DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 17-862/S-061

Baxter Healthcare Corporation
Attention: Eleanor Lescano
Regulatory Affairs Specialist
2 Esterbrook Lane
Cherry Hill, NJ 08003-4099

Dear Ms. Lescano:

Please refer to your supplemental new drug application for Reglan (metoclopramide) Injection submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA).

We acknowledge receipt of your submissions dated March 26, April 1, and April 16, May 4, and June 8, and June 29, 2009.

Reference is also made to our letter dated February 26, 2009 notifying you, under Section 505(o)(4) of the FDCA, of new safety information that we believe should be included in the labeling for Reglan (metoclopramide) Injection. This information pertains to the risk of tardive dyskinesia.

This supplemental new drug application provides for revisions to the labeling for Reglan (metoclopramide) Injection consistent with our February 26, 2009, letter and correspondences between FDA and Baxter dated May 6, May 18, June 2, June 24, and June 30, 2009.

We have completed our review of this supplemental application, as amended. This application is approved, effective on the date of this letter, for use as recommended in the agreed-upon labeling text.

Your approved Medication Guide will become part of the Risk Evaluation and Mitigation Strategy (REMS) **(b) (4)**

CONTENT OF LABELING

As soon as possible, but no later than 14 days from the date of this letter, please submit the content of labeling (21 CFR 314.50(1)) in structured product labeling (SPL) format as described at http://www.fda.gov/oc/datacouncil/spl.html that is identical to the attached labeling and Medication Guide. Upon receipt, we will transmit that version to the National Library of Medicine for public dissemination. For administrative purposes, please designate this submission, **"SPL for approved NDA 17-862/S-061."** In addition, within 21 days of the date of this letter, amend any pending supplement for this NDA.

We request that the revised labeling approved today be available on your website within 10 days of receipt of this letter.

Marketing the product with FPL that is not identical to the approved labeling text and in the required format may render the product misbranded and an unapproved new drug.

Please note that:

- this Medication Guide must be reprinted immediately following the last section of labeling or, alternatively, accompany the prescription drug labeling [21 CFR 201.57(c)(18) or 21 CFR 201.80(f)(2)]);

- you are responsible for ensuring that this Medication Guide is available for distribution to every patient who is dispensed a prescription for this product [21 CFR 208.24]);

- the final printed Medication Guide distributed to patients must conform to all conditions described in 21 CFR 208.20, including a minimum of 10 point text; and

- you are responsible for ensuring that the label of each container or package includes a prominent and conspicuous instruction to authorized dispensers to provide a Medication Guide to each patient to whom the drug is dispensed, and states how the Medication Guide is provided [21 CFR 208.24(d)]

LETTER TO HEALTH CARE PROFESSIONALS

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
Food and Drug Administration
Suite 12B05
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 Maureen Dewey, Regulatory Project Manager, at (301) 796-0845.

Sincerely,

{See appended electronic signature page}

Joyce Korvick, M.D., M.P.H.
Deputy Director for Safety
Division of Gastroenterology Products
Office of Drug Evaluation III
Center for Drug Evaluation and Research

Enclosure: Package Insert and Medication Guide

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

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