DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 20-038/S-032

Bayer HealthCare Pharmaceuticals, Inc.
Attention: Judy Tian
Deputy Director,
Global Regulatory Affairs
PO Box 1000
Montville, NJ 07045-1000

Dear Ms. Tian:

Please refer to your supplemental new drug application, S-032, dated July 11, 2008 and received July 14, 2008, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Fludara (fludarabine phosphate), 50 milligrams, for intravenous injection.

We acknowledge receipt of your electronic submissions dated July 11, and October 17, 2008.

This "Changes Being Effected" supplemental new drug application provides for revisions to the prescribing information included in the BOXED WARNING, WARNINGS, PRECAUTIONS and ADVERSE REACTIONS sections of the package insert.

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.

The final printed labeling (FPL) must be identical to the enclosed labeling text for the package insert.

Within 21 days of the date of this letter, submit 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 in content to the enclosed labeling text. 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 supplement NDA 20-038/S-032".**

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, please call Amy Tilley, Regulatory Project Manager, at (301) 796-3994.

Sincerely,

{See appended electronic signature page}

Robert Justice, M.D.
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

2/10/2009 06:46:28 PM