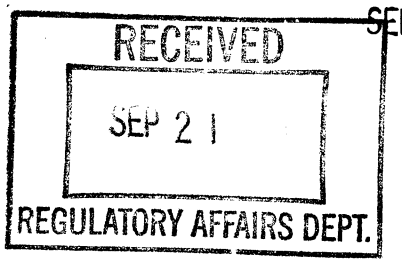
DEPARTMENT OF HEALTH & HUMAN SERVICES

75-143/S-005 and S-006

Food and Drug Administration
Rockville MD 20857

Barr Laboratories, Inc.
Attention: Christine Mundkur
2 Quaker Road
P.O. Box 2900
Pomona, NY 10970-0519



SEP 21 2000

Dear Madam:

This is in reference to your supplemental new drug applications dated June 25, 1999, submitted under section 505(j) of the Federal Food, Drug, and Cosmetic Act, for Hydroxyurea Capsules USP, 500 mg.

Reference is also made to your amendment dated April 7, 2000.

The supplemental applications provide for:

S-005: Addition of a new strength: Hydroxyurea Capsules USP, 250 mg;

S-006: Revision of the product labeling to reflect the new strength.

We have completed the review of these supplemental abbreviated applications and have concluded that the new 250 mg strength of the drug product is safe and effective for use as recommended in the submitted labeling. Accordingly, the application is approved. The drug product, Hydroxyurea Capsules USP, 250 mg can be expected to have the same therapeutic effect as that 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 these supplemental abbreviated applications require an approved supplemental application before the change may be made.

We remind you that you must comply with the requirements for an approved abbreviated application described 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 proposed or final printed labeling to the Division of Drug Marketing, Advertising, and Communications (HFD-40). 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-40) with a completed Form FD-2253 at the time of their initial use.

The material submitted is being retained in our files.

Sincerely yours,

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