



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service  
Food and Drug Administration  
Nashville District Office  
297 Plus Park Blvd.  
Nashville, TN 37217

September 1, 1999

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9/1/99  
JBA

Mr. Philander P. Claxton, III  
President  
CardioTech International  
255 N. Washington Street  
Rockville, MD 20850-1708

**WARNING LETTER - 99-NSV-21**

Dear Mr. Claxton:

During an inspection of your firm located in Winchester, Tennessee on August 9-12, 1999, our investigators determined that your firm manufactures blood pressure monitors. Under the Federal Food, Drug, and Cosmetic Act (the Act), these products are considered to be medical devices because they are used to diagnose or treat a medical condition or to affect the structure or function of the body.

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, manufacture, packing, storage or installation are not in conformance with the Current Good Manufacturing Practice (CGMP) regulations of the Quality System Regulation, as specified in Title 21, Code of Federal Regulations (CFR), Part 820. The 1978 Good Manufacturing Practices (GMP) for Medical Device regulations were superseded on June 1, 1997, by the Quality System Regulation.

The inspection revealed deviations from 21 CFR Part 820 including failure to conduct internal audits, failure to have set parameters for in-process and finished product test results, failure to calibrate test equipment, inadequate complaint investigations and written complaint procedures, incomplete Medical Device Reporting procedures and failure to have an approved label as part of your device master record.

We acknowledge receipt of your response dated August 16, 1999 concerning our investigators observations in regard to internal quality audits noted on the form FDA 483 issued at the conclusion of the August 9-12, 1999 inspection. We have reviewed your response and we need a copy of your current quality audit procedures including the questionnaires you are using in conducting these audits.

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 FDA 483 issued at the closure 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.

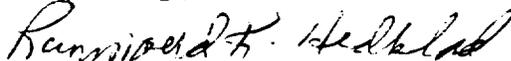
Federal agencies are advised of the issuance of all warning letters about devices so that they may take this information into account when considering the award of contracts. Additionally, no premarket submission for devices to which the GMP deficiencies are reasonably related will be cleared until the violations have been corrected. Also, no request for Certificates To Export 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 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 fifteen (15) working days of receipt of this letter of the specific steps you have taken to correct the noted violations, including an explanation of each step being taken to identify and make corrections to any underlying system problems necessary to assure that similar violations will not recur. If corrective action cannot be taken within fifteen (15) working days, state the reason for the delay and the time within which the corrections will be completed.

Your reply should be addressed to the attention of Joseph E. Hayes, Compliance Officer, Food and Drug Administration, 297 Plus Park Boulevard, Nashville, Tennessee 37217.

Sincerely,

  
Raymond K. Hedblad  
Director, Nashville District

RKH/kl

Enclosures:

FDA Form 483  
21 CFR Part 820

cc: Charles C. Myers  
Executive V.P. of Manufacturing  
CardioTech International  
511 Creasman Drive  
Winchester, TN 37398