



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

D1044 B HFI-30

1/10/98

Food & Drug Administration
1141 Central Parkway
Cincinnati, OH 45202

• January 6, 1998

WARNING LETTER
CIN-WL-98-125

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Lawrence E. Madson, Jr.
Thermo-Electric Co., Inc.
455 Route 30
Imperial, PA 15126

Dear Mr. Madson:

The Food and Drug Administration (FDA) conducted an inspection on November 25 & 26 & December 1 & 4, 1997 of your 1948 Columbus Road, Cleveland, Ohio location which manufactures Dickson Paraffin Baths. It is a device as defined by Section 201(h) of the Federal Food, Drug and Cosmetic Act (the Act).

Our inspection found this device is 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) for Medical Devices Regulation, as specified in Title 21, Code of Federal Regulations (CFR), Part 820.

The following deviations from Device GMP's were documented:

- o Failure to conduct planned and periodic audits of the quality and production system in accordance with written procedures.
- o Failure to document that the Paraffin Baths have been tested to specifications prior to release for distribution.
- o Failure to establish written procedures for the incoming inspection of components.
- o Failure to document the incoming physical inspections of components and to receive an acceptable certificate of analysis with the testing performed, the testing equipment used and the standard to which the component is tested.
- o Failure to maintain adequate Device Master Records which contain packaging or labeling specifications and approved signed assembly procedures, schematics and component specifications.

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- o Failure to establish procedures for reworking of devices failing final testing and to maintain documentation of devices that are reworked.
- o Failure to establish procedures covering documenting, investigating and reporting MDR complaints.
- o Failure to document the in-house calibration of testing thermometers.

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 closeout 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.

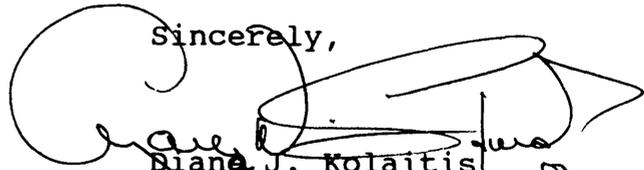
Federal agencies are advised of the issuance of all Warning Letters about devices so that they may take this into account when considering the award of contracts. Also, no requests for Certificates For Products For Export will be approved until the violations related to the subject devices have been 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. These actions include, but are not limited to, seizure, injunction, and/or civil penalties.

Please notify this office within 15 days of receipt of this letter, of the specific steps you will be taking to comply with our request.

Your response should be sent to Lawrence E. Boyd, Compliance Officer, Food and Drug Administration, 1141 Central Parkway, Cincinnati, Ohio 45202.

Sincerely,



Diana J. Kolaitis
Acting District Director
Cincinnati District

LEB/clc