

**EDOLPHUS "ED" TOWNS**  
MEMBER OF CONGRESS  
10TH DISTRICT, NEW YORK

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**GOVERNMENT REFORM**  
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CHAIRMAN

**Congress of the United States**  
**House of Representatives**  
**Washington, DC 20515-3210**

January 8, 2008

Commissioner Andrew C. von Eschenbach, M.D.  
Food and Drug Administration  
5600 Fishers Lane  
Rockville, MD 20857


Dear Dr. von Eschenbach:

I am writing in strong support of the Citizen Petition submitted by The Alliance Against Alveolar Soft Part Sarcoma ("TAAASPS") and the Sarcoma Foundation of America ("SFA"). The TAAASPS and SFA Citizen Petition requests that FDA issue a guidance document for the accelerated approval of drugs and biologics that are intended to treat rare cancers. I believe the Citizen Petition merits the Agency's careful consideration and FDA should move forward to issue the requested guidance document.

The Citizen Petition asks the Agency to provide guidelines for the approval of any drug or biological product that is intended to treat a rare cancer, but for which adequate and well-controlled studies may not be feasible due to the rarity of the cancer or ethical constraints in conducting such studies. As the Citizen Petition points out, rare cancers, such as alveolar soft part sarcoma, affect a small percentage of the U.S. population. Because of the rarity of the cancer, clinical trials are often difficult to conduct and complete. However, under the Agency's current approval process, such studies are necessary to the approval of the product. As a result, many people affected by rare cancers are left without a viable therapeutic treatment option. Indeed, unless surgery proves curative, there are currently no approved treatments for these rare cancers. By providing a guidance document concerning the approval of treatments for rare cancers, FDA can pave the way for companies to continue to develop and seek approval of products intended to treat rare diseases, and to ensure that these products reach patients who desperately need them.

I urge the Agency to act on the Citizen Petition's request and provide needed guidelines for the approval of drug and biologics intended to treat rare cancers. These guidelines can help preserve and promote public health by making products available to persons suffering from a rare cancer.

Sincerely,

  
Edolphus Towns  
Member of Congress

WASHINGTON OFFICE:  
SUITE 2232  
RAYBURN HOUSE OFFICE BUILDING  
WASHINGTON, DC 20515  
(202) 225-5936

BROOKLYN OFFICES:  
26 COURT STREET, SUITE 1510  
BROOKLYN, NY 11242  
(718) 855-8018

104-06 FLATLANDS AVENUE,  
BROOKLYN, NY 11238  
(718) 272-1175

1670 FULTON STREET  
BROOKLYN, NY 11213  
(718) 774-5682