



CERTIFIED MAIL
RETURN RECEIPT REQUESTED

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

WARNING LETTER

FLA-04-19

March 2, 2004

William E. O'Neal, President
Chambermaid Products, Inc.
3738 D Road
Loxahatchee, Florida 33470

Dear Mr. O'Neal:

During an inspection of your establishment located in Loxahatchee, Florida on January 28, 2004, FDA Investigator Sonia M. Monges determined that your establishment is a specification developer of a tabletop, steam sterilizer, which is defined as a medical device under section 201(h) of the Federal Food, Drug, and Cosmetic Act (the Act).

The investigator documented significant violations from the Quality System (QS) Regulation, Title 21, Code of Federal Regulations (CFR), Part 820, and the Medical Device Reporting regulations, Title 21, CFR, Part 803. These violations cause the device you manufacture to be adulterated within the meaning of Section 501(h) [21 U.S.C. §351(h)] and misbranded within the meaning of Section 502(t)(2) [21 U.S.C. §352(t)(2)] of the Act.

The investigator noted the following violations of the QS regulation:

1. Your firm failed to establish and maintain Quality System procedures as required by 21 CFR 820.20(e). There are no established procedures covering corrective and preventive action (CAPA), purchasing controls, nonconforming product, production/process controls and complaint handling (FDA 483, Item #1).
2. Your firm failed to establish and maintain procedures for implementing corrective and preventive action as required by 21 CFR 820.100(a). There are no procedures addressing CAPA activities as evidenced by the lack of complaint handling procedures and procedures addressing the identification, documentation, evaluation, segregation, and disposition of non-conforming product (FDA 483, Item #2).

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", with a large, sweeping flourish extending to the right.

Emma Singleton
Director, Florida District