



mdlan

Chicago District
300 S. Riverside Plaza, Suite 550 South
Chicago, Illinois 60606
Telephone: 312-353-5863

October 29, 1998

WARNING LETTER
CHI-2-99

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Mr. Delmar F. Bloem, President
ICS Medical Corporation
2227 Hammond Drive
Schaumburg, Illinois 60173

Dear Mr. Bloem:

During an inspection of your firm from August 10 to August 14, 1998, Investigator Tamara Alicea determined that your firm is a manufacturer of diagnostic ophthalmic devices. The products that your firm manufactures are devices as defined by Section 201(h) of the Federal Food, Drug, and Cosmetic Act (the Act).

The above-stated inspection revealed that these devices are adulterated within the meaning of Section 501(h) of the Act, in that the methods used in, or the facilities or controls used for the manufacturing, packing, storage, or installation are not in conformance with the Quality System Regulation (QSR) for Medical Devices, as specified in Title 21, Code of Federal Regulations (CFR), Part 820, as follows:

1. Failure to develop, monitor, and control the software development processes to ensure that the software used in [REDACTED] [REDACTED] conforms to its original design or any approved changes.
2. Failure to review the software development process to identify actions needed to prevent the recurrence of software nonconformances.
3. Failure to establish procedures to ensure that the design requirements are appropriate and address the intended use of the device, including the needs of the user and patient. These procedures shall include a mechanism for addressing incomplete, ambiguous, or conflicting requirements.
4. Failure to establish procedures to ensure that the device design is correctly translated into production specifications.

5. Failure to include in your complaint procedures steps to ensure that:
 - (a) When no investigation is made, the complaint records include the reason no investigation was made, and the name of the individual responsible for making that decision.
 - (b) The complaint records include the dates and results of the investigation, corrective action taken, and any reply to the complainant.

This letter is not intended as 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 (enclosed) issued to Mr. Allen P. Davis, Controller, 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 violations identified by the FDA. If the causes are determined to be systems problems, you must promptly initiate permanent corrective actions.

We acknowledge your response to our Form FDA 483 dated August 19, 1998. We have reviewed the response and it appears to address our concerns.

Further verification will be required to assure that your corrections are adequate. FDA can accomplish this verification through a reinspection of your firm, or you may arrange for an independent consultant to certify to FDA that your firm is in compliance with the QSR.

Until these violations are corrected and FDA has documentation to establish that such corrections have been made, 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.

Page 3

Please notify this office in writing within 15 working days of receipt of this letter of your chosen method for verifying the corrections. Your response should be sent to Rachel Evans, Acting Compliance Officer, Food and Drug Administration, 300 South Riverside Plaza, Suite 550 South, Chicago, Illinois 60606.

Sincerely,

/s/
Raymond V. Mlecko
District Director

Enclosure