



91743d

FEDERAL EXPRESS

Food and Drug Administration
555 Winderley Pl., Ste. 200
Maitland, Fl 32751

WARNING LETTER

FLA-01-83

September 13, 2001

Stuart K. Baker, Vice President
Clearwater Colon Hydrotherapy
4451-A South Pine Avenue
Ocala, Florida 34480

Dear Mr. Baker:

During an inspection of your establishment located in Ocala, Florida on August 8, 2001, FDA Investigator Ronald T. Weber determined that your establishment is a manufacturer and distributor of colonic irrigators, which are medical devices as defined by Section 201(h) of the Federal Food, Drug, and Cosmetic Act (the Act).

Under the Federal Food, Drug, and Cosmetic Act (the Act), the products that your firm manufactures are considered to be medical devices that are used to diagnose or treat medical conditions or to affect the structure or function of the body. The law requires that manufacturers conform to the Quality System (QS) Regulation for medical devices, as specified in Title 21, Code of Federal Regulations (CFR), Part 820.

The above-stated inspection revealed that the 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 manufacturing, packing, storage, or installation are not in conformance with the Quality System Regulation for medical devices, as specified in Title 21, Code of Federal Regulations (CFR), Part 820, as follows:

1. Your firm's management with executive responsibility has not ensured that an adequate and effective quality system has been fully implemented and maintained at all levels of the organization, as required by 21 CFR 820.20. For example, there is no established Quality System except for production and testing procedures (FDA 483, Item #1).
2. Your firm failed to establish and maintain procedures for conducting quality audits, as required by 21 CFR 820.22. For example, there are no written procedures for conducting internal quality audits and none have been performed (FDA 483, Item #2).

3. Your firm failed to establish and maintain procedures to control the design process, as required by 21 CFR 820.30(a). For example, established design control procedures were not followed when design changes were made to your two devices within the last year (FDA 483, Item #3).
4. Your firm failed to establish and maintain corrective and preventive action procedures addressing the cause of nonconformities related to product, process and the quality system, as required by 21 CFR 820.100(a)(2). For example, there are no written procedures to conduct failure investigations (FDA 483, Item #4).
5. Your firm failed to document corrective and preventive actions, as required by 21 CFR 820.100(b). For example, failure investigations reportedly accomplished were not documented (FDA 483, Item #5).
6. Your firm failed to establish and maintain procedures to receive, review and evaluate reported complaints, as required by 21 CFR 820.198(a). For example, there are no complaint handling procedures (FDA 483, Item #6).
7. Your firm failed to review and approve master records required by your own document control procedures, as required by 21 CFR 820.40(a). For example, device master records (DMR) are not signed and dated as having been approved by a designated individual (FDA 483, Item #7).

The specific violations noted in this letter and in the Inspectional Observations (FDA 483) issued to you 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.

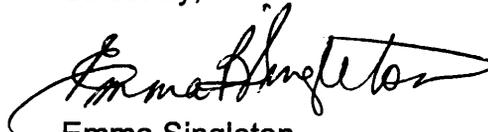
Federal agencies are advised of the issuance of all Warning Letters about devices so that they may take this information into account when considering the award of contracts. Additionally, no premarket submissions for Class III devices to which QS regulation deficiencies are reasonably related will be cleared until the violations have been corrected. 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 in writing within fifteen (15) working days of receipt of this letter, of any steps you may have taken to correct the noted violations, including (1) the time frames within which the corrections will be completed if different from those annotated on the FDA 483, (2) any documentation indicating the corrections have been achieved, and (3) 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.

Your response should be sent to Timothy J. Couzins, Compliance Officer, Food and Drug Administration, 555 Winderley Place, Suite 200, Maitland, Florida 32751, (407) 475-4728.

Sincerely,

A handwritten signature in black ink, appearing to read "Emma Singleton". The signature is fluid and cursive, with a long horizontal stroke extending to the right.

Emma Singleton
Director, Florida District