



12. J
d1665b

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

Certified-Return Receipt Requested

WARNING LETTER

NOV 7 1996

Dr. John Mendelsohn
President
M. D. Anderson Cancer Center
1515 Holcombe Boulevard
Houston, Texas 77030

Dear Dr. Mendelsohn:

During the period from April 8 to 12, 1996, Mr. Joel Martinez and Mr. Bruce Taylor, investigators from the FDA Dallas District Office, and Dr. Mary Andrich, Medical Officer from the Center for Biologics Research and Review, visited M. D. Anderson Cancer Center to examine records relating to the study of investigational under an Investigational New Drug (IND) exemption sponsored by your institution.

The inspection revealed that study subjects were billed for the which were with investigational in violation of Title 21, Code of Federal Regulations (CFR), Part 312.7(d). This regulation prohibits charging subjects for an investigational drug in a clinical trial under IND without prior written approval by FDA. The enclosed memorandum submitted to describes the extent of the commercialization of is not approved for

We conclude that M. D. Anderson Cancer Center did not exert adequate oversight of billing practices to prevent the commercialization of investigational drugs. As the sponsor of many INDs, your institution must develop procedures to prevent the future occurrence of illegal commercialization of investigational drugs.

This letter is not intended to be an all-inclusive list of deficiencies at your facility. It is your responsibility to ensure adherence to each requirement of the Federal Food, Drug and Cosmetic Act and Public Health Service Act and relevant regulations.

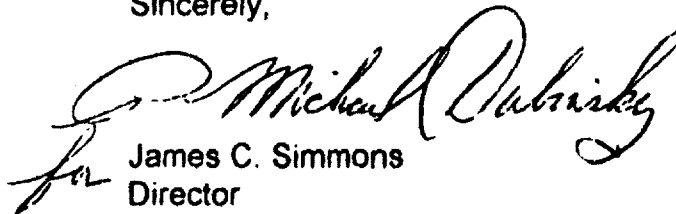
Failure to promptly correct these deviations may result in regulatory action being initiated by the Food and Drug Administration without further notice. These actions include, but are not limited to, termination of Investigational New Drug Applications (INDs) and/or injunction.

Please notify this office in writing, within 15 working 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. These steps should include, among other things, a review of billing records to determine the extent of commercialization of the radionuclides utilized in other investigational drug studies under other INDs. If corrective action cannot be completed within 15 working days, state the reason for the delay and the time within which the corrections will be completed. Your response should include any documentation necessary to show that correction has been achieved.

Your response should be sent to me at the following address:

Office of Compliance HFM-600
Center for Biologics Evaluation and Research
1401 Rockville Pike
Rockville, Maryland 20852-1448

Sincerely,

A handwritten signature in cursive script, appearing to read "James C. Simmons".

James C. Simmons
Director
Office of Compliance
Center for Biologics Evaluation
and Research

Enclosures

21 CFR Part 312 (revised as of April 1, 1996)
Memorandum dated January 31, 1996

cc: Leonard A. Zwelling, M. D.
Associate Vice President for Clinical and Translational Research