DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 22-273/S-001

APPROVAL LETTER

sanofi-aventis U.S. LLC
Attention: Laura Cooper
Sr. Manager, U.S. Regulatory Affairs
55 Corporate Drive
Bridgewater, NJ 08807

Dear Ms. Cooper:

Please refer to your supplemental new drug application dated December 23, 2008, received December 24, 2008, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Oforta (fludarabine phosphate) 10mg tablets.

We acknowledge receipt of your submission dated June 22, 2009.

This supplemental new drug application provides the labels that incorporate the labeling comments received from the Agency on April 20, 2009 subsequent to the March 23, 2009 Proprietary Trade Name Approval. In addition, there are some minor editorial changes and changes to the company name and address.

We completed our review of this application, as amended. This application is approved, effective on the date of this letter, for use as recommended in the agreed-upon labeling text.

As soon as possible, but no later than 14 days from the date of this letter, please submit the content of labeling [21 CFR 314.50(l)] in structured product labeling (SPL) format, as described at http://www.fda.gov/oc/datacouncil/spl.html, that is identical to the submitted labeling (package insert submitted June 22, 2009**).** Upon receipt, we will transmit that version to the National Library of Medicine for public dissemination. For administrative purposes, please designate this submission, "**SPL for approved NDA 22-273/S-001**."

In addition, submit three copies of the introductory promotional materials that you propose to use for this product. Submit all proposed materials in draft or mock-up form, not final print. Send one copy to the Division of Drug Oncology Products and two copies of both the promotional materials and the package insert 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 20705-1266

If you issue a letter communicating important information about this drug product (i.e., a "Dear Health Care Professional" letter), we request that you submit a copy of the letter to this NDA and a copy to the following address:

MEDWATCH
Food and Drug Administration
Suite 12B05
5600 Fishers Lane
Rockville, MD 20857

We remind you that you must comply with reporting requirements for an approved NDA (21 CFR 314.80 and 314.81).

If you have any questions, call James M. Saunders, Regulatory Project Manager, at (301) 796-0621.

Sincerely,

{See appended electronic signature page}

Robert L. Justice, M.D., M.S.
Director
Division of Drug Oncology Products
Office of Oncology Drug Products
Center for Drug Evaluation and Research

Enclosure

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

/s/

Robert Justice
7/17/2009 11:54:10 AM