



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Atlanta District Office

3126d

60 8th Street, N.E.
Atlanta, Georgia 30309

February 5, 2002

VIA FEDERAL EXPRESS

Dr. Roy W. Sweat
President
Sweat Chiropractic Clinic
3274 Buckeye Road NE
Atlanta, Georgia 30341

WARNING LETTER
(02-ATL-19)

Dear Dr/Sweat:

An inspection of your facility was conducted between December 11, 2001, and January 10, 2002, by Investigator Patricia F. Hudson. Our investigator found that in addition to being the specifications developer, you continue to perform quality assurance activities associated with your Atlas Orthogonal Adjusting Instrument. This product is a device as defined by Section 201(h) of the Federal Food, Drug, and Cosmetic Act (the Act).

Our investigator documented several significant deviations from the Quality System Regulation (QSR) as set forth in Title 21 of the Code of Federal Regulations (21 CFR), Part 820. These deviations cause the devices you distribute to be adulterated within the meaning of Section 501(h) of the Act. These deviations from the QSR include:

You have failed to establish and maintain procedures for finished device acceptance to ensure that each device meets acceptance criteria prior to release for distribution. No formal approved procedures have been established which address the final product inspection to be performed on each device.

You have failed to ensure that all inspection, measuring and test equipment is suitable for its intended purpose and is capable of producing valid results. You failed to establish and maintain procedures to ensure that this equipment is routinely calibrated and maintained. No such procedures had been established for the [REDACTED] Digital [REDACTED] Gauge used during final product inspection. There were no records of calibration available for this instrument until the gauge was calibrated after the inspection was initiated.

You have failed to establish and maintain procedures for the identification, documentation, validation or where appropriate verification, review, and approval of design changes before their implementation. Significant changes were made in the instrument by a previous contract manufacturer that were not reviewed or evaluated by you. You stated that you were aware of the changes but had not authorized them. One such change resulted in electrical problems that led to a product recall. You also provided a listing of recent changes made in your device by another contract manufacturer that you had not adequately assessed.

You have failed to adequately review and evaluate incoming complaints concerning your device. You have failed to establish any procedures to utilize in the determination of whether complaints should be reported to FDA under the Medical Device Reporting requirement in 21 CFR Part 803. Complaints were received through your contract manufacturer concerning two such complaints (#0000000024 and #0000000081) of malfunctioning devices involving hazards to patient safety. One complaint was even identified as an MDR event by the manufacturer. Neither complaint was forwarded to FDA.

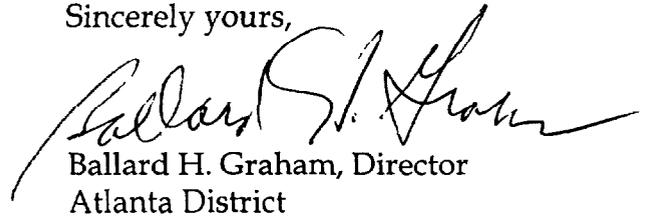
This letter is not intended to be an all-inclusive list of deficiencies at your facility. It is your responsibility to ensure adherence to each requirement of the Act and regulations. At the close of the inspection, the FDA 483 (Inspectional Observations) was issued to and discussed with you. The specific violations noted in this letter and in the FDA 483 are symptomatic of underlying problems in your firm's 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.

We acknowledge that corrections were promised to the investigator's observations during the inspection. No written response has been received to date. Of particular concern is that several of these observations were repeat violations that were discussed with you during our previous inspection conducted in 1996. These repeat deviations include failure to establish acceptance criteria, lack of control over changes in the device, and an inadequate complaint handling system. A copy of the FDA 483 issued at the conclusion of that inspection is enclosed.

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. You should take prompt action to correct these deviations. Failure to promptly correct these deviations may result in regulatory actions being initiated by the FDA without further notice. These actions include, but are not limited to, seizure, injunction, and/or civil penalties.

Please notify this office in writing within fifteen (15) 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 15 working days, state the reason for the delay and the time within which the corrections will be completed. Your response to this letter should be sent to Philip S. Campbell, Compliance Officer, at the address noted in the letterhead.

Sincerely yours,



Ballard H. Graham, Director
Atlanta District

Enclosure