DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

Our STN: BL 103946/5049

Sanofi-Synthelabo, Inc.
Attention: Dr. Sanjukta Bhaduri, MBBS, MFPM
sanofi-aventis, U.S. LLC
Senior Manager, US Regulatory Affairs, Marketed Products
55 Corporate Drive
Bridgewater, NJ 08807-0977

SEP 1 0 2007

Dear Dr. Bhaduri:

Your request to supplement your biologics license application for Elitek to update the labeling text in the OVERDOSAGE Section of the package insert has been approved.

We note your September 7, 2007, submission of content of labeling [21 CFR 601.14(b)] in structured product labeling (SPL) format; we will transmit it to the National Library of Medicine for public dissemination. Within 21 days of the date of this letter, amend any pending supplement(s) for this BLA with content of labeling in SPL format to include the changes approved in this supplement.

Marketing the product with labeling that is not identical to the approved labeling text may render the product misbranded and an unapproved new drug.

Please refer to http://www.fda.gov/cder/biologics/default.htm for important information regarding therapeutic biological products, including the addresses for submissions.

This information will be included in your biologics license application file.

Sincerely,

Patricia Keegan

Patricia Keegan, M.D.
Director
Division of Biologic Oncology Products
Office of Oncology Drug Products
Center for Drug Evaluation and Research

Enclosure: Package Insert