DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

ANDA 74-260

SEP - 3 1993

Purepac Pharmaceutical Co.
Attention: Ms. Joan Janulis
200 Elmora Avenue
Elizabeth, NJ 07207

Dear Ms. Janulis:

This is in reference to your abbreviated new drug application dated August 31, 1992 submitted pursuant to Section 505(j) of the Food, Drug, and Cosmetic Act, for Carbidopa and Levodopa Tablets USP, 10 mg/100 mg, 25 mg/100 mg, 25 mg/250 mg.

Reference is also made to your amendments dated September 15, 1992, and February 22, and August 2, 5, and 10, 1993.

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 Carbidopa/Levodopa 10 mg/100 mg, 25 mg/100 mg, and 25 mg/250 mg Tablets to be bioequivalent to those of the listed drugs (Sinemet^{R}, 10 mg/100 mg, 25 mg/100 mg, and 25 mg/250 mg Tablets, respectively, by Merck Sharp & Dohme). Your dissolution testing should be incorporated into the stability and quality control program using the same method as proposed in your application.

Under 21 CFR 314.70, 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. The Office of Generic Drugs should be advised of any change in the marketing status of these drugs.

We request that you submit, in duplicate, any proposed advertising or promotional copy which 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 proposed or final printed labeling to the Division of Drug Marketing, Advertising, and Communications (HFD-240). Please do not use Form FD-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-240) with a completed Form FD-2253 at the time of their initial use.

Sincerely yours,

Roger L. Williams, M.D.
Director
Office of Generic Drugs
Center for Drug Evaluation and Research

ADDENDUM

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The addition of a desiccant bag to the container/closure systems for the subject drug products should be submitted as a supplemental application (314.70(b)(2)(vii)) with 3-month accelerated stability data.