DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-174/S-021

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

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

Dear Ms. Allewell:

Please refer to your supplemental new drug application dated April 29, 2005, received May 2, 2005, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Mylotarg (gemtuzumab ozogamicin) for Injection.

This "Changes Being Effected" supplemental new drug application provides for changes in the **Dosage and Administration** section of the Mylotarg package insert. Specifically, **Table 10** on **REFRIGERATION STORAGE CONDTION TIMES was deleted** and **Table 11** on **ROOM TEMPERATURE STORAGE CONDITION TIMES** was modified to provide the information on storage conditions and times within one new table entitled **STORAGE CONDTION AND TIME FOR RECONSTITUTION, DILUTION, AND ADMINISTRATION**.

We completed our review of this application. 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 submitted labeling dated April 29, 2005.

Please submit an electronic version of the FPL according to the guidance for industry titled *Providing Regulatory Submissions in Electronic Format - NDA*. Alternatively, you may submit 20 paper copies of the FPL as soon as it is available but no more than 30 days after it is printed. Individually mount 15 of the copies on heavy-weight paper or similar material. For administrative purposes, designate this submission "**FPL for approved supplement NDA 21-174/S-021**." Approval of this submission by FDA is not required before the labeling is used.

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 reporting requirements for an approved NDA (21 CFR 314.80 and 314.81).

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

Sincerely,

{See appended electronic signature page}

Nallaperumal Chidambaram, Ph.D.
Chemistry Team Leader, DNDC I for the
Division of Oncology Drug Products, (HFD-150)
Office of New Drug Chemistry
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/

Nallaperumal Chidambaram

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