



RB 8/4/00 m485

August 3, 2000

Certified/Return Receipt Requested**WARNING LETTER**

KAN #2000-022

Food and Drug Administration
Kansas City District Office
11630 West 80th Street
P.O. Box 15905
Lenexa, Kansas 66285-5905

Telephone: (913) 752-2100

Earl R. Refsland, President & CEO
Allied Healthcare Products, Inc.
1720 Sublette Avenue
St. Louis, MO 63110

Dear Mr. Refsland:

We are writing to you because during an inspection of your firm located at the above address by the Food and Drug Administration (FDA) on March 7 through June 13, 2000, our investigators collected information that revealed serious regulatory problems involving emergency ventilators and circumcision clamps which your firm manufactures and distributes.

Under the Federal Food, Drug, and Cosmetic Act (Act), these products are considered to be medical devices. The law requires that manufacturers of medical devices conform to the requirements of the Quality System Regulations. This helps protect the public health by ensuring that medical devices are safe and effective.

In legal terms, your devices are adulterated under the meaning of Section 501(h) of the Act, in that the methods used in, or the facilities or controls used for manufacturing, packing, storage, or installation are not in conformity with the applicable requirements of Section 520(f)(1)(A) and the Quality System Regulation, promulgated thereunder in Title 21, Code of Federal Regulations (CFR), Part 820, to include, but not limited to the following:

Failure of management with executive responsibility to ensure that an adequate and effective quality system is established and maintained. For example, management controls are deficient regarding the conduct of audits, organizational structure, implementation of a corrective and preventive action system, and production and process controls.

Failure to follow standard operating procedure (SOP) QCP 17.1, for quality audits to assure that your quality system is in compliance with established requirements and to determine the effectiveness of your quality system. For example, audits were not conducted in accordance with the 1999 schedule, and there were no documented audit plans for 4 of 14 areas scheduled for audit.

Failure of the organizational structure to provide the necessary personnel with the independence and authority needed to perform tasks affecting quality. For example, assessment and release of in-process and finished devices is performed solely by line employees who produce or have responsibility for producing the devices, without any independent assessment.

Failure to have Quality Plans in place covering such medical devices as emergency ventilators and regulators.

Failure of your SOP QCP 14.1 (Corrective and Preventive Action) to include the analyses of quality data sources, the conduct of investigations to determine root causes, the verification and/or validation of corrective actions, or the submission of information for management review.

Failure to follow through with the review, evaluation and/or the investigation of complaints against your medical device products. For example, 138 of 380 complaints for 1999 are still open, and all complaints for 2000 are still open. In addition all complaint records are not maintained as required, in that all requested complaint records could not be provided.

Failure to follow SOP QCP 10.1 (In-Process and Finished Product Quality Assurance.....) in that in-process, final inspection and release activities have been performed by production personnel rather than QA personnel.

Failure of your sampling plans to be based on a valid statistical rationale. For example, SOP QCP 10.1 was revised to change sampling from each work order to an "audit basis", yet this term is not defined. The SOP also changed the sampling plan AQL of [REDACTED] to [REDACTED] to accommodate a reduction in the QA employees.

This letter is not intended to be an all-inclusive list of deficiencies at this 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 may be symptomatic of serious underlying problems in your firm's manufacturing and quality assurance systems. You are responsible for investigating and determining the cause of the violations identified by the FDA. If the causes are determined to be systems problems, you must promptly initiate permanent corrective actions.

A response letter from Mr. Vernon Trimble, Quality Assurance Director, dated June 29, 2000, to the Form FDA 483 issued at the close of the current inspection was received and reviewed prior to the issuance of this letter. We find this letter incomplete in the following respects:

FDA 483 Item 1 - Our review of the "Quality Policy" submitted with the response finds it to be outdated when compared to the document that was collected during the inspection.

FDA 483 Item 2 - The conduct of Quality Audits is a key element of a Quality System. Your SOP QCP 17.1 states that QA management has the responsibility for planning and ensuring quality audits are conducted. It appears management has not met this commitment. The response discusses employee training in the conduct of audits. Our observation did not address improperly conducted audits, but rather that they were not conducted as scheduled.

FDA 483 Item 4 - The response states "The QA Regulatory Affairs Coordinator is not directly involved in scheduling or conducting quality assurance audits and we would not expect him to be knowledgeable about these matters". However, documents we collected during the inspection indicate the person in that position is an auditor.

FDA 483 Item 19 - Our assessment during the inspection indicates the Lead line employee performing the inspection and release activities had not been trained. The employee was also evaluating his or her own work products, without independent assessment by QA/QC. In addition to final inspection and release, the employee also performed each of the documented sequences for the referenced work orders.

FDA 483 Item 20 - The response states that the decision to sample and inspection on an "audit basis" and to revise the AQL sampling levels was not made because of the reduction in QA staffing. However, we have copies of selected pages from your SOP QCP 5.2 F4 which indicates the rationale for the change in sampling, inspection and final release is "RESTRUCTURING OF RESPONSIBILITIES", and for the AQL change "DUE TO REDUCTION IN QA STAFF".

FDA 483 Item 25 - The Quality System Regulation (QSR) does not allow for the use of initials or other markings in lieu of a signature.

You should know that this serious violation of the law may result in FDA taking regulatory action without further notice to you. These actions include, but are not limited to, seizing your product inventory, obtaining a court injunction against further marketing of your product, or assessing civil money penalties. Also, other Federal agencies are informed about the Warning Letters we issue, such as this one, so that they may consider this information when awarding government contracts.

It is necessary for you to take action on this matter now. Please let this office know in writing within fifteen (15) working days from the date you received this letter what steps you are taking, in addition to the June 29 letter, to correct the problems. We also ask that you explain how you plan to prevent these violations from happening again. If you need more time, let us know why and when you expect to complete your correction

Page 4 of 4
August 3, 2000
Allied Healthcare Products, Inc.

Finally, you should understand that there are many FDA requirements pertaining to the manufacture and marketing of medical devices. This letter only pertains to the issue of Quality System Regulations, and does not necessarily address other obligations you have under the law. You may obtain general information about all of FDA's requirements for manufacturers of medical devices by contacting our Division of Small Manufacturers Assistance at 1-800-638-2041 or through the Internet at <http://www.fda.gov>.

Your reply should be sent to Clarence R. Pendleton, Compliance Officer, at the above address.

Sincerely,

May Waluske
Charles W. Sedgwick *for*
District Director
Kansas City District