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**CERTIFIED MAIL**  
**RETURN RECEIPT REQUESTED**

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

**WARNING LETTER**

**FLA-04-18**

March 1, 2004

Ronald G. Buck, President  
MedRx, Inc.  
1200 Starkey Road  
Suite 105  
Largo, Florida 33771

Dear Mr. Buck:

During an inspection of your establishment located in Largo, Florida on January 6-12, 2004, FDA Investigator Bill Tackett, Jr. determined that your firm manufactures a video otoscopy and audiometry system known as the Otowizard and the Vet Digitizer, which are devices as defined by section 201(h) of the Federal Food, Drug, and Cosmetic Act (the Act), [21 U.S.C. 321(h)].

The investigator documented significant violations from the Quality System (QS) Regulation, Title 21, Code of Federal Regulations (CFR), part 820, and the Medical Device Reporting regulations, Title 21 CFR part 803. These violations cause the devices you manufacture to be adulterated within the meaning of Section 501(h) [21 U.S.C. §351(h)] and misbranded within the meaning of Section 502(t)(2) [21 U.S.C. §352(t)(2)] of the Act.

The investigator noted the following violations of the QS regulations:

1. Your firm failed 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 CFR 820.20. Key components of the Quality System Requirements have not been established including: corrective and preventive actions (CAPA), internal quality audit procedures, management review procedures (FDA 483, Item #1).

2. Your firm failed to establish procedures for quality audits and conduct such audits to assure that the quality system is in compliance with the established quality system requirements and to determine the effectiveness of the quality system as required by 21 CFR 820.22. There was no quality system established (FDA 483, Item #s 2 & 3).
3. Your firm failed to establish and maintain procedures for implementing corrective and preventive action (CAPA) as required by 21 CFR 820.100(a). Your firm does not have procedures for analyzing quality data, investigating causes of nonconformities, verifying/validating CAPA, and disseminating information to those responsible for assuring the quality of the product (FDA 483, Item #7).
4. Your firm failed to establish and maintain procedures to ensure that all purchased or otherwise received product and services conform to specified requirements as required by 21 CFR 820.50. You have not established methods to evaluate suppliers, established lists of approved supplier lists, and maintained specifications and descriptions that clearly describe or reference specified quality requirements (FDA 483, Item #8).
5. Your firm failed to develop, conduct, control and monitor production processes to ensure that device(s) conform to specifications as required by 21 CFR 820.70(a). Instructions (SOPs) for manufacturing the Vet Digitizer were not established (FDA 483, Item #9).
6. Your firm failed to establish and maintain procedures for acceptance activities as required by 21 CFR 820.80(a). There are no procedures for the acceptance; testing, including: finished device testing; receiving, including: quarantine procedures for devices, components or other materials used throughout the manufacturing steps (FDA 483, Item #10).
7. Your firm failed to establish and maintain procedures to control product that does not conform to specified requirements as required by 21 CFR 820.90(a). Your firm does not have a procedure to address the identification, documentation, evaluation, segregation, and disposition of nonconforming product (FDA 483, Item #11).
8. Your firm failed to investigate complaints involving a possible failure of a device to meet any of its specifications as required by 21 CFR 820.198(c). The following complaints were not investigated:

- a) 1-1414 (6/17/03) Otowizard (Hardware) DSS board failure. No investigation documented.
- b) 1-1450 (7/9/03) Otowizard (Hardware) DSS board failure. No investigation documented.
- c) 1-1617 (10/10/03) Otowizard (Hardware and Software failures). Investigations status is shown as being complete, however, investigation states the problem to be unresolved, and a root cause has not been determined.
- d) 1-1744 (12/17/03) Otowizard (Hardware & Software failures) Mouse not responding. Report status states the investigation is complete, however, no investigation was documented.
- e) 1-1709 (12/4/03) Transportable Otowizard (Hardware) Unit failed to power up after shut down. Status states investigation is complete. However, firm indicated this problem is systemic and has discontinued purchasing components from subcontractor until the problem has been resolved.  
(FDA 483, Item #12).

- 9. Your firm failed to establish and maintain procedures to adequately control environmental conditions that could reasonably be expected to have an adverse effect on product quality as required by 21 CFR 820.70(c). There was no electro-static discharge (ESD) procedures or other precautions in effect when electronic circuit boards were being assembled (FDA 483, Item #13).
- 10. Your firm failed to establish procedures to ensure that device history records (DHRs) for each batch, lot or unit are maintained to demonstrate the device is manufactured in accordance with the device master record (DMR) and the Quality System regulations as required by 21 CFR 820.184. There are no established DHR procedures and the documents being used as DHRs do not include dates of manufacture, acceptance records, and identification of labeling including: manuals and guides (FDA 483, Item #15).
- 11. Your firm failed to ensure that the DMR refers to the location of quality assurance procedures and device specifications as required by 21 CFR 820.181(c). There is no procedure for maintaining device master records, and the current procedure does not contain or point to the location of key components of the DMR including: labeling specifications, quality assurance procedures and specifications (FDA 483, Item #16).

12. Your firm failed to establish and maintain procedures to control the design of the device in order to ensure that specified design requirements are met as required by 21 CFR 820.30(a), (b) & (g). There were no design control procedures including: a design and development plan that addresses risk analysis, validation and review for the Otowizard; and the validation of device software is incomplete because the software development plan and software validation protocol are inadequate for the Otowizard (FDA 483, Item #s 4, 5 & 6).
13. Your firm failed to remove all obsolete documents from all points of use or otherwise prevented from unintended use as required by 21 CFR 820.40(a). The assembly procedure on the floor for the Ultra Vac system on 1/6/04 was not the current revision (Rev. #7.5, August 22, 2003) (FDA 483, Item #14).

#### Medical Device Reporting (MDR)

Your devices are misbranded within the meaning of section 502(t)(2) in that there was a failure to comply with a requirement prescribed under section 519 of the Act respecting the devices as follows:

14. Your firm failed to establish and maintain written MDR procedures as required by 21 CFR 803.17 (FDA 483, Item #17).

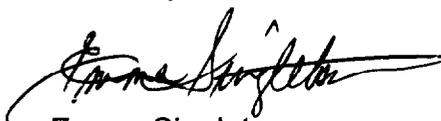
This letter is not intended to be an all-inclusive list of deficiencies at your facility. It is your responsibility to ensure adherence to each requirement of the Act and regulations. Federal agencies are advised of the issuance of all Warning Letters about devices so that they may take this information into account when considering the award of contracts.

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. Additionally, no premarket submissions for Class III devices to which QS regulation deficiencies are reasonably related will be cleared until the violations have been corrected. Also, no requests for Certificates for Products for Export will be approved until the violations related to the subject devices have been corrected. We have reviewed your response dated February 9, 2004 and find that the response is inadequate because it only promises to make the necessary corrective actions. Your response has been made part of the Florida District file.

Please notify this office in writing within fifteen (15) working days of receipt of this letter, of the steps you have taken to correct the noted violations, including (1) the time frames within which the corrections will be completed, (2) any documentation indicating the corrections have been achieved, and (3) an explanation of each step being taken to identify and make corrections to any underlying systems problems necessary to assure that similar violations will not recur.

Your response should be sent to Timothy J. Couzins, Compliance Officer, Food and Drug Administration, 555 Winderley Place, Suite 200, Maitland, Florida 32751, (407) 475-4728.

Sincerely,

A handwritten signature in black ink, appearing to read "Emma Singleton", with a long horizontal flourish extending to the right.

Emma Singleton  
Director, Florida District