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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Cincinnati District Office
Central Region
6751 Steger Drive
Cincinnati, OH 45237-3097

August 27, 2008

VIA FEDERAL EXPRESS

WARNING LETTER CIN-08-28666-22

Dr. Frank S. Scarpino, CEO
Fall Prevention Technologies
4601 Gateway Circle
Kettering, OH 45440-1713

Dear Dr. Scarpino:

During an inspection of your firm located in Kettering, Ohio, from May 5, 2008 through May 21, 2008, an investigator from the United States Food and Drug Administration (FDA) determined that your firm manufactures the Balanceback iVNG device intended for recording, viewing, and analyzing eye movements in support of identifying balance disorders in human patients. 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 for use in the diagnosis of disease or other conditions or the cure, mitigation, treatment, or prevention of disease, or are intended to affect the structure or function of the body.

The 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 Practices (CGMP) requirements of the Quality System (QS) regulation found at Title 21, Code of Federal Regulations (CFR), Part 820. We received two responses from Daniel K. Grossman, Quality Manager, dated June 3, 2008 and July 14, 2008, concerning our investigator's observations noted on the Form FDA 483, List of Inspectional Observations that was issued to him at the conclusion of the inspection. We address these responses below, in relation to each of the noted violations. The violations include, but are not limited to, the following:

1. Failure of management with executive responsibility to ensure that an adequate and effective quality system is implemented and maintained at all levels of the organization, as required by 21 CFR § 820.20. For example:

    a) Your firm has not established adequate quality system procedures, as required by 21 CFR § 820.20(e), for corrective and preventive action (CAPA), complaints, design controls, and records.

    b) Your quality audits, as required by 21 CFR § 820.22, did not assure that the firm's quality system is in compliance with the established quality system requirements. Specifically, your audits failed to identify significant deficiencies in your firm's quality systems, including but not limited to, CAPA, design controls, complaints, and records.

We have reviewed your response to these observations but are unable to assess its adequacy because you still need to retrain the Quality Management Representative and other employees, and this training is not scheduled for completion until September 30, 2008.

2. Failure to adequately establish and maintain procedures for implementing corrective and preventive action, as required by 21 CFR § 820.100. For example:

   a) Your documentation of CAPA activities was not complete, as required by 21 CFR § 820.100(b). Specifically, neither your CAPA nor data analysis procedures identify a complete list of quality data sources, the process for investigation of nonconformities, the verification/validation required of the proposed correction, or the process of implementing the corrective action.

   b) You have failed to implement the CAPA system, as required by 21 CFR 820.100(a). Specifically, you have made numerous changes to the software for the iVNG Balanceback system as a result of complaints but did not initiate a CAPA for any of these changes.

   c) You have failed to adequately analyze quality data sources to identify existing and potential causes of nonconforming product or other quality problems, as required by 21 CFR § 820.100(a)(1). Specifically, you did not adequately trend all complaints to identify existing and potential quality problems, and the trending that was conducted was insufficient to detect such problems. You also failed to review service records to determine whether they were complaints that needed to be documented in the complaint system.

We have reviewed your response but are unable to assess its adequacy because you still need to update and implement these procedures and to retrain employees and these corrective actions are not scheduled for completion until October and November, 2008 respectively.

3. Failure to adequately implement procedures for receiving, reviewing, and evaluating complaints, as required by 21 CFR § 820.198. For example, the investigator determined that out of 128 records reviewed, your firm had classified 50 as "concerns" when they met the definition of a complaint as defined by 21 CFR § 820.3(b), and your procedure QAP 0502, Distinguish Product Concern vs. Product Complaint. Further, all but one of the 128 records reviewed lacked documentation of an investigation or an explanation why an investigation was not conducted.

We cannot evaluate whether your response to this item is adequate based on the information provided. Please provide our office with additional information concerning the new tool that you will be using to manage and organize your complaints.

4. Failure to assure that service reports include applicable test and/or inspection data following the completion of service, as required by 21 CFR § 820.200(d)(6). For example, 19 of the 19 service records reviewed did not have documentation reflecting that the device was tested or inspected after the repair to ensure the device met its specifications.

Your response indicates that this item will be corrected by November 14, 2008. Please provide an update on the status of this corrective action.

5. Failure to review associated data and documentation for all finished devices before they are released for distribution, as required by 21 CFR § 820.80(d)(2). For example, 5 of 11 of the finished iVNG device history records reviewed by the investigator revealed that the devices had been released prior to written approval.

We acknowledge that you have fired one employee over this incident and hired and trained a new employee. We note that page 1 of the submitted training record for the new employee (Page 1 of Tab 3 of your response) contains spaces for training in procedures; however, none of these spaces are completed. In your response, please provide a copy of your general training procedure and the procedure for completing this form. Also, please provide an explanation for why the form is incomplete.

6. Failure to establish a Device Master Record for the iVNG, as required by 21 CFR § 820.181.

This item is not scheduled for completion until January 15, 2009. Please provide an explanation for the delay in completing corrective action for this item.

7. Failure to adequately implement procedures to control the design of a device in order to ensure that specified design requirements are met, as required by 21 CFR § 820.30. For example:

    a) Your design plan for the iVNG Balanceback system does not demonstrate that the design was developed in accordance with the approved design plan and design control requirements, as required by 21 CFR § 820.30(j).

    b) Your validation of your device design is incomplete in that the firm has not established a protocol for conducting validation testing and did not validate the software to ensure that devices conform to the defined user needs and intended uses, as required by 21 CFR § 820.30(g). Specifically, you have made 1,900 revisions to the software in three years without conducting validation testing.

    c) You have not established and implemented adequate procedures for the identification, documentation, validation, review, and approval of design changes before their implementation, as required by 21 CFR § 820.30(i). None of the design control procedures include information on how to make changes to the design. There have been numerous changes to the hardware and desktop and laptop software since the original design; however, there have been no engineering change orders or validation or, where appropriate, verification testing for any of these design changes.

You do not project complete correction for these items (which correspond to items 1-4 of the Form FDA 483) until December 2008. Please provide an update on the status of these corrections.

8. Failure to store records in a manner to minimize deterioration and loss, as required by 21 CFR § 820.180. For example, you could not locate service records requested by the FDA investigator.

Moreover, the firm could not access its computer program for documenting complaints prior to August 2007 and no other copies of these complaints are available.

We acknowledge your intention to update procedures and organize your documents in order to prevent their loss. In your response, please provide an update on your progress. Also, please provide an update on your efforts to locate the requested records that you were not able to locate during the inspection.

You should take prompt action to correct the violations addressed in this letter. Failure to promptly correct these violations may result in regulatory action being initiated by FDA 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. Additionally, no premarket approval applications for Class III devices to which the QS regulation deviations are reasonably related will be approved until the violations have been corrected. Requests for Certificates to Foreign Governments will not be granted until the violations related to the subject devices have been corrected.

We acknowledge your two letters in response to the Form FDA 483 that was issued at the conclusion of the inspection. We note that you promise gradual implementation of corrective actions over the next five months. Please notify this office in writing within fifteen (15) working days from the date you receive this letter as to the progress you have made in correcting these violations. Please address the specific issues raised above, and provide an explanation for why your corrective action for these deficiencies cannot be accomplished in a more timely fashion.

Your response should be sent to: Stephen J. Rabe, Compliance Officer. If you have any questions about the content of this letter please contact: Mr. Rabe at 513-679-2700 ext 163 or FAX 513-679-2775

Finally, you should know that this letter is not intended to be an all-inclusive list of the violations at your facility. It is your responsibility to ensure compliance with applicable laws and regulations administered by FDA. The specific violations noted in this letter and in the Inspectional Observations, Form 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 violations, and take prompt actions to correct the violations and to bring your products into compliance.

Sincerely,

Toniette K. Williams

Toniette K. Williams
Acting District Director

cc: David K. Grossman
Quality Manager
Fall Prevention Technologies