

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

ANDA 76-699

APPROVAL LETTER

AUG 27 2004

Schwarz Pharma, Inc.
Attention: Donna K. Multhauf
6140 W. Executive Drive
Mequon, WI 53092

Dear Madam:

This is in reference to your abbreviated new drug application (ANDA) dated March 28, 2003, submitted pursuant to Section 505(j) of the Federal Food, Drug, and Cosmetic Act (Act), for Parcopa Orally Disintegrating Tablets (Carbidopa and Levodopa Orally Disintegrating Tablets), 10 mg/100 mg, 25 mg/100 mg, and 25 mg/250 mg.

Reference is made to your amendments dated May 19, June 4, June 18, July 12, August 17, and August 24, 2004.

Reference is also made to the ANDA Suitability Petition submitted under Section 505(j)(2)(C) of the Act and approved on September 25, 2002. This approved petition permitted you to submit an ANDA for a drug product that differs in dosage form from that of the reference listed drug product (RLD). Specifically, your application provides for Carbidopa and Levodopa Orally Disintegrating Tablets, 10 mg/100 mg, 25 mg/100 mg, and 25 mg/250 mg. The reference listed drug product, Sinemet[®] Tablets USP, 10 mg/100 mg, 25 mg/100 mg, and 25 mg/250 mg of Bristol Myers Squibb Pharma Co., is approved as an immediate-release tablet for oral administration.

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 drug product, Carbidopa and Levodopa Orally Disintegrating Tablets, can be expected to have the same therapeutic effect as the corresponding strength of the listed drug product upon which the agency relied as the basis of safety and effectiveness. Your dissolution testing should be incorporated into the stability and quality control program using the same method proposed in your application.

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.

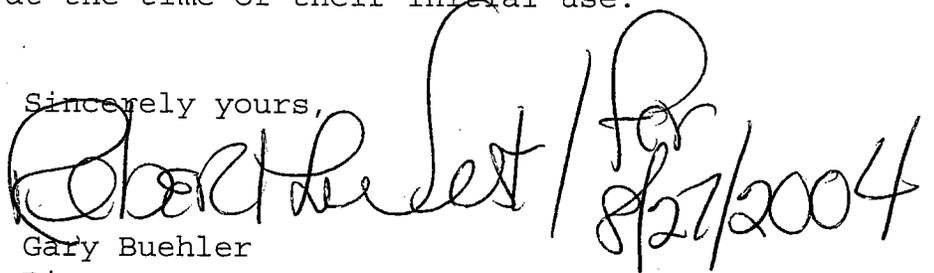
Post-marketing reporting requirements for this abbreviated application are set forth in 21 CFR 314.80-81 and 314.98. The Office of Generic Drugs should be advised of any change in the marketing status of this drug.

Promotional materials may be submitted to FDA for comment prior to publication or dissemination. Please note that these submissions are voluntary. If you desire comments on proposed launch promotional materials with respect to compliance with applicable regulatory requirements, we recommend you submit, in draft or mock-up form, two copies of both the promotional materials and package insert(s) directly to:

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

We call your attention to 21 CFR 314.81(b)(3) which requires that all promotional materials be submitted to the Division of Drug Marketing, Advertising, and Communications (HFD-42) with a completed Form FDA 2253 at the time of their initial use.

Sincerely yours,

A handwritten signature in cursive script, followed by a vertical line and the date "8/27/2004". The signature appears to be "Gary Buehler".

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

cc: ANDA 76-699
Division File
Field Copy
HFD-610/R. West
HFD-330
HFD-205
HFD-610/Orange Book Staff

Approved Electronic Labeling Located at:
\\Cdsesubogd1_000004.pdf

Endorsements:

HFD-645/K. Bernard/ *K Bernard 8/12/04; 8/24/04*
HFD-645/B. Arnwine/ *B Arnwine 8/25/04*
HFD-617/Y. Kong/ *Neil for 8/11/04*
HFD-613/K. Lee/ *vl. 8/13/04 No Changes in ACD*
HFD-613/L. Golson/ *L Golson 8/13/04*

*Robert West
8/27/2004*

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F/T by

APPROVAL