



Food and Drug Administration
555 Winderley Pl., Ste. 200
Maitland, FL 32751

VIA FEDERAL EXPRESS

WARNING LETTER

FLA-00-101

September 25, 2000

John M. Kilgore, M.D.
President and Chief Executive Officer
Nuclear Medicine of Central Florida, Inc.
128 S. Moon Avenue
Brandon, Florida 33511

Dear Dr. Kilgore:

FDA Investigators Karen G. Hirschfield and Joan S. Norton conducted an inspection of your facility located in Tampa, Florida, on April 28 through May 11, 2000. Information from this inspection along with information from the State of Florida found that your firm, Nuclear Medicine of Central Florida, Inc., is operating as a radiopharmaceutical manufacturer, producing and distributing the drug, Thallium-201, for injection.

We have been advised by the State of Florida that Nuclear Medicine of Central Florida is not operating in accordance with its laws and requirements governing the practice of pharmacy. Your firm is not registered as a nuclear pharmacy with the State of Florida; the radioactive material received was not manufactured under a proper United States Nuclear Regulatory Commission or State license; and, your firm lacks the proper radioactive materials license needed to process radiopharmaceuticals. While your firm has a radioactive materials license authorizing you to possess, use and transfer Thallium-201, that license is not a product license, as represented on your product label. The State of Florida has informed us that since patients being treated with the radiopharmaceutical product manufactured by Nuclear Medicine of Central Florida are not solely your patients, they cannot receive this prescription drug under your medical license. In addition, your firm does not have a permit that authorizes the manufacture or wholesale distribution of prescription drugs.

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The activities of Nuclear Medicine of Central Florida, Inc., related to radiopharmaceuticals, and the practice of nuclear pharmacy are, therefore, not in accordance with state law and, as a result, Nuclear Medicine of Central Florida does not qualify for exemption from registration with FDA. In accordance with applicable FDA guidelines, namely the 1984 Nuclear Pharmacy Guideline and Compliance Policy Guideline (CPG) 7132.16, the manufacture and distribution of this drug is outside the normal practice of pharmacy and is in violation of the Federal Food, Drug, and Cosmetic Act (the Act) as follows:

The drug, Thallium-201, that you manufacture, is a drug which may not be introduced or delivered for introduction into interstate commerce under section 505(a) of the Act, since it is a new drug within the meaning of section 201(p) of the Act and no approval of a new drug application filed pursuant to section 505(b) of the Act is effective for such drug.

The drug, Thallium-201, is further misbranded within the meaning of section 502(a) in that its labeling is false and misleading because it states that the drug is licensed by the Florida Office of Radiation Control, which statement is contrary to fact.

The drug, Thallium-201, is further misbranded within the meaning of section 502(f)(1) in that its labeling fails to bear adequate directions for the use for which it is offered and it is not exempt from this requirement under Title 21, Code of Federal Regulations (21 CFR), Part 201.115, since it is a new drug within the meaning of section 201(p) and no approval of an application filed pursuant to section 505(b) is effective for this drug and it is not exempt from this requirement under 21 CFR 201.100.

The drug, Thallium -201, is further misbranded within the meaning of section 502(o) in that it was manufactured in an establishment not duly registered under section 510 of the Act and the article has not been listed as required by section 510(j).

The inspection revealed that this drug is adulterated within the meaning of section 501(a)(2)(B) of the Act in that it is a drug product and the methods used in, or the facilities or controls used for, its manufacture, processing, packing or holding do not conform to or are not operated or administered in conformity with current good manufacturing practice (GMP) regulations for drugs specified in 21 CFR 211 as follows:

Your firm has not tested the Thallium-201 for purity, quality, sterility, pyrogens, or stability.

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Your firm does not regularly receive Certificates of Analysis covering the radiochemical received from the supplier, nor does your firm perform any tests on the incoming radiochemical, which is prominently labeled as not tested for sterility or pyrogenicity.

Scientifically sound and appropriate product specifications, standards and test procedures for this product, to assure that components, containers, closures, and finished products conform to appropriate standards of identity, strength, quality and purity the finished product purports or is represented to possess have not been established.

Written procedures for the manufacturing operation have not been established, nor are master or batch production or control records being prepared for Thallium-201.

Testing equipment such as the Dose Calibrator used to determine the radioactivity of the Thallium-201 has not been properly calibrated, nor have the test results for the Cesium-137 calibration source been recorded.

No environmental controls are maintained, nor is any environmental monitoring performed.

No reserve samples are maintained (for impurity or sterility issues).

This letter is not intended to be an all-inclusive list of deficiencies at your facility. It is your responsibility to ensure adherence to all requirements of the Act and regulations. We acknowledge receipt of your letter dated July 7, 2000, to FDA Investigators Karen G. Hirschfield and Joan S. Norton, in which you inquire as to whether or not you have the right, under the "practice of medicine", to prepare your patient's doses of radiopharmaceuticals in your own lab. As noted above, whether you operate as a nuclear pharmacy or as a manufacturer, your firm must comply with all applicable state laws. The State of Florida has advised us that your firm does not hold permits to operate either as a nuclear pharmacy or as a manufacturer and, further, that you are not authorized by the State to administer or dispense prescription drugs under your medical license to persons other than your own patients. The State of Florida has notified us that patients being treated with your firm's radiopharmaceuticals are not your patients.

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You should take prompt action to correct these violations. Failure to promptly correct these violations 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.

Please notify this office in writing within fifteen (15) working days of receipt of this letter, of the specific steps you have taken to correct these violations and to prevent the recurrence of similar violations. If corrective action cannot be completed within fifteen working days, state the reason for the delay and the time within which corrections will be completed.

Your response should be sent to the Food and Drug Administration, Florida District Office, 555 Winderley Place, Ste. 200, Maitland, Florida 32751, Attention: Martin E. Katz, Compliance Officer.

Sincerely,

A handwritten signature in black ink, appearing to read "Emma R. Singleton". The signature is fluid and cursive, with a long horizontal stroke extending to the right.

Emma R. Singleton
Director, Florida District