

**CENTER FOR DRUG EVALUATION AND RESEARCH**

***APPLICATION NUMBER:***

**17-558**

**APPROVABLE LETTER (S)**

NDA 17-558

CERTIFIED MAIL

A. H. Robins Company  
Attention: Jack Freund, M.D.  
1407 Cummings Drive  
Richmond, Virginia 23220

Gentlemen:

Reference is made to your New Drug Application dated January 4, 1974, submitted pursuant to Section 505(b) of the Federal Food, Drug, and Cosmetic Act for the preparation Robinul Injectable.

Reference is also made to your submissions dated March 29; June 4, 10; July 15; August 5 and 20, 1974.

We have completed the review of this application as submitted with draft labeling. However, before the application may be approved it will be necessary for you to submit final printed labeling for the drug. The labeling should be identical in content with the draft copy. If additional information relating to the safety or effectiveness of this drug becomes available before we receive the final printed labeling, revision of that labeling may be required.

Please submit twelve (12) copies of the printed labels and other labeling.

In addition, we would appreciate your submitting in duplicate the advertising copy which you intend to use in your proposed promotional or advertising campaign. Please submit one (1) copy directly to the Division of Drug Advertising with a copy of the package insert and the other to the Division of Surgical-Dental Drug Products, Office of Scientific Evaluation.

The drug may not be legally marketed until you have been notified in writing that the application is approved.

Sincerely yours,

J. Richard Crout, M.D.  
Director  
Bureau of Drugs

APPROVABLE LETTER

cc: BLT-DO (HFR-3250)  
NDA 17-558orig.

HFD-1, HFD-100,

HFD-160, HFD-13,

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R/D Init. by RAJerussi 8/22/74; JKInscoc 8/22/74; and MClark 8/22/74

Final typed nm 8/23/74.

*m. clark md 8/23/74* *P. G. Walter 8/23/74* *J. R. Crout - 8/30/74*