DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 20-221/S-024

MedImmune
Attention: Lisa P. Freeman
Associate Director, Oncology
Regulatory Affairs
One MedImmune Way
Gaithersburg, MD 20878

Dear Ms. Freeman:

Please refer to your supplemental new drug application S-024, dated May 23, 2007, received May 23, 2007, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Ethyol® (amifostine) for injection.

We acknowledge receipt of your submission dated October 20 (electronic), 2008.

This "Changes Being Effected" supplemental new drug application provides for strengthening the information provided regarding cutaneous reactions. In the WARNINGS and PRECAUTIONS sections the sub-section hypersensitivity has been reorganized and a new sub-section inserted titled cutaneous reactions. In the ADVERSE REACTIONS section, sub-section titled controlled clinical trials, text has been revised to update the rate of clinically significant hypocalcemia observed in clinical trials and adds the events of malaise and rash.

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

Within 21 days of the date of this letter, submit content of labeling [21 CFR 314.50(l)] in structured product labeling (SPL) format, as described at http://www.fda.gov/oc/datacouncil/spl.html, that is identical in content to the enclosed labeling text. Upon receipt, we will transmit that version to the National Library of Medicine for public dissemination. For administrative purposes, please designate this submission "**SPL for approved supplement NDA 20-221/S-024".**

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
Food and Drug Administration
5515 Security Lane
HFD-001, Suite 5100
Rockville, MD 20852

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, please call Susan Jenney, Regulatory Project Manager, at (301) 796-1372.

Sincerely,

{See appended electronic signature page}

Robert Justice, M.D.
Director
Division of Drug Oncology Products
Office of Oncology Drug Products
Center for Drug Evaluation and Research

Enclosure

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

11/7/2008 06:57:32 PM