



NDA 18-983/S-035

Schwarz Pharma, Inc.
Attention: Donna Multhauf
P.O. Box 2038
Milwaukee, WI 53201

Dear Ms. Multhauf:

Please refer to your supplemental new drug application dated March 20, 2002, received March 21, 2002, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Colyte (PEG and Electrolytes) for Oral Solution.

This supplemental new drug application provides for a revision in the "Instructions" section of the labeling to instruct the pharmacist to dispense the product with all Flavor Packs to the consumer, and for the consumer to mix the flavoring with the unflavored Colyte before reconstitution.

We have completed the review of this supplemental application and have concluded that adequate information has been presented to demonstrate that the drug product is safe and effective for use as recommended in the agreed upon labeling text. Accordingly, the supplemental application is approved effective on the date of this letter.

The final printed labeling (FPL) must be identical to the submitted draft labeling (immediate container and carton labels submitted March 20, 2002).

Please submit the copies of final printed labeling (FPL) electronically according to the guidance for industry titled *Providing Regulatory Submissions in Electronic Format - NDA* (January 1999). Alternatively, you may submit 20 paper copies of the FPL as soon as it is available but no more than 30 days after it is printed. Please individually mount ten of the copies on heavy-weight paper or similar material. For administrative purposes, this submission should be designated "FPL for approved supplement NDA 18-983/S-035." Approval of this submission by FDA is not required before the labeling is used.

If a letter communicating important information about this drug product (i.e., a "Dear Health Care Professional" letter) is issued to physicians and others responsible for patient care, 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 Alice Kacuba, R.N., MSN, RAC, Regulatory Health Project Manager, at (301) 827-1602.

Sincerely,

{See appended electronic signature page}

Liang Zhou, Ph.D.
Chemistry Team Leader for the
Division of Gastrointestinal and Coagulation Drug
Products, (HFD-180)
DNDC II, Office of New Drug Chemistry
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/

Liang Zhou
9/16/02 02:39:20 PM