



DEPARTMENT OF HEALTH AND HUMAN SERVICES

HFI-35

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Food and Drug Administration
Cincinnati District Office
Central Region
6751 Steger Drive
Cincinnati, OH 45237-3097
Telephone: (513) 679-2700
FAX: (513) 679-2773

May 14, 2001

**CERTIFIED MAIL
RETURN RECEIPT REQUESTED**

**WARNING LETTER
CIN-WL-01-7541-0**

William J. Koteles, President
Pemco, Inc.
5663 Brecksville Road
Independence, OH 44131

Dear Mr. Koteles:

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 April 17-19, 2001, our Investigator collected information that revealed serious regulatory problems involving heart pumps which are manufactured and distributed by your firm.

Under the Federal Food, Drug, and Cosmetic Act (the Act), heart pumps are considered to be medical devices. The law requires that manufacturers of medical devices conform with the requirements of the Quality System Regulation (QSR) as specified in Title 21, Code of Federal Regulations (CFR), Part 820.

The inspection revealed that your 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 the manufacture, processing, packing, storage or distribution are not in conformance with the requirements of the Quality System Regulation as follows:

Failure to have a corrective and preventative action plan. Procedures addressing documentation of corrective and preventive action activities have not been established, defined, documented and implemented.

Failure to have an adequate complaint handling program. Your firm's complaint records are incomplete. Of twenty-five complaint forms reviewed by the FDA Investigator, nine did not have a review by signature/date, seven were missing the MDR and safety assessment, two were signed by the same person who did the investigation, and three did not indicate if the product was returned to your firm. In addition, service requests are not adequately reviewed to identify

systematic problems and problems that may qualify as complaints. For example, of [REDACTED] service records on heart pumps your firm received since March 1997 none included documentation that any inspections/investigations were conducted to determine the cause of the problem with the device. In some cases there was no documentation that the problem with the device was corrected.

Failure to maintain adequate record keeping procedures to demonstrate that the device is manufactured in accordance with the device master record and the Quality Systems Regulation. Device history records are incomplete. Out of thirty-one device history records reviewed by the FDA Investigator, five had no final review signature/date and one had no documentation that all finished product testing was completed e.g., the "current leakage test" which is conducted prior to the release of the heart pump for distribution.

This letter is not intended to be an all-inclusive list of deficiencies at your facility. It is your responsibility to assure adherence to each requirement of the Act and regulations. The specific violations noted in this letter and in the FDA 483 issued at the closeout of the FDA 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.

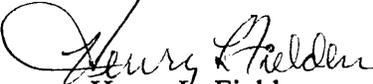
Federal agencies are advised of the issuance of all Warning Letters about drugs and devices so that they may take this information into account when considering the award of contracts. Also, no requests for Certificates for Products for Export will be approved until the violations related to the subject 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. Possible 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 prevent the recurrence of similar violations. 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.

Your response to this Warning Letter should be sent to Evelyn D. Forney, Compliance Officer, Food and Drug Administration, 6751 Steger Drive, Cincinnati, Ohio 45237-3097.

Sincerely,


Henry L. Fielden
District Director
Cincinnati District