DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 17-854/S-044

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® (metoclopromide, USP) Tablets, 5 mg and 10 mg.

In addition, we refer to NDA 17-854/S-045, dated October 22, 2002, received October 23, 2002, containing final printed labeling (FPL). Supplemental new drug application, NDA 17-854/S-045, was approved simultaneously with NDA 17-854/S-044.

This Prior Approval supplemental new drug application provides for:

1) revisions to the package insert (PI) for Reglan® Tablets to reflect deletion of information relating to Reglan® Syrup and Reglan® Injectable;

2) revisions to the manufacturer/distributor statement, NDC numbers and tablet descriptions to reflect Schwartz Pharma, Inc. information;

3) and minor editorial revisions.

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

The labeling in this submission is superseded by supplement NDA 17-854/S-045 which was approved simultaneously with NDA 17-854/S-044. Therefore**,** submission of FPL is not required.

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 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) 827-7475.

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 03:42:32 PM
for Dr. Robert Justice