



m24807

Certified – Return Receipt RequestedFood and Drug Administration  
Center for Biologics Evaluation and Research  
1401 Rockville Pike  
Rockville MD 20852-1448

MAR 26 1999

Warning LetterJingwu Zhang, M.D., Ph.D.  
Baylor College of Medicine  
6501 Fannin Street, Room NB302  
Houston, Texas 77030-3498

CBER-99- 016

Dear Dr. Zhang:

During an inspection ending November 30, 1998, investigators from the Food and Drug Administration documented that you administered \_\_\_\_\_  
\_\_\_\_\_ to human subjects in violation of the Public Health Service Act (PHS Act) and the Federal Food, Drug, and Cosmetic Act (FD&C Act).

\_\_\_\_\_ are a biological product as defined in Section 351(i) of the PHS Act (as amended November 21, 1997), in that they are a biological product applicable to the prevention, treatment, or cure of diseases or injuries to human beings, and accordingly, must be licensed pursuant to Section 351(a) of the PHS Act. \_\_\_\_\_ are also a drug within the meaning of Section 201(g) of the FD&C Act, in that they are intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man.

The inspection revealed that Section 505(a) of the FD&C Act and Section 351(a) of the PHS Act are being violated in that you are administering \_\_\_\_\_ a somatic cell therapy product as well as an unapproved new drug, without an approved product license application (PLA) in effect pursuant to Section 351(a) of the PHS Act, or an investigational new drug application (IND) in effect pursuant to Section 505(i) of the FD&C Act. The definition of a somatic cell therapy can be found in the enclosed copy of the Federal Register dated October 14, 1993. In accordance with the statutory provisions governing biological products and drugs, a somatic cell therapy product must be the subject of an IND or of an approved PLA regardless of whether the product is shipped across state lines.

\_\_\_\_\_ used in your studies involving human subjects are also misbranded under Section 502(f)(1) of the FD&C Act, in that the labeling fails to bear adequate directions for the purposes for which the drug is intended because adequate directions cannot be written for unapproved new drugs.

This letter is not intended to be an all-inclusive list of deviations observed at your facility. It is your responsibility to ensure adherence to each requirement of the FD&C and PHS Acts and relevant regulations.

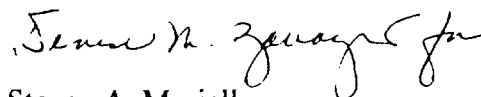
You should take prompt action to correct these deviations. Failure to promptly correct these deviations may result in regulatory action being initiated by the Food and Drug Administration without further notice. These actions include, but are not limited to, seizure and/or injunction, and disqualification.

You should notify this office in writing, within 15 business days of receipt of this letter, of the specific steps you have taken to correct the noted violations, including an explanation of each step taken to prevent a recurrence of similar violations. If corrective action cannot be completed within 15 business days, state the reasons for the delay and the time within which the corrections will be completed. Corrective actions would include, but are not limited to, discontinuing administration of \_\_\_\_\_ to human subjects and the submission of an IND.

An IND application and information packet is enclosed. Any IND application should be submitted to Dr. Kathryn C. Zoon, Center for Biologics Evaluation and Research, HFM-99, Suite 200N, 1401 Rockville Pike, Rockville, Maryland 20852-1448. Questions regarding submission of an IND application and assistance may be directed to the Office of Communications, Training, and Manufacturers Assistance at (800) 835-4709.

Your response to this letter should be sent to my attention at the following address: Food and Drug Administration, Center for Biologics Evaluation and Research, HFM-600, Suite 200N, 1401 Rockville Pike, Rockville, Maryland 20852-1448.

Sincerely yours,



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

Enclosures: Federal Register, October 14, 1993

Information on Submitting a Sponsor-Investigator IND, including Title 21 of the Code of Federal Regulations Part 312

