DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 20-221 / S-017

Medlmmune Oncology, Inc
35 W. Watkins Mill Road
Gaithersburg, MD 29878

Attention: Hanne Johansen, Ph.D.
Senior Director, Worldwide Regulatory Affairs

Dear Dr. Johansen:

Please refer to your supplemental new drug application dated and received on March 11, 2003 submitted under section 505(b)pursuant to section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act for Ethyol® (amifostine) for Injection

This "Changes Being Effected" supplemental new drug application provides for a Geriatric Use subsection and updated safety information pertaining to cutaneous reactions under the **WARNINGS**, **PRECAUTIONS**, and **ADVERSE REACTIONS** sections.

We have completed the review of this supplemental application and have concluded that adequate information has been presented to demonstrate that the drug product is safe and effective for use as recommended in the draft labeling submitted on March 11, 2003. Accordingly, the supplemental application is approved effective on the date of this letter.

Please submit the Final Printed Labeling (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 ten of the copies on heavy-weight paper or similar material. For administrative purposes, this submission should be designated "FPL for approved supplement NDA 20-221 / S-017." 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, HF-2
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 Maureen Pelosi, Regulatory Project Manager, at (301) 594-5778.

Sincerely,

{See appended electronic signature page}

Richard Pazdur, M.D.
Director
Division of Oncology Drug Products
Office of Drug Evaluation I
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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