



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

g 4428d

November 18, 2003

CBER-04-002

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

WARNING LETTER

**CERTIFIED MAIL**  
**RETURN RECEIPT REQUESTED**

Mr. Andrew Oldham  
Cancer Therapeutics, Inc.™  
357 Riverside Drive  
Franklin, TN 37064

Dear Mr. Oldham:

The Office of Compliance and Biologics Quality of the Food and Drug Administration (FDA)'s Center for Biologics Evaluation and Research has obtained information from your Internet website, <http://www.cancer-therapeutics.com>, that reveals a serious regulatory problem involving Autologous Cancer Cell Vaccine (ACCV) and Tumor Derived Activated Cells (TDAC), which are commercially distributed by your firm.

Your website recommends or suggests use of ACCV and TDAC for the treatment of cancer. Specifically, the web page discussing AACV (<http://www.cancer-therapeutics.com/accv.html>) states that "using ACCV can enhance a patient's immune system in attacking invading cancer cells . . . remaining after surgery, radiation and/or chemotherapy have failed." Other examples of claims on that web page include the following:

- "Can stimulate the patient's immune system to attack invading cancer cells and has the potential to generate a clinical response."
- "ACCV therapy can be considered for patients having a malignancy . . ."
- "Specific emphasis should be placed on melanoma and renal cell carcinoma."

That same web page makes it clear that ACCV is also a vaccine. In addition to stating the product name itself, which includes the word "vaccine," the web page states that on average you produce "sufficient vaccine for 4-10 injections." Finally, the web page claims that ACCV works through its effect on a patient's immune system, which is how vaccines function. The web page discussing TDAC (<http://www.cancer-therapeutics.com/tdac.html>) contains statements that are virtually identical to those set forth above for ACCV.

Consequently, the ACCV and TDAC are (1) intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease and (2) vaccines applicable to the prevention, treatment, or cure of a disease. They are, therefore, drugs under section 201(g) of the Federal Food, Drug, and Cosmetic Act (FDCA), 21 U.S.C. 321(g), and biological products under section 351(i) of the Public Health Service Act (PHSA), 42 U.S.C. 262.

Our records do not show that approval has been obtained for ACCV or TDAC for the treatment of cancer. [REDACTED]

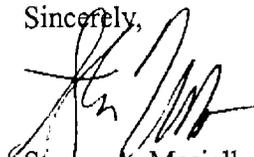
[REDACTED] Accordingly, these products are being introduced into interstate commerce or delivered for introduction into interstate commerce without valid biologics licenses or approved new drug applications, and without INDs, in violation of section 505(a) of the FDCA, 21 U.S.C. 355(a), and section 351(a) of the PHSA, 42 U.S.C. 262(a). Under the PHSA, an approved new drug application is not required for a product covered by a valid biologics license, 42 U.S.C. 262(j).

You should take prompt action to correct these violations. Please notify this office in writing within 15 working days of receipt of this letter of the steps you have taken or will take to correct the noted violations and to prevent their recurrence. If the corrective action(s) cannot be completed within 15 working days, state the reason for the delay and the time within which the correction(s) will be completed. Your response should be sent to the U.S. Food and Drug Administration, Center for Biologics Evaluation and Research, Office of Compliance and Biologics Quality, HFM-610, 1401 Rockville Pike, Suite 100 N, Rockville, MD 20852-1448, Attention Mr. Steven Masiello, Director, Office of Compliance and Biologics Quality.

Failure to promptly correct these violations may result in initiation of regulatory action such as seizure and/or injunction without further notice.

This letter is not intended to be an all-inclusive review of your web site or of your products. It is your responsibility to ensure that you comply with all applicable requirements of the FDCA and the PHSA and FDA implementing regulations.

Sincerely,



Steven A. Masiello  
Director  
Office of Compliance and Biologics Quality  
Center for Biologics Evaluation and Research