



DEPARTMENT OF HEALTH & HUMAN SERVICES

ANDA 76-310

Food and Drug Administration
Rockville MD 20857

SEP 29 2005

Par Pharmaceutical, Inc.
Attention: Julie Szozda
Sr. Associate, Regulatory Affairs
One Ram Ridge Road
Spring Valley, NY 10977

Dear Madam:

This is in reference to your abbreviated new drug application (ANDA) dated December 23, 2001, submitted pursuant to Section 505(j) of the Federal Food, Drug, and Cosmetic Act (the Act), for Cabergoline Tablets, 0.5 mg.

Reference is also made to the Tentative Approval letter issued by this office on November 30, 2005, and to your amendments dated February 28, 2002; and August 5, September 7, and December 1, 2005.

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 Cabergoline Tablets, 0.5 mg, to be bioequivalent and, therefore, therapeutically equivalent to the listed drug (Dostinex® Tablets, 0.5 mg, of Pharmacia and Upjohn Company). 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.

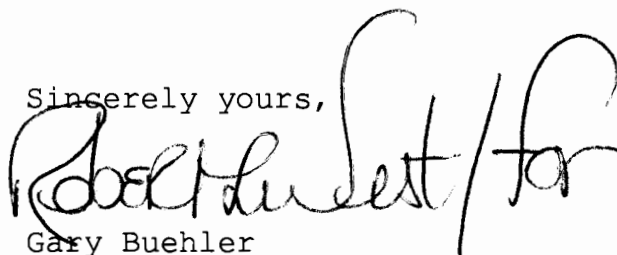
Postmarketing reporting requirements for this abbreviated application are set forth in 21 CFR 314.80-81 and 314.98. The Office of Generic Drugs should be advised of any change in the marketing status of this drug.

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
Center for Drug Evaluation and Research
Division of Drug Marketing, Advertising, and Communications
5901-B Ammendale Road
Beltsville, MD 20705

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 with a completed Form FDA 2253 at the time of their initial use.

Sincerely yours,

A handwritten signature in black ink, appearing to read "Gary Buehler" with a stylized flourish at the end.

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