WARNING LETTER

Vevazz LLC

MARCS-CMS 592118 — DECEMBER 26, 2019

Delivery Method:

United Parcel Service

Product:

Medical Devices

Recipient:

Mr. Jamie Fettig

Owner

Vevazz LLC

216 1st St, Ste A
Eaton, CO 80615
United States

Issuing Office:

Office of Medical Device and Radiological Health Operations (Division 3)

United States

WARNING LETTER
CMS # 592118

December 26, 2019

Dear Mr. Fettig:

During an inspection of your firm located in Eaton, CO, on June 3, 2019 through June 20, 2019, an investigator from the United States Food and Drug Administration (FDA) determined that your firm manufacturers low level LED light therapy devices including the Vevazz Contour (Contour), a product with large and small LED paddles that are attached to the body with straps, and the Vevazz Bed (Bed), a bed with LEDs. 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 any function of the body.

FDA has reviewed materials collected during the inspection, your firm's websites (vevazz.com, slimlinesystem.com),***1*** and you firm's prior correspondence with FDA regarding the marketing of the Contour. Based on this review, FDA has determined that the Contour and Bed are adulterated under section 501(f)(1)(B) of the Act, 21 U.S.C. § 351(f)(1)(B), because your firm does not have an approved application for premarket approval (PMA) in effect pursuant to section 515(a) of the Act, 21 U.S.C. § 360e(a), or an approved application for an investigational device exemption (IDE) under section 520(g) of the Act, 21 U.S.C. § 360j(g) for the devices as described and marketed. The Contour is misbranded under section 502(o) the Act, 21 U.S.C. § 352(o), because your firm introduced or delivered for introduction into interstate commerce for commercial distribution this device with significant changes or modifications to the intended use, design, and components without submitting a new premarket notification to FDA as required by section 510(k) of the Act, 21 U.S.C. § 360(k), and 21 CFR 807.81(a)(3). The Contour is also misbranded under section 502(a) of the Act, 21 U.S.C. § 352(a), and 21 CFR 807.97 because representations on your website create an impression of official approval of your device and are misleading. The Bed is misbranded under section 502(o) of the Act, 21 U.S.C. § 352(o), because your firm did not notify FDA of its intent to introduce each device into commercial distribution, as required by section 510(k) of the Act, 21 U.S.C. § 360(k).

The Contour

Major Changes or Modifications to the Contour's Intended Use

Your firm holds two 510(k) clearances for low level LED light therapy devices. In a letter received by FDA on November 30, 2018, you indicated that the Contour was marketed under both of the following premarket notification numbers:

 The "Vevazz LED" was cleared under K172111 and is a prescription device that is intended "to provide the non-invasive dermatological aesthetic treatment for the reduction of circumference of hips, waist, and thighs."
 The "Vevazz LED Heat Lamp" was cleared under K162763 and is a prescription device intended to emit "energy in the infrared spectrum and is to be used to provide topical heating for the purpose of elevating tissue temperature for the temporary relief of minor muscle and joint pain, arthritis, stiffness or muscle spasms; the temporary increasing of local blood circulation and/or temporary relaxation of muscle."

However, statements on your firm's websites and in materials collected during the inspection suggest that the device is also intended for the treatment of neuropathy,**2** inflammation, and other uses, which constitute major changes or modifications to its intended uses for which your firm lacks clearance or approval. Examples include:

- "VevazzTM Contouring is [a] safe, painless, and completely non-invasive treatment for fat loss, spot reduction and aesthetic body contouring. Other treatments Light therapy has been proven to help are Cellulite Reduction, Scar Treatment, Wrinkle Reduction, Skin Tightening, Neuropathy, Pain and Inflammation."
- "LED Light Paddles Options:...Green: Best for Cellulite" "Infrared: Best for stretch marks, scars, neuropathy, pain and inflammation."
- "Natural Neuropathy Treatment in Only 7 minutes treatment time!"
- "Vevazz light therapy treatment of low intensity initiate analgesic, anti-inflammatory and biostimulatory effects, resulting in an increase in local microcirculation and increased healing. Increasing microcirculation induces an essential function in the tissue repair process and in pain control. This process allows increases in oxygenation and nutritional supply to tissues. This process allows for the expulsion of metabolic byproducts, which may contribute to reduce pain and inflammation. Furthermore it stimulates repair and regrowth of nerve tissue."

Statements that indicate the Contour is intended for the treatment of neuropathy are not supported by your firm's clearances. In addition, this intended use raises new questions of safety and effectiveness not addressed by your firm's clearances, including, but not limited to, increased risk of burns, wounds, skin trauma, tissue injury, and delayed healing because patients with neuropathy may have an increased safety risk when using the Contour due to absent or reduced sensation of the nerves in the skin. This use also raises public health concerns because patients may use the Contour before or instead of seeking other medical care, which

could delay treatment of an underlying injury or disease. For example, if treatment or diagnosis is delayed for a patient with neuropathy caused by diabetes, the patient could experience foot ulcers or, depending on the severity of the diabetes, require amputation.

In a letter to FDA received on November 30, 2018, you stated that you believe the Contour may be legally marketed for the treatment of neuropathy because pain is a symptom of neuropathy and the device was cleared to temporarily relieve pain under K162763. While pain may be a symptom of neuropathy or other tissue damage, use of the Contour to temporarily relieve a symptom does not treat the underlying disease or condition causing the symptom. The treatment of neuropathy is a different intended use than the temporary relief of pain, and, therefore, different evidence is necessary to demonstrate a reasonable assurance of safety and effectiveness for a device intended to treat neuropathy. Your firm has not provided any evidence to FDA to demonstrate the Contour's safety and effectiveness for treating neuropathy. To date, FDA is unaware of any low level LED light therapy device approved or cleared for the treatment of neuropathy or evidence that would substantiate the safety and efficacy of your device for that use.

Your firm is also marketing the Contour to treat inflammation. In a letter to FDA received on November 30, 2018, you stated that you believe the Contour is cleared to treat inflammation under K162763, and that alternatively, the Contour's treatment of inflammation is a use that is exempted from premarket notification requirements under 21 CFR 890.5500 (Infrared Lamp). We disagree.

Treatment of inflammation is a different intended use than the intended use (temporary pain relief, temporary muscle relaxation, and temporary increase in circulation) for which the Contour was cleared under K162763. Further, devices classified under 21 CFR 890.5500 (Infared Lamp) are not intended to treat inflammation. Generic devices of this type topically heat tissue for medical purposes, including, but not limited to, temporary pain relief, temporary muscle relaxation, and a temporary increase in circulation. Devices classified under 21 CFR 890.5500 (Infrared Lamp) are exempt from premarket notification unless they exceed the limitations on exemption at 21 CFR 890.9. Because the Contour is intended for uses different from those of legally marketed devices classified under 21 CFR 890.5500 (Infrared Lamp), it exceeds the exemption at 21 CFR 890.9(a).

As explained above, your firm is marketing the Contour for a different intended use than cleared in K162763 and permitted by 21 CFR 890.5500, namely to treat inflammation. This unapproved intended use raises public health and safety concerns because patients experiencing inflammation may be at risk for burns and tissue injury due to modified skin sensitivity or delayed healing if, for example, the underlying condition causing the inflammation may be untreated or exacerbated due to treatment with the

Contour before or instead of seeking medical care. Your firm has not provided any evidence to FDA to demonstrate the Contour's safety and effectiveness to treat inflammation, and, to date, FDA is unaware of any low level LED light therapy device approved or cleared for the treatment of inflammation or evidence that would substantiate the safety and efficacy of your device for that use.

In addition, statements that the Contour may be used to reduce cellulite, treat scars, reduce fine lines and wrinkles, and tighten skin are not supported by your firm's clearances. In a letter to FDA received on November 30, 2018, you explained that statements that the Contour reduces cellulite; treats scars, fine lines, and wrinkles; and tightens skin, generally relate to other manufacturers' "equipment" and that you "include" the equipment in the Contour "system" or tell customers where to purchase the equipment. However, the statements on your website (and included above) specifically reference the Contour and do not mention other equipment, manufacturers, or upgrades to your device to accommodate such equipment and/or make such uses possible. To date, there is no low level LED light therapy device that is approved or cleared to treat scars and/or tighten skin, and your firm has not provided evidence to FDA to demonstrate the safety and efficacy of any of these new uses (including to reduce cellulite or treat fine lines and wrinkles). In addition, we remind you that integrating other equipment into the Contour system may require submission of a premarket notification to FDA as required by section 510(k) of the Act, 21 U.S.C. § 360(k), and 21 CFR 807.81(a)(3)(i), if it is a change or modification in the device that could significantly affect the safety or effectiveness of the device, e.g., a significant change or modification in the design.

Changes or Modifications That Could Significantly Affect the Contour's Safety or Effectiveness

Based on a review of materials collected during the inspection and statements made on your website, your firm made significant changes or modifications in the design and components of the Contour as cleared under K172111 and K162763, which could significantly affect the safety or effectiveness of the device. For example, the Contour was cleared with a 650 nm wavelength under both clearances, but you added 532 nm and 840 nm as additional wavelengths. Your firm also increased the number of LEDs in the small paddles from 4 to 28 and increased the number of paddles containing LEDs from 16 to 32. Increasing the number of available wavelengths, the number of LEDs, and the number of paddles could increase the risk of burns to the patient because, during use, the LEDs come into contact with the patient's skin and the number of increased paddles with varying wavelengths could result in a larger skin-contacting- surface-area than the amount of skin contacted with a 650 nm wavelength under the firm's two existing clearances. To date, your firm has not provided evidence to FDA to substantiate the safety and efficacy of these changes to the Contour's design and components. Further, because the mechanism of action for the reduction of circumference of the hips, waist, and thighs by low level light therapy devices is not well understood, it is uncertain whether increasing LED contact with the skin could significantly affect the safety or effectiveness of the device as cleared and marketed under K172111.

Representations that Create an Impression of FDA Approval

The Contour is also misbranded under section 502(a) of the Act, 21 U.S.C. § 352(a), because representations on your firm's website create an impression of official approval of the device and are misleading. In addition, 21 CFR 807.97 states that any representation that creates an impression of official approval of a device because of complying with the premarket notification regulations is misleading and constitutes misbranding. Your website contains such representations. For example, your website states: "VevazzTM Contouring is a clinically proven non-invasive fat loss treatment that is pain free that doesn't require recovery time, plus is natural, safe, effective and FDA approved" and "Natural. Safe. Effective. FDA Approved." Further, under an "FDA-approval" tab, your website states:

- □ "FDA approvals obtained by Vevazz:

1. Class 1 Device: FDA registered for adjacent treatment of obesity
2. 510(k) Clearance: *FDA Cleared for Pain and Inflammation, as well as Immediate Fat Loss and Body Contouring Only. for Pain and inflammation, some of the symptoms of Neuropathy
3. Body Contouring: *FDA Cleared for Pain and Inflammation, as well as Immediate Fat Loss and Body Contouring Only. for 510k for immediate (1 visit) Body Contouring results"

In addition to misbranding, these statements further support the false impression that FDA has evaluated and cleared the Contour for the unapproved uses described above.

The Bed

Our inspection, review of materials collected during the inspection, and review of your firm's websites also revealed that your firm is currently marketing an unapproved device, the Bed. Specifically, under the "Vevazz Bed" tab, your firm's website states:

- □"[The Bed] is safe, painless, and completely non-invasive. Red light has been shown to help with fat loss, spot reduction and aesthetic body contouring. Other treatments red light has been shown to help are Anti-aging, and wrinkles."
- □"No other device in the market offers such a short treatment time per surface area and no staff required!"
- □"Vevazz's LED light works in only 7 minutes per session."
- □Under the headings "Red light benefits and the Vevazz Bed difference" and "what has red light has [sic] been shown to help with?," a number of benefits are described, including: reversal of sun or UV damage to the skin; wound healing; increased

blood flow/circulation; reduced pain and/or inflammation; treatment of acne; reduction of appearance of wrinkles; pigmentation spots, stretch marks and/or scarring; and "Skin rejuvenation, restoration, oxygenation and/or hydration, Collagen/Elastin production/reorganization of skin structure, elasticity and/or metabolism."

The Bed is not approved or cleared by FDA for marketing in the United States.

The Face Mask

During our review of your website, FDA learned that your firm is marketing the Face Mask, a mask with LED lights, in the United States without marketing clearance or approval, in violation of the Act. Specifically, under the "Face Mask" tab, your firm's website states:

- "Face treatment mask with 3 different LED lights for optimal treatment of Wrinkles, Scars, Acne and Skin Tightening."
- "Red Light<650-730nm> Will stimulate the production of collagen. Collagen is an essential protein used to repair damaged tissue and to replace old tissue. Beat [sic] for fine lines, and will also help to reduce large pores."
- "Green Light<525-550nm> The balance of green light can balance color pigment, reduce fine lines, nutrient aging skin, speed up the healing process of the wound, and lighten the scare [sic]."

Under section 201(h) of the Federal Food, Drug, and Cosmetic Act (the Act), 21 U.S.C. § 321(h), the Face Mask 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 to affect the structure or any function of the body. We have determined that the Face Mask is adulterated under section 501(f)(1)(B) of the Act, 21 U.S.C. § 351(f)(1)(B), because your firm does not have an approved application for premarket approval (PMA) in effect pursuant to section 515(a) of the Act, 21 U.S.C. § 360e(a), or an approved application for an investigational device exemption (IDE) under section 520(g) of the Act, 21 U.S.C. § 360j(g) for the device as described and marketed. The Face Mask is also misbranded under section 502(o) of the Act, 21 U.S.C. § 352(o), because your firm did not notify FDA of its intent to introduce each device into commercial distribution, as required by section 510(k) of the Act, 21 U.S.C. § 360(k). For a device requiring premarket approval, the notification required by section 510(k) of the Act, 21 U.S.C. § 360(k), is deemed satisfied when a PMA is pending before the agency. 21 CFR 807.81(b). The kind of information that your firm needs to submit in order to obtain clearance or approval for the device is described on the Internet

at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/default.htm (http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/default.htm). The FDA will evaluate the information that your firm submits and decide whether the product may be legally marketed.

Current Good Manufacturing Practice Requirements

The inspection also revealed that your firm's Vevazz LED light therapy 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 requirements of the Quality System regulation found at 21 CFR Part 820. Operations observed in your facility during the inspection included final acceptance testing and release of finished devices received from suppliers, customer service, administration, incoming acceptance, storage, and distribution.

We received a response dated July 8, 2019 from you, concerning our investigator's observations noted on the Form FDA 483, List of Inspectional Observations (FDA 483) that was issued on June 20, 2019. We address the response below, in relation to each of the noted violations. These violations include, but are not limited to, the following:

1. Procedures for receiving, reviewing, and evaluating complaints by a formally designated unit have not been established3 and maintained per the requirements of 21 CFR 820.198.

During our recent inspection, your CEO / Office Manager provided a Complaint Handling Procedure, QP33, Rev. 00, dated 6/3/2019. This draft procedure was dated the day our inspection began and had not been reviewed or approved as required by your Document and Data Control Procedure, QP03, Issue 0, issued 6/2/2019. During the inspection, we reviewed complaints that described potentially serious issues such as "burning sensation on skin" and "paddles too hot and burning patients." The complaints did not include all required information per the regulatory requirements of 21 CFR 820.198 or your requirements under the Complaint Handling Procedure.

Your response indicates you will implement the "complaints procedure" by 12/25/2019. We cannot evaluate the adequacy of your firm's response and proposed actions at this time as you have not provided objective evidence of corrections to date.

For reference, the Agency defines a complaint under 21 CFR 820.3(b). Your firm should review this definition and the requirements under 21 CFR 820.198 to ensure that a procedure that meets these regulatory requirements is established. We request that you notify our office when a procedure has been updated, as necessary, and established. Please provide a copy of the

established procedure (highlighting any changes) and examples of complaint records that demonstrate the procedure was established, including documentation of complaints received, as applicable, and the results of the "review [of] all previous customer complaints for evaluation against complete complaint information."

2. Procedures for design control have not been established and maintained per the requirements of 21 CFR 820.30, to include a complete risk analysis.

During our inspection, the Design Control Procedure, QP34, Rev. 00, dated 6/3/2019, and the Design Change Control Procedure, QP37, Rev. 00, 6/3/2019, were provided. These draft procedures were dated the day our inspection began and had not been reviewed or approved as required by your Document and Data Control Procedure, QP03, Issue 0, issued 6/2/2019. The Design Control Procedure states that devices developed before the Procedure became effective may follow a retrospective approach for documenting design; however, the documents provided did not document any such retrospective approach.

In general, many design documents reviewed during the inspection were not approved, were not complete, and did not follow an established procedure. For example, a Design Plan, document DDP01, Rev 00 was provided, but it is undated and has no signatures demonstrating the document is approved as required by your Document and Data Control Procedure. In addition, two design checklists were provided dated November 2014. The checklists refer to a "Product Brief" that could not be provided upon request. The checklists were not signed and did not demonstrate approval (i.e., all places for "sign off" were left blank). Design reviews, verification and validation, and design changes should follow an approved procedure and be governed by document controls that demonstrate appropriate review, approval, and control.

The Software Validation Procedure, QP11, Issue: 0, Date of Issue: 6/2/2019, (issued the day before our preannounced inspection began) was also provided during the inspection. All documents related to software validation should be aligned per the requirements of your design procedures and this Software Validation Procedure. We recommend that you review your procedures against 21 CFR 820.30 to ensure all requirements are met because the software validation documents provided during the inspection do not appear to have been governed by a procedure at the time of performance. In addition, the Software Validation Report dated July 2016 references a **(b)(4)** minute default setting for the run time of "The Vevazz" yet the treatment time is listed in the "Vevazz" User Manual as 7 minutes. The test plan referred to within this report was requested, but could not be provided. Per the two different treatment times indicated in clearances, the device and related software should be validated to demonstrate consistent performance for either treatment time based on the indication(s) for use.

Your firm's Software Validation and Risk Mitigation Procedures reference risk assessment. The Software Level of Concern document provided to address risk analysis lists mitigations to defined risks such as visual inspection, however no documentation of visual inspection or other mitigating steps could be provided during the inspection. Without adequate records documenting performance of risk mitigation steps, there is no assurance that the risks identified with the device have been adequately controlled/mitigated to reduce the hazards to the user as required per your Hazard Analysis document, rev 0, no release date.

Your response indicates you will implement the "design control procedures" by 12/25/2019, and compile the Design History File (DHF) by 12/26/2020. We cannot evaluate the adequacy of your firm's response and proposed actions at this time as you have not provided objective evidence of corrections.

As applicable, design control documents should demonstrate they have been reviewed, approved, implemented, and appropriately controlled to be considered "established." We have included an FDA guidance document titled, "Design Control Guidance for Medical Device Manufacturers" to assist in your corrections. We request that you review this document and 21 CFR 820.30 and provide a summary of your corrections, including if you developed new procedures made updates to existing procedures.

3. Procedures to ensure that all purchased or otherwise received product and services conform to specified requirements have not been established and maintained per the requirements of 21 CFR 820.50.

During our inspection, the Supplier Management Procedure, QP31, Rev. 00, dated 6/3/2019, was provided. This draft procedure was dated the day our inspection began and had not been reviewed or approved as required by your Document and Data Control Procedure, QP03, Issue 0, issued 6/2/2019. Your firm could not provide documentation demonstrating evaluation and qualification of your supplier for the contract manufacture of your Vevazz LED devices labeled to treat pain, inflammation, neuropathy, and obesity as required by your unapproved procedure.

Your response indicates you will implement the "purchasing and supplier management procedures" by 12/25/2019, and compile an Approved Supplier List (ASL) by 12/26/2020. We cannot evaluate the adequacy of your firm's response and proposed actions at this time as you have not provided objective evidence of corrections.

We ask that you review 21 CFR 820.50, establish procedures to meet the requirements, including the retention of applicable records. Please be aware in your review of this section that the regulation also applies to consultants. Please provide our office a timeframe for when this can be completed, a copy of the procedure(s) once established (highlighting changes as applicable), and an example of records demonstrating the procedure has adequately corrected this violation.

4. Procedures for finished device acceptance have not been established and maintained per the requirements of 21 CFR 820.80(d).

During our inspection, your CEO / Office Manager told our investigator that you perform a functionality test of finished devices upon receipt from your contract manufacturer. He described this as a meter test of the **(b)(4)** and described using a **(b)(4)** meter. No procedure was provided governing this performance / acceptance testing method or its acceptance criteria, and documentation of the results of this testing were not consistently observed during record review. In addition, the instructions for use (IFU) of the meters being used were not followed and processes relevant to using these devices for measurement such as defining **(b)(4)** are not addressed in a procedure to ensure consistent performance.

Your response indicates you will implement a "device acceptance procedure" via batch record review and final device testing instructions by 12/25/2019. We cannot evaluate the adequacy of your firm's response and proposed actions at this time as you have not provided objective evidence of corrections.

The final acceptance practices your firm is using are inadequate because they do not meet the requirements of 21 CFR 820.80, specifically test procedures explaining how finished device acceptance should be conducted have not been established. We suggest that you review 21 CFR 820.80 and establish procedures to meet the requirements, including retention of applicable records. Please provide our office a timeframe for when this can be completed, a copy of the procedure once it is established, and examples of records that demonstrate that the procedure was established.

5. Procedures to ensure equipment is routinely calibrated, inspected, checked and maintained have not been adequately established and maintained per the requirements of 21 CFR 820.72(a).

During our inspection, your CEO / Office Manager provided the Product Realization Procedure, QP05, Rev. 0, issued 06/02/19, the day before our preannounced inspection began. He also provided the IFUs for both the **(b)(4)** meter used in the final acceptance meter test described above. Records were not available to demonstrate these meters were calibrated for use **(b)(4)** per your firm's Product Realization Procedure requirement to determine the effectiveness of the sensor used for measurement every **(b)(4)**.

Your response indicates you will implement a "calibration procedure" and calibrate all critical instruments by 12/25/2019. We cannot evaluate the adequacy of your firm's response and proposed actions at this time as you have not provided objective evidence of corrections.

Please review 21 CFR 820.72, ensure your procedure meets all requirements, and provide calibration certificates upon completion for the meters used in final acceptance testing.

6. Procedures have not been established and maintained to control product that does not conform to specified requirements per 21 CFR 820.90.

During our inspection, your CEO / Office Manager stated your firm does not have established procedures for controlling product that does not conform to specified requirements. Then, your CEO / Office Manager later provided your Product Realization Procedure, QP05, Issue: 0, Date of Issue: 6/2/2019, issued the day before our preannounced inspection began. This Procedure requires nonconforming product to be segregated and requires reworked product to meet the same specifications as conforming products. However, your CEO / Office Manager stated that your firm does not have a segregated area for nonconforming product and disposition of units that fail the meter tests is not documented.

Your response indicates you will implement a "nonconformance procedure" and review any critical nonconformances by 12/25/2019. We cannot evaluate the adequacy of your firm's response and proposed actions at this time as you have not provided objective evidence of corrections.

Nonconformity is defined in 21 CFR 820.3(q). We request that you review this definition and all requirements of 21 CFR 820.90 and establish a procedure to meet these requirements. We request that you notify our office when the procedure has been fully established including providing a sample of nonconformance records, as appropriate. Please provide a copy of the new or updated procedure and a few examples of how this procedure has been implemented.

7. Procedures for corrective and preventive action (CAPA) have not been established and maintained per the requirements of 21 CFR Part 820.100.

During our recent inspection, you provided three CAPA related procedures: Corrective and Preventive Actions, QP-07; Corrective Action, QP-20; and Preventive Action, QP-23, all of which were in initial revision and issued 6/2/2019, the day before our preannounced inspection began. During the inspection your CEO / Office Manager stated that one corrective action of a "**(b)(4)**" was performed as a result of complaints received. No documentation could be provided related to this change, and the CEO / Office Manager could not provide any additional details related to whether this was also a design change, when it took place, any documented investigation, or CAPA effectiveness check. Your Corrective and Preventive Action Procedure indicates "corrective actions" will be initiated based on nonconformities, complaints, etc.; the "corrective action" will be investigated; a CAPA will be

proposed; and the CAPA will be reviewed and approved by the Quality Representative. At the time of our inspection, the CEO / Office Manager stated that you, Mr. Fettig, are the owner and Quality Representative. It was also noted that you are typically onsite **(b)(4)** per year.

Your response indicates you will implement a "CAPA procedure" and review previous quality events "for applicability to Corrective Actions and Preventative Actions" by 12/25/2019. We cannot evaluate the adequacy of your firm's response and proposed actions at this time as you have not provided objective evidence of corrections.

We request that you review these CAPA-related procedures to ensure they meet all requirements under 21 CFR 820.100 and that you also ensure you are able to comply with your own requirements (or update those requirements to fit your current operations). If new procedures or changes to procedures are required, please notify our office and provide a copy of the new/updated procedures, highlighting changes as necessary. Please also provide details related to the regulator change referenced during the inspection.

8. A device master record has not been maintained, per the requirements of 21 CFR 820.181.

During our inspection, you could not provide a Device Master Record (DMR) for your Vevazz LED devices. A DMR is a compilation of specifications for design, production, quality assurance, packaging, labeling, etc. which helps to ensure a medical device is manufactured according to the most current specifications and applicable procedures.

Your response indicates you will create a DMR by 12/25/2019. We cannot evaluate the adequacy of your firm's response and proposed actions at this time as you have not provided objective evidence of corrections.

A DMR should provide all current specifications for the device in one place, and the DMR should be updated as various specifications are updated. Our investigator noted differences between the power light energy output listed in your labeling compared to your clearances. This is an example of a specification that should be defined in the DMR. We ask that you review the requirements under 21 CFR 820.181 and provide a copy of the DMR with the complete list of specifications when complete. You do not necessarily need to provide all related documents as they will be reviewed during your next inspection.

9. A device history record has not been maintained per the requirements of 21 CFR 820.184.

During our inspection, your CEO / Office Manager provided the Product Realization Procedure, QP05, Issue: 0, Date of Issue: 06/02/2019, which appears to be the only procedure that we were provided that, although incomplete, governs how Device History Records (DHRs) are maintained. This procedure refers to a Quality Plan / DHR for each product. Your CEO / Office Manager explained the devices are contract manufactured offsite and then tested at your facility. The CEO / Office Manager stated that no DHR is generated at either site. The CEO / Office Manager also explained the testing procedure for final acceptance, but could not provide records demonstrating that these activities have been consistently performed for your distributed Vevazz LED devices. The Product Realization Procedure does not include requirements for inclusion of the following in the DHR: dates of manufacture; quantity manufactured; quantity released for distribution; acceptance records which demonstrate the device is manufactured in accordance with the DMR; primary identification label and labeling used for each production unit; and any unique device identifier (UDI) or universal product code (UPC).

Your response indicates you will create a DHR by 12/27/2020. We cannot evaluate the adequacy of your firm's response and proposed actions at this time as you have not provided objective evidence of corrections.

We request that you review the requirements of 21 CFR 820.184 and establish a procedure to meet these requirements. Please notify our office when this procedure has been established and provide a copy as well as an example of a completed DHR.

10. Procedures for training and identifying training needs have not been adequately established per the requirements of 21 CFR 820.25.

During our inspection, your CEO / Office Manager provided the Training Procedure, QP12, Rev. 00, dated 06/02/2019. This Procedure requires that "HR" maintain a personnel file for each employee with quality system responsibilities including qualification data, job description, and training records to include training on processes that may affect quality. Training records were requested for the two employees who perform the meter test described above for final acceptance, and no records could be provided.

During the inspection, the CEO / Office Manager told our investigator your firm did not have certain procedures that our investigator later identified in documents provided by your firm. It is the responsibility of the personnel at your firm to find and provide applicable procedures and records relevant to the requirements of the quality system regulations during an FDA inspection. Almost all procedures provided during our inspection were dated either the day before or the day our inspection began. During the inspection, your firm could not demonstrate that employees were trained on the new procedures.

Your response indicates you will implement a “training procedure” and develop a training plan for all employees by 12/25/2019. We cannot evaluate the adequacy of your firm’s response and proposed actions at this time as you have not provided objective evidence of corrections.

Please review the requirements of 21 CFR 820.25 to ensure your training procedure meets all requirements. You should conduct training to the new procedures that were or will be drafted and ensure that it is clear what specific regulatory terms mean when they are used in a procedure. Be prepared for training records to be reviewed as part of your next inspection. In addition, upon completion of training, please provide records to our office demonstrating the employees who perform the meter test have been trained to do so.

11. Procedures for quality audits have not been established per 21 CFR 820.22.

During our inspection your CEO / Office Manager provided the Quality Audit Procedure, QP14, Issue: 0, Date of Issue: 6/2/2019, issued the day before our preannounced inspection began. The Procedure requires annual audits. The CEO / Office Manager indicated that your firm has not ever conducted any quality audits of your quality system.

Your response states that you will implement a “quality audit procedure” by 12/27/2020. We cannot evaluate the adequacy of your firm’s response and proposed actions at this time as you have not provided objective evidence of corrections.

We request that you review the requirements of 21 CFR 820.22 and ensure your established procedure meets all regulatory requirements including re-auditing deficient matters. Please provide us a copy of the procedure (highlighting any changes) as well as the date of and evidence demonstrating your first audit has been completed. Be prepared to provide evidence of any audits (but not the results) as well as your overall audit plan during your next inspection.

12. Management with executive responsibility has not reviewed the suitability and effectiveness of the quality system per the requirements of 21 CFR 820.20(c).

You provided a Management Responsibility Procedure, QP01, Issue: 0, Date of Issue: 6/2/2019, issued the day before our preannounced inspection began. This Procedure, along with your Quality Manual, QSM-13 (undated), requires that a documented Management Representative conduct management reviews **(b)(4)** per year. There is no appointed and documented Management Representative pursuant to requirements of your Procedure (and as required by 21 CFR 820.20(b)(3)), and your CEO / Office Manager stated no management reviews have been conducted to date. It is of note that the titles and related responsibilities

described in your Quality Manual and your Management Responsibility Procedure as well as those referenced during our inspection are inconsistent. You should review all documentation, including your website, and update as necessary to reflect consistent titles and responsibilities.

Your response indicates you will implement a "management review procedure" by 12/27/2019. We cannot evaluate the adequacy of your firm's response and proposed actions at this time as you have not provided objective evidence of corrections.

We request that you review 21 CFR 820.20 and provide a summary of your corrections and evidence of the completion of your first management review.

Our inspection also revealed that your firm's Vevazz LED light therapy 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 device that is required by or under section 519 of the Act, 21 U.S.C. § 360i, and 21 CFR Part 803 - Medical Device Reporting. Significant violations include, but are not limited to, the following:

1. Written Medical Device Reporting (MDR) procedures have not been implemented per the requirements of 21 CFR 803.17.

During our recent inspection, your CEO / Office Manager initially told our investigator your firm did not have an MDR procedure. Later that day, the CEO / Office Manager provided a Medical Device Reporting Procedure, QP 30, Rev. 00, dated 6/3/2019, which the CEO / Office Manager stated was provided by your consultant electronically during the inspection. This draft procedure was dated the day our inspection began and had not been reviewed or approved per the requirements of your Data Control Procedure. In addition, no complaints or other documents reviewed during our inspection demonstrated that, pursuant to 21 CFR 820.198, an evaluation whether the complaint represented an event required to be reported under 21 CFR Part 803 occurred.

Your response indicates you will implement a "MDR procedure" by 12/25/2019. We cannot evaluate the adequacy of your firm's response and proposed actions at this time as you have not provided objective evidence of corrections.

We request that you review the requirements of 21 CFR Part 803 and ensure your procedure meets these requirements. Please notify our office when complaints begin to be evaluated for Medical Device Reporting according to the regulations so that these may be reviewed as part of your next inspection.

Our office requests that Vevazz, LLC immediately cease activities that result in the misbranding or adulteration of its low level LED light therapy devices, such as the commercial distribution of the devices for the uses discussed above.

Your firm should also 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 FDA without further notice. These actions include, but are not limited to, seizure, injunction, and civil money penalties. Additionally, premarket approval applications for Class III devices to which the Quality System regulation violations are reasonably related will not be approved until the violations have been corrected. Also, requests for Certificates to Foreign Governments (CFG) may not be granted. More information on processes for persons denied a CFG can be found at https://www.fda.gov/regulatory-information/search-fda-guidancedocuments/process-request-review-fdas-decision-not-issue-certain-export-certificates-devices (https://www.fda.gov/regulatory-information/search-fda-guidancedocuments/ process-request-review-fdas-decision-not-issue-certain-export-certificates-devices).

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 (which must address systemic problems) 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. If your firm does not believe that the devices are in violation of the Act (as described herein), please include your reasoning and any supporting information for our consideration. Your firm's response should be comprehensive and address all violations included in this Warning Letter.

If you have any questions regarding the content of this letter, please contact Compliance Officer, Lauren Priest at 303-236-9663 or at Lauren.Priest@fda.hhs.gov. Please send your reply electronically to oradevices3firmresponse@fda.hhs.gov.

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,
/S/

Binita Ashar, M.D., M.B.A., F.A.C.S.
Director
OHT4: Office of Surgical and Infection Control
Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

/S/

Shari J. Shambaugh
Program Division Director
Office of Medical Device and Radiological Health
Division 3/West

Cc:
Mr. Jamie Fettig
8172 Tone St.
Las Vegas, NV 89123

---

1 Last accessed December 17, 2019.

2 Neuropathy refers to general diseases or malfunctions of the peripheral nerves. Signs and symptoms may include numbness, pain, muscle weakness, heat intolerance, and changes to sensation. There are many causes of neuropathy (e.g., trauma, infections, disease), and if its root cause is left undiagnosed or untreated, neuropathy may result in serious complications.

3 For your reference, FDA defines "establish" under 21 CFR 820.3(k) as "define, document (in writing or electronically), and implement."

More Warning Letters (/inspections-compliance-enforcement-and-criminal-investigations/compliance-actions-and-activities/warning-letters)