DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-793

Schwarz Pharma, Inc.
Attention: Donna Multhauf
Director, Regulatory Affairs
6140 West Executive Dr.
Mequon, WI 53092-4467

Dear Ms. Multhauf:

Please refer to your new drug application (NDA) dated July 30, 2004, received August 10, 2004, submitted pursuant to section 505(b)(1) of the Federal Food, Drug, and Cosmetic Act for TRADENAME (metoclopramide orally disintegrating tablets), 5 mg and 10 mg.

We acknowledge receipt of your submissions dated August 24, and November 29, 2004; February 17, March 8, May 2, 9, and 24, June 2, and 6, 2005.

We also refer to the teleconference held between representatives of Schwarz Pharma and the Agency on June 9, 2005 in which we discussed labeling that was electronically mailed to us on June 9, 2005.

We further refer to the letter received via facsimile on June 9, 2005 which contains your agreement to revise the 5 mg and 10 mg sample blister carton labeling.

This new drug application provides for the use of TRADENAME (metoclopramide orally disintegrating tablets) for short-term (4 to 12 weeks) therapy for adults with symptomatic, documented gastroesophageal reflux who fail to respond to conventional therapy and for symptoms associated with diabetic gastroparesis (diabetic gastric stasis).

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) for the package insert, immediate containers, sample blister cards, and sample display cartons must be identical to the enclosed labeling. Marketing the products with FPL that is not identical to the approved labeling text may render the products misbranded and an unapproved new drug. The FPL for your 5 mg and 10 mg sample blister cartons must be revised by deleting following statements as agreed in your June 9, 2005 facsimile:

(b)(4)

(b)(4)

Marketing the products without these changes to the 5 mg and 10 mg sample blister cartons text may render the products misbranded and an unapproved new drug.

The electronic labeling rule published December 11, 2003 (68 FR 69009) requires submission of labeling content in electronic format effective June 8, 2004. For additional information, consult the following guidances for industry regarding electronic submissions: *Providing Regulatory Submissions in Electronic Format – NDAs* (January 1999) and *Providing Regulatory Submissions in Electronic Format – Content of Labeling* (February 2004). The guidances specify that labeling to be submitted in *pdf* format. To assist in our review, we request that labeling also be submitted in MS Word format. If formatted copies of all labeling pieces (i.e. package insert, patient package insert, container labels, and carton labels) are submitted electronically, labeling does not need to be submitted in paper. Approval of this submission by FDA is not required before the labeling is used.

All applications for new active ingredients, new dosage forms, new indications, new routes of administration, and new dosing regimens are required to contain an assessment of the safety and effectiveness of the product in pediatric patients unless this requirement is waived or deferred. We are deferring submission of your pediatric studies from birth to 16 years until June 10, 2010.

Your deferred pediatric studies for Symptomatic Gastroesophageal Reflux and of Symptoms Associated with Diabetic Gastroparesis (Diabetic Gastric Stasis) required under section 2 of the Pediatric Research Equity Act (PREA) are considered required postmarketing study commitments. The statuses of these postmarketing studies shall be reported annually according to 21 CFR 314.81. These commitments are listed below.

1) Single and multiple-dose pharmacokinetics (PK), pharmacodynamics (PD) and safety study in pediatric patients aged 1 to 16 years.

   Protocol submission by: December 10, 2005 (6 mos. post-approval)
   Study start: June 10, 2006 (1 year post-approval)
   Final report submission: June 10, 2010 (5 years post approval)

2) Single and multiple-dose pharmacokinetics (PK), pharmacodynamics (PD) and safety study in pediatric patients aged less than 1 year.

   Protocol submission by: December 10, 2005 (6 mos. post-approval)
   Study start: June 10, 2007 (2 years post-approval)
   Final report submission: June 10, 2013 (8 years post approval)

Submit final study reports to this NDA. For administrative purposes, all submissions related to this/these pediatric postmarketing study commitment(s) must be clearly designated "**Required Pediatric Study Commitments**".

In addition, submit three copies of the introductory promotional materials that you propose to use for this product. Submit all proposed materials in draft or mock-up form, not final print. Send one copy to this division and two copies of both the promotional materials and the package insert directly to:

Division of Drug Marketing, Advertising,
and Communications, HFD-42
Food and Drug Administration
5600 Fishers Lane
Rockville, MD 20857

We have not completed validation of the regulatory methods. However, we expect your continued cooperation to resolve any problems that may be identified.

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}

Joyce Korvick, M.D., M.P.H.
Deputy 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

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