



DEPARTMENT OF HEALTH AND HUMAN SERVICES

11263511
Food and Drug Administration
Atlanta District Office
HUI-35 (initials)

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

February 26, 1999

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Theo Fritz
Chairman of the Board
Berchtold, GmbH
Tuttlingen, Germany
Ludwigstaler Strasse 27
Postfach 40 47
D-78505

WARNING LETTER

Dear Mr. Fritz:

An inspection of your firm located in Charleston, South Carolina, was conducted on January 19-27, 1999. Our investigators found that you were manufacturing surgical and patient examination lights. These products are devices as defined by Section 201(h) of the Federal Food, Drug, and Cosmetic Act (the Act).

Our investigators 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 manufacture and distribute to be adulterated within the meaning of Section 501(h) of the Act.

You have failed to establish and maintain a quality system appropriate for the medical devices that you manufacture. Management with executive responsibility had not established a policy and objectives for, and commitment to, quality. A management representative had not been identified to ensure that the quality policy was understood, implemented, and maintained at all levels of your organization. Key personnel at your facility were unaware of a quality policy. You have not established a quality plan which defines the quality practices, resources, and activities relevant to your devices. You have failed to establish a procedure for management with executive responsibility to review the suitability and effectiveness of the quality system at defined intervals. No management reviews were conducted in 1997 or 1998. You have also failed to maintain a quality system record as required.

You have failed to establish appropriate procedures for quality audits to assure that the quality system is in compliance with the established quality system requirements and to determine the effectiveness of the quality system. The current procedure for conducting audits failed to include an established frequency for the audits. The procedure failed to assign responsibility for conducting the audit. There was no requirement for a reaudit of deficient areas, the preparation of a final report with the audit results, or the review by management having responsibility for the areas being audited. Although an internal quality audit was conducted in September 1998, we would question the overall effectiveness of your audit program based on the nature of the QSR deviations noted during our current inspection.

You have failed to establish and implement appropriate complaint handling procedures. The complaint procedure "GMP006 CUSTOMER COMPLAINT" was deficient in that it failed to assure that complaints are processed in a uniform and timely manner, complaints are evaluated for Medical Device Reporting requirements, and investigations are conducted as appropriate. Your firm has failed to formally designate a responsible unit for receiving, reviewing, and evaluating complaints. There was no procedure available which addressed the Medical Device Reporting requirements described in 21 CFR Part 803.

Our investigators reviewed all complaints received since 1998 and the vast majority had no failure investigation and no documentation of the reason for not conducting an investigation. When no investigation is made, you must maintain a record that includes the reason for that decision and the name of the individual responsible for the decision not to investigate.

Our review of your complaints revealed that there were no servicing procedures which addressed service visits conducted as a result of a complaint. There was no assurance that these serviced devices met their established specifications after servicing. These reports did not always contain the actual service performed and any test and inspection data associated with the service visit.

You have failed to establish and maintain procedures for implementing corrective and preventive action. These procedures should include requirements for analyzing such sources of quality data as quality audit reports, service records, and complaints. The problems noted above would raise a question as to whether all significant sources of quality data are being analyzed to identify existing and potential causes for nonconforming product or other quality problems.

You have failed to establish and maintain device master records for any of the devices currently manufactured. Your Charleston employees were not able to locate a formal device master record or any document that referenced the location of the device master record contents. This is not only required under the QSR but also in your procedure "GMP025 MASTER DEVICE RECORD PROCEDURE."

You have failed to establish and maintain procedures to ensure that all purchased or otherwise received products and services conform to specified requirements. You have not evaluated your suppliers on the basis of their ability to meet specified requirements. Although there was

a procedure on file entitled "GMP007 QUALITY AUDIT WORKSHEET" for this purpose, no quality survey had been completed for any of your suppliers. You have not established a record of acceptable suppliers.

You had failed to establish formal approved component specifications or acceptance/rejection criteria for components received at this facility. You had not established which components would be subjected to physical inspection or accepted based on certificates of conformance.

No procedure was available which addressed the inspection level for the incoming inspection of components. The sampling of incoming components was not performed in accordance with an established sampling plan based on a valid statistical rationale. The incoming component inspection records (packing lists) reviewed did not clearly indicate the acceptance and/or rejection of these components.

The change control procedure on file did not provide for control over your firm's quality system procedures including those for acceptance, manufacturing, and finished product testing procedures for your devices. No change control documents were available for the numerous changes made to your operating procedures manual. This failure to have appropriate controls in place could explain the three uncontrolled manuals noted in the production area during the course of the inspection.

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 Inspectional Observations (FDA 483) was issued to and discussed with William R. Apperson, President. A copy of the FDA 483 is enclosed for your review. The specific violations noted in this letter and in the FDA 483 are symptomatic of serious 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.

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.

We are in receipt of a February 9, 1999, response from Mr. Apperson to the FDA 483. The response acknowledges the serious nature of the observations but does not include a definitive plan for addressing the deviations noted. You may reference the February letter in your Warning Letter response, if you feel that it adequately addresses any of the issues raised in this letter. Your response should be sent to Philip S. Campbell, Compliance Officer, at the address noted in the letterhead.

Sincerely yours,

for 
Ballard H. Graham, Director
Atlanta District

Enclosure

cc: William R. Apperson
Berchtold Corporation
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Charleston, SC 29419