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San Francisco District
1431 Harbor Bay Parkway
Alameda, CA 94502-7070
Telephone: 510/337-6700

WARNING LETTER

November 30, 2000

via Federal Express

FDA Reference #: 2954824

MQSA Facility ID: 222213
Inspection ID: 2222130002

Wayne L. McDade
Maui Medical Group
2180 Main Street
Wailuku, HI 96793

Dear Wayne L. McDade,

We are writing to you because on November 14, 2000, your Pukalani, HI facility was inspected by a representative of the State of Hawaii, acting in behalf of the Food and Drug Administration (FDA). This inspection revealed a serious regulatory problem involving the mammography at your facility.

Under a United States Federal law, the Mammography Quality Standards Act of 1992, 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 inspection revealed the following Level 1 finding at your facility:

- Level 1: Mammograms were processed in processor 1, [REDACTED], room Darkroom 1 at site Maui Medical Group, when it was out of limits on 6 days

The specific problem noted above appeared on your MQSA Facility Inspection Report, which was issued to your facility at the close of the inspection. This problem is identified as Level 1, because it identifies a failure to meet a significant MQSA requirement.

Because this condition may be symptomatic of serious underlying problems that could compromise the quality of mammography at your facility, it represents a serious 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 Directed Plan of Correction, charging your facility for the cost of on-site monitoring, assessing civil money penalties up to \$10,000 for each failure to substantially comply with, or each day of failure to substantially comply with, MQSA Standards, suspension or revocation of your facility's FDA certificate, or obtaining a court injunction against further mammography.

In addition, your response should address the Level 2 finding that was listed on the inspection report provided to you at the close of the inspection. This Level 2 findings is:

- Level 2: Corrective actions for processor QC failures were not documented at least once for processor 1, [REDACTED], room Darkroom 1 at site Maui Medical Group

It is necessary for you to act on this matter immediately. Please explain to this office in writing within fifteen (15) working days from the date you received this letter:

- the specific steps you have taken to correct all of the violations noted in this letter;
- each step your facility is taking to prevent the recurrence of similar violations;
- equipment settings (including technique factors), raw test data, and calculated final results, where appropriate; and
- sample records that demonstrate proper record keeping procedures, if the findings relate to quality control or other records (Note: Patient names or identification should be deleted from any copies submitted).*

Please submit your response to:

Russell A. Campbell, Compliance Officer
San Francisco District
U. S. Food and Drug Administration
1431 Harbor Bay Parkway
Alameda, CA 94502

**This note is not applicable for letters which also address patient notification*

Finally, you should understand that there are many FDA requirements pertaining to mammography. This letter pertains only to findings of your inspection 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, Food and Drug Administration, P.O. Box 6057, Columbia, MD 21045-6057 (1-800-838-7715) or through the Internet at <http://www.fda.gov>.

If you have more specific questions about mammography facility requirements, or about the content of this letter, please feel free to contact Russell A. Campbell, Compliance Officer, at 510-337-6861.

Sincerely yours,



For

Roger L. Lowell
Acting District Director

Steven R. Gillenwater