DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-673/S-005
NDA 21-673/S-007

Darlene Noci, RAC
Associate Director, Regulatory Affairs
Genzyme Corporation
500 Kendall Street
Cambridge, MA 02142

Dear Ms. Noci:

Please refer to your supplemental new drug applications S-005, dated December 19, 2007, received December 19, 2007 and S-007, dated April 08, 2008, received April 08, 2008, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Clolar (Clofarabine) 1 mg/ml intravenous solution.

We acknowledge receipt of your submissions dated December 19, 2007, April 2 and 8, July 1, September 16, and October 17 (electronic), 2008.

The supplemental new drug application (S-005) provided for the use of Clolar (Clofarabine) 1 mg/ml intravenous solution for the treatment of pediatric patients 1 to 21 years old with relapsed or refractory acute lymphoblastic leukemia after at least two prior regimens. Randomized trials demonstrating increased survival or other clinical benefit have not been conducted.

The "Changes Being Effected" Supplemental new drug application (S-007) provided updated language to the Warnings and Precautions: Hepatic and Renal Impairment Section.

We completed our review of these applications, as amended. These applications are 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 enclosed labeling (text for the package insert). 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 supplements NDA 21-673/S-005 and 21-673/S-007**."

The final printed labeling (FPL) must be identical to the enclosed labeling (text for the package insert). Please submit an electronic version of the FPL according to the guidance for industry titled *Providing Regulatory Submissions in Electronic Format - NDA*. For administrative purposes, designate these submissions "**FPL for approved supplements NDA 21-673/S-005 and 21-673/S-007**." Approval of this submission by FDA is not required before the labeling is used.

You may request advisory comments on proposed introductory advertising and promotional labeling. To do so, submit, in triplicate, a cover letter requesting advisory comments, the proposed materials in draft or mock-up form with annotated references, and the package insert(s) 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 Lisa Skarupa, Regulatory Project Manager, at (301) 796-2219.

Sincerely,

{See appended electronic signature page}

Ann Farrell, M.D.,
Deputy 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/

Ann Farrell

10/17/2008 04:38:49 PM