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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

WARNING LETTER

FLA-08-12

February 29, 2008

Mr. Ronald Feinstein
President and CEO
Philips Lifeline, Inc.
111 Lawrence Street
Framingham, MA 01702-8156

Dear Mr. Feinstein:

During an inspection of your firm's subsidiary, Health Watch, Inc., located at 6400 Park of Commerce Blvd, Suite 1, Boca Raton, Florida 33487-8226 on December 3-4, 2007, an investigator from the United States Food and Drug Administration (FDA) determined that your firm manufactures the 3000 and 6000 model Health Watch (HW) Personal Response System, a class II device in accordance with Title 21 Code of Federal Regulations section 890.3725 (21 C.F.R. § 890.3725). Under section 201(h) of the Federal Food, Drug, and Cosmetic Act (the Act), (21 U.S.C. § 321(h)), this product is a device because it is intended for use in the diagnosis of disease or other conditions or in the cure, mitigation, treatment, or prevention of disease, or is intended to affect the structure or function of the body.

This inspection revealed that this device is 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, its 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. Failure to ensure that an adequate and effective quality system with oversight by management with executive responsibility has been fully implemented and maintained at all levels of your organization as required by 21 C.F.R. § 820.20. Your firm has not established, implemented and maintained an effective quality system at all levels of your organization including a Corrective and Preventive Action (CAPA) procedure, an Internal Audit procedure, a Management Review procedure, a Quality Policy, and a Quality Plan that defines quality practices, resources and activities.

- Failure to establish written procedures for management review at appropriate intervals to ensure that the quality system satisfies the requirements of the QS and the established quality policy and objectives of your firm, as required by 21 C.F.R. § 820.20(c).
- Failure to appoint a management representative to ensure quality system requirements are met, and to report to management the performance of the quality system, as required by 21 C.F.R. § 820.20(b)(3).
- Failure to have management with executive responsibility to ensure the quality policy has been fully implemented and maintained, as required by 21 C.F.R. § 820.20(a).

2. Failure to establish and implement written procedures for the following:

- Failure to establish and maintain procedures for implementing corrective and preventive actions, as required by 21 C.F.R. § 820.100(a). You do not have written corrective and preventive action procedures.
- Failure to establish and maintain procedures to adequately control environmental conditions where the environmental conditions could reasonably be expected to have an adverse effect on product quality, as required by 21 C.F.R. § 820.70(c). For example, there are no written procedures for environmental conditions for what, when, and how to monitor and test for electrostatic discharge in the receiving, repair, and shipping areas of the facility.
- Failure to implement procedures to control documents required under the QS regulation, as required by 21 C.F.R. § 820.40. Specifically, you have no document control of your operator training packet that is used to train new employees who field calls from subscribers.

3. Failure to establish and maintain procedures for receiving, reviewing, and evaluating complaints by a formally designated unit and to ensure that all complaints are processed in a uniform and timely manner, as required by 21 C.F.R. § 820.198(a). For example:

- Failure to establish a formally designated complaint unit
- Failure to have a working document to record complaints implemented
- Failure to have documentation of complaints for the last two years
- Failure to have written procedures stating each complaint will be evaluated to determine if an investigation is necessary and/or whether the complaint is a Medical Device Reportable event.

4. Failure to document calibration dates, the individual performing each calibration, and the next calibration date for inspection, measurement and test equipment, as required by 21 C.F.R. § 820.72(b)(2). For example, there is no documentation of the calibration dates, the individuals performing the calibration, or the next calibration date for the multi-meter used in repair of the personal response system HW units for testing battery voltage, testing conductivity of circuits on printed circuit boards, and assessing shorted circuits.

5. Failure to establish procedures for identifying training needs and for ensuring that all personnel are trained to adequately perform their assigned responsibilities, as required by 21 C.F.R. § 820.25(b). Your firm's training of operators was inadequate in that:

- You have no document control of your operator training packet that consists of multiple, separate, non-sequentially numbered training documents.
- Your operator training protocol is not linked to your written training procedures and has no document control to include management approval prior to implementation.
- You do not have documentation of reviewing and approving an operator's training and testing records and results prior to the employee being released to receive medical alarm calls.

We acknowledge receipt of your firm's response from David R. Jones, Director Quality Assurance, Regulatory Affairs and Philips Business Excellence, Philips Home Healthcare Solutions, dated December 20, 2007. We have reviewed your response and have concluded it is inadequate as follows:

- In paragraph #5 it states that "Health Watch is no longer a device manufacturer". We disagree with your conclusion that your firm is no longer a device manufacturer. The definition of a manufacturer in 21 C.F.R. § 820.3(o) states:

"Manufacturer means any person who designs, manufactures, fabricates, assembles, or processes a finished device. Manufacturer includes but is not limited to those who perform the functions of contract sterilization, installation, relabeling, remanufacturing, repacking, or specification development, and initial distributors of foreign entities performing these functions."

In paragraph #4 your response states that "Health Watch plans to cease all board-level service repair activities at this facility by January 31, 2008", however "returned units will only have their batteries replaced and be cleaned and functionally checked against the standard...prior to reshipment to customers". We consider the replacement of batteries, cleaning, and functionality checks as manufacturing. Therefore the CGMP requirements of the QS regulation in Title 21, C.F.R. Part 820 are applicable to your facility located in Boca Raton, FL.

- During the inspection it was noted that your firm has approximately [REDACTED] Health Watch personal monitoring systems that were installed in homes throughout the United States and are currently being monitored by your firm. There is no mention of how your firm intends to ensure that these [REDACTED] Health Watch systems are appropriately maintained, repaired, and monitored for the life of the devices. Your response only mentions other companies' devices.

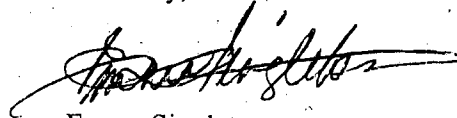
You should take prompt action to correct the violations addressed in this letter. Failure to promptly correct these violations may result in regulatory action being initiated by the Food and Drug Administration without further notice. These actions include, but are not limited to, seizure, injunction, 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. Additionally, premarket approval applications for Class III devices to which the Quality System regulation deviations are reasonably related will not 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.

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, or similar violations, 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 Brant M. Schroeder, Compliance Officer, Food and Drug Administration, 555 Winderley Place, Suite 200, Maitland, Florida 32751, (407) 475-4763.

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 (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,



Emma Singleton
Director, Florida District

cc: Mark Schwartz
Vice President and Chief Information Officer
6400 Park of Commerce Blvd.
Ste. 1
Boca Raton, Florida 33487-8226