



NDA 17-854/S-045

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 October 22, 2002, received October 23, 2002, 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 the following changes:

- 1) Addition of a new subsection titled "**Neuroleptic malignant Syndrome (NMS)**" to the **WARNINGS** section and a new subsection titled "**Neuroleptic malignant Syndrome**" to the **ADVERSE REACTIONS** section of the package insert (PI);
- 2) Revisions to the **General** subsection of the **PRECAUTIONS** section of the PI regarding aldosterone information;
- 3) Addition of **Geriatric Use** and **Other Special Populations** subsections under the **PRECAUTIONS** section of the PI;
- 4) And, additional safety information to the **OVERDOSAGE** section.

We completed our review of this supplemental new drug application. It is approved, effective on the date of this letter, for use as recommended in the final printed labeling (FPL) submitted on October 22, 2002.

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, HF-2
FDA
5600 Fishers Lane
Rockville, MD 20857

We remind you that you must comply with the requirements for an approved NDA set forth under 21 CFR 314.80 and 314.81.

If you have any questions, call Susan Daugherty, Consumer Safety Officer, at (301) 827-7475.

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

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/s/

Joyce Korvick
4/22/03 03:54:55 PM
for Dr. Robert Justice