DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 17-854/S-040

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 August 25, 2000, received August 28, 2000, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Reglan® (metoclopromide, USP) Tablets, 5 mg and 10 mg.

Your submission of October 22, 2002, constituted a complete response to our February 28, 2001, action letter.

This supplemental new drug application provides for the addition of a **Geriatric Use** subsection to the **PRECAUTIONS** section of the package insert and deletes information relating to Reglan® Syrup and Reglan® Injectable products.

We completed our review of this supplemental new drug application, as amended. 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

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
4/22/03 01:47:42 PM
for Dr. Robert Justice