# CENTER FOR DRUG EVALUATION AND RESEARCH

***APPLICATION NUMBER:***

# 022018Orig1s000

# OTHER ACTION LETTERS

DEPARTMENT OF HEALTH & HUMAN SERVICES
Public Health Service
Food and Drug Administration
Rockville, MD 20857

NDA 22-018

Pharmacare Limited
ATTN: Lorraine Hill
Building 12, Healthcare Park
Woodlands Drive
Woodmead, Johannesburg, 2158
South Africa

Dear Ms. Hill:

Please refer to your new drug application (NDA) 22-018 dated, February 16, 2006 received on February 24, 2006, submitted pursuant to section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act for Lamivudine/Zidovudine Tablets, 150 mg/300 mg.

We acknowledge receipt of your submissions dated:

| | |
|---|---|
| February 16, 2006 | May 17, 2006 |
| February 18, 2006 | August 1, 2006 |
| March 14, 2006 | August 16, 2006 |

This NDA provides for the use of Lamivudine/Zidovudine Tablets, 150 mg/300 mg, in combination with other antiretroviral agents 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 immediate container and carton labels). Also refer to your submission emailed to the Agency on August 7, 2006 and to the agreed upon label emailed on August 7, 2006 for the immediate container and carton labels. Based on the data provided, expiration dating period is (b) (4) for lamivudine/zidovudine tablets (b) (4)
The tentative approval 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 products upon which you base your application are subject to a period of patent protection and therefore, final approval of your application under section 505(b) may not be made effective until the period has expired. If you have questions as to when this date will be please contact the Agency at the information provided below.

At least 180 days prior to the expiration of patent protection 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. That amendment should include final printed labels and labeling complying with all United States regulations (uniqueness of drug product appearance per 21 CFR 206; child-resistant packaging per 16 CFR 1700, etc.).

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. after the period of patent protection, you are required to join the antiretroviral pregnancy registry at that time and make the appropriate labeling change that references the existence of the pregnancy registry.

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 the period of patent protection has expired, 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 Monica Zeballos, Pharm.D., Regulatory Project Manager at (301) 796-0840 or via email at monica.zeballos@fda.hhs.gov

Sincerely yours,

*{See appended electronic signature page}*

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

Attachments: PI, Immediate container & carton label

CC: Mark Moshier/Keith Guinta, U.S. Agent for Pharmacare Limited
ShorePharm LLC
76 South Orange Avenue, Suite #203
South Orange, NJ 07079

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

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/s/

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Jeffrey Murray
8/23/2006 02:16:46 PM