



DEPARTMENT OF HEALTH & HUMAN SERVICES

ANDA 77-980

Food and Drug Administration
Rockville MD 20857

JUN 22 2006

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 October 25, 2005, submitted pursuant to Section 505(j) of the Federal Food, Drug, and Cosmetic Act (the Act), for Lamivudine Oral Solution, 10 mg/mL.

Reference is also made to your amendments dated December 7, 2005; and January 4, February 9, February 14, March 15, April 11, and April 20, 2006.

This application was reviewed under the expedited review provisions of the President's Emergency Program for AIDS Relief.

We have completed the review of this abbreviated application, and based upon the information you have presented to date we have concluded that the drug is safe and effective for use as recommended in the submitted labeling. However, we are unable to grant final approval to your application at this time because of the patent issue noted below. Therefore, the application is **tentatively approved**. This determination is based upon information available to the agency at this time, (i.e., information in your application and the status of current good manufacturing practices (cGMPs) of the facilities used in the manufacture and testing of the drug product). This determination is subject to change on the basis of new information that may come to our attention.

The reference listed drug product (RLD) upon which you have based your application, Epivir® Oral Solution, 10 mg/mL, of GlaxoSmithKline, is currently 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. Patents No. 5,047,407 (the '407 patent) and 6,004,968 (the '968 patent) are scheduled to expire on May 17, 2010, and September 20, 2018, respectively. Your application contains paragraph III certifications to the '407 and '968 patents under Section 505(j)(2)(A)(vii)(III) of the Act. These certifications state that Cipla Limited will not market Lamivudine Oral Solution, 10 mg/mL under this ANDA prior to the expiration of the '407 and '968 patents. Therefore, final approval of your application may not be made effective pursuant to 21 U.S.C. 355(j)(5)(B)(ii) of the Act until the '407 and '968 patents have expired, i.e., September 20, 2018.

In order to reactivate your application prior to final approval, please submit a "MINOR AMENDMENT - FINAL APPROVAL REQUESTED" 90 days prior to the date you believe that your application will be eligible for final approval. This amendment should provide the legal/regulatory basis for your request for final approval, and it should also identify changes, if any, in the conditions under which the product was tentatively approved, i.e., updated information such as final-printed labeling, chemistry, manufacturing, and controls data as appropriate. This amendment should be submitted even if none of these changes were made. This amendment should be designated clearly in your cover letter as a "MINOR AMENDMENT - FINAL APPROVAL REQUESTED". In addition, we note your commitment to have an Antiretroviral Pregnancy Registry in place prior to your application receiving full approval. We also note your commitment to join the Hypersensitivity Reaction Registry prior to your application receiving full approval.

In addition to the amendment requested above, the agency may request at any time prior to the date of final approval that you submit an additional amendment containing the requested information. Failure to submit either or, if requested, both amendments may result in rescission of the tentative approval status of your application, or may result in a delay in the issuance of the final approval letter.

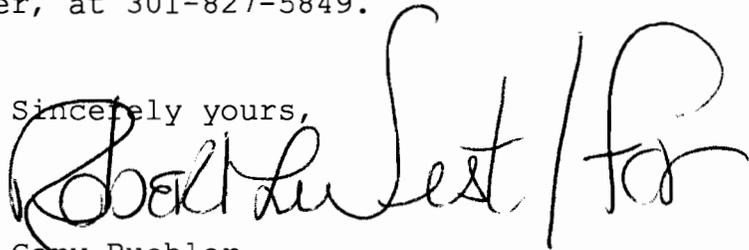
Any significant changes in the conditions outlined in this abbreviated application as well as changes in the status of the manufacturing and testing facilities' compliance with current good manufacturing practices (CGMPs) are subject to agency review before final approval of the application will be made. Such changes should be submitted as an amendment to the ANDA and categorized as representing either "major" or "minor" changes. The amendment will be reviewed according to OGD policy in effect

at the time of receipt. Your submission of multiple amendments prior to final approval may also lead to a delay in the issuance of the final approval letter.

Please note that this drug product may not be marketed without final Agency approval under Section 505 of the Act. The introduction or delivery for introduction into interstate commerce of this drug product before the final approval date is prohibited under Section 501 of the Act and 21 U.S.C. 331(d). Also, until the agency issues the final approval letter, this drug product will not be deemed approved for marketing under 21 U.S.C. 355 and will not be listed in the "Orange Book". Should you believe that there are grounds for issuing the final approval letter prior to September 20, 2018, you should amend your application accordingly.

For further information on the status of this application or upon submitting an amendment to the application, please contact Ted Palat, Project Manager, at 301-827-5849.

Sincerely yours,

A handwritten signature in black ink, appearing to read "Gary Buehler" followed by a large, stylized flourish that resembles a vertical line with a loop at the top and a horizontal bar at the bottom, possibly indicating a signature for a specific role or department.

Gary Buehler

Director

Office of Generic Drugs

Center for Drug Evaluation and Research