DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 17-558/S-047, S-048

Baxter Healthcare Corporations Anesthesia & Critical Care
95 Spring Street
New Providence, NJ 07974

Attention: Priya Jambhekar
Director, Regulatory Affairs

Dear Ms. Jambhekar:

Please refer to your supplemental new drug applications dated June 19 and August 9, 2001, received June 20 and August 10, 2001, respectively, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Robinul (glycopyrrolate) Injectable.

We acknowledge receipt of your submission dated August 6, 2001 (S-047).

Supplement S-047 provides for a revised **WARNINGS** section. The warning regarding asthma is deleted from the first sentence.

Supplement S-048 provides for a revised **PRECAUTIONS** section. A **"Geriatric Use"** subsection is added in accordance with the requirements of 21 CFR 201.579f)(10).

We have completed our review of these applications and they are approved, effective on the date of this letter.

The final printed labeling (FPL) must be identical to the submitted labeling (package insert submitted June 19 and August 9, 2001).

Please submit the FPL electronically 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, in no case more than 30 days after it is printed. Please individually mount ten of the copies on heavy-weight paper or similar material. For administrative purposes, this submission should be designated "FPL for approved supplement NDA 17-558/S-047, S-048." Approval of this submission 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 Stradley, Regulatory Project Manager, at (301) 827-7430.

Sincerely,

{See appended electronic signature page}

Bob Rappaport, M.D.
Acting Division Director
Division of Anesthetic, Critical Care,
and Addiction Drug Products
Office of Drug Evaluation II
Center for Drug Evaluation and Research

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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