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FEDERAL EXPRESS

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

WARNING LETTER

FLA-02-53

July 22, 2002

Wayne C. McCullough
President and Chief Operating Officer
Perry Baromedical Corporation
36630 Interstate Parkway
Riviera Beach, Florida 33404

Dear Mr. McCollough:

During an inspection of your establishment located in Riviera Beach, Florida on January 23 through February 1, 2002, FDA Investigator Michelle S. Dunaway determined that your establishment is a manufacturer of hyperbaric chambers. Under section 201(h) of the Federal Food, Drug, and Cosmetic Act (the Act), hyperbaric chambers are medical devices because they are intended to treat medical conditions or to affect the structure or function of the body. The investigator documented violations of the Act causing the device(s) to be adulterated within the meaning of section 501(h) and misbranded within the meaning of section and 502(t)(2) of the Act.

The Act 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 device(s) are adulterated under section 501(h) 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 as follows:

1. Your firm failed to establish and maintain an adequate and effective quality system at all levels of the organization as required by 21 CFR 820.20(a), (b), (c), (d), & (e). For example, your firm failed to establish its policy and objectives for, and commitment to, quality; failed to establish procedures for conducting management reviews; failed to conduct management reviews; failed to establish a management representative(s) with executive responsibility for quality(FDA 483, Item #s 1, 4, 5, 11, 12, 13).
2. Your firm failed to establish procedures for quality audits and to conduct such audits to assure that the quality system is in compliance with the established

system as required by 21 CFR 820.22. For example, no quality audits have been conducted and none are scheduled to assure the quality system is effective (FDA 483, Item #2 & 3).

3. Your firm failed to establish and maintain procedures for receiving, reviewing, and evaluating complaints by a formally designated unit as required by 21 CFR 820.198. For example, complaints are not defined, documented nor processed in a timely manner (FDA 483, Item #s 6 & 7).
4. Your firm failed to establish and maintain procedures for implementing corrective and preventive action as required by 21 CFR 820.100(a). For example, no procedures have been established to identify and review quality data sources and other potential problems, and for conducting investigations of product failures and nonconforming product (FDA 483, Item #s 8 & 9).
5. Your firm failed to establish and maintain procedures to control the design of the device in order to ensure that specified design requirements are met as required by 21 CFR 820.30(a), (b), (c), (d), (e), (f) and (g). For example, there are no written design control procedures; there was no design plan established for the Sigma 34 design project; there are no formally approved inputs for the Sigma 34 design project; the essential outputs for the Sigma 34 design project are not identified; there was no acceptance criteria established before verification/validation activities were conducted for the Sigma 34; and the design review minutes dated 7/28/00 do not list meeting attendees (FDA 483, Item #s 17, 18, 19, 20, 21 and 22).

Your devices are also misbranded within the meaning of section 502(t)(2) in that there was a failure to furnish material or information required by or under section 519 respecting the devices. These violations include, but are not limited to the following:

6. Your firm failed to establish written procedures for Medical Device Reporting as required by 21 CFR 803.17 (FDA 483, Item #15).
7. Your firm failed to submit a written report to the FDA within 10 days of initiating the correction involving the Magnatrol valve as required by 21 CFR 806.10(b). For example, your firm initiated corrective action on June 11, 2001 requesting that hyperbaric operators inspect the operability of the Magnatrol valves, change the inspection schedule from annually to monthly and install a full flow ball valve in line to facilitate the monthly inspection (FDA 483, Item #16).
8. Your firm failed to submit a written report to the FDA within 10 days of initiating the correction involving the Magnatrol Valve as required by 21 CFR 806.10(b). For example, your firm initiated corrective action on June 11, 2001, requesting that hyperbaric operators inspect the operability of the Magnatrol

Valves, change the inspection schedule from annually to monthly, and install a full flow ball valve in line to facilitate the monthly inspection (FDA 483, Item #16).

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.

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. 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.

We have reviewed your response dated February 21, 2002 and find your responses to FDA 483, Item #s 2-24 to be inadequate because they fail to provide documented evidence of corrective actions taken.

Please notify this office in writing within fifteen (15) working days of receipt of this letter, of the steps you have taken to correct the noted violations, including (1) the time frames within which the corrections will be completed, (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", with a long horizontal flourish extending to the right.

Emma Singleton
Director, Florida District