



NDA 18-983/S-037

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

Dear Ms. Multhauf:

Please refer to your supplemental new drug application dated April 24, 2003, received April 25, 2003, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Colyte® (PEG-3350 and Electrolytes) for Oral Solution.

Your submission of April 24, 2003 constituted a complete response to our January 15, 2003 action letter. This supplemental new drug application provides for the following:

1. The DESCRIPTION section of the package insert has been revised to retain the list of ingredients in the flavor packs.
2. Although not an approvability issue, the top bottle label has been revised to add the phrase "Peel Here" to show how to open the bottle label to expose the package insert.

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 April 24, 2003.

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 Tanya Clayton, Regulatory Project Manager, at (301) 827-4005.

Sincerely,

{See appended electronic signature page}

Robert L. Justice, M.D., M.S.
Division Director
Division of Gastrointestinal and Coagulation Drug
Products, HFD-180
Office of Drug Evaluation III
Center for Drug Evaluation and Research

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/s/

Joyce Korvick
10/23/03 04:12:51 PM
for Dr. Robert Justice