DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-174/S-015

Wyeth Pharmaceuticals, Inc.
P.O. Box 8299
Philadelphia, PA 19101-8299

Attention: Patricia Johnson
Associate Director II
Worldwide Regulatory Affairs

Dear Ms. Johnson:

Please refer to your supplemental new drug application dated January 28, 2004, received January 29, 2004, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Mylotarg (gemtuzumab ozogamicin) for Injection 5 mg/20 mL.

We acknowledge receipt of your submissions dated April 15, May 17 and 25, 2004.

This supplemental new drug application provides for revision of the package insert in DOSAGE AND ADMINISTRATION section based on test data from two compatibility studies.

We completed our review of this supplemental new drug application. This supplement is approved, for use as recommended in the draft labeling submitted May 25, 2004.

Please submit the FPL electronically 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, in no case more than 30 days after it is printed. Please individually mount 15 of the copies on heavy-weight paper or similar material. For administrative purposes, this submission should be designated "FPL for approved supplement NDA 21-174/S-015." The final printed labeling (FPL) must be identical to the draft labeling submitted May 25, 2004. 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) 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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