



Food and Drug Administration  
Center for Biologics Evaluation and Research  
1401 Rockville Pike  
Rockville MD 20852-1448

JAN 17 2008

Rory Kearney, President  
CareToLive  
P.O. Box 464  
Thorofare, NJ 08086-0464

Re: Docket No. 2007P-0297/CP1

Dear Mr. Kearney:

I am writing to inform you that the Food and Drug Administration (FDA) has not yet completed its response to the issues raised in your citizen petition submitted on July 27, 2007. In your citizen petition, you request the Commissioner of Food and Drugs to reconsider FDA's failure to grant approval to a biologics license application for Provenge.

We are still considering your request and supporting information stated in your citizen petition. 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 yours,

Jesse L. Goodman, M.D., M.P.H.  
Director

Center for Biologics Evaluation and Research

cc: Division of Dockets Management  
(HFA-305)