DEPARTMENT OF HEALTH AND HUMAN SERVICES

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Food and Drug Administration
New Orleans District Office
Nashville Branch Office
297 Plus Park Blvd.
Nashville, TN 37217

Telephone: 615-781-5380
Facsimile: 615-781-5391

September 12, 2003

VIA FEDERAL EXPRESS
OVERNIGHT DELIVERY

FACILITY ID #168203

Jeffery J. Laborde, M.D.
Laborde Diagnostics at South College
1101 South College Drive, Suite 200
Lafayette, LA 70503

Warning Letter No. 03-NSV-29

Dear Dr. Laborde:

An inspection of your facility was conducted on August 21, 2003, by a representative of the State of Louisiana acting on behalf of the U.S. Food and Drug Administration (FDA). This inspection revealed serious compromises in the quality of the mammography services offered by this facility.

Under the Mammography Quality Standards Act of 1992 (MQSA), Title 42, *United States Code* § 236b, your facility must meet specific requirements for mammography. These requirements help protect the health of women by assuring that a facility can perform quality mammography.

The recent inspection at this facility revealed the following Level 2 Repeat finding:

Level 2 (Repeat)

Medical audit and outcome analysis was not conducted separately for each individual on site with Laborde Diagnostics at South College. [See Title 21, *Code of Federal Regulations* (CFR), 900.12(f)(1).]

The specific deficiency noted above appeared on the MQSA Post Inspection Report, which was given to your facility by the state inspector along with instructions on how to respond to this finding. Your facility responded to this same noncompliance issue in a letter dated September 16, 2002, to the New Orleans District office. The letter stated that to achieve corrective action, your facility would purchase a computerized reporting system to streamline Quality Control (QC) and patient reporting that includes an extensive medical audit section and analysis. You reported that this system was purchased on September 16, 2002, and would be in place by the next month. However, the state inspector found this same violation during the August 2003 inspection.

Because the continued failure to resolve this violation may be symptomatic of serious underlying problems that could compromise the quality of mammography at this facility, it represents a violation of the law which may result in FDA taking regulatory action without further notice to you. These actions include, but are not limited to, placing your facility under a Direct Plan of Correction, charging your facility for the cost of on-site monitoring, seeking civil money penalties up to $10,000 for each failure to substantially comply with MQSA standards, seeking suspension or revocation of your facility's FDA certificate, or seeking a court injunction against further mammography. [See Title 42, *United States Code* § 263b(h)-(j).]

In addition, you should address the following Level 3 Repeat deficiency that also was listed on the inspection report:

Level 3 Repeat

The required personnel qualification documents were not available during the inspection. [See 21 CFR 900.12(a)(4).]

This noncompliance violation had been cited during your last three annual inspections. Our letter of December 9, 2002, stated that your facility's response dated September 16, 2002, failed to adequately respond to this item. Mr. Paul N. Guidry, Chief Technologist, responded by letter dated December 17, 2002, stating a new software system was purchased which allowed credentialing information to be maintained at your facility. However, the state inspector found this same violation during the August 2003 inspection.

It is your responsibility to ensure adherence to each requirement of MQSA and FDA's regulations. You are responsible for investigating and determining the cause of these deficiencies and for promptly initiating permanent corrective actions.

Within fifteen (15) working days after receiving this letter, you should notify FDA in writing of each step your facility is taking to prevent the recurrence of any similar violations. Your response should include the following:

- The specific steps you have taken to correct the Level 2 Repeat and Level 3 Repeat violations as outlined in this letter;

- Each step your facility is taking to prevent the recurrence of similar violations; and,

- Sample records that demonstrate proper record-keeping procedures relating to QC or any other records that are appropriate to the noncompliance finding (NOTE: Patient names or other information that would reveal the patient's identity should be deleted from any submitted copies).

If your facility is unable to complete these corrective actions within 15 working days, you should state the reason for the delay and the time within which the corrections will be completed.

Your reply should be directed to Joseph E. Hayes, Compliance Officer, U.S. Food and Drug Administration, 297 Plus Park Boulevard, Nashville, Tennessee 37217, telephone 615/781-5389, extension 125, with a copy to the State of Louisiana. Should you have questions regarding the technical aspects of

this letter or concerning MQSA standards, you may contact Karen Smallwood, Radiation Specialist, at 615/781-5380, extension 144.

Finally, you should understand that there are many requirements pertaining to mammography. This letter pertains only to violations related to the recent inspection of your facility and does not necessarily address other obligations you have under the law. You may obtain general information about all of FDA's requirements for mammography facilities by contacting the Mammography Quality Assurance Program, U.S. Food and Drug Administration, Post Office Box 6057, Columbia, Maryland 21045-6057 (1-800-838-7715) or through the Internet at http://www.fda.gov/cdrh/mammography/index.html.

Sincerely,

Patricia K. Schafer

Patricia K Schafer
Acting District Director
New Orleans District

CED:krs

Enclosures:
Facility letter dated 9/16/2002
FDA letter dated 12/9/2002
Facility letter dated 12/17/2002

cc: State of Louisiana
Radiation Surveillance Section
Post Office Box 4312
Baton Rouge, Louisiana 70821-4312
ATTN: Joseph Noble

Priscilla F. Butler, MS
Director, Breast Imaging Accreditation Programs
Standards and Accreditation Department
American College of Radiology
1891 Preston White Drive
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