



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 22-096

Strides Arcolab Limited
ATTN: Aloka Sengupta, President ATM
Strides House, Bilekahalli
Bannerghatta Road
Bangalore 560076
India

Dear Mr. Sengupta:

Please refer to your new drug application (NDA) 22-096 submitted under rolling review with the final major submission dated December 8, 2006 received on December 11, 2006, submitted pursuant to section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act for Lamivudine/Zidovudine Tablets (150mg/300mg) Co-packaged with Efavirenz Tablets (600mg).

We acknowledge receipt of your submissions dated:

September 11, 2006	December 20, 2006	May 15, 2007
September 21, 2006	April 6, 2007	May 17, 2007
December 8, 2006	May 14, 2007	May 24, 2007

This NDA provides for the use of Lamivudine/Zidovudine Tablets Co-packaged with Efavirenz Tablets (150mg/300mg/600mg) in combination with other antiretrovirals 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, medication guide, and immediate container and carton labels). Also refer to your original submission for immediate container and carton labels and to the agreed upon labeling emailed May 24, 2007 for the package insert and patient package insert. Based on the data provided, the expiration dating period is 24 months for Lamivudine/Zidovudine Tablets Co-packaged with Efavirenz Tablets in HDPE containers, closed by a snap cap with a tear-off tamper-evident strip, when stored below 30°C.

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 United States 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 United States before final approval.

If you have any questions, call Vasavi Reddy, RPh, Regulatory Project Manager at (301) 796-0793 or via email at Vasavi.reddy@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: Tentatively Approved PI, Med-guide, and Immediate container & carton labels

CC: Dr. Nehru Gaddipati/Peter Riebling, U.S. Agents for Strides Arcolab Limited
41 Veronica Avenue
Somerset, NJ 08873

**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
6/1/2007 02:52:53 PM