



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

October 10, 2006

FILE COPY

William C. Betrand, Jr.
MedImmune Oncology, Inc.
One MedImmune Way
Gaithersburg, Maryland 20878

Dear Mr. Betrand:

Your petition requesting the Food and Drug Administration to 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 being treated with radiotherapy, was received by this office on 10/10/2006. It was assigned docket number 2006P-0410/CP1 and it was filed on 10/10/2006. Please refer to this docket number in future correspondence on this subject with the Agency.

Please note that the acceptance of the petition for filing is a procedural matter in that it in no way reflects an agency decision on the substantive merits of the petition.

Sincerely,

Jennie Butler, Director
Division of Dockets Management
Office of Management Programs
Office of Management

2006P.0410

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