DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 17-862/S-050
NDA 17-862/S-051

Baxter Healthcare Corporation, Anesthesia and Critical Care
Attention: Laura Cooper
Manager, Regulatory Affairs
95 Spring Street
New Providence, NJ 07974

Dear Ms. Cooper:

Please refer to your supplemental new drug applications dated February 26, 2002, received February 27, 2002 and dated October 31, 2002, received November 4, 2002, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Reglan® (metoclopromide injection, USP) Injection.

Your submission of March 9, 2004, constituted a complete response to our November 13, 2003, action letter.

These supplemental new drug applications provide for the following:

1. Removal of references to Reglan Tablets and Reglan Syrup in the Reglan Injection package insert (PI) so that the Reglan Injection PI includes labeling applicable to only Reglan Injection.

2. Addition of text pertaining to Neuroleptic Malignant Syndrome to the **WARNINGS** and **ADVERSE REACTIONS** of the package insert (PI).

3. Addition of text to the **Geriatric Use** subsection of the **PRECAUTIONS** section that was requested in the approvable letter for NDA 17-862/S-044, dated February 28, 2001.

4. Addition of safety information to the **PRECAUTIONS** and **OVERDOSAGE** sections.

We completed our review of these applications, as amended. These applications are approved, effective on the date of this letter, for use as recommended in the agreed-upon labeling text.

The final printed labeling (FPL) must be identical to the submitted labeling (package insert submitted March 9, 2004).

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 submissions should be designated "FPL for approved supplement NDA 17-862/S-050 and S-051." 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

Please submit one market package of the drug product when it is available.

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 Susan Daugherty, Consumer Safety Officer, at (301) 827-7456.

Sincerely,

{See appended electronic signature page}

Robert L. Justice, M.D., M.S.
Director
Division of Gastrointestinal and
Coagulation Drug Products
Office of Drug Evaluation III
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/

Joyce Korvick
4/19/04 11:53:27 AM
for Dr. Robert Justice