



DEPARTMENT OF HEALTH AND HUMAN SERVICES

HFI-85

Public Health Service

M2274h

Food and Drug Administration  
Cincinnati District Office  
Central Region  
6751 Steger Drive  
Cincinnati, OH 45237-3097  
Telephone: (513) 679-2700  
FAX: (513) 679-2771

December 24, 1998

**WARNING LETTER**  
**CIN-WL-99-68**

**CERTIFIED MAIL**  
**RETURN RECEIPT REQUESTED**

Alexander Dybbs, Ph.D., President  
Sonogage Inc.  
26650 Renaissance Parkway  
Cleveland, OH 44128

Dear Mr. Dybbs:

We are writing to you because during an inspection of your firm at the above address by the Food and Drug Administration (FDA) on November 23, 1998, our Investigator collected information that revealed serious regulatory problems involving the Corneo Gage Ultrasonic Pachometer which is manufactured and distributed by your firm.

Under the Federal Food, Drug and Cosmetic Act (the Act), this product is considered to be a medical device. 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 the 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 the manufacture, processing, packing, storage or distribution are not in conformance with the requirements of the Quality System Regulation as follows:

Failure to establish and document a formal quality assurance program. Planned and periodic audits of the quality program in accordance with written procedures are not done. Your firm has never conducted an internal audit.

Failure to establish, maintain and implement procedures for implementing corrective and preventative action. For example, a complaint/repair file is maintained that is supposed to indicate the reason for the failure of a device and how the problem was corrected. However, there is no procedure for how the corrections and preventive actions are handled and who is responsible for handling corrective and preventive actions. Furthermore, corrective and preventative actions taken are not always documented. For example, there were complaint/repair records that indicated that the failure of the device was a result of a manufacturing error and there was no documentation of an investigation of the reason for the failure.

Failure to maintain records that provide evidence that the components for your device have gone through defined acceptance activities. There is no documentation of incoming acceptance of the PC boards or probes used to assemble the Corneo Gage Ultrasonic Pachometer. The probes and PC boards are the main two components of the Pachometer. The components are inspected and tested in accordance to written procedures and specifications but none of the testing is documented. Also, failure of components to meet specification are not recorded.

Failure to establish and maintain written design control procedures to ensure that specified design requirements are met, for example, the firm does not have a design change procedure.

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 problem you must promptly initiate permanent corrective actions.

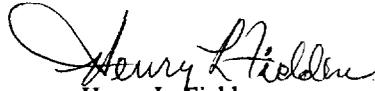
Federal agencies are advised of the issuance of all Warning Letters about drugs and devices so that they may take this information into account when considering the award of contracts. Also, no requests for Certificates for Products for Export will be approved until the violations related to the subject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

Sincerely,



Henry L. Fielden  
Acting District Director  
Cincinnati, Ohio

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