DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 022311/S-001

SUPPLEMENT APPROVAL

Genzyme Corporation
Attention: Laura Mondano
55 Cambridge Parkway
Cambridge, MA 02142

Dear Ms. Mondano:

Please refer to your Supplemental New Drug Application (sNDA) dated August 21, 2009, received August 21, 2009, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Mozobil® (plerixafor injection) 20 mg/mL.

This "Changes Being Effected" supplemental new drug application provides for revisions to the Effects on Electrocardiogram subsection to Section 12.2, as requested by the FDA on June 22, 2009, and to the Pharmacodynamics subsection of the package insert.

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

CONTENT OF LABELING

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 to the enclosed labeling text for the package insert and include the labeling changes proposed in any pending "Changes Being Effected" (CBE) supplements. 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/UCM072392.pdf.

The SPL will be accessible from publicly available labeling repositories.

POSTMARKETING REQUIREMENTS UNDER 505(o)

We remind you of your Postmarketing Requirements (PMRs) in your submission dated December 11, 2008, these PMRs remain open. The requirements are listed below.

2. To provide follow up safety and efficacy information for trial 3101-LTF for 5 years which will include death and disease status (relapse or disease-free). Updated status reports to be submitted annually.

   Protocol Submission Date: April 3, 2006
   Trial Start Date: December 15, 2006
   First Annual Report: February 2010
   Second Annual Report: February 2011
   Third Annual Report: February 2012
   Fourth Annual Report: February 2013
   Fifth Annual Report: February 2014

3. To provide follow up safety and efficacy information for trial 3102-LTF for 5 years which will include death and disease status (relapse or disease-free). Updated status reports to be submitted annually.

   Protocol Submission Date: April 20, 2006
   Trial Start Date: January 11, 2007
   First Annual Report: February 2010
   Second Annual Report: February 2011
   Third Annual Report: February 2012
   Fourth Annual Report: February 2013
   Fifth Annual Report: February 2014

POSTMARKETING COMMITMENT

We remind you of your Postmarketing Commitment (PMC) in your submission dated December 11, 2008, this PMC remains open. The commitment is listed below.

5. Design, conduct and submit a clinical trial to evaluate weight based and flat dosing schedules in lower weight NHL patients. The applicant should conduct sparse PK sampling and measure CD34+ cell counts at time points similar to those in protocol AMD3100-3101.

   Protocol Submission: by September 30, 2009
   Trial Start: by March 31, 2010
   Trial Completion: by September 30, 2012
   Final Report Submission: by April 30, 2013

Submit clinical protocols to your IND for this product. Submit nonclinical and chemistry, manufacturing, and controls protocols and all study final reports to this NDA. In addition, under 21 CFR 314.81(b)(2)(vii) and 314.81(b)(2)(viii), you should include a status summary of each commitment in your annual report to this NDA. The status summary should include expected summary completion and final report submission dates, any changes in plans since the last annual report, and, for clinical studies, number of patients entered into each study. All submissions, including supplements, relating to these postmarketing study commitments should

be prominently labeled "**Postmarketing Study Commitment Protocol**", "**Postmarketing Study Commitment Final Report**", or "**Postmarketing Study Commitment Correspondence**."

REPORTING REQUIREMENTS

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 Amy Tilley, Regulatory Project Manager, at 301-796-3994.

Sincerely,

{See appended electronic signature page}

Ann Farrell, M.D.
Acting Director
Division of Hematology Products
Office of Oncology Drug Products
Center for Drug Evaluation and Research

ENCLOSURE:
Content of Labeling

Application Type/Number	Submission Type/Number	Submitter Name	Product Name
NDA-22311	SUPPL-1	GENZYME CORP	MOZOBIL

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

/s/

ANN T FARRELL
06/14/2010