General Medical Company 6/2/16

Department of Health and Human Services

Public Health Service
Food and Drug Administration
Los Angeles District

19701 Fairchild
Irvine, California 92612-2506
Telephone (949) 608-2900
Fax (949) 608-4415

WARNING LETTER

VIA UNITED PARCEL SERVICE
SIGNATURE
REQUIRED

WL #31-16

June 2,
2016

Mr. Thomas F. Greany, President
General Medical Company
123 W. Bellevue Drive, Suite 2
Pasadena, California 91105-2549

Dear Mr. Greany:

During an inspection of your firm located in Pasadena, California, from October 21 through October 30, 2015, an investigator from the United States Food and Drug Administration (FDA) determined that you manufacture and distribute over the counter iontophoresis devices which utilize a direct current with the intended use of controlling hyperhidrosis in the underarm area, as well as the hands and feet. The specific names of the devices your firm manufactures are the Drionic Hand/Foot Device and the Drionic Armpit Device. 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.

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 requirements of the Quality System Regulation found at Title 21, Code of Federal Regulations (CFR), Part 820.

We received a response from you, dated November 17, 2015, to the observations noted on Form FDA-483, List of Inspectional Observations that was issued to your firm. We address these responses below, in relation to each of the noted violations. These violations include, but are not limited to, the following:

1) Failure to adequately establish and maintain procedures for receiving, reviewing, and evaluating complaints by a formally designated unit to ensure that, among other things, oral complaints are documented upon receipt, and complaints are evaluated to determine whether the complaint represents an event which is required to be reported to FDA under 21 CFR part 803, as required by 21 CFR 820.198(a).

Specifically, a review of 136 complaints from October 1, 2013 through the closeout of the inspection found the following two complaints were not evaluated to determine whether they represented an event which is required to be reported to FDA under 21 CFR part 803:

- Complaint 16486, dated October 1, 2013, which referenced: “The customer asked for a refund. Experienced a prolonged rash. Asked her if she was alright she said yes. Her dermatologist was treating her.”
- Complaint 229920, dated April 29, 2015, which referenced: “Customer’s father***returned the unit. Claimed that it burned his daughter’s hand. We offered to pay any emergency medical care or out of pocket medical cost***”

In addition, you reported to our investigator that you fail to maintain a record of verbal complaints.

2) Failure to review and evaluate all complaints to determine whether an investigation is necessary, as required by 21 CFR 820.198(b).

Specifically, you did not evaluate any of the 136 complaints reviewed during the investigation to determine whether an investigation was necessary. It does not appear investigations were performed for any of these complaints, and your firm did not maintain documentation that referenced the reason no investigation was made and the name of the individual responsible for the decision not to investigate.

3) Failure to review, evaluate and investigate complaints that involved the possible failure of a device to meet its specifications when necessary, as required by 21 CFR 820.198(c).

Specifically, the following device failures were not evaluated and investigated:

- Complaint dated October 19, 2015, unnumbered, referencing a device that had a broken battery contact that was repaired and returned to the customer the same day.
- Complaint 24737, dated October 6, 2015, referencing a broken battery contact that was repaired and returned to the customer that same day.
- Complaint 22803, dated August 24, 2015, referencing broken battery contacts that were repaired and returned to the customer.
- Complaint 22575, dated May 19, 2015, referencing a battery holder that fell out. The entire unit was replaced at no charge to the customer.

Additionally, the following complaints reference devices that were returned by customers. No investigations were conducted to determine if the devices failed to meet specifications:

- Complaint AMZ-8930633, dated October 14, 2015. The compliant file references: “Customer returned requesting refund. The devices did not work for her. The unit was refurbished and placed in that section of inventory.”
- Complaint 24330, dated September 21, 2015. The compliant file references: “Customer returned requesting refund. Barely used but they needed to be refurbished”.
- Complaint 22580, dated August 13, 2015. The complaint file references: “Customer returned no reason given”.
- Complaint 23082, dated July 3, 2015. The complaint file references: “Customer returned no reason given”.

We reviewed your response dated November 17, 2015. We find this response to be inadequate because you have not completed the corrective actions necessary to correct the referenced deficiencies in complaint handling. We acknowledge your

statement that you intend to complete a comprehensive procedure for a Corrective and Preventive Action Process, and to develop a formal and more clearly articulated complaint handling procedure that includes the MDR evaluation process for each patient. You also stated that you plan to retrospectively review all complaints opened since the 2013 FDA inspection to determine if any trends exist and to implement corrective actions if trends are identified.

4) Failure to adequately establish and maintain procedures for corrective and preventive action (CAPA), as required by 21 CFR 820.100(a).

For example, your firm has not established and maintained corrective and preventive action procedures that include requirements for analyzing sources of quality data, including returned product, to identify existing and potential sources of non-conforming product or other quality problems. For example, the inspection found your CAPA file referenced many events associated with customers not being aware of precautions for your devices; however, your firm did not identify actions needed to prevent and correct their recurrence. For example, your files contained the following:

- Complaint #22285, dated 3/9/15 referenced a “returning customer” (type of device not specified) that found metal implants are contra-indicated.
- Complaint #23327, dated 5/8/15 referenced “Customer had two contraindications atrial fibrillation and metal implants.” You provided records to our investigator that showed your firm returned their Drionic Hand/Foot device.
- Complaint #AMZ7161826, dated 6/1/15 referenced “Customer returned due to contraindication. Metal implant in her wrist.” You provided records to our investigator that showed your firm returned their Drionic Hand/Foot device.
- Complaint #23641, dated 6/15/15 referenced “Customer has metal implants. Returned it unused.” You provided records to our investigator that showed your firm returned their Drionic Hand/Foot device.

Your firm did not analyze these complaints, or identify any corrective or preventive actions to ensure your customers are aware of the contraindications associated with the use of your devices.

We reviewed your response dated November 17, 2015. We find this response to be inadequate because you have not completed the corrective actions necessary to correct this deficiency. We acknowledge your statement that you intend to complete a comprehensive procedure for a Corrective and Preventive Action Process and to retrospectively review all complaints opened since the 2013 FDA inspection to determine if any trends exist, to review non-conforming material, service and quality audit trends, and to implement corrective actions in accordance with your new procedures.

5) Failure to maintain a device master record, as required by 21 CFR

820.181. Specifically, your firm does not maintain device specifications, including, for example, appropriate drawings, component specifications, production process specifications that include equipment specifications, production methods and procedures, and production environment specifications, quality assurance procedures and specifications, including acceptance criteria, and packaging and labeling instructions.

We reviewed your response dated November 17, 2015, and cannot evaluate this aspect of the response because you did not provide supporting documentation. Specifically, you stated you plan to initiate a Device Master Record (DMR) for each product in accordance with 21 CFR 820.181, but provided no further evidence of its implementation.

6) Failure to adequately validate with a high degree of assurance a process whose results cannot be fully verified by subsequent inspection and test according to established procedures, as required by 21 CFR 820.75(a). For example, your firm failed to validate the **(b)(4)** process associated with the **(b)(4)** that is used to **(b)(4)** your Drionic Underarm Device case. Your firm also failed to validate the **(b)(4)** processes used to **(b)(4)** to the printed circuit board assemblies and repair of defective/rejected printed circuit boards used in your devices.

7) Failure to review and evaluate the process and perform revalidation, where appropriate, when changes or process deviations occur, as required by 820.75(c). Specifically, your firm failed to conduct validations/revalidations in 2011 when the **(b)(4)** and **(b)(4)** were moved from your Los Angeles, CA manufacturing site to the Pasadena, CA manufacturing site. At this time, you did not adequately re-validate the **(b)(4)** and **(b)(4)** processes, including qualifying the installation and operation of this equipment, to meet predetermined specifications.

We reviewed your response dated November 17, 2015, and cannot evaluate this aspect of the response because you did not provide supporting documentation. You stated you plan to initiate a corrective action to address this deficiency, and to retrospectively review your production lines to determine what lines need process validation, and well as what equipment requires an IQ and OQ to be performed, but provided no further evidence of implementation of these corrective actions.

8) Failure to adequately establish and maintain procedures for acceptance activities, as required by 21 CFR 820.80(a). For example, your firm did not maintain records to demonstrate that receiving, in-process or final acceptance activities were conducted on any of your devices manufactured through the inspection in October 2015 prior to their being released for distribution, including documentation that the device passed final testing.

We reviewed your response dated November 17, 2015 and cannot evaluate this

aspect of the response because you did not provide supporting documentation. You stated you plan to initiate a corrective action to address this deficiency, and that you hired an outside consultant to assist you in developing appropriate acceptance activities, procedures and work instructions, but provided no further evidence of implementation of these corrective actions.

9) Failure to maintain a device history record that demonstrates that the device was manufactured in accordance with the device master record and 21 CFR 820, as required by CFR 820.184. For example, your firm's device history records do not include the dates of manufacture, the quantity manufactured, the quantity released for distribution, the primary identification label and labeling used for each production unit and any unique device identifier, universal product code or other device identification(s) and control number(s) used. Additionally, as your device master record has not been maintained, as referenced in item (5) above, your device history records do not include acceptance records which demonstrate your devices are manufactured in accordance with a device master record.

We reviewed your response dated November 17, 2015, and find it inadequate. You stated you plan to initiate a corrective action to address this deficiency, and that you hired an outside consultant to assist you in developing a device history record, but provided no further evidence of implementation of these corrective actions.

10) Failure to adequately establish procedures or instructions for performing servicing activities and verifying that servicing meets specified requirements, as required by 21 CFR 820.200(a). For example, your firm does not have procedures or work instructions for performing service, repair, or refurbishing of your Drionic Devices. Your firm does not maintain documentation that references the type of repair needed, and the activities conducted to repair, service, and refurbish devices.

We reviewed your response dated November 17, 2015, and cannot evaluate this aspect of the response because you did not provide supporting documentation. You stated you plan to have your consultant to assist you in reviewing your servicing procedures, but provided no further evidence of implementation of these corrective actions.

11) Failure to ensure that management with executive responsibility has reviewed the suitability and effectiveness of the quality system at defined intervals and with sufficient frequency, as required by 21 CFR 820.20(c). Specifically, your firm's Management Review Procedures state that management with executive authority will conduct a management review at least once annually, and that the review will be completed within 60 days of the quality audit. However, you stated that your firm failed to conduct management reviews in 2013, 2014 and 2015.

We reviewed your response dated November 17, 2015, and cannot evaluate this

aspect of the response because you did not provide supporting documentation. You stated you plan to hold a formal Management Review in January, 2016, but provided no further evidence of implementation of this corrective action.

12) Failure to conduct quality audits in accordance with your established procedures to ensure 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. Specifically, your firm's Quality Audit Procedures state that audits are to be conducted annually during the last three months of the year. However, your firm failed to conduct quality audits in 2013, 2014, and 2015.

We reviewed your response dated November 17, 2015, and cannot evaluate this aspect of the response because you did not provide supporting documentation. You stated you plan to have a third party audit conducted in February, 2016, but provided no further evidence of implementation of this corrective action.

Our inspection also revealed that the Drionic Hand/ Foot, and Drionic Armpit iontophoresis devices, for which you manufacture under a licensing agreement and commercially distribute to your own customers without a health care provider's prescription, 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 under section 520(g) of the Act, 21 U.S.C. § 360j(g).

These devices are also misbranded under section 502(o) the Act, 21 U.S.C. § 352(o), because your firm did not notify the agency of its intent to introduce these devices 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 C.F.R. 807.81(a)(3)(i).

The kind of information that your firm needs to submit in order to obtain approval or clearance for the device is described on the Internet at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/defaul The FDA will evaluate the information that your firm submits and decide whether the product may be legally marketed.

Further, your Drionic Hand/Foot, and Drionic Armpit iontophoresis devices are misbranded under section 502(f)(1) of the Act, 21 U.S.C. § 352(f)(1), in that the labeling for these devices fails to bear adequate directions for use. Your cleared Drionic Hand/Foot and Drionic Armpit iontophoresis devices, K831320, are prescription devices; and thus, they must comply with the requirements in 21 CRF 801.109. These requirements include, but are not limited to, the following: being "sold

only to or on the prescription or other order of such practitioner for use in the course of his professional practice" [21 C.F.R. 801.109(a)(2)]; and the label of the Drionic Hand/Foot, and Drionic Armpit iontophoresis devices must bear the statement: "Caution: Federal law restricts this device to sale by or on the order of a _____", the blank to be filled with the word "physician", "dentist", "veterinarian", or with the descriptive designation of any other practitioner licensed by the law of the state in which he practices to use or order the use of the device [21 C.F.R. 801.109(b)(1)]. However, these devices are being sold on your firm's website, www.drionic.com , without requiring a prescription or other order from a licensed practitioner. Moreover, the labels of these devices fail to bear the above-quoted cautionary statements.

Your firm 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 FDA without further notice. These actions include, but are not limited to, seizure, injunction, and civil money penalties. Also, 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 award of contracts. 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. Requests for Certificates to Foreign Governments will not be granted until the violations related to the subject devices have been corrected.

We also note that your Subderm TM device, **K853635**, is a prescription device, as described in 21 CRF 801.109. As such, should you choose to manufacture and sell the Subderm TM device, it must be sold on the order of prescription from a health practitioner and in accordance with all other applicable laws and regulations.

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. Your firm's response should be sent to:

CAPT Larry Howell
Acting Director, Compliance Branch
Food and Drug Administration
19701 Fairchild
Irvine, CA 92612-2506

Refer to the identification number 487535 when replying. We remind you that only written communication is considered official. If you have any questions about the content of this letter please contact Dr. William Vitale, Compliance Officer at 949-608-2919.

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/
CDR Steven E. Porter, Jr.
Los Angeles District Director

Cc:
David M. Mazzera, Ph.D.
Chief, Food and Drug Branch
California Department of Public Health
Food and Drug Branch
1500 Capitol Avenue, MS-7602
Sacramento, CA 95899-7413

More in 2016