DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 17-558/S-045, S-046, S-049, S-050

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

Attention: Laura Cooper
Manager, Regulatory Affairs

Dear Ms. Cooper:

Please refer to your supplemental new drug applications submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Robinul (glycopyrrolate for injection, USP) Injection.

Supplement Number	Submission date	Receipt date
S-045	April 5, 2001	April 11, 2001
S-046	April 10, 2001	April 11, 2001
S-049	December 3, 2001	December 4, 2001
S-050	November 5, 2002	November 6, 2002

We acknowledge receipt of your submissions dated May 9 (S-045), August 6, 2001 (S-045 and S-046), July 7, October 20, 2003 (S-049, S-050), February 5 (S-049, S-050), May 6 and November 3, 2004.

Your submission of May 6, 2004, constituted a complete response to our June 30, 2003, action letter.

These supplemental new drug applications provide for the following

S-045 proposes extensive revisions to the package insert including editorial and formatting changes.

S-046 proposes revisions to the **DESCRIPTION** section, and "**Carcinogenesis, Mutagenesis, Impairment of Fertility"** and "**Pregnancy"** subsections of the **PRECAUTIONS** section of the package insert.

S-049 proposes revisions to the **CONTRAINDICATIONS** section of the package insert.

S-050 proposes revisions to the **DESCRIPTION**, **CONTRAINDICATIONS**, **WARNINGS**, and **ADVERSE REACTIONS** sections and **"General," "Pregnancy**," and **"Nursing Mothers"** subsections of the **PRECAUTIONS** section of the package insert.

We have completed our review of these applications, as amended and they are approved, effective on the date of this letter, with the minor editorial revisions listed below and indicated in the enclosed labeling.

1. Include the following statement in the **PRECAUTIONS: Pediatric Use** subsection.

   Safety and effectiveness in pediatric patients below the age of 16 years have not been established.

The final printed labeling (FPL) must be identical to the enclosed labeling text which includes the minor editorial revision listed above.

We remind you of your commitment, dated November 3, 2004, to provide the partition coefficient values for the package insert within three months of the date of this letter.

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 15 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-045, S-046, S-049, S-050." 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 Ms. Sara Stradley, Regulatory Health Project Manager, at (301) 827-7410.

Sincerely,

{See appended electronic signature page}

Bob Rappaport, M.D.
Acting Director
Division of Anesthetic, Critical Care,
and Addiction Drug 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/

Rigoberto Roca
11/5/04 04:59:34 PM
for Bob Rappaport, M.D.