



NDA 17-854/S-047

CBE-0 SUPPLEMENT

Schwartz Pharma, Inc.
Attention: Donna K. Multhauf, Director
Regulatory Affairs and Quality Assurance
6140 W. Executive Drive
Mequon, WI 53092

Dear Ms. Multhauf:

Please refer to your supplemental new drug application dated February 24, 2004, received February 24, 2004, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Reglan[®] (metoclopramide, USP) Tablets, 5 mg and 10 mg.

This "Changes Being Effected" supplemental new drug application provides for revisions to the **PRECAUTIONS, INDICATIONS AND USAGE**, and **DOSAGE AND ADMINISTRATION** sections of the package insert.

We completed our review of this application and it is 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 enclosed labeling (text for the package insert).

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 17-854/S-047." 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.

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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, Regulatory Project Manager, 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

Enclosure: Labeling

**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
7/26/04 05:15:47 PM
for Dr. Robert Justice