CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

17-558

APPROVAL LETTER

NDA 17-558

FEB 6 1975

A. H. Robins Company
Attention: Alan N. Young
1407 Commings Drive
Richmond, Virginia 23220

Gentlemen:

This acknowledges the receipt on December 20, 1974, of your communication dated December 19, 1974, enclosing printed labeling pursuant to your new drug application for Robinul Injectable.

We also acknowledge receipt of your additional communication dated January 10, 1975.

The application was filed on December 20, 1974.

It is understood from the discussion in person on January 10, 1975, between your representative Mr. Alan Young and Mr. S Koch of this Administration that either of the following conditions must be complied with prior to marketing of the drug for indications in anesthesia:

1. Submission of satisfactory printed labels, immediate container and carton, for the 1 ml. vial.

2. Submission of a statisfactorily revised printed package insert in which the HOW SUPPLIED section reflects the availability of a 1 ml. ampul in place of a 1 ml. vial.

It is also understood from the discussion by telephone on January 13, 1975, between Mr. Alan Young and Mr. S. Koch that the Usual Dose statement on the 5 ml. multiple dose vial immediate container and carton labels and on the 5 x 1 ml. ampul carton will be shortened to read only "Consult directions before use," and that these temporary revisions will be accomplished and submitted for our review prior to marketing of this drug for anesthesia indications. Further, it is understood that this recommended or usual dose statement will be revised at the next printing to agree with the comparable statement as printed on the 20 ml. multiple dose vial labels; i.e., "For dosage and other directions for use, consult accompanying product literature."

We have completed the review of this application and have concluded that the drug is safe and effective for use as recommended in the submitted labeling. Accordingly, the application is approved.

The enclosures summarize the conditions relating to the approval of this application.

Please submit two market packages of the drug when available.

Sincerely yours,

Marion J. Finkel

Marion J. Finkel, M.D.
Acting Associate Director
for New Drug Evaluation
Bureau of Drugs

Enclosures: Records and Reports Requirement (310.300)
Conditions of Approval of NDA

cc BLT-DO
NDA 17-558
HFD-160
HFD-108
HFD-13
HFL-10
R/D by CMNealey(HFD-160)1/15/75
R/D init. by: SKoch 1/15/75
RAJerussi 1/15/75
JKInscoe 1/16/75
MClark 1/16/75
Mag Card 1/17/74:jw

CONDITIONALLY APPROVAL

Clarence K. Dodgen 1/21/75 M. Clark MD 1/21/75