June 22, 2001

Thomas F. McLeod, Ph.D.
Radiation Safety Officer
Mount Sinai Medical Center
4300 Alton Road
Miami Beach, Florida 33140

Dear Dr. McLeod:

I am responding to your letter dated May 16, 2001 in which you asked for clarification on the regulation of off label uses for pre-market approval (PMA) procedures. Specifically you asked whether the Nuclear Regulatory Commission (NRC) considers this a misuse or misadministration and would, therefore, choose to regulate this directly.

Florida, as an Agreement State, has regulatory jurisdiction including authorizing medical uses of radionuclides and defining any special terms and conditions for their use. NRC has established policies and guidance which Agreement States can adopt and use. We have discussed and are forwarding a copy of your letter to Michael Stephens in the Florida Bureau of Radiation Control (850-487-2437) for appropriate action. We suggest you contact him for information regarding your use of these materials.

Sincerely,

/RA/

Paul H. Lohaus, Director
Office of State and Tribal Programs

cc: Michael Stephens, FL

Thomas F. McLeod, Ph.D. June 22, 2001

Distribution:
DIR RF (1-104)
SDroggitis
BGUsilton
Florida State File

DCD (SP06)
PDR (YES✓)

Response to incoming document: ML011430184

DOCUMENT NAME: G:\JGZ\MTsinailetter.wpd

OFFICE	STP	STP:DD	STP:D	
NAME	JGZabko:gd	FCombs	PHLohaus	
DATE	06/12/01	06/12/01	06/22/01	

OFFICIAL RECORD COPY STP-AG-6