



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville, MD 20857

ANDA 78-112

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

Dear Sir:

This is in reference to your abbreviated new drug application (ANDA) dated December 26, 2005, submitted pursuant to section 505(j) of the Federal Food, Drug, and Cosmetic Act (the Act), for Didanosine For Oral Solution (Pediatric Powder), 10 mg/mL, packaged in 2 gram and 4 gram containers.

Reference is made to the tentative approval letter issued by this office on October 5, 2006, and to your amendments dated August 9, and December 11, 2006; and January 22, and February 21, 2007.

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 For Oral Solution (Pediatric Powder), 10 mg/mL to be bioequivalent and, therefore, therapeutically equivalent to the reference listed drug, Videx For Oral Solution, 10 mg/mL, of Bristol Myers Squibb Company Pharmaceutical Research Institute (Bristol).

The reference listed drug product (RLD) referenced in your application, Bristol's Videx For Oral Solution, was subject to a period of patent protection. The following patents and expiration dates are currently listed in the agency's

publication titled Approved Drug Products with Therapeutic Equivalence Evaluations, the "Orange Book":

<u>U.S. Patent Number</u>	<u>Expiration Date</u>
4,861,759 (the '759 patent)	March 1, 2007
5,254,539 (the '539 patent)	March 1, 2007
5,616,566 (the '566 patent)	March 1, 2007

Your ANDA contains a Paragraph III Certification to the listed patents under section 505(j)(2)(A)(vii)(III) of the Act. This certification states that Aurobindo Pharma USA, Inc will not market Didanosine For Oral Solution, 10 mg/mL, prior to the expiration of these patents. The agency recognizes that these patents expired on March 1, 2007, and that they no longer preclude the agency from approving your application.

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.

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.

Sincerely yours,

{See appended electronic signature page}

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

**This is a representation of an electronic record that was signed electronically and
this page is the manifestation of the electronic signature.**

/s/

Robert L. West
3/8/2007 03:02:05 PM
for Gary Buehler