ANDA 090455

OFFICE OF GENERIC DRUGS

Food and Drug Administration
HFD-600, Metro Park North II
7500 Standish Place, Room 150
Rockville, MD 20855-2773
Fax: 240-276-9327

FAX TRANSMISSION COVER SHEET

APPLICANT: Strides Arcolab Limited TEL: 410-603-1380

ATTN: Anil Sachdeva FAX: 732-249-0225

FROM: Benjamin Danso FDA CONTACT PHONE: (240) 276-8527

Dear Sir:

This facsimile is in reference to your abbreviated new drug application dated March 26, 2008, submitted pursuant to Section 505(j) of the Federal Food, Drug, and Cosmetic Act for Ergocalciferol Capsules, 1.25 mg.

We are pleased to inform you that this application is APPROVED!

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville, MD 20857

ANDA 090455

Strides Inc.
U.S. Agent for Strides Arcolab Ltd.
Attention: Anil Sachdeva
Director, Regulatory Affairs
201 South Main Street
Suite #3
Lambertville, NJ 08530

Dear Sir:

This is in reference to your abbreviated new drug application (ANDA) dated March 26, 2008, submitted pursuant to section 505(j) of the Federal Food, Drug, and Cosmetic Act (the Act), for Ergocalciferol Capsules USP, 1.25 mg (50,000 USP Units of Vitamin D).

Reference is also made to your amendments dated April 25, and July 9, 2008; January 16, and October 20, 2009; January 11, January 29, June 10, and July 29, 2010.

We have completed the review of this ANDA and have concluded that adequate information has been presented to demonstrate that the drug is safe and effective for use as recommended in the submitted labeling. Accordingly the ANDA is approved, effective on the date of this letter. The Division of Bioequivalence has determined your Ergocalciferol Capsules USP, 1.25 mg (50,000 USP Units of Vitamin D) to be bioequivalent and, therefore, therapeutically equivalent to the reference listed drug, Drisdol Capsules USP, 1.25 mg (50,000 USP Units of Vitamin D), of Sanofi Aventis US, LLC. Your dissolution testing should be incorporated into the stability and quality control program using the same method proposed in your application.

Under section 506A of the Act, certain changes in the conditions described in this ANDA require an approved supplemental application before the change may be made.

We note that if FDA requires a Risk Evaluation & Mitigation Strategy (REMS) for a listed drug, an ANDA citing that listed drug also will be required to have a REMS, See 505-1(i).

Postmarketing reporting requirements for this ANDA are set forth in 21 CFR 314.80-81 and 314.98. The Office of Generic Drugs should be advised of any change in the marketing status of this drug.

Promotional materials may be submitted to FDA for comment prior to publication or dissemination. Please note that these submissions are voluntary. If you desire comments on proposed launch promotional materials with respect to compliance with applicable regulatory requirements, we recommend you submit, in draft or mock-up form, two copies of both the promotional materials and package insert(s) directly to:

Food and Drug Administration
Center for Drug Evaluation and Research
Division of Drug Marketing, Advertising, and Communications
5901-B Ammendale Road
Beltsville, MD 20705

We call your attention to 21 CFR 314.81(b)(3) which requires that all promotional materials be submitted to the Division of Drug Marketing, Advertising, and Communications with a completed Form FDA 2253 at the time of their initial use.

As soon as possible, but no later than 14 days from the date of this letter, submit, using the FDA automated drug registration and listing system (eLIST), the content of labeling [21 CFR 314.50(l)] in structured product labeling (SPL) format, as described at http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm, that is identical in content to the approved labeling (including the package insert, and any patient package insert and/or Medication Guide that may be required). Information on submitting SPL files using eLIST may be found in the guidance for industry titled "SPL Standard for Content of Labeling Technical Qs and As" at http://www.fda.gov/downloads/DrugsGuidanceComplianceRegulatoryInformation/Guidances/U CM072392.pdf

The SPL will be accessible via publicly available labeling repositories.

Sincerely yours,

(See appended electronic signature page)

Keith Webber, Ph.D.
Deputy Director
Office of Pharmaceutical Science
Center for Drug Evaluation and Research

Application Type/Number	Submission Type/Number	Submitter Name	Product Name
ANDA-90455	ORIG-1	STRIDES ARCOLAB LTD	ERGOCALCIFEROL

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

/s/

ROBERT L WEST
08/03/2010
Deputy Director, Office of Generic Drugs
for Keith Webber, Ph.D.