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Food and Drug Administration
Minneapolis District
240 Hennepin Avenue
Minneapolis MN 55401-1999
Telephone: 612-334-4100

PURGED EK

February 25, 2000

xc: HFI-35
DWA

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Refer to MIN 00 - 20

Boaz Avitall, M.D., Ph.D.
President
AvidCare
152 West Wisconsin Avenue
Milwaukee, Wisconsin 53203

Dear Dr. Avitall:

We are writing to you because on December 6-22, 1999, investigators from the Food and Drug Administration (FDA) collected information that revealed a serious regulatory problem involving the Home Health Monitoring Systems (including the Clinical Monitoring Station) that you manufacture.

Under a United States Federal law, the Federal Food, Drug, and Cosmetic Act (the Act), these products are considered to be medical devices because they are used to diagnose or treat a medical condition or to affect the structure or function of the body. Home Health Monitoring Systems and their associated software are medical devices as defined by Section 201(h) of the Act.

Our inspection found that the devices are adulterated within the meaning of Section 501(h) of the Act in that the methods used in, facilities or controls used for manufacturing, packing, storage, or installation of the medical devices are not in conformance with the Good Manufacturing Practices (GMP) requirements set forth in the Quality System Regulations for Medical Devices as prescribed by Title 21, Code of Federal Regulations (CFR), Part 820.

Our inspection found that your products are in violation of the law because of:

1. Failure of management with executive responsibility to ensure that the quality policy is understood, implemented, and maintained at all levels of the

Page Three

Boaz Avital, M.D., Ph.D.
February 25, 2000

- (ii) There is no record that a complete validation of software change to the HHM software was accomplished. HHM version 3MA0007H, 7I, 7J, 8A, 8B, 8C, and 8D are not validated, including their compatibility with the Clinical Monitoring Station software versions 1.13 and 1.14.
- 5. Failure to establish and maintain procedures for implementing corrective and preventive action (CAPA) [21 CFR 820.100(a)] in that:
 - a. Procedures for implementing CAPA are not defined, documented, completed or followed and there is no management review of complaints and returned product service reports;
 - b. CAPA procedures addressing the analysis of sources of quality data to identify existing and potential causes of non-conforming product or other quality problems are not defined, documented, completed or followed. Specifically, failure analysis data are not gathered in a manner that facilitates trending and corrective and preventive actions to be implemented. Complaint forms are missing the data needed to identify potential trends in non-conforming and/or returned products.
- 6. Device Master Records (DMR) are not maintained in accordance with 21 CFR 820.181 or prepared and approved in accordance with 21 CFR 820.40 in that the DMR requires the finished device to include blood glucose monitoring, but the finished device (configuration C1) is not capable of performing the blood glucose monitoring function. Also, the DMR does not include or refer to the INR, spirometry and body temperature specifications included in current released software version for the HHM and the Clinical Monitoring station. Additionally, approval of documents does not include signature and approval date of an authorized individual.

Your firm failed to obtain a new 510(k) or pre-market approval after making significant changes to the Home Health Monitoring Systems and their associated software.

Therefore, the Home Health Monitoring Systems and their associated software are adulterated within the meaning of Section 501(f)(1)(B) in that they are Class III devices under Section 513(f) and do not have an approved application for pre-market approval in effect pursuant to Section 515(a) or an approved application for an Investigational Device Exemption under Section 520(g).

Page Four

Boaz Avitall, M.D., Ph.D.
February 25, 2000

The Home Health Monitoring Systems are misbranded within the meaning of Section 502(o) in that a notice or other information respecting the modification to the devices was not provided to the FDA as required by 21 CFR 807.81(a)(3)(i). The devices are further misbranded within the meaning of Section 502(o) in that a notice or other information respecting the new intended use of the device was not provided to the FDA as required by 21 CFR 807.81(a)(3)(ii).

This letter is not intended to be an all-inclusive list of deficiencies at your facility. As president, the most responsible individual at AvidCare, it is ultimately your responsibility to ensure that devices manufactured at your facility in Milwaukee, WI, are in compliance with each requirement of the Act and regulations.

The specific violations noted in this letter and in the form 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.

You should know that this serious violation of the law may result in FDA taking regulatory action without further notice to you. These actions include, but are not limited to, seizing your product inventory, obtaining a court injunction against further marketing of the product, or assessing civil money penalties. Also, other Federal agencies are informed about the Warning Letters we issue, such as this one, so that they may consider this information when awarding government contracts. Additionally, no pending applications for pre-market approval (PMAs) or export approval requests will be approved and no pre-market notifications [Section 510(k)'s] will be found to be substantially equivalent for products manufactured for your facility until the violations have been corrected.

We received Dr. William K. Genthe's letter dated January 6, 2000, responding to the form FDA-483 issued on December 22, 1999. Although the response promises correction of the concerns referenced in the form FDA-483, it lacks specific documentation, including procedures, forms, and reports that would allow us to assess the effectiveness of the proposed corrective actions.

Please note that your firm must be registered as a medical device establishment and must list the products that you manufacture on the forms that were provided to you by the investigators during the inspection.

Page Five

Boaz Avital, M.D., Ph.D.
February 25, 2000

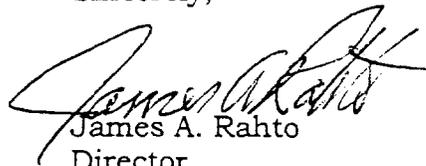
Your responses to the specific items will be evaluated by inspection to verify that the procedures, documentation, and training you have proposed have been effectively implemented.

Please let this office know in writing within 15 working days from the date you received this letter what steps you are taking to correct the problem. We also ask that you explain how you plan to prevent this from happening again. If you need more time, let us know why and when you expect to complete your correction. Please direct your response to Compliance Officer Howard E. Manresa at the address indicated on the letterhead.

Finally, you should understand that there are many FDA requirements pertaining to the manufacture and marketing of medical devices. This letter pertains only to the issue of current Good Manufacturing Practices for your devices and does not necessarily address other obligations you have under the law. You may obtain general information about all of FDA's requirements for manufacturers of medical devices by contacting our Division of Small Manufacturers Assistance at 1-800-638-2041 or through the Internet at <http://www.fda.gov>.

If you have more specific questions about how FDA marketing requirements affect your particular device or about the content of this letter please feel free to contact Mr. Manresa at (612) 334-4100 ext. 156.

Sincerely,



James A. Rahto
Director
Minneapolis District

HEM/ccl

Enclosure: FDA-483, 12/22/99