



DEPARTMENT OF HEALTH AND HUMAN SERVICES

HFI-35
Food and Drug Administration
Atlanta District Office

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

June 28, 1999

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Lauren Andersen, President & CEO
Andersen Products, Inc.
3202 Caroline Drive
Haw River, NC 27258

Warning Letter
(99-ATL-22)

Dear Ms. Andersen:

During an inspection of your firm located in Haw River, North Carolina, on April 19 - 29, 1999, our investigator determined that your firm still manufactures and distributes sterile medical devices including nasogastric tubes, sump pumps/tubes, intestinal tubes and wound drainage tubes. The investigator also documented serious deviations from FDA's Good Manufacturing Practice/Quality System Regulation, as specified in Title 21 Code of Federal Regulations (21 CFR), Part 820. These deviations cause your devices to be adulterated within the meaning of Section 501(h) of the Federal Food, Drug and Cosmetic Act (the Act), as follows:

1. Failure to validate the testing equipment used to test the filter integrity of the *Shirley Wound Drain's* vent filters.
2. Validation of the bag sealing process using the Packaging Aids Impulse Sealer is incomplete in that no performance testing was conducted to assure that the sealer can consistently produce an acceptable seal over a period of time. This process is used to seal the primary and secondary bags of sterile devices such as the *Shirley Wound Drain*.
3. Validation of the laboratory autoclave [REDACTED] is incomplete in that no loading pattern(s) was defined for the full chamber challenge. It is essential that a product-loading pattern be established to define the maximum/minimum load density requirements for an established (validated) cycle. In addition, no yearly revalidation studies have been conducted on this instrument since 1995, even though the validation protocol requires them. This autoclave is used in the preparation of sterile microbiological media used in the incubation of biological indicators (BI). The results obtained with these BIs are essential in determining whether the sterilization of routine production loads of medical devices is successful.

4. Failure to investigate complaints involving the possible failure of a device to meet any of its specifications, and to document the results of these investigations. Specifically, there were five product complaints (dated 4/5/93, 11/4/93, 2/2/94, 7/29/94, and 1/17/97) involving possible failure to meet specifications which were not investigated. Moreover, current complaint handling procedures do not define how complaints are to be evaluated and investigated (when necessary), and the actions to be taken for nonconforming products as required under an adequate Corrective and Preventive Action Program.
5. The validation of the Sterijet sterilization process is incomplete in that you have failed to generate sufficient data to correlate the ethylene oxide (EO) lethality kinetics between the EOGas Chamber (utilized in sub-lethal cycles) and the Sterijet Aeration Rooms (utilized in half/full cycle EO sterilization validation studies). In addition, there were several instances (PQR 9512 and PQR 9507) where the final report lacks conclusionary findings.
6. Failure to document any periodic maintenance and humidity sensor calibrations for the Herrtronic Herrmidifier (humidifier). This instrument is used as backup system to the primary humidification system in the Pre-conditioned Manufacturing Area.
7. Failure to establish procedures for the identification, documentation, validation or where appropriate verification, review, and approval of design changes to existing devices.
8. Failure to monitor/test the microbiological and chemical quality of the deionized water used in the formulation of microbiological media.

Additionally, the above-stated inspection revealed that your devices are misbranded within the meaning of Section 502(t)(2) of the Act, in that your firm failed to submit information to the FDA as required by the Medical Device Reporting (MDR) regulation, as specified in 21 CFR Part 803. Specifically, you failed to submit an MDR serious injury report to FDA after receiving information on 4/18/97, which reasonably suggested that one of your commercially distributed devices (*AN10.11-Nasogastric Tube, lot # 961272*) had caused or contributed to a serious injury. A serious injury MDR report is required for this incident.

You have also failed to submit an MDR malfunction report to FDA after receiving information on 4/5/93, which reasonably suggested that two of your commercially distributed devices (*AN21-Miller-Abbott Type Intestinal Tube, lot #925533*) had malfunctioned and could cause or contribute to a serious injury if the malfunction recurred. An MDR malfunction report is required for this incident.

The MDR reports for those events described above should be submitted to the address below. Please be advised that when you submit retrospective reports you should include a cover letter describing the reports as retrospective submissions and the reason for the submission.

Division of Surveillance Systems (HFZ-533)
Office of Surveillance and Biometrics
Food and Drug Administration

1350 Piccard Drive
Rockville, Maryland 20850

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 (copy enclosed) 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 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 devices to which the GMP 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 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) 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 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 fifteen working days, state the reason for the delay and the time within which the corrections will be completed.

We acknowledge receipt of a letter from Stephanie K. Wissinger, Acting Director of Quality Assurance, dated May 19, 1999, and addressed to Philip Campbell. That letter was in response to the Form FDA 483 issued to Ms. Wissinger on April 29, 1999. We have reviewed the proposed corrective actions described in her letter, and they appear to adequately address the violations noted. You can refer to that letter in your answer to this one.

Your response should be sent to Carlos A. Bonnin, Compliance Officer, Food and Drug Administration, 60 Eighth Street, N.E., Atlanta, Georgia 30309.

Sincerely,

A handwritten signature in black ink, appearing to read "Ballard H. Graham". The signature is fluid and cursive, with a long horizontal flourish extending to the right.

Ballard H. Graham, Director
Atlanta District

Enclosure

cc: Stephanie K. Wissinger, Director of Marketing/Quality Assurance
Andersen Products, Inc.
3202 Caroline Drive
Haw River, NC 27258