEMENT(S) PROVIDES FOR:

Update of the manufacturing and control information.

9. AMENDMENTS AND OTHER *(Reports, etc.)* DATES

10. PHARMACOLOGICAL CATEGORY	11. HOW DISPENSED	12. RELATED IND/NDA/DMF(S)
Anticholinergic	☒ RX ☐ OTC	

13. DOSAGE FORM (S)	14. POTENCY *(ies)*
Tablets	1 mg and 2 mg (Forte)

15. CHEMICAL NAME AND STRUCTURE
N.F. XIV

16. RECORDS AND REPORTS
CURRENT ☐ YES ☐ NO
REVIEWED ☐ YES ☐ NO

17. COMMENTS
A Environmental Impact Anaylisis Report is included. The need for such a report is questionable since this supplement is not a major action, only a restatement of Robins' procedures.

18. CONCLUSIONS AND RECOMMENDATIONS

Approve supplement

JUL 13 1977

19. REVIEWER

NAME	SIGNATURE	DATE COMPLETED
R.J. Wolters	R.J. Wolters 7-12-77	6/25/77

DISTRIBUTION ☑ ORIGINAL JACKET ☐ REVIEWER ☐ DIVISION FILE

FORM FDH 2266 (7/75) PREVIOUS EDITION MAY BE USED UNTIL SUPPLY IS EXHAUSTED.

cc: HFD-110 HFD-110/CSO HFD-110/wolters/mw/7/5/77

1 Page(s) Withheld

✓ Trade Secret / Confidential (b4)

_____ Draft Labeling (b4)

_____ Draft Labeling (b5)

_____ Deliberative Process (b5)

Withheld Track Number: Chemistry-12-827
S014

CENTER FOR DRUG EVALUATION AND RESEARCH

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

Sincerely yours,

THD 5/27/77

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/SCSO
HFD-110/ALBrown/5/23/77/vh/5/25/77

SUPPLEMENT ACKNOWLEDGEMENT

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 Original
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

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.

[redacted] b(4)

Frances Aaroe

Mrs. Frances Aaroe
Staff Assistant
Regulatory Affairs

pjp

ACTION:
REVIEWER:
DATE:

RECEIVED
MAY 23 1977
HFD-110
BUREAU OF DRUGS

NOTICE OF APPROVAL
NEW DRUG APPLICATION OR SUPPLEMENT

NDA NUMBER: 12-827S-014

DATE APPROVAL LETTER ISSUED: JUL 13 1977

TO: Press Relations Staff (HFI-40)

FROM:
- [X] Bureau of Drugs
- [ ] 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
- [ ] ORIGINAL NDA
- [X] SUPPLEMENT TO NDA
- [ ] ABBREVIATED ORIGINAL NDA
- [ ] SUPPLEMENT TO ANDA

CATEGORY
- [X] HUMAN
- [ ] 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
- [ ] RX
- [ ] 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.)*

Gylcopyrrolate 1 mg and 2 mg (Forte)

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

Update of the manufacturing and controls inforamtion.

FORM PREPARED BY

NAME		DATE
R.J. Wolters	R J Wolters	7-12-77

FORM APPROVED BY

NAME		DATE
J.F. Langston	James F Langston	7/12/77

FORM FD 1642 (2/75) PREVIOUS EDITION MAY BE USED UNTIL SUPPLY IS EXHAUSTED.

cc: HFI-40 HFD-110 HFD-/CSO HFD-110/Wolters/7/5/77