DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 202685 **TENTATIVE APPROVAL**

Strides Incorporated
Attention: Anil Sachdeva, Director of Regulatory Affairs
U.S. Agent for Strides Arcolab Limited in India
201 South Main Street, Suite # 3
Lambertville, New Jersey 08530

Dear Mr. Sachdeva:

Please refer to Strides' New Drug Application (NDA) 202685 dated and received November 22, 2011, submitted pursuant to section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act for Lamivudine, Nevirapine and Zidovudine Tablets for Oral Suspension, 30 mg/50 mg/60 mg.

We acknowledge receipt of your submissions dated:

December 30, 2010	January 20, 2012	July 23, 2012 (2)
February 24, 2011	February 24, 2012	August 2, 2012
May 5, 2011	April 4, 2012	August 9, 2012
September 24, 2011	June 7, 2012	September 20, 2012
November 2, 2011		

We remind you based on your amendment dated and received September 20, 2012, the drug substance, Lamivudine USP, for this product is sourced only from (b) (4) sites. If in the future Strides wishes to add any additional drug substance lamivudine manufacturing sites, a post-tentative approval amendment to this application is expected.

This NDA provides for the use of Lamivudine, Nevirapine and Zidovudine Tablets for Oral Suspension, 30 mg/50 mg/60 mg alone or in combination with other antiretrovirals for the treatment of HIV-1 infection in children weighing 5 to 25 kg.

This NDA was reviewed under the President's Emergency Plan for AIDS Relief (PEPFAR).

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, immediate container and carton labels). Also refer to your April 4, 2012, submission for the revised immediate container and carton labels and the agreed-upon labeling emailed on September 20, 2012, for the package insert and medication guide. Based on the data provided, the expiration dating period is 24 months for Lamivudine, Nevirapine and

Zidovudine Tablets for Oral Suspension, 30 mg/50 mg/60 mg, in HDPE bottles of 60 tablets with desiccant sachets, induction seals and Child Resistant caps or Non-Child Resistant caps, when stored at up to 30ºC (86ºF).

This determination is based upon information available to the Agency at this time [i.e., information in your application and the status of current good manufacturing practices (cGMPs) of the facilities used in manufacturing and testing of the drug product]. This determination is subject to change on the basis of any new information that may come to our attention.

The listed reference drug products [Epivir® (lamivudine) and Combivir® (lamivudine and zidovudine)] upon which you base your application are subject to a period of patents' protection and therefore, final approval of your application under section 505(c)(3) of the Act [21 U.S.C. 355(c)(3)] 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.

Two or six months prior to the expiration of the patents' protection, as appropriate, submit an amendment to this application identifying changes, if any, in the conditions under which your product was tentatively approved. Any changes to the conditions outlined in this NDA require our review before final approval and the goal date for our review will be set accordingly. Your amendment should include updated labeling, chemistry, manufacturing and controls 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 designated clearly in your cover letter as a "**FINAL APPROVAL REQUESTED**."

We remind you that you are expected to comply with the reporting requirements provided in 21 CFR 314.80 and 314.81. If the 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 patents' 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, this NDA is not deemed approved. If you believe that there are grounds for issuing the final approval letter before the period of patents' protection has expired, you should amend your application accordingly.

Please note that this drug product may not be marketed in the United States without final Agency approval under Section 505 of the Act. The introduction or delivery for introduction into interstate commerce of this drug product before the final approval date is prohibited under Section 501 of the Act and 21 U.S.C. 331(d).

If you have any questions, please contact Monica Zeballos, Pharm.D., Senior Program Consultant, at (301) 796-0840 or 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

Enclosures: Draft PI, medication guide, immediate container and carton labels

Emailed CC: Rajiv Alex, POC for Strides Arcolab Limited in India

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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.

/s/

JEFFREY S MURRAY
09/21/2012