DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville, MD 20857

ANDA 90-094

Aurobindo Pharma USA, Inc.
U.S. Agent for: Aurobindo Pharma Limited
Attention: Blessy Johns
2400 Route 130 North
Dayton, NJ 08810

Dear Madam:

This is in reference to your abbreviated new drug application (ANDA) dated October 26, 2007, submitted pursuant to section 505(j) of the Federal Food, Drug, and Cosmetic Act (the Act), for Didanosine Delayed-Release Capsules, 125 mg, 200 mg, 250 mg, and 400 mg.

Reference is also made to your amendments dated November 27, and December 7, 2007; and January 10, January 28, March 25, April 17, July 3, July 11, July 31, August 19, and September 11, 2008.

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

We have completed the review of this ANDA and have concluded that adequate information has been presented to demonstrate that the drug is safe and effective for use as recommended in the submitted labeling. Accordingly the ANDA is approved, effective on the date of this letter. The Division of Bioequivalence has determined your Didanosine Delayed-Release Capsules, 125 mg, 200 mg, 250 mg, and 400 mg, to be bioequivalent and, therefore, therapeutically equivalent to the reference listed drug, Videx EC Delayed-Release Capsules (Pellets), 125 mg, 200 mg, 250 mg, and 400 mg, respectively, of Bristol Myers Squibb Co.

Your dissolution testing should be incorporated into the stability and quality control program using the same method proposed in your application.

The "interim" dissolution specifications are as follows:

Dissolution testing should be conducted in 1000 mL of 0.1 N HCl (Acid Stage) and 0.1 N HCl: 0.02 M Tribasic Sodium Phosphate (3:1), pH 6.8 (Buffer Stage); using apparatus 1 (Basket) at 100 rpm. The test product should meet the following "interim" specifications: Acid Stage (NMT [redacted]) in 120 minutes, and for the Buffer Stage: NLT [redacted] (Q) in 45 minutes.

The "interim" dissolution tests 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 if 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.

Under section 506A of the Act, certain changes in the conditions described in this ANDA require an approved supplemental application before the change may be made.

We note that if FDA requires a Risk Evaluation & Mitigation Strategy (REMS) for a listed drug, an ANDA citing that listed drug also will be required to have a REMS, See 505-1(i).

Postmarketing reporting requirements for this ANDA 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 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.

Within 14 days of the date of this letter, submit updated content of labeling [21 CFR 314.50(1)] in structured product labeling (SPL) format, as described at http://www.fda.gov/oc/datacouncil/spl.html, that is identical in content to the approved labeling. Upon receipt and verification, we will transmit that version to the National Library of Medicine for public dissemination. For administrative purposes, please designate this submission as "***Miscellaneous Correspondence - SPL for Approved ANDA 90-094***".

Sincerely yours,

{See appended electronic signature page}

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