



DEPARTMENT OF HEALTH AND HUMAN SERVICES, FOOD AND DRUG ADMINISTRATION

4298 Elysian Fields Avenue
New Orleans, LA 70122-3896
Telephone (504) 589-7166
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HF-1-35

9/10/97
EJF

426

September 10, 1997

WARNING LETTER NO. 97-NOL-63

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Dr. Rena B. Zimmerman
Medical Director
Deland & Noell Corp.
dba Meridian Radiation Oncology Center
1724 23rd Avenue, Bldg. C
Meridian, MS 39301

Dear Dr. Zimmerman:

During an inspection of your contract biologics irradiation facility, located at 1724 23rd Avenue, Meridian, Mississippi, on June 25-26, 1997, our investigator documented violations of Section 501(a)(2)(B) of the Federal Food, Drug, and Cosmetic Act and Title 21, *Code of Federal Regulations* (21 CFR), Parts 211 and 606.

Deviations noted included: (1) failure to validate the linear accelerators under conditions which simulate blood product irradiation configurations; (2) incomplete written procedures for the irradiation of blood and blood products in both accelerators under varying conditions (i.e. field size, frozen or thawed product, number of units irradiated, etc.); and (3) no record of employee training since August 1995, even though new employees have been hired since then and your training program requires annual retraining.

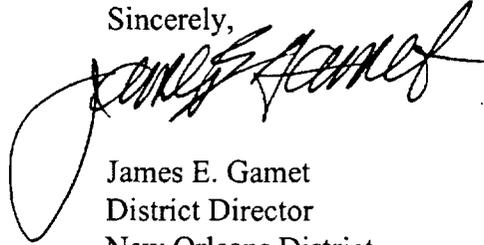
The above violations are not intended to be an all-inclusive list of deficiencies at your facility. As Medical Director, it is your responsibility to assure that your establishment is in compliance with all requirements of the federal regulations.

You should take prompt action to correct these deviations. Failure to promptly correct these deviations may result in regulatory action without further notice. Such action includes seizure 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 and to prevent their recurrence. 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 reply should be directed to Barbara D. Wright, Compliance Officer, U.S. Food and Drug Administration, 4298 Elysian Fields Ave., New Orleans, Louisiana 70122-3848. Should you have any questions concerning the contents of this letter, or if you should desire a meeting with the agency staff, you may contact Ms. Wright at (504) 589-7166.

Sincerely,

A handwritten signature in black ink, appearing to read "James E. Gamet". The signature is written in a cursive style with a large, looping initial "J".

James E. Gamet
District Director
New Orleans District