



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-854

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) 21-854 dated February 8, 2007 received on February 23, 2007, submitted pursuant to section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act for Stavudine/Lamivudine (40mg/150mg) Tablets Co-packaged with Nevirapine (200 mg) Tablets.

The February 8, 2007 submission constituted a complete response to our September 27, 2006 action letter.

We acknowledge receipt of your submissions dated:
December 11, 2006
February 8, 2007

This NDA provides for the use of Stavudine/Lamivudine (40 mg/150mg) Tablets Co-packaged with Nevirapine (200 mg) Tablets 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 on March 7, 2007 and March 9, 2007 for the package insert and medguide, respectively. The co-package consists of two HDPE bottles, each closed by a snap cap with a tear-off tamper-evident strip, within a carton. Based on the data provided, the expiration dating periods are 15 months (lamivudine/stavudine tablets) and 24 months (nevirapine tablets), when the products are 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
3/13/2007 04:57:57 PM