



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration

Dallas District
4040 North Central Expressway
Dallas, Texas 75204-3128

June 20, 2007

Ref: 2007-DAL-WL-19

WARNING LETTER

CERTIFIED MAIL
RETURNED RECEIPT REQUESTED

Mr. Timothy B. Smith, President and CEO
Avazzia, Inc.
13154 Coit Road, Suite 200
Dallas, Texas 75240-5787

Dear Mr. Smith:

During an inspection of your firm located at the above-referenced address on April 16 through 27, 2007, an investigator from the United States Food and Drug Administration (FDA or Agency) determined that your firm manufactures hand-held and battery-operated transcutaneous electro-stimulators (TENS), such as the Tennant Biomodulator™, Body-Stim™ Device, Best-Pro 1™ Biofeedback Device, Best-RSJ™ Device, Med Best and Med Sport Device, and their device accessories that are intended for "symptomatic relief and management of chronic, intractable pain, and adjunctive treatment in the management of post-surgical and post-traumatic pain." 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 are intended to affect the structure or any function of the body.

This 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 Practice (CGMP) requirements of the Quality System (QS) regulation found at Title 21, Code of Federal Regulations (CFR), Part 820.

The FDA investigator issued the observations, which are listed on the Form FDA 483 (Inspectional Observations), to you at the end of the inspection on April 27, 2007. On May 22, 2007, the FDA's Dallas District Office (DAL-DO) received your two individual

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responses, both dated May 18, 2007, responding to Observation 12 and Observation 15. On May 29, 2007, the DAL-DO received another eight individual responses, dated May 22 through 25, 2007, responding to Observation 1, 6, 8, 10, 24, 25, 26, and 27. Overall, your firm's responses are incomplete as your firm has not adequately and completely responded to all inspectional observations and the specific issues cited in this warning letter, established a comprehensive corrective action plan and conducted a complete internal quality audit to address gaps in your quality system, and provided a timeframe for completing all corrective actions and verifying their effectiveness. FDA follow-up inspections will be necessary to assure that your firm's corrections are adequate.

These violations include, but are not limited to, the following:

Quality System Violations

1. Failure to establish and maintain adequate complaint handling procedures for receiving, reviewing, and evaluating complaints by a formally designated unit and to ensure that all the requirements of 21 CFR § 820.198 are met. FDA 483 Item 1, 7, 10, 24, 25, and 27.
 - a. Six service reports of malfunctioned devices and device accessories were not considered complaints; and the dates and the results of the investigations, inspection data, and corrective actions were not adequately documented (e.g., there were no records of your firm's contact and follow-up with the users, testing conducted and the testing results attached or referenced in the service reports). See Service Report # 0621404, 0633201, 0621801, 0631703, 0708201, and 0627102.
 - b. Three service reports (0621404, 0633201, and 0621801) and two complaints (07180503 and 08080504) were not adequately reviewed, evaluated, and documented to determine if they represent MDR reportable events for reporting to FDA at the time your firm received these user reports. Service Report 0621404, dated 8/2/06, and 0633201, dated 11/28/06, for the Tennant Biomodulators documented that "a conductive glove and shock have been shocking/burned people at the lowest setting." Service Report 0621801, dated 8/7/06, for the Tennant Biomodulator documented "a power surge." Complaint 07180503, dated 7/18/05, and 08080504, dated 8/8/05, for the Best RSI/Med Best/Tennant Biomodulator devices documented that "there is an output surge that is painful to user" and that "output surge is uncomfortable to user," respectively.

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2. Failure to establish and maintain procedures for the identification, documentation, validation or verification, review, and approval of design changes before their implementation, as required by 21 CFR § 820.30(i). FDA 483 Item 10 and 13. For example:
 - a. Engineering Change Notice (ECN) 20050802 (software revision 12 to 13) for the AV1 device family, which was initiated on 8/2/05 and released to production on 8/6/05, documented software engineering changes that were ambiguous or lacked sufficient details to describe the reason for the design changes. For example, your firm described the engineering changes as "put more [REDACTED] [REDACTED]". There were no validation test protocol and test results to verify the effectiveness of the software design changes. This ECN did not document or reference design inputs (complaints, service requests, internal engineering testing, etc.) that led to these software design changes. It was evidenced that the power surge issue was not effectively corrected and later resulted in another software design change in ECN 20051028, dated 11/8/05.
 - b. ECN 20051028 (software revision 17 to 18) which was released to production on 11/8/05 in an attempt to correct the same power surge issue in the AV1 device family model without establishing an engineering test protocol and maintaining the test results to verify the effectiveness of the software design change. We noted that an engineering test protocol entitled "AV1 System Test Specification and Report Form – ECR 20051028," Revision 1, dated 7/24/06, was in still "Draft" at the time of the inspection and did not document specific test instructions, acceptance criteria, and the report summary to verify that the "software bugs" had been fixed. See page 7 and 8 of the document. It appears that your two software upgrades (ECN 20050802 and 20051028) released to production on 8/6/05 and 11/8/05 were not effective as your firm later received three service reports for the Tennant Biomodulators between 8/06 and 11/06 for the same power surge issue.
3. Failure to establish and maintain adequate procedures for validating the device design to ensure that design risk analysis is conducted and documented, that the device conforms to user needs and intended uses, that acceptance criteria are established prior to performing validation activities, that design testing is conducted under actual or simulated use conditions, and that the design testing results are documented, as required by 21 CFR § 820.30(g). FDA 483 Item 16, 17, 18, 19, 20. For example:

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- a. Your firm failed to conduct and document adequate risk analyses that discuss the safe use of your devices with/without their accessories (e.g., pencil probes for dental, acupuncture, and facial uses, U probes for genital incontinence, finger probes, ear clips, ball probes, comb probes, conductive socks and gloves, conductive pads, and body and limb wraps). See your past risk analysis, dated 5/1/04. Your brief handwritten risk analysis which was prepared and provided to the FDA investigator on 4/18/07 during the inspection did not follow or reference any recognized risk analysis standard, define the risks and risk reduction in qualitative or quantitative terms.
- b. Your design validation did not explain whether the devices were tested with or without the attached device accessories and did not include user/market testing and test results or explain why this type of testing was not needed.
- c. Your software revision history for the Best AV1 Device Family documented that at least [REDACTED] software design changes have been initiated between 8/12/04 and 12/5/06. Your firm was unable to produce records of design validation results, including software validation, to prove that the Best Pro 1 device meets its design specifications for the four treatment modes (Relax/Assess, Stimulate, Deep and Acute Stimulate) as outlined in your "Best Pro Software and Hardware Specification" document, revision dated 9/25/04, and the "Best Pro Software Specification" document, revision dated 2/26/07.
- d. Your firm's "Memo to File" for the software validation of the Best Pro 1 Device, prepared and dated 4/18/07 during the inspection, and the Software Validation Report, Revision 2, dated 11/7/06, for the Med Best, Med Sport, and Best Pro 1 Devices only document the general functional test requirements without attaching or referencing their software codes, software code testing, I/O (Input/Output) interface testing between the hardware and software, and the actual test results for each of the functional test requirements listed in these two documents.
- e. Your "Proto 1 Product Description Revision 040405," signed and dated 4/20/07 during the inspection, did not (e)(1) document the IR (Initial Reading of the Relax/Assess mode) specification range; (e)(2) clearly explain how the device's internal software computes the IR value using the [REDACTED] the device's internal circuit and that of the human tissue when the Best Pro 1 device makes an initial contact with the skin; (e)(3) clearly explain how the IR responses shown in Figure 22 and 23 simulated by [REDACTED] are equivalent to that of human tissue; and (e)(4) attach the actual IR test results. See page 9 and 10 of this document.

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4. Failure to establish and maintain adequate acceptance procedures, including inspections, tests, or verification activities, for incoming product and for documenting the acceptance or rejection of the incoming product, as required by 21 CFR § 820.80(b) and 820.80(e). FDA 483 Item 8 and 26. For instance, your firm failed to document the actual test results of device outputs, the signature and date of the individual(s) conducting incoming acceptance inspection or testing of the [REDACTED] the Best AV1 devices of various models received from your contract manufacturer. See your incoming inspection/testing form "Verification QF-82-04-01-2," dated 3/29/07. In another instance, of the [REDACTED] Med Best devices tested, your firm rejected and reworked 3 devices as recorded in the "Final Assembly Best Product Traveler," dated 2/16/06. However, this final product assembly traveler did not reference or document specific test procedures or instructions, and acceptance criteria.
5. Failure to establish adequate procedures for finished device acceptance to ensure that each production run, lot, or batch of finished devices meets acceptance criteria and that acceptance activities are documented and reviewed prior to releasing the devices for distribution, as required by 21 CFR § 820.80(d) and 820.80(e). FDA 483 Item 9 and 23. For example:
 - a. Your firm's final test procedure (WI-82-04-05, Revision C, dated 8/30/06) using the fingers to feel the device output is not a validated scientific test method or lacks specific acceptance criteria to demonstrate how the Best AV1 devices of various models meet their approved design specifications (e.g., devices' quantifiable outputs that generate a specific pattern of LED display, audible sounds, specific power levels corresponding to a waveform of specific frequencies, voltages, and currents).
 - b. Your firm replaced defective device components in the devices that failed final testing and then retested the devices. However, there are no records of the actual test results of the retested devices. See NCR (Nonconformance Report) 200704319-01, dated 3/19/07, NCR 20060224-07, 20060224-06, 20060224-05, 20060224-04, and 20060213-03, all dated 2/24/06.
6. Failure to establish and maintain adequate procedures for rework, including retesting and reevaluation of the nonconforming product after rework, to ensure that the product meets its current approved specifications, as required by 21 CFR § 820.90(b)(2). FDA 483 Item 11. For example, your firm failed to establish rework procedures that convert one device model to another device model (e.g. from Med Best to Body Stim).

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7. Failure to maintain device master records (DMR) to include or refer to the location of, device specifications, production process specifications, quality assurance procedures, and packaging and labeling specifications, and to ensure that each DMR is prepared and approved in accordance with 21 CFR § 820.40, as required by 21 CFR § 820.181. FDA 483 Item 3, 4, and 5. For example:
 - a. Your firm's DMR did not reference the packaging and labeling specifications (the labels and device's owner manual) approved for use for the Best Pro 1 Device and certain quality assurance and labeling procedures.
 - b. Your firm's DMR did not reference production process procedures and/or diagrams that describe what specific manufacturing activities are conducted at your contract manufacturers and at your firm.

We address your responses as follows in relation to each of the noted observations.

FDA 483 Item 1, 24, and 25:

Your two individual 5/24/07 responses are incomplete. Your firm's responses to Observation 1 stated "when the accessory was removed from the skin, the burning sensation stopped." While you explained the circumstances surrounding the patients' use of your devices and that there was no evidence of tissue injury, your firm's investigation into the root cause of power surge, follow-up contact and discussion with your users or distributor, and your deliberation results using your MDR procedures should have been documented at the time you received the complaints in 2005 and 2006. See Customer Complaint 07180503 and 08080504. We further noted that your complaint records attached to your responses contain handwritten notes and changes that are not always legible. Additionally, you failed to review your MDR procedures for adequacy and explain what corrective action you will take to prevent this deficiency from occurring again.

FDA 483 Item 6:

Your 5/22/07 response is incomplete. You revised your "Operational Procedure QOP-74-03," dated 5/24/07, to identify the required sampling plans in Table 1, 2, and 3 used for the inspection or testing of incoming components, device assemblies and accessories. You did not attach a list of these products or explain what they are. Your revised inspection form "Verification QF-82-04-01-2," dated 5/17/07, does not identify (a) how each type of incoming product is inspected or functional tested, and (b) acceptance criteria. Additionally, you have not justified why you use the "pass/fail" test result instead of the actual quantifiable test result to prove that your devices and components are manufactured in conformance to your approved design specifications. See Warning Letter Item 4 and 5.

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FDA 483 Item 8:

Your 5/25/07 response is incomplete. You simply explained that your firm revised the six procedures listed to add the signatures and the names of the individuals conducting the testing. However, you failed to explain how your components, accessories, assemblies, and finished devices are inspected or tested, and how their inspection/test results are documented. See our evaluation of your 5/22/07 response to FDA 483 Item 6 and Warning Letter 4.

FDA 483 Item 10 and 27:

Your 5/24/07 response is incomplete. You explained that your response to FDA 483 Item 10 was closely related to FDA 483 Item 27. You failed to explain why the Tennant Biomodulators did not receive the design upgrade to correct the power surge issue and whether this issue was effectively corrected in all device models. We noted that using the fingers to "feel" the device output during factory testing is not a scientific test method.

FDA 483 Item 11:

Your response 5/24/07 is incomplete. See Warning Letter Item 6.

FDA 483 Item 26:

Your 5/25/07 response is incomplete. You failed to address the underlying issues cited in Warning Letter 4 and 5.

Responding to This Warning Letter

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 (21 CFR Part 820) 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

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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 Thao Ta, Compliance Officer, Dallas District Office, Food and Drug Administration, HFR-SW140, 4040 N. Central Expressway, Suite 300, Dallas, Texas 75204. If you have any questions about the content of this letter please contact Mr. Ta at 214-253-5217.

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 yours,



Andrew Blake Bevill
Acting Dallas District Director

ABB:txt

cc:
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