



DEPARTMENT OF HEALTH & HUMAN SERVICES

HFI-35
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5/18/98

Public Health Service
Food and Drug Administration

Los Angeles District
19900 MacArthur Boulevard Suite 300
Irvine, California 92612-2445
Telephone (714) 798-7600

Certified Mail
Return Receipt Requested

WARNING LETTER

May 12, 1998

WL-30-8

Mr. James T. Lavan
General Manager
Lumisys, Inc.
1350 N. Kolb Road
Tucson, AZ 85715

Dear Mr. Lavan:

During an inspection of your firm conducted between March 31 to April 17, 1998, our investigator determined that the firm manufactures "MammoWorks" an interactive database designed for mammography practices and teleradiology devices. These products are devices as defined by Section 201(h) of the Federal Food, Drug, and Cosmetic Act (the Act).

Our inspection revealed that these devices are adulterated within the meaning of Section 501(h) of the Act, in that the methods used in, and the facilities and controls used for the design, manufacture, packaging, labeling, storage, installation, or servicing are not in conformance with the Good Manufacturing Practice (GMP) requirements set forth in the Quality System Regulation as prescribed by Title 21, Code of Federal Regulations, Part 820, as follows:

1. Failure to develop, conduct, control and monitor production processes to ensure that a device conforms to its specifications [21 CFR 820.70]. For example, your firm does not have sufficient evidence which provides a high degree of assurance that your production process and duplication equipment used to produce your software computer disks, for your published products will consistently produce products which meet their pre-determined specifications and quality attributes. Additionally, obsolete manufacturing procedures were disclosed in your disk duplication area.

2. Failure to control procedures for receiving, reviewing, and evaluating complaints [21 CFR 820.198]. For example, your firm does not have sufficient evidence which provides a high degree of assurance that the computer software used for monitoring customer complaints and performing other quality system activities will generate and maintain information to properly evaluate customer complaints and contain explanations for reasons not conducting complaint investigations.

3. Failure to establish, control and maintain written procedures for conducting planned and periodic quality audits to assure that the quality system is in compliance with the established quality system requirements and to determine the effectiveness of the quality system [21 CFR 820.22]. For example, your firm has no schedule for conducting planned quality audits and the evaluation of deficient matters are not documented to ensure that management having responsibility for deficient matters have reviewed the results of each quality audit.

4. Failure of management with executive responsibility to establish and implement policies and objectives for, and commitment to quality [21 CFR 820.20].

This letter is not intended to be an all-inclusive list of deficiencies at your facility. It is your responsibility to ensure adherence to each requirement of the Act and regulations. The specific violations noted in this letter and in the form FDA 483 issued at the closeout of the inspection may be symptomatic of serious underlying problems in your firm's manufacturing and quality assurance systems. You are responsible for investigating and determining the causes of the violation identified by the FDA. If the causes are determined to be systems problems, you must promptly initiate permanent corrective actions.

We acknowledge that you have submitted to this office a response concerning our investigator's observations noted on the form FDA 483. It appears that the response is adequate. A follow-up inspection will be required, however, to assure that your corrections are adequate.

Until it has been determined that your corrections are adequate, federal agencies are advised of the issuance of all Warning Letters about devices so that they may take this information into account when considering the award of contracts. Additionally, no pending submissions for premarket clearance for devices to which the GMP violations are reasonably related will be cleared. Also, no requests for Certificates to Foreign Governments for Export will be approved.

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You should take prompt action to correct deviations whether identified by our investigator or your internal systems audits. Failure to promptly correct these deviations 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, injunctions, and/or civil penalties.

Please notify this office in writing within 15 working days of receipt of this letter, of the anticipated date that your facility will be ready for reinspection.

Your response should be sent to:

Dannie E. Rowland
Compliance Officer
U.S. Food and Drug Administration
19900 MacArthur Blvd., Suite 300
Irvine, CA 92612-2445

Sincerely,


Elaine C. Messa
District Director

cc: State Department of Public Health
Environmental Health Services
Attn: Chief, Food and Drug Branch
601 North Seventh Street
PO Box 942732
Sacramento, CA 94234