



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

ANDA 76-491

Food and Drug Administration
Rockville MD 20857

FEB 5 2004

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

Dear Madam:

This is in reference to your abbreviated new drug application (ANDA) dated September 6, 2002, submitted pursuant to Section 505(j) of the Federal Food, Drug, and Cosmetic Act (Act), for TriLyte™ (Polyethylene Glycol 3350, Potassium Chloride, Sodium Bicarbonate and Sodium Chloride for Oral Solution, 420 g, 1.48 g, 5.72 g, and 11.2 g, respectively, per bottle (with flavor packs)).

Reference is also made to your amendments dated March 25, July 30, August 28, November 10, November 24 and December 5, 2003; and January 12, 2004.

We have completed the review of this abbreviated application and have concluded that the drug is safe and effective for use as recommended in the submitted labeling. Accordingly, the application is approved. The Division of Bioequivalence has determined your TriLyte™ (Polyethylene Glycol 3350, Potassium Chloride, Sodium Bicarbonate, and Sodium Chloride for Oral Solution), to be bioequivalent and, therefore, therapeutically equivalent to the listed drug (NuLYTELY® (Polyethylene Glycol 3350, Potassium Chloride, Sodium Bicarbonate, and Sodium Chloride for Oral Solution) of Braintree Laboratories, Inc.).

Under Section 506A of the Act, certain changes in the conditions described in this abbreviated application require an approved supplemental application before the change may be made.

Post-marketing reporting requirements for this abbreviated application are set forth in 21 CFR 314.80-81 and 314.98. The Office of Generic Drugs should be advised of any change in the marketing status of this drug.

We request that you submit, in duplicate, any proposed advertising or promotional copy that you intend to use in your initial advertising or promotional campaigns. Please submit all proposed materials in draft or mock-up form, not final print. Submit both copies together with a copy of the final printed labeling to the Division of Drug Marketing, Advertising, and Communications (HFD-40). Please do not use Form FDA 2253 (Transmittal of Advertisements and Promotional Labeling for Drugs for Human Use) for this initial submission.

We call your attention to 21 CFR 314.81(b)(3) which requires that materials for any subsequent advertising or promotional campaign be submitted to our Division of Drug Marketing, Advertising, and Communications (HFD-40) with a completed Form FDA 2253 at the time of their initial use.

Sincerely yours,

(b)(6)

Gary Buehler
Director
Office of Generic Drugs
Center for Drug Evaluation and Research