DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-174/S-012,-014

Wyeth Pharmaceuticals, Inc.
87 CambridgePark Drive
Cambridge, MA 02140

Attention: Jennie K. H. Allewell
Director, Worldwide Regulatory Affairs

Dear Ms. Allewell:

Please refer to your supplemental new drug application S-014 dated September 22, 2003 received September 23, 200, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Mylotarg (gemtuzumab ozogamicin) for Injection 5mg/20mL.

This supplemental new drug application provides for updates to the **ADVERSE REACTIONS, Other Clinical Experience** section.

We also refer to your May 21, 2004 final printed labeling (FPL) for S-012, which was approved April 16, 2004. We note that this FPL supersedes S-014.

We completed our review of this supplemental new drug application. It is approved, effective on the date of this letter, for use as recommended in the final printed labeling (FPL) submitted on May 21, 2004, which we accept.

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, HFD-410
FDA
5600 Fishers Lane
Rockville, MD 20857

We remind you that you must comply with the requirements for an approved NDA set forth under 21 CFR 314.80 and 314.81.

If you have any questions, call Sean Bradley, R.Ph., Regulatory Project Manager, at (301) 594-5770.

Sincerely,

{See appended electronic signature page}

Richard Pazdur, M.D.
Director
Division of Oncology Drug Products
Office of Drug Evaluation 1
Center for Drug Evaluation and Research

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

/s/

Richard Pazdur

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