



DEPARTMENT OF HEALTH & HUMAN SERVICES

HF1-35  
Public Health Service  
Food and Drug Administration  
m3045n

Dallas District  
3310 Live Oak Street  
Dallas, Texas 75204-6191

September 20, 1999

Ref: 99-DAL-WL-27

**WARNING LETTER**

**VIA FACSIMILE  
AND FEDERAL EXPRESS**

Mr. Michael M. Barbour, President  
Henley Healthcare, Inc.  
120 Industrial Blvd.  
Sugar Land, Texas 77478

Dear Mr. Barbour:

During an inspection of your firm located in Sugar Land, Texas, on February 24 – March 19, 1999, our investigator determined that your firm manufactures Fluidotherapy units and traction machines. These products are devices as defined by Section 201(h) of the Federal Food, Drug, and Cosmetic Act (the Act).

The inspection revealed the Fluidotherapy units are misbranded within the meaning of Section 502(t)(2) of the Act, in that information was not provided to FDA as required by the Medical Device Reporting Regulation, 21 CFR Part 803. For example:

- A complaint dated 4/24/97 involved a fire with a Model 115 Fluidotherapy unit, which is believed to have started when parts of the foam distributor fell off and contacted the heater. This event is a reportable malfunction, because the device or a similar device would be likely to cause or contribute to a death or serious injury if the malfunction were to recur, and was required by 21 CFR 803.50(a)(2) to be reported to FDA.
- A complaint dated 11/26/97 involved a short circuit and spark/flame with a Model 110D Fluidotherapy unit, which was determined to have been caused by long metal bolts that protruded into the inner housing, causing the housing to contact the electrical connectors for the heater. Electric current, in the range of 13 amperes, flowed from the heater connectors through the metal bolts to the aluminum legs of the device. This event is a reportable malfunction, because the device or a similar device would be likely to cause or contribute to a death or serious injury if the

malfunction were to recur, and was required by 21 CFR 803.50(a)(2) to be reported to FDA.

In addition, FDA's Center for Devices and Radiological Health/Office of Device Evaluation reviewed the labeling and promotional material obtained during this inspection. Their review found that these materials included a number of statements/claims that FDA had objected to during the review of premarket (510(k)) submissions for your devices and which you had agreed to remove or qualify, as well as several new claims. The following statements/claims are objectionable and should be removed:

- Statements such as "... because dry heat continuously kills bacteria" "don't worry about germs – the high temperatures of dry heat and Cellex's inert nature inhibit bacterial growth." These devices are not self-sterilizing because they do not reach a high enough temperature. Therefore, any references to killing bacteria or inhibiting bacterial growth should be deleted or substantiated with valid scientific data.
- References to the use of Fluidotherapy for Treatment of Range of Motion, unless qualified by the phrase "when it is used in combination with exercise."
- References to Treatment of Blood Flow Insufficiency, unless qualified by the word "local."
- Statements such as "Heat penetration and blood flow increase significantly," unless the word "significantly" is removed and the blood flow is qualified by the word "local."
- The claim that "Fluidotherapy causes mechanical and thermal stimulation which produces counter-irritation."
- The reference to the treatment of arthritis, unless revised to state "symptoms of non-rheumatoid arthritis."
- The reference to "post-surgical therapy." Heat usually aggravates post-operative swelling, and it is not clear when heat is indicated post-surgically and for what purpose.
- Any reference to the reduction of edema or swelling, or to compression or pulsed compression. These statements/claims constitute a major change in the intended use of your device and require the submission of a new premarket notification.

Also, please provide a description of the Fluidotherapy models (such as the Model 115) for which you have not submitted a 510(k) and an explanation for why a 510(k) was not

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submitted. Please refer to the document "Deciding When to Submit a 510(k) for a Change to an Existing Device," which is available on FDA's homepage (<http://www.fda.gov/cdrh/indexps.html#P>).

The statement "This unique technology is approved for sale by the U.S. Food and Drug Administration (FDA) ..." in the brochure "Fluidotherapy Heat+Stimulation+Compression Combination Therapy that works" is misleading and should be deleted. Any representation that creates an impression of official approval of a device because of complying with the premarket notification regulations is misleading and constitutes misbranding (21 CFR 807.97).

The above-referenced inspection also revealed that these 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 their manufacturing, packing, storage, or installation are not in conformance with the Current Good Manufacturing Practice (CGMP) requirements for devices set forth in the Quality Systems Regulation specified in Title 21, Code of Federal Regulations (CFR), Part 820.

The following violations were provided to you on the FDA-483 and are also discussed below. Further, we are in receipt of your response to the FDA-483, dated June 15, 1999, and the results of that review are also indicated below.

1. Failure to have an adequate Device Master Record (DMR) for device and component specifications as required by 21 CFR 820.181. For example, dimensional and space clearance specifications for the four column base bolts (part # BOL0006) used in the production of the Fluidotherapy Device Models 110D/DE prior to 1/98 were not specified; and
2. Failure of the acceptance activities to include inspections, tests, or other verification activities to assure conformance with specified requirements, as required by 21 CFR 820.80; and
3. Failure to monitor and control process parameters, component and device characteristics during production as required by 21 CFR 820.70(a)(2). For example, space clearance between the long column base bolts and the heater shield was not checked to prevent the potential occurrence of an electrical contact being transferred to the pedestal base of the Fluidotherapy Device Models 110D and 110DE.

The FDA inspection revealed your firm conducted a recall, via a service bulletin, of the referenced devices January, 1998 after receipt of a complaint on November 21, 1997. The complainant's product failure investigation indicated the base bolts protruded far

enough into the inner housing to contact the thin metal shroud, causing it to collapse into and contact the electrical connectors for the heater. This contact in turn caused an 13-Amp current to flow from the heater connectors through the metal bolts into the aluminum legs of the device.

It is your firm's responsibility to assure all production controls and component specifications are properly used to assure the safety and functionality of the devices. Inspection records reviewed by this office and information obtained during the inspection indicated your firm looked at the complainant's unit when it came back along with other units currently manufactured. Your staff indicated it was obvious there was little clearance between the longer base bolts and the heater, confirming what the complainant had found. It appears the bolt length specification and space clearance were not properly defined, evaluated, and reviewed by your management before implementation, and the proper space clearance was not checked during production, to prevent this kind of problem.

As correction, your firm replaced the excessively long bolt (part #BOL0006) with shorter bolt (part #BOL0049) as indicated in ECN 1739, dated 1/23/98. The size of bolt #0006 was not defined in the ECN or attached documentation. Our investigator asked to review the Bill of Material (BOM)/DMR specifications in effect when the complainant's unit was manufactured. Your staff indicated the old DMR and redline change was not available. Our further review of the Work Order Pick List under Work Order (W.O.) #12270278, dated 6/2/97, revealed no length specification and part number listed for the longer base bolts.

In order to correct the above violations, your firm should perform a comprehensive review of all procedures, including Device Master Record and Device History Record, to identify any missing specifications, quality attributes, and discrepancies. Please inform this office of the progress after completion of your review.

4. Failure to establish and maintain documented instructions, standard operating procedures (SOP's), and methods that define and control the manner of production as required by 21 CFR 820.70(a)(1). For example, the handwritten assembly procedure "Building Procedure for Fluido 110", dated 10/98, was neither legible nor readable.
5. Failure to review and approve changes to specification, method, process, or procedure as required by 21 CFR 820.40(b). For example, the handwritten assembly procedure referenced above contained changes without management review and approval.

A copy of the handwritten Fluid0110 Assembly Procedure was provided to our investigator during the inspection. In order to determine the adequacy of your manufacturing procedure with regard to the January, 1998 recall of the referenced devices, this office conducted a further review of the procedure. This procedure, as written, is difficult to follow because of illegible handwriting, unorganized technical descriptions, and inadequate drawings. This procedure also contains changes (line throughs) without documenting management review and approval. Your firm should perform a review of this procedure and other handwritten procedures to assure they are legible, readable, and contain correct manufacturing information as intended. Please provide this office with documentation to support your correction and documentation of training or re-training of employees involved.

6. Failure to verify or validate the corrective action to ensure that such action is effective and does not adversely affect the finished device as required by 21 CFR 820.100(a)(4). For example, engineering changes to use a shorter base bolt and [REDACTED] were not adequately validated or verified by adequate means of documentation or documented testing.

In the June 15, 1999 response letter, you indicated "the approval signatures on the ECN provide evidence of documented verifications of the revisions prior to implementation. Further verification and retrospective validation of the device is supported by the functional performance of units produced following implementation of the ECN in January, 1998." This rationale is not adequate for the following reasons:

ECN 1739 attached to your response letter does not indicate any documented verification or validation activities. Even if you believe this change only requires a simple verification, your rationale should be either documented or referenced in this ECN or in other related documents. Further, you have not documented and provided how the verification was done, the verification acceptance criteria, and who performed the verification. The approval signatures on this ECN must be supported by evidence of documentation.

Also, in ECN 1739, your staff documented "additionally [REDACTED] to conform to the [REDACTED] Standard." Neither this ECN nor your response provided evidence of documented testing or evaluation to assure conformance with this standard. Further, there is no assurance provided to demonstrate ECN 1739, implemented as corrective action, is effective and does not cause additional problems or adversely affect the device.

In your response, you also stated "the [REDACTED] in accordance with generally accepted electrical standards." You have not provided identification of these electrical standards.

The design control provision of the Quality System Regulation was effective June 1, 1997. As such, it is your firm's responsibility to comply with design controls. ECN 1739, to change bolts and [REDACTED] was considered a design change as evidenced in the January, 1998 Service Bulletin. In your separate response to FDA-483 Item 9 concerning design control procedures, you stated "to date, this SOP has not been exercised due to the fact that Henley has not generated any new product design or made significant modifications to existing products which would require the use of the design control procedure." This statement clearly indicated Henley had not used design controls for ECN 1739 to ensure compliance with the requirements of 820.30, especially 820.30(l) Design Changes. Whether a change is a simple or complex design change, Henley should follow 820.30(l) for establishing proper design documentation and refer to [www.fda.gov/cdrh](http://www.fda.gov/cdrh) for more information on design controls.

Our review of the complainant's failure investigation of the unit Model 110D, S/N [REDACTED], indicated ECN 1739 was a significant change because it was intended to improve the safety of the device. Because of "lethal effects" of a potential electrical contact, Henley should have at least performed a risk analysis to validate or verify ECN 1739. Your Director of Engineering indicated to our investigator that the changes in ECN 1739 were verified visually and results of the verification were not documented. In our view, "visual verification" alone without further documented evaluation via a documented risk analysis procedure does not constitute an adequate risk analysis.

In order to correct the cited violation, Henley should perform a current review of the design control procedures and other changes for compliance with design controls and should provide training to employees involved. After completing the corrective action, please provide this office with necessary documentation to show evidence of correction.

7. The corrective and preventive action procedure addressing documentation of CAPA activities was not complete as required by 21 CFR 820.100(b). For example, 72 out of the 98 CPARs entered through 1/21/99 had not been closed out by Quality Assurance (see FDA-483 Item 1).

In the June 15, 1999 response, you stated "The number of CPARs logged in the Corrective and Preventive Action Request Log from 6/15/98 – 2/25/99 was 107; 45 of which were closed and 62 (not 72) remained open at the time of the inspection. Subsequently, all 1998 CPARs and all but 2 from 1999 have been closed out." You have not provided copies of the closed reports for evidence of correction.

You further stated "The bulk of the CPARs included items that were rejected during the incoming, receiving inspection due, in part, to incomplete documentation of component/part specifications on a Receiving Inspection Document (RID). Historically, Henley maintained specifications on the Item Data Master Sheet of [REDACTED] (computer software). Subsequent to the Company's development and implementation of a Quality System Program, component specifications have been completed and/or are in-process of conversion into the newly implemented Documentation Control System." You have not provided a description of the newly implemented Documentation Control System and assurance that component specifications entered into the Documentation Control System are reviewed for completeness and accuracy. You should also provide up-to-date employee training to prevent incomplete documentation of component specifications and training on the new Documentation Control System. Please provide training documentation for our review of evidence of correction.

You also stated "All future investigation of CPA's will be fully documented and copies of the investigation results will be attached to the completed CPAR. Copies of all CPA reports are maintained by the Quality Assurance Manager and discussed at the regular Quality Review meetings." Please provide this office with management review procedures for controlling your Quality Review meetings for our review. During the inspection, the FDA investigator asked your Director of Regulatory Affairs how your firm was detecting recurring quality problems. Your staff indicated that CPARs, SROs, and other quality concerns were discussed at the quality improvement meetings, and that this information was confidential. As per 21 CFR 820.100 (Corrective and Preventive Action), 820.90 (Nonconforming Product), results of corrective action along with sources of quality data, e.g., trending data, are subject to FDA inspection and review. If results of CAPA and related data are documented or referenced in the quality improvement meetings, then affected portions of the meeting minutes are subject to FDA review.

8. Failure to analyze service reports with an appropriate statistical method to identify existing and potential causes of nonconforming product in accordance with 21 CFR 820.100, as required by 21 CFR 820.200. For example, the trending of Service Request Orders (SRO) by number was performed only for the time period 1/98 – 8/98 (FDA-483 Item 1); and service reports were not analyzed following appropriate statistical methods to identify potential quality problems (FDA-483 Item 5)

In your response, you stated "Subsequent to the FDA inspection, all SROs from September, 1998 through May 31, 1999 have been reviewed with representative trending and quality data analysis. The results of these data have been reviewed with the responsible department/individuals as well as Executive Management. Statistical

analysis of quality data has been implemented in accordance with SOP 1701 – Statistical Techniques.” You have not provided SOP 1701 (Statistical Techniques), documentation of trending data and results of corrective action, if taken, to demonstrate evidence of correction.

9. Service reports do not include the test and inspection data as required by 21 CFR 820.200 (d)(6). For example, service reports (SROs) generated electronically do not fully characterize repair and failure modes and document action taken to bring the item back to specification, e.g., SRO 10006495, 10007599, 10008913 (FDA-483 Item 4).

In your response, you stated “the repair code(s) are not always listed on all SROs. This is due, in part, to the fact that at the time the SRO is initiated, the actual repair(s) needed to bring the unit part/component/device into specifications may not be known.” Our review of the referenced SRO’s indicated these service reports were generated in July and October of 1998, and as such, all relevant repair data should have been completed at the time of the inspection. Please provide copies of the closed SRO’s for evidence of correction.

As corrective action, you indicated “more care and attention to the completion of the SRO form and follow-up testing of such repairs will be documented in the future. Testing results will be attached to the original SRO upon completion,” and that “Specific training programs have been implemented.”

Your response did not indicate if all applicable servicing procedures have been revised and approved as a result of the training programs. Please provide this office with training records and training documentation to show evidence of corrective action.

10. Failure to document evaluation of complaints for possible MDR events as required by 21 CFR 820.198(d), 803.17(b)(1); and
11. Failure to establish written MDR procedures as required by 21 CFR 803.17.

FDA-483 Item 3 cited your firm for not documenting MDR evaluations of Product Experience Form #017330FMS0001, dated 11/26/97, regarding a short circuit/fire incident in a Model 110D Fluidotherapy unit. Your response indicated that the incident was thoroughly investigated by the company, and in your staff’s opinion, this complaint did not warrant an MDR report. You have not provided records of the MDR evaluation of this incident to support a non-MDR report.

You further indicated a written report of the MDR event was not formally documented in a format consistent with that in the MDR regulation, and that a MDR guidance manual

will be developed and completed by July 31, 1999. You have not provided this office with the MDR guidance manual and training documentation for evidence of correction.

Our further review of inspection records revealed another complaint report that was not MDR investigated and documented for possible MDR reporting. For example, Complaint Number 98-0001, dated 6/26/98, documented a possible malfunction with a Cervical Traction Machine TRA0060. The complainant reported the unit was jerking during cervical traction and the patient interrupt switch did not release.

Service repair records documented the unit was sent back to the factory for recalibration, and that the customer still experienced the same mechanical symptoms after the unit was recalibrated. The unit then locked and would not release. The harness was cut to release the patient. Telephone logs attached to the complaint report documented two patients involved in the incident complained of pain.

According to the hospital incident report, one of the patients felt increased pulling and jerky movements, and complained of increased pain on the neck. Your complaint investigation indicated the unit was working properly and the customer needed training for end user(s).

This incident was deemed, as documented in the complaint report, to be not MDR reportable. You have not documented any rationales and/or decisions based on the referenced records to show why this incident was not MDR reportable.

12. Failure of the complaint files to include all necessary records of complaint investigations as required by 21 CFR 820.198. For example:

- Complaint #98-0001, dated 6/26/98, did not include all dates and results of the investigation.
- Complaint #98-0002, dated 5/22/98, did not include the device serial number, results of the investigation, or reason why no investigation was made.
- Complaint, dated 11/26/97, pertaining to a Fluidotherapy Model 110D malfunction, did not include the results of any internal investigation, or evaluation as to whether it was MDR reportable or not.
- Complaint, dated 4/24/97, regarding a fire incident in a Model 115D Fluidotherapy device, did not include the results of any internal investigation and/or corrective action taken.

In your response for Complaint #98-0001, you indicated "the memo written by the manufacturing supervisor was signed but not dated."

For Complaint #98-0002, you indicated "it was true that the serial number of the unit was not recorded in the file for this complaint."

For Complaint dated 11/26/97, you indicated "the report of the internal investigation was not formally written up outside of the issuance of an Engineering Change Notice to revise the manner the unit was assembled."

For Complaint dated 4/24/97, you indicated "although not thoroughly investigated in the file, this incident was thoroughly investigated internally."

Henley has not provided a corrective action plan to address the deviations as stated above in your response. Specifically, you should review the current complaint handling procedure for adequacy, review of recent complaint records to assure they include all necessary documentation, and provide training or retraining to employees. Please inform this office of your progress and provide documentation to show evidence of correction.

13. Failure to develop, conduct, control, and monitor production processes to ensure that a device conforms to its specifications, as required by 21 CFR 820.70. For example, the specified time interval for the Fluidotherapy device to reach a specified temperature has not been defined and validated.
14. Failure to document evaluation and investigation of nonconforming product as required by 21 CFR 820.90(a). For example, 8-Model 110D and 1-Model 115D Fluidotherapy units failed to heat up within a specified time limit during production testing.

In your response to FDA-483 Item 5, you indicated the primary issue with the test procedure is to ensure the units will heat to a specified temperature and cool down within a representative time frame. You have not defined what constitutes a representative time frame and what action to be taken if the device fails to meet this requirement.

You further indicated that the time interval for the Fluidotherapy unit to reach a specified temperature varies because of different operating conditions (e.g., if the unit was not "cold" when first turned on, the media may have retained some heat, and therefore, it would not take as long to reach the specified temperature as a unit that was cold). The device history records (Fluidotherapy Manufacturing Traveler), referenced in FDA-483

Item 5, do not show if the devices were previously turned on before testing or calibration to support your statement.

If the devices were not turned on prior to testing, they should be able to heat up and cool down to within a specified time interval during testing. The possible time interval should have been defined and validated during design controls for this device and used as acceptance criteria during production testing. The actual elapsed times for the devices to heat up and cool down along with specified time limits were recorded on the device history records. If this specification did not serve as a useful indication of quality attributes, why did you monitor and record it during testing.

Our review of the inspection report indicated your General Manager of Manufacturing explained to the FDA investigator that if a unit heated up slowly and cooled down quickly or heated up quickly and cooled down slowly, then that would indicate a problem with the [REDACTED]. Your staff further indicated they would investigate the out-of-specification results for the nine Fluidotherapy units referenced in FDA-483 Item 5. Your response has not provided documentation of failure investigation for our review.

15. Failure to establish procedures to assure finished devices meet all acceptance activities before distribution, as required by 21 CFR 820.80(d). For example, the final acceptance status of traction machines were not clearly identified on the DHR (FDA-483 Item 5).

Your response indicated that in the future, only designated individual(s) will have the authority for release to stock/inventory, and that, these individuals are "area manager" for all finished product. The documentation will be reviewed and released by the designated individual(s) who will affix his/her signature and date of acceptance on the specific document. You have not provided procedures that incorporate the proposed corrective action and training documentation.

16. Failure to establish and maintain procedures to ensure that equipment is routinely calibrated, inspected, checked, and maintained as required by 21 CFR 820.72. For example, calibration records do not include actual temperature readings before and after calibration, specific calibration dates and calibration due dates, for the Fluidotherapy Dial Thermometers, as listed on FDA-483 Item 6.

Your response indicated the Fluidotherapy equipment calibration procedure has been modified and all calibration activities will be more thoroughly documented in the future via the modified Calibration Checklist and Log Book. You have not provided a complete copy of the revised calibration procedure, Checklist, and Log Book for our review.

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You should provide training or retraining to employees in charge of calibration activities, and training documentation for our verification.

In addition, FDA-483 Item 8 cited your firm for not documenting evaluation and approval of the supplier for the controller boards for the Fluidotherapy and traction devices. In response to this observation, you stated that all future contractors and/or subcontractors will be formally evaluated for quality conformity and compliance with SOP 0502 Supplier Quality and WIN 0022 Supplier Audit Checklist. These referenced procedures have not been provided for our review.

In the June 15, 1999 response, you stated shortly after the inspection, a fire occurred in the warehouse at the 120 Industrial Blvd. building and caused extreme smoke and water damage in the building. The building and its contents were rendered inaccessible and all records and files were boxed and sent to a restoration facility for recovery and cleaning. Access to pertinent files supporting the response to the FDA-483 observations has contributed greatly to the delay in Henley's response letter, dated June 15, 1999.

We acknowledge your commitment to gather information and records to develop the written response to the inspectional observations. However, we are quite concerned with the fire incident at your facility and are unable to confirm if it has caused any damages to, or contamination of, finished devices in stock, manufacturing equipment and material used for production, quality system records, etc. You should be aware of the requirements of 21 CFR 820.70(e), Contamination Control, and other provisions of the Quality System Regulation (QSR), to prevent distribution of the nonconforming product as a result of this incident. Please provide this office with a damage assessment report for our review.

This letter is not intended to be an all-inclusive list of deficiencies at your facility. It is Henley Healthcare's responsibility to ensure adherence to each requirement of the Act and regulations. The specific violations noted in this letter and in the FDA-483 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.

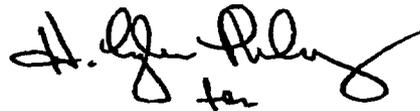
Until these violations are corrected, and FDA has documentation to establish that such corrections have been made, federal agencies will be advised of the issuance of this Warning Letter so that they may take this information into account when considering the award of contracts.

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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 15 working days of receipt of this letter, of the specific steps you have taken to identify and correct 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 frame within which the corrections will be completed. Your reply should be directed to Thao Ta, Acting Compliance Officer, at the above letterhead address.

Sincerely yours,

A handwritten signature in black ink, appearing to read "J. R. Baca". The signature is fluid and cursive, with a large, sweeping flourish at the end.

Joseph R. Baca  
Dallas District Director