DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-841

Pharmacare Limited t/a Aspen Pharmacare
Attention: Lorraine Hill
Regulatory Affairs Executive and Responsible Pharmacist
Building 12, Healthcare Park
Woodlands Drive, Woodmead
Johannesburg, 2158
South Africa

Dear Ms. Hill:

Please refer to your new drug application dated December 8, 2004, received January 13, 2005, submitted pursuant to section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act for Lamivudine 150mg/Zidovudine 300mg Tablets co-packaged with Nevirapine 200mg Tablets.

We acknowledge receipt of your submissions dated:

September 21, 2004	October 26, 2004	January 13, 2005	January 21, 2005
September 27, 2004	December 3, 2004	January 17, 2005	January 24, 2005 (4)
October 6, 2004	December 7, 2004	January 19, 2005	
October 20, 2004	December 20, 2004	January 20, 2005	

This NDA provides for the use of Lamivudine 150mg/Zidovudine 300mg Tablets co-packaged with Nevirapine 200mg Tablets for the treatment of HIV-1 infection.

We completed our review of this application. It is tentatively approved under 21 CFR 314.105 for use as recommended in the agreed upon labeling (refer to the enclosed text for the package insert and patient package insert). Also refer to your submission dated December 24, 2004 and to the agreed upon labeling as documented in your submission dated January 24, 2005 for the immediate container and carton labels**.** This determination is contingent upon information available to the Agency at this time (i.e., information in your application and the status of current good manufacturing practices of the facilities used in manufacturing and testing of the drug product) and is, therefore, subject to change on the basis of any new information that may come to our attention.

The listed reference drug product upon which you base your application is subject to a period of patent protection and exclusivity protection and therefore, final approval of your application under section 505(b) may not be made effective until the period has expired, i.e., July 30, 2018.

At least 180 days prior to July 30, 2018 or when requested, submit an amendment to this application identifying changes, if any, in the conditions under which your product was tentatively approved. This information should include updated labeling, chemistry, manufacturing and controls data, and a safety update.

Failure to submit this amendment will prompt a review of the application that may result in rescission of the tentative approval letter.

Any significant change in the conditions outlined in this NDA requires our review before final approval may be granted.

We remind you that you are expected to comply with the reporting requirements provided in 21 CFR 314.80 and 314.81. If the combination product is to be mass distributed in developing countries, a system of collecting and reporting adverse drug reactions by the distributor would be desirable (e.g., through governmental or nongovernmental agencies distributing the products).

We remind you that, should you intend to market this product in the U.S., you are expected to amend your application with container labeling that is compliant with the Poison Prevention Packaging Act as it applies to child resistant packaging.

Before we issue a final approval letter, this NDA is not deemed approved. If you believe that there are grounds for issuing the final approval letter before July 30, 2018, you should amend your application accordingly.

This product may be considered misbranded under the Federal Food, Drug, and Cosmetic Act if it is marketed in the U.S. before final approval.

If you have any questions, call Nitin Patel, R.Ph., Regulatory Project Manager, at (301) 827-2335**.**

Sincerely,

{See appended electronic signature page}

Debra Birnkrant, M.D.
Director
Division of Antiviral Drug Products
Office of Drug Evaluation IV
Center for Drug Evaluation and Research

CC:
Mr. Mark Moshier
U.S. Agent and President of ShorePharm LLC
76 South Orange Avenue, Suite 203
South Orange, NJ 07079

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

/s/

Jeffrey Murray

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