



DEPARTMENT OF HEALTH & HUMAN SERVICES

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6/10/98
Public Health Service
Food and Drug Administration
CINCINNATI DISTRICT OFFICE

1141 Central Parkway
Cincinnati, OH 45202-1097

June 4, 1998

WARNING LETTER
CIN-WL-98-298

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Mr. Joseph E. Grimm, President
Grimm Scientific Industries
P.O. Box 2143
Marietta, Ohio 45750

Dear Mr. Grimm:

The Food and Drug Administration (FDA) conducted an inspection on May 5 and 6, 1998 of your paraffin bath manufacturing facility. Paratherm Paraffin Baths are devices as defined by Section 201(h) of the Federal Food, Drug and Cosmetics Act (the Act). The investigator found deviations from the Quality System Regulations, Good Manufacturing Practice (GMP) for Medical Devices as listed in Part 820 of Title 21 Code of Federal Regulations (CFR). This causes the Paratherm Paraffin Baths to be 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 Quality System, Part 820.

The following deviation from the Device Quality System Regulations were documented:

- ▶ Failure to conduct planned and periodic audits of the quality and production system.
- ▶ Failure to establish and implement an adequate complaint handling system and to determine Medical Device Reportability of events.
- ▶ Failure to establish and implement an adequate failure investigation program.
- ▶ Failure to ensure that the finished devices meets all specifications prior to distribution.
- ▶ Failure to validate changes to manufacturing process specifications.
- ▶ Failure to establish, maintain and implement procedures for implementing corrective and preventive action.

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 action.

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.

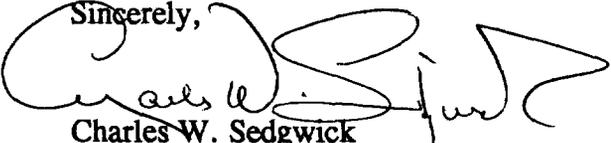
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You should take prompt action to correct these deviations. Failure to promptly correct these deviations may result in regulatory action being initiated by the Food and Drug Administration without further notice. These actions include, but are not limited 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,

Charles W. Sedgwick
Acting District Director
Cincinnati District

LEB/jp