



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration

919231

San Francisco District
1431 Harbor Bay Parkway
Alameda, CA 94502-7070
Telephone: 510/337-6700

VIA FEDEX

WARNING LETTER

Our Reference: 2916556

October 25, 2001

Gary F. Burbach
Chief Executive Officer
ADAC Laboratories
540 Alder Drive
Milpitas, CA 95035

Dear Mr. Burbach,

During an inspection of your firm located in Milpitas, California, on September 18 to 25, 2001, our investigator determined that your firm manufactures a gamma camera system and a radiation therapy planning system. Gamma camera systems and radiation therapy systems are medical 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, or the facilities or controls used in the manufacturing, packing, and storage are not in conformance with the current good manufacturing practice (cGMP) requirements for the Quality System Regulation, as specified in Title 21, Code of Federal Regulations (CFR), Part 820, as follows:

1. Failure to validate or, where appropriate, verify changes to the device before their implementation [21 CFR 820.30(i)]. Specifically our investigation disclosed the validation for the change made under ECO 88016 to the collision sensor of the Forte Gamma Camera System failed to have defined predetermined acceptance criteria and test methodology. Our investigation also found that the actual test results from the validation were not available for review. This change was not effective in triggering the rear collision sensor on all distributed Forte product. Your firm then initiated another design change under ECO 88194 to correct the same problem in all the distributed Forte product. No validation or verification activities were performed. Additionally, changes to the Forte, made under ECOs 88095 and 87668 failed to have defined predetermined acceptance criteria and test methodologies and the actual test results for the validation or verification activities were not available for review.
2. Failure to effectively implement your procedures for design changes [21 CFR 820.30(i)]. Specifically, your procedure, *Engineering Change Order Process at ADAC Milpitas*, SOP-10, requires a test protocol be developed for changes requiring

an ECO Test Report. Your firm failed to establish protocols for the design changes made under ECOs 88016, 88194, 88095 and 87668.

In addition, our investigation revealed that your devices as misbranded within the meaning of Section 502(t)(2) of the Act in that your establishment failed to submit information to the Food and Drug Administration as required by the Medical Device Reports of Corrections and Removals Regulation, as Specified in 21 CFR Part 806. Specifically, your firm failed to report to FDA within ten (10) days of initiating a correction and removal action for your Pinnacle³ Treatment Planning System due to a software defect that resulted in incorrect Source to Surface Distance (SSD) values.

We acknowledge receipt of your firm's letters dated September 26, October 10, and October 12, 2001 to the form FDA-483 that was issued to your firm on September 25, 2001. We also acknowledge the telephone conversation between John Allison, Vice President, RA & QA, ADAC Labs and FDA Compliance Officer Russell Campbell on October 18, 2001. After reviewing your responses, it is still not clear as to the methodology and criteria used by your firm in determining when a field action is reportable under the Corrections and Removals Regulation, especially as stated in your SOP-27-01. You have requested a meeting with San Francisco District's Recall and Emergency Coordinator to discuss the requirements regarding Recall and Corrections. We believe a meeting would be productive and beneficial in providing your company additional assistance in achieving compliance with the Medical Device Reports of Corrections and Removals Regulation.

In addition, our review of your responses to Form FDA 483 found that as part of your corrective actions for items 3 and 4, retraining was performed to existing procedures. The Quality System Regulation, 21 CFR 820.25(b), requires that you identify training needs and ensure that all personnel are trained adequately to perform their assigned duties. You should review your training program to determine if you are adequately identifying training needs, including periodic training updates to existing procedures if needed. Corrective actions should be initiated if your evaluation finds deficiencies.

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 regulation. The specific violations noted in this letter and in the Form FDA 483 issued at the conclusion 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 violation identified by the FDA. If the causes are determined to be systems problems, you must promptly initiate permanent corrective actions.

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

reasonable related will be cleared until the violations have been corrected. Also, no requests for Certificates of Exportability will be approved until the violation related to the subject device have been corrected.

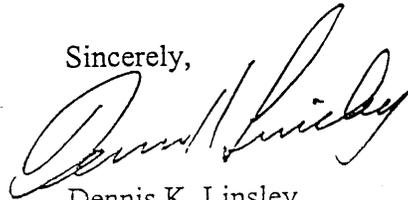
You should take prompt action to correct these deviations. Failure to promptly correct these deviations may result in regulatory action being initiated by the Food and Drug Administration without further notice. These actions include, but are not limited to seizure, injunction, and/or civil penalties.

In your responses you have requested a meeting with San Francisco District's Recall and Emergency Coordinator. Please contact Russell A. Campbell, Compliance Officer, at (510) 337-6861 to arrange this meeting. At this meeting, please also be prepared to provide information and documentation of the specific steps you have taken to correct the noted violations. If you have any questions relating to this letter please contact Compliance Officer, Russell A. Campbell.

Any written responses submitted prior to the meeting should be sent to:

Russell A. Campbell
Compliance Officer
Food and Drug Administration
1431 Harbor Bay Parkway
Alameda, CA 94502

Sincerely,

A handwritten signature in black ink, appearing to read "Dennis K. Linsley", written in a cursive style.

Dennis K. Linsley
District Director