DEPARTMENT OF HEALTH & HUMAN SERVICES

ANDA 76-643

Food and Drug Administration
Rockville MD 20857

JUN 10 2005

Ranbaxy, Inc.
Attention: Abha Pant
U.S. Agent for: Ranbaxy Laboratories Limited
600 College Road East
Princeton, NJ 08540

Dear Madam:

This is in reference to your abbreviated new drug application (ANDA) dated January 21, 2003, submitted pursuant to Section 505(j) of the Federal Food, Drug, and Cosmetic Act (the Act), for Carbilev™ Tablets (Carbidopa and Levodopa Tablets for Oral Suspension), 10 mg/100 mg, 25 mg/100 mg and 25 mg/250 mg.

Reference is also made to your amendment dated March 22, 2005. Reference is also made to the ANDA Suitability Petition submitted under Section 505(j)(2)(c) of the Act and approved on August 9, 2002. This approved petition allowed the agency to accept an ANDA for Carbilev™ Tablets, a drug product that differs in dosage form from that of the reference listed drug (RLD). Specifically, the RLD is supplied as an oral tablet and Carbilev™ Tablets are to be supplied as tablets for oral suspension.

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 Carbilev™ Tablets (Carbidopa and Levodopa Tablets for Oral Suspension), 10 mg/100 mg, 25 mg/100 mg, and 25 mg/250 mg to be bioequivalent to the listed drug (Sinemet® Tablets 10 mg/100 mg, 25 mg/100 mg, and 25 mg/250 mg, respectively, of Bristol Meyers Squibb Pharma Co.). 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,

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