

March 4, 1997

WARNING LETTER
CHI-19-97Chicago District
300 S. Riverside Plaza, Suite 550 South
Chicago, Illinois 60606
Telephone: 312-353-5863CERTIFIED MAIL
RETURN RECEIPT REQUESTEDMr. Hiroshi Shiiba, CEO
Acoma X-Ray Industry Co., Ltd.
3-22-8 Hongo, Bunkyo-Ku
Tokyo, Japan

Dear Mr. Shiiba:

During an inspection of the Wheeling, IL facility of Acoma Medical Imaging, Inc. from December 31, 1996 to February 11, 1997, Investigator Chad Shmear determined that Acoma Medical Imaging manufactures X-ray tables and tube stands. X-ray tables and tube stands are devices as defined by Section 201(h) of the Federal Food, Drug, and Cosmetic Act (the Act).

The devices are adulterated under Section 501(h) in that the methods used in, or the facilities or controls used for manufacturing, packaging, storage, or installation are not in conformance with the Good Manufacturing Practice Regulations (GMP) for Medical Devices specified in Title 21, Code of Federal Regulations (CFR), Part 820:

1. Complaint files do not include documentation of a decision not to investigate the complaints, or complaint investigation documentation does not always include the control number of the device or the nature of the complaint. For example, complaint numbers 25, 28, 100 and 105 do not include a description of the complaint.
2. Device history records do not always include all documentation to ensure that the device is manufactured in accordance with the device master record. For example, records are not kept to document in-process product failures or device reprocessing.
3. Test records are not maintained for finished device testing (after complete assembly) of the mobile c-arm units.

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 pertinent regulations. The specific violations noted in this letter and in the enclosed FDA 483 issued to Mr. John Lee, President of Acoma Medical Imaging, Inc., 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 action.

We acknowledge that Mr. James Lambrecht, Program Director of Acoma Medical Imaging, Inc., has submitted a response, dated February 12, 1997, to the FDA 483. We have reviewed the response and find that it does not adequately address our concerns. We recognize Acoma Medical's commitment to make necessary correction, but the response lacks the specificity or detail to ensure that appropriate measures are being taken.

Until corrections are 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. Additionally, no pre-market submissions for devices to which the GMP deficiencies are reasonably related will be cleared until the violations have been corrected. Also, no requests for Certificates For Export Products will be approved until the violations related to the subject devices have been corrected.

You should take prompt action to correct these deficiencies and any manufacturing or quality systems deviations identified by your internal 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, injunction, and/or civil penalties.

Please notify this office in writing within 15 working days of receipt of this letter with a detailed response to the deficiencies identified in this letter. If your response cannot be completed within 15 working days, state the reason for the delay and the time within which the corrections will be completed.

Your correspondence should be sent to Stephen D. Eich, Compliance Officer.

Sincerely,

/s/

Raymond V. Mlecko
District Director

Enclosure

cc: Mr. John Lee
President, Acoma Medical Imaging, Inc.
150 Chaddick
Wheeling, IL 60090