



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

October 29, 2007

FILE COPY

Peter O. Safir
Heather D. Banuelos
Covington & Burling LLP
1201 Pennsylvania Avenue, N.W.
Washington, DC 20004-2401

Dear Mr. Safir and Ms. Banuelos:

Your petition on behalf of The Alliance Against Alveolar Soft Part Sarcoma and the Sarcoma Foundation of America, requesting the Food and Drug Administration to issue a guidance document for the accelerated approval of drugs and biologics that are intended to treat rare cancers, including alveolar soft part sarcoma, was received by this office on 10/26/2007. It was assigned docket number 2007P-0420/CP1 and it was filed on 10/26/2007. 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,

Gloria Ortega
Division of Dockets Management
Office of Management Programs
Office of Management

2007P-0420

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