

CENTER FOR DRUG EVALUATION AND RESEARCH

Approval Package for:

APPLICATION NUMBER:

12-827/S035

Trade Name: Robinul Forte Tablets

Generic Name: (glycopyrrolate)

Sponsor: A.H. Robins Company

Approval Date: April 22, 1986

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APPLICATION NUMBER:

12-827/S035

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APPLICATION NUMBER:
NDA 12-827/S035

APPROVAL LETTER

APR 22 1986

12-796/S-040
✓12-827/S-035

A. H. Robins Company
Attention: Linda Y. Harver
1211 Sherwood Avenue
P.O. Box 26609
Richmond, Virginia 23261-6609

Dear Ms. Harver:

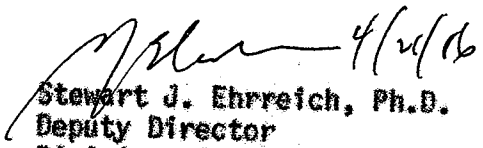
Please refer to your March 20, 1986 supplemental new drug applications submitted under section 505(b)(1) of the Federal Food, Drug, and Cosmetic Act for Quindex (quinidine sulfate) Capsules and Robinul (glycopyrrolate) Tablets.

The supplemental applications provide for / _____ / to be an alternate supplier of the high density polyethylene bottles. b(4)

We have completed the review of these supplemental applications and they are approved. Our letters of October 11, 1977 and December 17, 1975 detailed the conditions relating to the approval of these applications.

We remind you that you must comply with the requirements for an approved NDA set forth under 21 CFR 314.80 and 314.81.

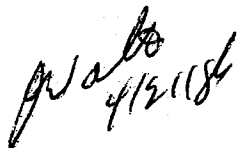
Sincerely yours,


Stewart J. Ehrreich, Ph.D.
Deputy Director
Division of Cardio-Renal Drug Products
Office of Drug Research and Review
Center for Drugs and Biologics

cc:

✓ Original NDA
HFN-110
HFN-110/CSO
HFN-83
HFN-232 (with labeling)
HFN-110/RJWalters/SJEhrreich/4/17/86
ww/4/18/86/0883k

APPROVAL


4/12/86

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APPLICATION NUMBER:
NDA 12-827/S035

CHEMISTRY REVIEW(S)

CHEMIST'S REVIEW <small>(If necessary, continue any item on 8" x 10 1/2" paper. Key continuation to item by number.)</small>		1. ORGANIZATION HFN-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		APR 22 1986	
4. DATE NDA APPROVED		5. IF PRIOR TO OCT 10, 1962, DATE APPROVED FOR EFFICACY	
6. NAME OF DRUG Robinul	7. NONPROPRIETARY NAME Glycopyrrolate		8. SUPPLEMENT NUMBER DATE S-035 3-20-86
9. PURPOSE OF SUPPLEMENT Provides for tablets as (b)(4) alternate supplier tablets HDPE containers		10. AMENDMENT DATE(S)	
11. OTHER DATE (Report, etc.)		12. PHARMACOLOGICAL CATEGORY Anticholinergic Agent	
13. AF NUMBER (b)(4)		16. RELATED IND/NDA/MF(s) DMF	
14. DOSAGE FORM Tablets	15. HOW DISPENSED <input checked="" type="checkbox"/> RX <input type="checkbox"/> OTC		(b)(4)
17. POTENCY (ies) 1 mg	18. DRUG REQUIRES <input type="checkbox"/> NDA <input type="checkbox"/> ANDA		
19. CHEMICAL NAME		20. RECORDS AND REPORTS CURRENT REVIEWED <input checked="" type="checkbox"/> YES <input type="checkbox"/> NO <input checked="" type="checkbox"/> YES <input type="checkbox"/> NO	
21. CHEMICAL FORMULA			
22. REMARKS (b)(4) was recently aquired by _____ The bottles are currently supplied by _____ is (b)(4) then listed as an alternate manufacturing site. They will use the same molds, resins, and procedures. Letter of authorization to refer to DMF _____ as included. (b)(4)			
23. CONCLUSIONS <p style="text-align: center;">Approve application</p>			
24. REVIEWER			
NAME R.J. Wolters	SIGNATURE <i>R. J. Wolters</i> 4/21/86		DATE COMPLETED 4-18-86
DISTRIBUTION <input checked="" type="checkbox"/> ORIGINAL JACKET <input type="checkbox"/> DUPLICATE JACKET <input type="checkbox"/> REVIEWER			

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NDA 12-827/S035

ADMINISTRATIVE and CORRESPONDENCE
DOCUMENTS

A. H. Robins Company
Research Laboratories
1211 Sherwood Avenue
P. O. Box 26609
Richmond, Virginia 23261-6609
Telephone (804) 257-2361

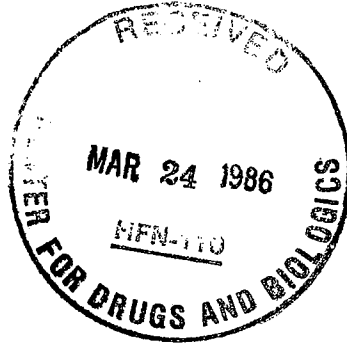
ORIGINAL

A-H-ROBINS

Division of Cardio-Renal Drug
Products
HFN 110, Room 16 B-30
Center for Drugs and Biologics
Food and Drug Administration
5600 Fishers Lane
Rockville, MD 20857

March 20, 1986

Re: NDA 12-827
(Robinul Tablets)



Gentlemen:

This original supplement to the above-cited approved new drug application for Robinul Tablets (glycopyrrolate) provides for an alternate supplier of high density polyethylene bottles.

Enclosed in triplicate are revised packaging materials specifications for the following container for the _____ tablet package size: b(4)

These specifications are the same as those previously approved except that _____ is listed as an additional supplier. On _____ became a wholly-owned subsidiary of _____ the manufacturer of bottles marketed under the _____ has requested that we obtain approval of _____ alternate manufacturing site of _____ bottles used to package products of the A. H. Robins Company. _____ will use the same molds and resin as the parent company. _____ Attached is authorization to refer to their entire Drug Master File _____ updated on August 29, 1985. b(4) b(4) b(4) b(4) b(4) b(4) b(4)

A similar supplement has been submitted to NDA _____ NDA _____ b(4)

Sincerely,

Linda Y. Harver

Linda Y. Harver
Drug Registration Specialist

/dlm

Enclosures

2 Page(s) Withheld

 § 552(b)(4) Trade Secret / Confidential

 § 552(b)(4) Draft Labeling

 § 552(b)(5) Deliberative Process