



DEPARTMENT OF HEALTH & HUMAN SERVICES

94885d

Public Health Service
Food and Drug Administration
Los Angeles District

19701 Fairchild
Irvine, California 92612-2506
Telephone (949) 608-2900

WARNING LETTER

CERTIFIED MAIL **RETURN RECEIPT REQUESTED**

July 26, 2004

W/L: 34-04

Peter J. Bonin
Chief Executive Officer
Tenacore Holdings Inc.
647 E. Young Street
Santa Ana, CA 92705

Dear Mr. Bonin:

During an inspection of your firm located in Santa Ana, California, from May 17 to 24, 2004, our investigator determined that your firm repackages, relabels, and distributes Pulse Oximeter probes, Ultrasound, and Toco transducers. These products are devices as defined by Section 201 (h) of the Federal Food, Drug, and Cosmetic Act (the Act) [21 U.S.C. § 321(h)].

Our inspection disclosed that the devices are adulterated within the meaning of Section 501(h) of the Act [21 U.S.C. § 351(h)], in that the methods used in, or the facilities or controls used in, repackaging and relabeling your devices are not in conformance with the Good Manufacturing Practice (GMP) requirements under the Quality System Regulations, as specified in Title 21, Code of Federal Regulations (CFR), Part 820, as follows:

1. Failure to establish, maintain, and control a quality system that is appropriate for specific devices manufactured [21 CFR 820.20]. For example,
 - Management with executive responsibility has not established a policy and objectives for, and commitment to, quality, as required by 21 CFR 820.20(a).
 - No quality plan defining the quality practices, resources, and activities relevant to devices that are designed and manufactured has been established or implemented, as required by 21 CFR 820.20(d).

- No quality system procedures and instructions have been established and implemented, as required by 21 CFR 820.20(d).
 - No procedures for conducting management reviews, as required by 21 CFR 820.20(c).
 - No management representative has been appointed or documented to ensure that quality system requirements are effectively established and maintained and reporting on the performance of the quality system activities to management with executive responsibility, as required by 21 CFR 820.20(b)(3).
2. Failure to establish and implement procedures for receiving, reviewing and evaluating complaints by a formally designated unit to ensure that all complaints are processed in a uniform and timely manner [21 CFR 820.198]. Additionally, no Medical Device Reporting (MDR) procedures have been established to determine whether a complaint represents an event which is required to be reported under 21 CFR Part 803.
 3. Failure to establish procedures for implementing corrective and preventive action [21 CFR 820.100].
 4. Failure to maintain the device master record for repacking and relabeling specifications, including methods and processes used [21 CFR 820.181(d)].
 5. Failure to establish and maintain procedures for the control of storage areas and stock rooms for product to prevent mixups, damage, deterioration, contamination, or other adverse effects pending use or distribution and to ensure that no obsolete, rejected, or deteriorated product is used or distributed [21 CFR 820.150(a)].
 6. Failure to establish and implement procedures for acceptance or rejection of incoming product to ensure that all acceptance activities are inspected, tested, or otherwise verified as conforming to specified requirements [21 CFR 820.80].
 7. Failure to establish and implement procedures for conducting quality audits and failure to conduct and document audits to verify that the quality system is effective in fulfilling the quality system objectives [21 CFR 820.22].
 8. Failure to establish and maintain procedures to ensure that all purchased or otherwise received product and services conform to specified requirements [21 CFR 820.50].

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 Form FDA 483 issued at the conclusion of the inspection may be symptomatic of serious underlying problems in your firm's manufacturing and quality assurance system. You are responsible for investigating and determining the causes of the violations identified by the FDA. If the causes are

Letter to Mr. Bonin

Page 3

determined to be systems problems, you must promptly initiate permanent corrective actions.

Federal Agencies are advised of the issuance of all Warning Letters pertaining to medical devices so that they may take this information into account when considering the award of contracts. Additionally, no remarket submissions for devices to which the GMP deficiencies are reasonably related will be cleared until the violations have been corrected. Also, no requests for Certificate For Exportability 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.

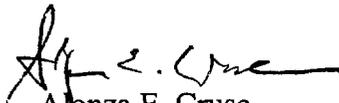
You should notify this office within fifteen (15) working days of receipt of this letter of the specific steps you have taken to correct the noted violations including an explanation of each step being taken to identify and prevent the recurrence of similar violations. If corrective action cannot be completed within (15) working days, state the reason for the delay and the time within which the corrections will be completed.

If you have any questions regarding this letter, please contact Mariza M. Jafary, Compliance Officer at 949-608-2977.

Your written reply should be addressed to:

Pamela Schweikert
Director, Compliance Branch
Food and Drug Administration
19701 Fairchild
Irvine, CA 92612-2446

Sincerely,


Alonza E. Cruse
District Director