



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration

g4647d

April 14, 2004

Chicago District
550 West Jackson Blvd., 15th Floor
Chicago, Illinois 60661
Telephone: 312-353-5863

WARNING LETTER
CHI-7-04

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Mr. Russell E. Froelich, President
Imaging Technology Division of
Computron Display Systems, Inc.
1697 W. Imperial Court
Mt. Prospect, IL 60056

Dear Mr. Froelich:

Our review of information collected during an inspection of your firm located at the above referenced address on October 14 and 15, 2003, revealed that your firm manufactures tables for C-arm Fluoroscopic applications. These products are devices as defined in Section 201(h) of the Federal Food, Drug, and Cosmetic Act (the Act) [21 U.S.C. 321(h)].

The above-stated inspection revealed that the devices are adulterated within the meaning of Section 501(h) of the Act [21 U.S.C 351(h)], in that the methods used in, or the facilities or controls used for their manufacturing, packing, storage, or installation are not in conformance with the Current Good Manufacturing Practice (CGMP) requirements of the Quality System Regulations for medical devices, as specified in Title 21, Code of Federal Regulation (CFR), Part 820. At the close of the inspection, you were issued a Form FDA 483, which lists a number of significant GMP inspectional observations including, but are not limited to, the following:

- Failure to establish and maintain a quality system that is appropriate for the specific medical devices being manufactured by your firm [21 CFR 820.5].
- Failure to establish quality system procedures and instructions for medical devices being manufactured by your firm [21 CFR 820.20 (e)].
- Failure of management with executive responsibility to establish its policy and objectives for, and commitment to, quality [21 CFR 820.20(a)].

- Failure to establish a quality plan which defines how the requirements for quality will be met [21 CFR 820.20(d)].
- Failure to establish and maintain procedures for implementing corrective and preventive actions [21 CFR 820.100(a)].
- Failure to establish and maintain a device master record for the CMC-Basic or the CMC-(H/L/T) C-arm fluoroscopic tables [21 CFR 820.181].
- Failure to establish and maintain procedures for design and design changes in order to ensure that specified design requirements are met [21 CFR 820.30 (a)&(i)].
- Failure to establish and maintain procedures for acceptance of incoming products [21 CFR 820.80 (b)].
- Failure to establish and maintain procedures for quality audits and conduct of such audits [21 CFR 820.22].
- Failure to establish and maintain procedures to control documents required under 21 CFR Part 820 [21 CFR 820.40].
- Failure to establish and maintain procedures for receiving, reviewing and evaluating complaints by a formally designated unit [21CFR 820.198].
- Failure to establish and maintain procedures for control of finished devices to ensure that only devices approved for release are distributed [21 CFR 820.160(a)].
- Failure to establish and maintain procedures to ensure that device history records for each lot, batch or unit are maintained to demonstrate that the device is manufactured in accordance with the device master record [21 CFR 820.184]. For example, the firm has a checklist called the CMC-Basic form used to ensure units manufactured conform to specification. CMC-Basic1 C-Arm Table was manufactured under job number [REDACTED]. The device history record was not maintained to demonstrate the device was manufactured in accordance with the device master record. The firm could not find the CMC-Basic Form for this unit manufactured under job number [REDACTED].
- Failure to establish procedures for identifying training needs and ensure that all personnel are trained to adequately perform their assigned responsibilities.

- Failure to establish training procedures to make employees aware of device defects which may occur from improper performance of their specific jobs [21 CFR 820.25(b)].

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 FDA 483 issued at the close of the inspection may be symptomatic of serious underlying problems in your firm's manufacturing and quality assurance systems.

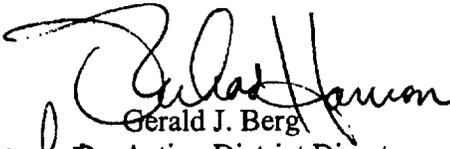
You are responsible for investigating and determining the causes of the violations identified by the FDA. You also must promptly initiate permanent corrective and preventative action on your quality system.

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.

You should take prompt action to correct these violations. Failure to promptly correct these violations 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, injunction, and/or civil penalties.

Please send your reply to the attention of Matthew J. Sienko, Compliance officer, at the above address. If you have questions regarding any issue in this letter, please contact Mr. Sienko at 312-596-4213.

Sincerely



Gerald J. Berg
Acting District Director