

DEPARTMENT OF HEALTH & HUMAN SERVICES



Food and Drug Administration
Rockville MD 20857

The Honorable Patrick J. Tiberi
Member, U.S. House of Representatives
3000 Corporate Exchange Drive, Suite 310
Columbus, OH 43231

FEB 05 2010

Dear Mr. Tiberi:

Thank you for your letter of January 6, 2010, on behalf of your constituent, Mr. Kerry Donahue of Dublin, Ohio. Mr. Donahue writes to express his support for approval of the drug Provenge (sipuleucel-T) for the treatment of prostate cancer.

Generally, the Food and Drug Administration (FDA or the Agency) is prohibited by law from confirming or denying the existence of a product application, unless the sponsor or the manufacturer of the product publicly acknowledges the application or provides the Agency with written authorization to release or disclose information contained in its application. In the case of Provenge, Dendreon Corporation (Dendreon), the product's sponsor, has information on the status of ongoing trials and enrollment on their Web site at <http://www.dendreon.com/pipeline/sipuleucel%5Ft/>.

On October 6, 2008, Dendreon issued a press release announcing "Interim Data from Phase 3 Provenge IMPACT Trial." This information can be found on the sponsor's Web site at: <http://investor.dendreon.com/releasedetail.cfm?ReleaseID=338495>. Additional information about Provenge may be obtained from the sponsor's Web site at <http://www.dendreon.com>.

By way of background, before a new product is marketed, FDA must determine whether the data submitted in the sponsor's Biologics License Application (BLA) show the product to be safe and effective for its intended use. The required documentation in a BLA provides critical information, such as results of clinical trials; components and composition of the biologic; results of animal studies; how the biologic behaves in the body; how it's manufactured, processed and packaged; manufacturing quality controls; and labeling information. A team of experts reviews this complex information to determine if the benefits of using the drug outweigh potential risks. Once a review of the application is completed, FDA may take one of three actions: deny the application, approve the application (i.e. license the biological product), or issue a "complete response letter," requesting additional information from the sponsor. On its Web site, Dendreon stated that it received a complete response letter from FDA for its BLA for Provenge. It is important to note that a complete response letter is not a final determination about the merits of the application. Instead, it is a step that the Agency

takes when it does not have sufficient data to assess safety and effectiveness of the biological product, as well as sufficient information, to determine that the facility in which the biological product is manufactured, processed, packed, or held will ensure the continued safety, purity, and potency of the biological product (42 *United States Code* (U.S.C.) 262 (a)(2)(C)). FDA continues to work with sponsors to resolve any outstanding issues.

In some instances, FDA seeks advice from its advisory committees. The primary role of an advisory committee is to provide independent expert advice. As part of its review of the BLA, FDA's Center for Biologics Evaluation and Research sought the advice of its Cellular, Tissue and Gene Therapy Advisory Committee on March 29, 2007. A transcript of the meeting and related information is available on the Internet at: <http://www.fda.gov/ohrms/dockets/ac/cber07.htm#CellularTissueGeneTherapies>. It should be noted that FDA carefully considers the advice and recommendations of its advisory committees as part of the overall review process of a BLA. However, advice from the advisory committees is not binding, and final decisions such as whether to approve a BLA are made by FDA alone.

We realize that waiting for a promising new therapy to be approved can be frustrating. Please be assured that FDA recognizes its responsibility to work with the pharmaceutical industry to shepherd new products to the marketplace that are safe and effective, and places a high priority on expeditiously reviewing all new product applications.

Thank you for contacting us concerning this matter. If you have further questions, please let us know.

Sincerely,



Jeanne Ireland
Assistant Commissioner
for Legislation