DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 17-558/S-053

Baxter Healthcare Corporation
Anesthesia & Critical Care
95 Spring Street
New Providence, New Jersey 07974

Attention: Laura Cooper
Manager, Regulatory Affairs

Dear Ms. Cooper:

Please refer to your supplemental new drug application dated January 27, 2005, received January 28, 2005, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Robinul Injection (glycopyrrolate injection, USP).

We acknowledge receipt of your submissions dated February 2 and February 4, 2005.

This "Changes Being Effected" supplemental new drug application provides for revisions in the package insert in the **DOSAGE AND ADMINISTRATION** sections due to errors in the information.

We have completed our review of this application, as amended, and it is approved effective on the date of this letter, for use as recommended in the agreed-upon labeling text and with the minor editorial revisions listed below and indicated in the enclosed labeling.

The dosing parameters in the **DOSING AND ADMINISTRATION** section of the label should be modified as indicated in the three items below and incorporated into the label at the time of the next printing. All other proposed label changes are acceptable.

1. Adult preanesthetic medication dose = 0.004 mg/kg

2. Pediatric preanesthetic medication dose = 0.004 mg/kg except infants 1 month to 2 years of age who may require up to 0.009 mg/kg.

3. Pediatric intra-operative dose for anticholinergics effect = 0.004 mg/kg not to exceed 0.1 mg in a single dose which may be repeated if needed at 2-3 minute intervals.

The final printed labeling (FPL) must be identical, and include the minor editorial revisions indicated, to the enclosed labeling (text for the package insert). These revisions are terms of the approval of this application.

Please submit an electronic version of the FPL according to the guidance for industry titled *Providing Regulatory Submissions in Electronic Format - NDA*. Alternatively, you may submit 20 paper copies of the FPL as soon as it is available but no more than 30 days after it is printed. Individually mount 15 of the copies on heavy-weight paper or similar material. For administrative purposes, designate this submission "**FPL for approved supplement NDA 17-558/S-053**." Approval of this submission(s) by FDA is not required before the labeling is used.

If you issue a letter communicating important information about this drug product (i.e., a "Dear Health Care Professional" letter), we request that you submit a copy of the letter to this NDA and a copy to the following address:

MEDWATCH, HFD-410
FDA
5600 Fishers Lane
Rockville, MD 20857

We remind you that you must comply with reporting requirements for an approved NDA (21 CFR 314.80 and 314.81).

If you have any questions, call Sara E. Stradley Regulatory Project Manager, at (301) 827-7430.

Sincerely,

{See appended electronic signature page}

Bob Rappaport, MD
Director
Division of Anesthesia, Analgesia
and Rheumatology Products
Office of Drug Evaluation II
Center for Drug Evaluation and Research

Enclosure

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

Bob Rappaport

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