U.S. Food and Drug Administration

Inspections, Compliance, Enforcement, and Criminal Investigations

Cybernet Systems Corp.

Department of Health and Human Services

Public Health Service
Food and Drug Administration
Detroit Dlstnct
300 River Place
Suite 5900
Detroit, MI 48207
Telephone: 313-393-8100
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WARNING LETTER
2010-DET-06

VIA FEDERAL EXPRESS

January 15, 2010

Heidi N. Jacobus
Chairman and Chief Executive Officer
Cybernet Systems Corporation
727 Airport Boulevard
Ann Arbor, Michigan 48108

Dear Ms. Jacobus:

During an inspection of your firm located in Ann Arbor, Michigan on 9/09/2009-10/30/2009, an investigator from the United States Food and Drug Administration (FDA) determined that your firm manufactures the MedStar System line of products which includes: CHF MedStar Set, COPD MedStar Set, and Diabetes MedStar Set. Under section 201(h) of the Federal Food, Drug, and Cosmetic Act (the Act), 21 U.S.C. 321(h), these products are devices because they are intended for use in the diagnosis of disease or other conditions or in the cure, mitigation, treatment, or prevention of disease or are intended to affect the structure or function of the body.

This inspection revealed that these 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 for, their manufacture, packing, storage, or installation are not in conformity with the Current Good Manufacturing Practice (CGMP) requirements of the Quality System (QS) regulation found at Title 21, **Code of Federal Regulations** (C.F.R.), Part 820. These violations include, but are not limited to, the following:

1. Management with executive responsibility has failed to ensure that an adequate quality system, as defined in 21 CFR 820.3(v), has been fully implemented and maintained at all levels of your organization, as required by 21 CFR 820.20 as is evidenced by the observations below. In addition, your firm has not designated a management representative, as required by C.F.R. 820.20(b)(3), and you have not established management review procedures, as required by 21 C.F.R. 820.20(c), nor conducted management reviews since 2004.

2. Failure to conduct quality audits, to assure the quality system is in compliance with the established requirements and to determine the effectiveness of your quality system as required by 21 C.F.R. 820.22. At the time of the inspection, your firm had not conducted a quality audit since 2004.

3. Design validation failed to include testing of production units under actual or simulated use conditions as required by 21 C.F.R. 820.30(g). For example, the MedStar System design history records do not include documentation to demonstrate that the physiological data (e.g. blood pressure and heart rate readings) obtained from the patient is the identical data transmitted from the MedStar Collection Server.

4. Your firm failed to establish effective and complete procedures for implementing corrective and preventative action operations, as required by 21 CFR 820.100. For example, there has been no investigation into complaints involving the physiological measurement device ports becoming loose c delaminating from the circuit board of MedStar units (MedStar product family, model # 533-xxx). Moreover, your firm has not verified that the addition of the port strain relief to the devices was effective and does not adversely affect the finished device.

5. Your firm has failed to establish compliant handling procedures, as required by 21 C.F.R. 820.198. Between 2/18/2008 and 2/3/2009, your firm documented twenty-nine (29) product returns involving one or more models of your MedStar units where the product failed. Medical RMA numbers 2008-02-26-0016, 2008-04-24-0026 and 200901-07-0058 represent returned units due to broken ports, and were returned because of alleged deficiencies related to the identity, quality, durability, reliability, safety, effectiveness or performance of the device after release for distribution as defined in 21 C.F.R 820.3(b). Your firm failed to review, evaluate and investigate these complaints in accordance with 21 C.F.R. 820.198.

6. Failure to establish procedures for acceptance of incoming product as required by 21 C.F.R. 820.80(b). For example, your firm has not established incoming acceptance procedures for spirometry measurement devices, a component of the MedStar finished device.

You should take prompt action to correct the violation(s) addressed in this letter. Failure to promptly correct these violation(s) 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 money penalties. Also 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. Requests for Certificates to Foreign Governments will not be granted until the violations related to the subject devices have been corrected.

Please notify this office in writing within fifteen (15) working days from the date you receive this letter of the specific steps you have taken to correct the noted violations, including an explanation of how you plan to prevent these violations(s), or similar violations(s), from occurring again. Include

documentation of the corrective action you have taken. If your planned corrections will occur over time, please include a timetable for implementation of those corrections.

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, Your response should be sent to Catherine V. Quinlan, Compliance Officer, Food and Drug Administration at 300 River Place, Suite 5900, Detroit, Michigan 48207. If you have any questions about the content of this letter please contact: Ms. Quinlan at (313)393-8153 or you may forward facsimile to (313) 393-8139.

Finally, you should know that this letter is not intended to be an all-inclusive list of the violations(s) at your facility. It is your responsibility to ensure compliance with applicable laws and regulations administered by FDA. The specific violations(s) noted in this letter and in the Inspectional Observations, Form FDA 483 (FDA 483) issued at the closeout of the inspection may be symptomatic of serious problems in your firm's manufacturing and quality assurance systems. You should investigate and determine the causes of the violation(s), and take prompt actions to correct the violations (s) and to bring your products into compliance,

Sincerely,

/S/

Joanne M. Givens
District Director
Detroit District Office

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