



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

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Food and Drug Administration  
New Orleans District  
Nashville Branch  
297 Plus Park Blvd.  
Nashville, TN 37217

August 4, 2000

*Carroll*  
*8/4/00*  
*JEM*

CERTIFIED - RETURN RECEIPT REQUESTED

Phoenix Medical Products  
1535 Cold Springs Road  
Mountain City, TN 37683

Attn: Dennis H. Foley  
President and CEO

WARNING LETTER 00-NSV-20

Dear Mr. Foley:

During an inspection of your establishment located in Mountain City, Tennessee on June 26-29, 2000, our investigator determined that your establishment manufactures thoracentesis, paracentesis and pneumothorax devices. These are devices as defined by Section 201(h) of the Federal Food, Drug, and Cosmetic Act (the Act).

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 manufacturing, packing, storage, or installation are not in conformance with Current Good Manufacturing Practice (CGMP) requirements 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 The 1978 Good Manufacturing Practices (GMP) for Medical Device Regulations were superceded on June 1, 1997 by the Quality System Regulation.

The June 26 - 29, 2000 inspection revealed the following deviations:

1. Failure to validate any of [redacted] injection molding machines used to produce components of the thoracentesis devices and failure to document any validation of the [redacted] pouch sealer used to seal the sterile barrier packaging for those devices.

2. Failure to validate the [REDACTED] leak testing system, which consists of several separate but interactive pieces of equipment.
3. Failure to analyze and/or trend in-process and finished device acceptance criteria, including concessions granted to permit use of non-conforming material.
4. Failure to follow your internal audit procedures in that the person performing [REDACTED] audits was not independent of others having direct authority for the activities being audited, and your Q. A. manager did not assign personnel to perform the [REDACTED] audits.
5. Failure to document adequate training of the Q. C. inspectors performing receiving, in-process and final acceptance activities.

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 establishment'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 requests for Certificates to Foreign Governments 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.

Mr. Dennis H. Foley - Page 3

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 systems problems necessary to assure that similar violations will not recur. If corrective action cannot be completed within fifteen (15) working days, state the reason for the delay and the time within which the corrections will be completed.

We acknowledge receipt of your July 6, 2000, response to the FDA Form 483 issued to you on June 29, but do not consider it an adequate response to the deficiencies reported by our investigator. Your second response dated July 25, was received yesterday and will be reviewed promptly.

Any further response should be directed to the attention of Joseph E. Hayes, Compliance Officer, at the above letterhead address.

Sincerely,



Carl E. Draper, Director  
New Orleans District Office

CED/kl