DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

ANDA 77-167

DEC 3 2004

Barr Laboratories, Inc.
Attention: Nicholas Tantillo
2 Quaker Rd
P.O. Box 2900
Pomona, NY 10970

Dear Sir:

This is in reference to your abbreviated new drug application (ANDA) dated May 28, 2004, submitted pursuant to Section 505(j) of the Federal Food, Drug, and Cosmetic Act (Act), for Didanosine Delayed-release Capsules, 200 mg, 250 mg and 400 mg.

Reference is also made to your amendments dated July 23, August 18, September 21, October 7, October 21, October 22, October 27, December 1, and December 2, 2004.

This ANDA was reviewed under the expedited review provisions of the President's Emergency Plan for AIDS Relief (PEPFAR).

The listed drug referenced in your application, Videx® EC Delayed-release Capsules of Bristol Myers Squibb Company Pharmaceutical Research Institute, is subject to a period of patent protection. As noted in the Agency's publication entitled Approved Drug Products with Therapeutic Equivalence Evaluations, the "Orange Book", U.S. patent 4,861,759 (the '759 patent) and U.S. patent 5,254,539 (the '539 patent) are each scheduled to expire on March 1, 2007. Your application contains paragraph IV certifications to each patent under Section 505(j)(2)(A)(vii)(IV) of the Act stating that each patent is invalid, unenforceable or will not be infringed by Barr's manufacture, use, or sale of Didanosine Delayed-release Capsules under this ANDA. Section 505(j)(5)(B)(iii) of the Act provides that approval of an ANDA shall be made effective immediately, unless an action is brought against Barr Laboratories, Inc. (Barr) for infringement of either of the patents which were the subjects of the paragraph IV certifications. This action must have been brought against Barr prior to the expiration of 45 days from the date the notice you provided top the NDA/patent holder(s) under paragraph (2)(B)(i) was received. You have

notified the Agency that Barr complied with the requirements of Section 505(j)(2)(B) of the Act, and that Barr entered into a non-exclusive patent licensing agreement with the patent holder, the United States Public Health Service (USPHS), relating to the '759 and '539 patents. Pursuant to the patent license agreement, Barr received a non-exclusive license to manufacture and market Didanosine Delayed-release Capsules upon approval of this ANDA by the Agency.

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 Didanosine Delayed-release Capsules, 200 mg, 250 mg, and 400 mg, to be bioequivalent and, therefore, therapeutically equivalent to the listed drug (Videx® EC Delayed -release Capsules 200 mg, 250 mg, and 400 mg, respectively, of Bristol Myers Squibb Company Pharmaceutical Research Institute).

Your dissolution testing should be incorporated into the stability and quality control program using the same method proposed in your application. The "interim" dissolution test(s) and tolerances should be finalized by submitting dissolution data from the first three production size batches. These data should be submitted as a "Special Supplement - Changes Being Effected" if there are no revisions to be made to the "interim" specifications or when the final specifications are tighter than the "interim" specifications. In all other instances, the information should be submitted in the form of a Prior Approval Supplement.

With this approval, Barr is eligible for 180-day generic drug exclusivity for Didanosine Delayed-release Capsules 200 mg, 250 mg, and 400 mg as provided for under the Drug Price Competition and Patent Term Restoration Act of 1984 (Hatch-Waxman Amendments) in Section 505(j)(5)(B)(iv) of the Act. This is because the Agency has concluded that Barr was the first ANDA applicant to submit a substantially complete ANDA for Didanosine Delayed-release Capsules 200 mg, 250 mg, and 400 mg, containing paragraph IV certifications to each patent noted above. This exclusivity will begin to run from the date of first commercial marketing of the drug. Please submit correspondence to the ANDA to inform the Agency of the date of first commercial marketing.

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,

(b)(6) [redacted]

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