



1990 MacArthur Blvd., Ste 300
Irvine, California 92612-2445
Telephone (949) 798-7600

WARNING LETTER

Certified Mail
Return Receipt Requested

March 11, 2002

Constantine Voyagis, M.D.
Medical Director
Office of Constantine M. Voyagis
436 North Roxbury Drive, Suite #102
Beverly Hills, CA 90210-5056

W/L Number: 30 - 02
Inspection ID: 1289670007
CFN: 20-29,624
FEI: 1000518953

Dear Dr. Voyagis:

We are writing to you because on January 30, 2002, your facility was inspected by a representative of the State of California acting on behalf of the U. S. Food and Drug Administration (FDA). This inspection revealed a serious regulatory problem involving the mammography at your facility.

Under the Mammography Quality Standards Act of 1992 (MQSA), 42 U.S.C. § 263b, 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 findings at your facility:

- Level 2: 1 of 5 random reports reviewed did not contain an acceptable assessment category. This is a **REPEAT** violation.

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 repeat Level 2 because it identifies a failure to meet a significant MQSA requirement in Title 21 Code of Federal Regulations section 900.12(c)(1)(iv).

The background on this situation involves a trend of MQSA noncompliance. On January 23, 2001, your facility was inspected (Inspection ID number: 1289670006) with a partial finding of "****5 of 5 random reports reviewed did not contain an assessment category***". On March 29, 2001, you wrote us a letter and stated "****Also beginning on this date assessment categories on the mammography reports will be implemented, according to the ACR Breast Imaging Reporting and Date System***." On April 17,

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2001, we telephoned you and explained that the written response was not acceptable. Further, it was explained what was required to bring your facility into compliance. We received your letter dated April 30, 2001; however, this correspondence failed to even mention the corrective action of bringing the assessment category problem to resolve. On May 14, 2001, we telephoned you again explaining that there was no response to the Level 2 problem. No further correspondence was received from you in this matter. For your 2002 MQSA inspection, the same problem has been detected again. As you should be aware, the MQSA regulations are quite specific on what the written report of the results of each mammography examination shall contain including final assessment of findings terminology.

- Level 2: Medical audit and outcome analysis was not performed annually. This is a violation of Title 21 Code of Federal Regulations section 900.12(f)(2).

- Level 2: Medical audit and outcome analysis was not done separately for each individual. This is a violation of Title 21 Code of Federal Regulations section 900.12(f)(1).

- Level 2: Medical audit and outcome analysis was not done for the facility as a whole. This is a violation of Title 21 Code of Federal Regulations section 900.12(f)(1).

- Level 3: The required personnel qualification documents were not available during the inspection. This is a **REPEAT** violation. This is a violation of Title 21 Code of Federal Regulations section 900.12(a)(4).

Because these conditions may be symptomatic of serious underlying problems that could compromise the quality of mammography at your facility, they represent serious violations 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 (DPC), 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.

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 receive 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;

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- equipment settings (including technique factors), raw test data, and calculated final results, where appropriate; and

- please provide 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).

Your response should also specifically address the repeat violations that were not corrected from the previous inspection and why they were not corrected prior to the inspection of January 30, 2002.

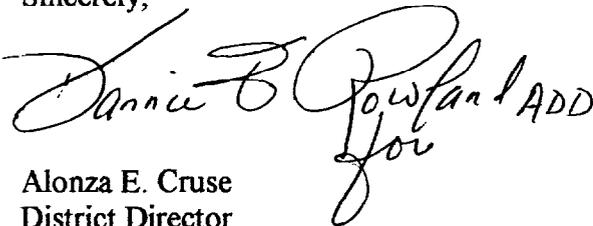
Please submit your response to:

Thomas L. Sawyer
Director, Compliance Branch
U.S. Food & Drug Administration
19900 MacArthur Blvd., Suite #300
Irvine, CA 92612-2445
Phone: (949) 798-7600

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 (telephone number: 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 Scott Goff (the Compliance Officer assigned to this case) at telephone number 949-798-7644.

Sincerely,

The signature is handwritten in black ink. It reads "Alonza E. Cruse" in a cursive style, followed by "District Director" in a simpler, more legible script. There are some additional scribbles and the word "ADD" written above the signature.

Alonza E. Cruse
District Director