## Inspections, Compliance, Enforcement, and Criminal Investigations

# VE Valley Electronics GmbH 3/1/13

Department of Health and Human Services

Public Health Service
Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

**March 1, 2013**

**WARNING LETTER**

**VIA UNITED PARCEL SERVICE**

Hubertus Rechberg
Manager
VE Valley Electronics GmbH
Breite 2
Murnau Am Staffelsee D-82418, Germany

Dear Mr. Rechberg:

During an inspection of your firm located in Murnau Am Staffelsee, Germany, on October 15-18, 2012, an investigator from the United States Food and Drug Administration (FDA) determined that your firm manufactures the Lady Comp, Baby Comp, and Pearly fertility devices. 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 to affect the structure or function of the body.

Our inspection revealed that the Lady Comp, Baby Comp, and Pearly fertility devices are misbranded under section 502(t)(2) of the Act, 21 U.S.C. § 352(t)(2), in that your firm failed or refused to furnish material or information respecting the devices that is required by or under section 519 of the Act, 21 U.S.C. § 360i, and 21 CFR Part 803 - Medical Device Reporting. We received a response from your firm dated October 26, 2012, concerning our investigator's observations noted on the Form FDA 483 (FDA 483), List of Inspectional Observations, that was issued to your firm. We address this response below, in relation to the noted violation. This violation includes, but is not limited to, the following:

Failure to adequately develop, maintain and implement written medical device reporting (MDR) procedures, as required by 21 CFR 803.17(a). For example, at the closure of the inspection, your firm submitted a revised MDR procedure titled, "Qualitätsmanagement, P08_06, Meldung von Vorkommnissen," Index 04, Datum 2012-10-17 GF, Seite 1/6. We reviewed your firm's response and the revised MDR procedure, P08_06, Index 04, and conclude that they are not adequate. The

following issues were noted:

1. P08_06, Index 04, does not establish internal systems that provide for timely and effective identification, communication, and evaluation of events that may be subject to MDR requirements. For example, the procedure includes definitions from 21 CFR 803.3, but omits the definition of the terms "become aware," and "caused or contributed," and definitions of the terms "reasonably known," and "reasonably suggests," found respectively in 21 CFR 803.50(b) and 803.20(c)(1). The exclusion of these terms from the procedure may lead your firm to make an incorrect reportability decision when evaluating a complaint that may meet the criteria for reporting under 21 CFR 803.50(a).
2. P08_06, Index 04, does not establish internal systems that provide for timely transmission of complete medical device reports. Specifically, the following are not addressed:

   a. Instructions for how to obtain the FDA 3500A form.

   b. Instructions for how to complete the FDA 3500A form. While your firm includes instructions for completing the FDA 3500 form, as a manufacturer, your firm is required to complete and submit MDRs to FDA utilizing the FDA 3500A form.

   c. References to the appropriate form to use for submission of MDRs to FDA. Your firm references FDA form 3417 for submission of supplemental MDRs. The correct form for use is the FDA 3500A form. In addition, the procedure references the FDA 3500 form for initial submission of MDRs to FDA for death, serious injury, and malfunctions. Please note that the correct form for submission of MDRs to FDA is the FDA 3500A form.

   d. The procedure does not include the address for where to submit MDR reports: FDA, CDRH, Medical Device Reporting, P.O. Box 3002, Rockville, MD 20847-3002.

If your firmwishes to submit MDR reports via electronic submission, it can follow the directions stated at the following URL: http://www.fda.gov/ForIndustry/FDAeSubmitter/ucm107903.htm[1]

If your firm wishes to discuss MDR reportability criteria or to schedule further communications, it may contact the MDR Policy Branch at 301-796-6670 or by email at MDRPolicy@fda.hhs.gov.

Federal agencies may be advised of the issuance of Warning Letters about devices so that they may take this information into account when considering the awarding of contracts.

Please notify this office in writing within fifteen business days from the date you receive this letter of the specific steps your firm has taken to correct the noted violations, as well as an explanation of how your firm plans to prevent these violations, or similar violations, from occurring again. Include documentation of the corrections and/or corrective actions (including any systemic corrective actions) that your firm has taken. If your firm's planned corrections and/or corrective actions will occur over time, please include a timetable for implementation of those activities. If corrections and/or corrective actions cannot be completed within fifteen business days, state the reason for the delay and the time within which these activities will be completed. Your firm's response should be comprehensive and address all violations included in this Warning Letter. Please provide a translation of documentation not in English to facilitate our review.

In addition, FDA has noted nonconformances with regards to section 501(h) of the Act, 21 U.S.C. § 351(h), which are deficiencies within your firm's quality system pertaining to current good manufacturing practice requirements specified in the Quality System regulation found at 21 CFR Part 820. These nonconformances include, but are not limited to, the following:

1. Failure to establish and maintain procedures for validating the device design. Design validation shall be performed under defined operating conditions on initial production units, lots, or batches,

or their equivalents. Design validation shall ensure that devices conform to defined user needs and intended uses and shall include testing of production units under actual or simulated use condition, as required by 21 CFR 820.30(g). For example:

a. There was no design validation procedure defining what validation activities were needed for the design project specific to the Lady Comp device.

b. No temperature testing was conducted on the new revision of the device. The 2007 Lady Comp design project included a design input requirement that the device operates over a temperature range of **(b)(4)** to **(b)(4)** degrees Celsius. However, the firm only referenced a temperature test that was conducted in 2002 on the older revision of the Lady Comp device.

Your firm's response dated October 26, 2012, appears to be adequate in that your firm revised the design validation plan to include **(b)(4)** tests. Additionally, your firm revised the test plan for the fertility devices to define the additional **(b)(4)** tests that included the pass/fail criteria. Your firm implemented the validation and test plans through the completion of the **(b)(4)** test for the Lady Comp device on October 23, 2012. Your firm provided a copy of the validation and test plans and completed test report for our review.

2. Failure to establish and maintain procedures for defining and documenting design output in terms that allow an adequate evaluation of conformance to design input requirements. Design output procedures shall contain or make reference to acceptance criteria and shall ensure that those design outputs that are essential for the proper functioning of the device are identified. Design output shall be documented, reviewed, and approved before release, as required by 21 CFR 820.30(d). For example, the Software Qualification for the Lady Comp, Baby Comp, and Pearly Comp does not define acceptance criteria for the **(b)(4)** test.

Your firm's response dated October 26, 2012, appears to be adequate in that your firm revised the design validation plan to include the **(b)(4)** tests. Your firm also revised the test plan for the fertility devices to define the **(b)(4)** tests that included the pass/fail acceptance criteria. Your firm implemented the validation and test plans through the completion of the **(b)(4)** tests for the fertility devices on October 26, 2012. Your firm provided a copy of the validation and test plans and completed test report for our review.

3. Failure to establish and maintain adequate procedures to ensure that formal documented reviews of the design results are planned and conducted at appropriate stages of the device's design development, as required by 21 CFR 820.30(e). For example, the design control procedure (P03 02) requires that design reviews be completed at the end of the completion of all technical documentation. The design review for the Lady Comp device was completed June 16, 2008, prior to the completion of the software qualification for the Lady Comp device, which was completed October 17, 2008. No design review was conducted after the software qualification.

The adequacy of your firm's response, dated October 26, 2012, cannot be determined at this time. Your firm completed a new design review for the Lady Comp device that included software validation. Additionally, your firm stated that training would be conducted on the current design review procedure. However, the evidence of implementation to include the training documentation was not provided in the response.

4. Failure to establish and maintain adequate procedures for receiving, reviewing, and evaluating complaints by a formally designated unit. Such procedures shall ensure that complaints are evaluated to determine whether the complaint represents an event that is required to be reported to FDA under part 803, Medical Device Reporting, as required by 21 CFR 820.198(a)(3). For example, the customer complaint handling procedures did not include the requirements for reviewing and evaluating complaints for the need to be filed as medical device reports. The procedure was updated towards the end of the FDA Inspection on October 17, 2012, and provided to the FDA Investigator for review.

Your firm's response dated October 26, 2012, appears to be adequate in that your firm updated the complaint handling procedure that included a provision for evaluating each complaint for MDR reporting and revised the complaint handling form to include MDR guidance. This updated procedure was provided to the FDA Investigator on October 17, 2012. Additionally, your firm provided documentation of the employee training that was conducted for the complaint handling procedure and other MDR related processes.

5. Failure to establish and maintain adequate procedures to ensure that Device History Records (DHRs) for each batch, lot, or unit are maintained to demonstrate that the device is manufactured in accordance with the Device Master Record (DMR) and the requirements of 21 CFR 820, as required for 21 CFR 820.184. For example, the DHRs for the Lady Comp device does not include the acceptance records which demonstrate that the device is manufacturedin accordance with the DMR and that all required components were included in the final package.

Your response dated October 26, 2012, is not adequate. Your firm created a procedure (P05-04A1 - Rev 2 - Date: October 17, 2012) that demonstrated the final packaging requirements for the devices shipped to the USA. However, this procedure did not address the DHR overall acceptance record requirements for the devices and only focused on final packaging requirements. Additionally, no training was provided on the P05-04A1 procedure to the employees.

6. Failure to establish and maintain adequate procedures for finished device acceptance to ensure that each production run, lot, or batch of finished devices meets acceptance criteria. Finished devices shall be held in quarantine or otherwise adequately controlled until released. Finished devices shall not be released for distribution until the activities required in the DMR are completed, as required by 21 CFR 820.80(d)(1). For example, your firm did not have written requirements for the final acceptance, review, release and documentation of compliance with the DMR for the Lady Comp devices.

The adequacy of your firm's response, dated October 26, 2012, cannot be determined at this time. Your firm created a new document (P05F02) that explained the final testing process. However, the adequacy of P05F02 could not be determined since your firm did not include this procedure for review. Additionally, no documentation of employee training was provided for the P05F02 procedure.

7. Failure to establish and maintain procedures to control documents by designating an individual to review for adequacy, and approve prior to issuance, all documents established to meet the requirements of this part, as required by 21 CFR 820.40(a). For example, the Approval of Documentation procedure

Your firm's response dated October 26, 2012, is not adequate. Your firm revised the procedures for P09 04 and P03 02. However, the two procedures were not translated into English. Additionally, no documentation of employee training was provided for review.

Your firm's response to this letter should be sent to: Food and Drug Administration, Center for Devices and Radiological Health, Office of Compliance, Field Operations Branch, White Oak Building 66, Room 2609, 10903 New Hampshire Ave., Silver Spring, MD 20993. Refer to CMS case #392454 when replying. If you have any questions about the contents of this letter, please contact: Debra E. Demeritt at telephone 301-796-5770 or fax 301-847-8137.

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

violations and bring the products into compliance.

Sincerely yours,
/S/
Steven D. Silverman
Director
Office of Compliance
Center for Devices and
Radiological Health

cc:
U.S. Agent
Jessica Griger
Valley Electronics LLC
25505 Collins Wharf Road
Eden, Maryland 21822

**Close Out Letter**

- VE Valley Electronics GmbH - Close Out Letter 1/23/14[2]

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1. http://www.fda.gov/ForIndustry/FDAeSubmitter/ucm107903.htm
2. /ICECI/EnforcementActions/WarningLetters/ucm388190.htm