NDA 21-837
NDA 22-177

Strides Arcolab Limited
ATTN: Aloka Sengupta, President ATM
Strides House, Bilekahalli
Bannerghatta Road
Bangalore - 560 076
India

Dear Mr. Sengupta:

Please refer to your new drug applications (NDAs) 21-837 dated September 18, 2007, received on September 20, 2007, and 22-177 dated November 7, 2007, received on November 9, 2007, submitted pursuant to section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act for Stavudine/Lamivudine/Nevirapine 40 mg/150 mg/200 mg and 30 mg/150 mg/200 mg Tablets, respectively.

The September 18, 2007 and November 7, 2007, submissions constituted complete responses to our September 14, 2007 action letter for NDA 21-837 and October 31, 2007 action letter for NDA 22-177.

We acknowledge receipt of your submissions for 21-837 dated:

September 21, 2007 (2)

These NDAs provide for the use of Stavudine/Lamivudine/Nevirapine 40 mg/150 mg/200 mg and Stavudine/Lamivudine/Nevirapine 30 mg/150 mg/200 mg Tablets for the treatment of HIV-1 infection.

We completed our review of these applications. They are **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 the immediate container and carton labels and to the agreed-upon labeling emailed on March 19, 2008, for the package insert and medication guide. Based on the data provided, the expiration dating period is 24 months for Stavudine/Lamivudine/Nevirapine Tablets (both formulations) in HDPE containers, closed by a snap cap with a tear-off tamper-evident strip, when stored below 25°C (77°F).

The tentative approval is contingent upon information available to the Agency at this time (i.e., information in your applications 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 applications are subject to a period of patent protection and therefore, final approval of your applications 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 a "**MINOR AMENDMENT – FINAL APPROVAL REQUESTED**" as an amendment to these applications identifying changes, if any, in the conditions under which your products were tentatively approved. This information should include updated labeling, chemistry, manufacturing and control data, and a safety update. This amendment should include draft final printed labels and labeling which comply with all United States regulations (uniqueness of drug product appearance per 21 CFR 206; child-resistant packaging per 16 CFR 1700, etc.). 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.**"

Failure to submit this amendment will prompt a review of the applications that may result in rescission of the tentative approval status of your applications, or may result in a delay in the issuance of the final approval letter.

Any significant change in the conditions outlined in these NDAs 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. In addition, an updated package insert (PI) must be submitted under the Structured Product Labeling requirements (http://www.fda.gov/oc/datacouncil/spl.html) as defined by the Physician's Labeling Rule [21 CFR 201.56, 201.57].

Before we issue a final approval letter, these NDAs are 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 applications accordingly.

These products 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, please call Monica Zeballos, Pharm.D., Senior Program Consultant at (301) 796-0840 or via email at monica.zeballos@fda.hhs.gov.

Sincerely yours,

{See appended electronic signature page}

Jeffrey Murray, M.D., M.P.H.
Deputy Director
Division of Antiviral Products
Office of Antimicrobial Products
Center for Drug Evaluation and Research

Attachments: Draft PI, MedGuide, and immediate container and carton labels

Emailed CC: Dr. Nehru Gaddipati, U.S. Agent 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

3/20/2008 09:04:54 PM