



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration
Los Angeles District *34478d*

19701 Fairchild
Irvine, California 92612-2506
Telephone (949) 608-2900

WARNING LETTER

January 6, 2004

Certified Mail
Return Receipt Requested

W/L 18-04

George C. Koutures
President
Ambco Electronics.
15052 Redhill Avenue, Suite D
Tustin, CA 992780

Dear Mr. Koutures:

During an inspection of your medical device firm located in Tustin, California, conducted from October 4 to October 10, 2003, our investigator determined that your firm manufactures automatic, semi-automatic, and manual audiometers. These audiometers are devices as defined by Section 201(h) of the Federal Food, Drug, and Cosmetic Act (the Act).

Our inspection disclosed that 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 manufacturing, packing, and storage are not in conformance with the Good Manufacturing Practice (GMP) requirements for the Quality System Regulation, as specified in Title 21, Code of Federal Regulations (CFR), Part 820, as follows:

1. Failure to establish, maintain and control a quality system that is appropriate for specific device manufactured [21 CFR 820.5 and 21 CFR 820.20]. For example,
 - Management with executive responsibility has not ensured that quality system requirements are effectively established and maintained.
 - Management with executive responsibility has not established a quality policy and objectives for, and commitment to, quality for specific devices.
 - No quality plan defining the quality practices, resources, and activities relevant to devices that are designed and manufactured has been established or implemented.
 - No quality system procedures and instructions have been established and implemented.

- No management representative has been appointed to ensure that quality system requirements are effectively established and maintained and to report on the performance of the quality system activities to management with executive responsibility.
 - No procedures for conducting management reviews have been established and no documented management reviews have been conducted.
2. Failure to establish and implement procedures for conducting quality audits and failure to conduct and document audits to verify that the quality system is effective in fulfilling the quality system objectives [21 CFR 820.22].
 3. Failure to establish procedures for implementing corrective and preventive action, specifically including the analysis of sources of quality data to identify existing and potential causes of nonconforming product or other quality problems [21 CFR 820.100].
 4. Failure to establish and implement procedures for receiving, reviewing, and evaluating complaints by a formally designated unit to ensure that all complaints are processed in a uniform and timely manner [21 CFR 820.198]. Additionally, no Medical Device Reporting procedures have been established.
 5. Failure to establish and implement procedures to control the design process of a device [21 CFR 820.30].
 6. Failure to establish and implement procedures for document control and to designate an individual(s) to review documents for adequacy and approval prior to issuance or when changes have been made to the documents [21 CFR 820.40].
 7. Failure to establish and implement procedures to ensure that all purchased or otherwise received product and services conform to specified requirements [21 CFR 820.50].
 8. Process validation activities and results have not been documented [21 CFR 820.75].
 9. Failure to establish and implement procedures for addressing the identification, documentation, evaluation, segregation, disposition and investigation of nonconforming product [21 CFR 820.90].

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 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 system. You are responsible for investigating and determining the causes of the violations identified by the Food and Drug Administration (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 reasonably related will be cleared until the violations have been corrected. Also, no requests for Certificates For Exportability will be approved until the violations related to the subject devices 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 FDA without further notice. These actions include, but are not limited to, seizure, injunction, and/or civil penalties.

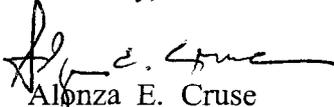
Please notify this office in writing within 15 working days of receipt of this letter, of the specific steps you to correct the noted violations, including an explanation of each step being taken to identify and make corrections to any underlying systems problems necessary to assure that similar violations will not recur. If corrective action cannot be completed within 15 working days, state the reason for the delay and the time within which the corrections will be completed.

If you have any questions relating to this letter please contact Senior Compliance Officer, Dannie E. Rowland at 949-798-7649. You may obtain general information about all of FDA's requirements for manufacturers of medical devices through the Internet at <http://www.fda.gov>.

Please submit your response to:

Acting Director, Compliance Branch
Food and Drug Administration
19701 Fairchild
Irvine, CA 92612-2445

Sincerely,



Alonza E. Cruse
District Director
Los Angeles District Office

Cc: State Department of Public Health
Environmental Health Services
Attn: Chief, Food and Drug Branch
601 North 7th Street, MS-35
Sacramento, CA 94234-7320