DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

APR 2 2007

0388 7 APR -5 P3:09

William C. Bertrand, Jr.
Senior Vice President and General Counsel
MedImmune Oncology, Inc.
One MedImmune Way
Gaithersburg, MD 20878

Re: Docket No. 2006P-0410/CP1

Dear Mr. Bertrand:

I am writing to inform you that the Food and Drug Administration (FDA) has not yet resolved the issues raised in your citizen petition received by the Agency on October 10, 2006. Your petition requests that we not approve any abbreviated new drug application for an amifostine product with labeling that omits dosage, administration, and other information related to the consequences of using the drug to reduce the incidence of xerostomia in head and neck cancer patients treated with radiotherapy.

We have been unable to reach a decision on your petition because it raises complex issues requiring extensive review and analysis by Agency officials. This interim response is provided in accordance with FDA regulations on citizen petitions (21 CFR 10.30(e)(2)). We will respond to your petition as soon as we have reached a decision on your request.

Sincerely,

Jane A. Axelrad

Jane A. Axelrad
Associate Director for Policy
Center for Drug Evaluation and Research

2006P-0410

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