



NDA 21-174/S-024

Wyeth Pharmaceuticals
87 CambridgePark Drive
Cambridge, MA 02140

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

Dear Ms. Allewell:

Please refer to your supplemental new drug application dated August 17, 2005, received August 18, 2005, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Mylotarg (gemtuzumab ozogamicin) for Injection 5 mg/20 mL.

This "Changes Being Effected" supplemental new drug application provides for changes to the Adverse Events section of the Mylotarg package insert.

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 August 17, 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-024.**" 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}

Robert Justice, M.D.
Acting Director
Division of Drug Oncology Products
Office of Oncology Drug Products
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/

Robert Justice
10/4/2005 10:49:58 AM