



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville, MD 20857

ANDA 78-030

Byron Chemical Company, Inc.
U.S. Agent for: Cipla Limited
Attention: Nicholas Cola
 President
40-11 23rd Street
Long Island City, NY 11101

Dear Sir:

This is in reference to your abbreviated new drug application (ANDA) dated December 8, 2005, submitted pursuant to section 505(j) of the Federal Food, Drug, and Cosmetic Act (the Act), for Stavudine for Oral Solution USP, 1 mg/mL, packaged in 200 mL bottles (upon reconstitution).

Reference is also made to the tentative approval letter issued by this office on October 29, 2007; and to your amendments dated October 8, October 29, November 26, and December 30, 2008; and January 22, January 27, and March 16, 2009.

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 Stavudine for Oral Solution USP, 1 mg/mL, to be bioequivalent and, therefore, therapeutically equivalent to the reference listed drug, Zerit for Oral Solution, 1mg/mL, of Bristol-Myers Squibb Company Pharmaceutical Research Institute.

The reference listed drug product (RLD) referenced in your application, Zerit for Oral Solution, 1 mg/mL of Bristol-Myers Squibb Company Pharmaceutical Research Institute was subject to a period of patent protection. As noted in the agency's publication titled Approved Drug Products with Therapeutic Equivalence Evaluations, the "Orange Book" U.S. Patent No. 4,978,655 (the '655 patent) expired on December 24, 2008.

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 78-030**".

Sincerely yours,

{See appended electronic signature page}

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