Western/Scott Fetzer Company 10/10/14

Department of Health and Human Services

Public Health Service
Food and Drug
Administration
Cincinnati District Office
Central Region
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October 10, 2014

VIA UPS

WARNING LETTER
CIN-15-441366-03

Robert McBride
CEO
Scott Fetzer
28800 Clemens Road
Westlake, OH 44145

Dear Mr. McBride:

During an inspection of your firm, Western Enterprises/Scott Fetzer Company, located at 875 Bassett Road, Westlake, OH 44145,on July 10 through September 2, 2014, an investigator from the United States Food and Drug Administration (FDA) determined that your firm is a manufacturer of medical gas pressure regulators and suction regulators. 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.

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. We received a response from Gary Heeman, Group President of Western Enterprises dated September 16, 2014, concerning our investigator's observations noted on the Form FDA 483, List of Inspectional Observations (FDA 483) that was issued to your firm. We address this response below, in relation to each of the noted violations. These violations include, but are not limited to, the following:

1. Failure to establish and maintain procedures for analyzing processes, work operations, concessions, quality audit reports, quality records, service records, complaints, returned product, and other sources of quality data to identify existing and potential causes of nonconforming product, or other quality problems, as required by 21 CFR 820.100(a)(1). Specifically,

Your "Corrective Action Procedure", #WEOP0838, dated 2/5/14, does not adequately address the evaluation and analysis of quality data. You have three quality data sources that are not clearly defined and are not adequately analyzed and evaluated to determine if corrective and preventive action need to be initiated commensurate with the significance and risk of the nonconformity. For example:

a) Only the top six Complaint failure codes listed in your Pareto Analysis Report are evaluated to determine if a corrective action should be initiated. During the May of 2014 quarterly management review meeting only the top 6 complaint failure codes were reported and reviewed for further action. There were 26 remaining failure codes identified in the Pareto report that were not reported or evaluated for potential corrective action.

b) Only the top six "Line Fallout" (failed final inspection) codes for each product (OxyTOTE, and NexGen) listed in your Trending Analysis reports are evaluated to determine if a corrective action should be initiated. During the May of 2014 quarterly management review meeting only the top 6 Line Fallout failure codes were reviewed for further action. There were several additional failure codes for each of these 3 products that were not reported or evaluated for potential corrective action.

c) Scrap is not documented and analyzed as a data source to identify existing and potential causes of nonconforming product, or other quality problems. Additionally, action and/or alert limits have not been established to

identify if corrective or preventive action is required.

d) Neither the Corrective Action Procedure nor the Customer Complaint Procedure define when and how complaint trend codes are defined and utilized; and these codes are not accurately documented to assure a statistical data analysis can be performed. For example, only one failure code was assigned to 81 devices because they were recorded on one complaint form. Also, the failure codes are not changed to assure the correct failure is documented after it is identified during the failure investigation.

Your response, dated, September 16, 2014, regarding changes to your procedures cannot be assessed at this time. Your response states that your Corrective Action and Customer Complaint procedures will be revised by November 30, 2014. It also states that all complaint codes, fallout codes and scrap will be analyzed and reported during the management review for evaluation of all failure codes for potential corrective and preventive actions.

Your response regarding complaint trend codes is not adequate, in that it does not address performing a retrospective review of complaints to assure the correct failure code was documented after the failure investigation.

2. Failure to review, evaluate and investigate complaints involving the possible failure of a device to meet any of its specifications, as required by 21 CFR 820.198(c). Specifically,

The failure investigation for Complaint #1140314-7 received on 3/14/14 involving an "ignition" event on the OxyTOTE regulator, is inadequate. The outside laboratory who performed the investigation stated that "further chemical and/or metallurgical analysis could be considered to provide additional information pertaining to the origin, ignition mechanisms, and propagation characteristics associated with the incident". You closed this complaint without any further testing and there was no documented rationale as to why this testing was not needed.

Your response, dated, September 16, 2014, cannot be assessed at this time. Your response states that your Customer Complaint Procedure will be revised by November 30, 2014 to specify that in the event an investigation concludes that further testing/analysis could be considered to provide additional information, and further testing is not conducted, a rationale as to why the testing was not conducted will be documented.

3. Failure to establish and maintain adequate procedures for receiving, reviewing, and evaluating complaints by a formally designated unit, as required by 21 CFR 820.198(a). Specifically, your "Customer Complaint Procedure", #WEOP0821, dated 2/5/14, has not been adequately established in that:

a) Sections 3.1.1 and 4.1 of this procedure are not being followed, in that a complaint was not documented on the "customer complaint initiation form". A complaint that you became aware of on 4/21/14, involving an "ignition" event on a medical gas pressure regulator that you contract manufacture, was not entered into your complaint system until 7/25/14 during the current FDA inspection.

b) Sections 3.4.3, 3.4.7 and 4.5 of this procedure are not being followed in that there are complaints that are not being processed in a "uniform and timely" manner. For example, three complaints on the **(b)(4)** product line received in 2011 are still open.

c) The customer complaint procedure does not address reviewing and updating the risk analysis for each product based on post-market data. "Risk Analysis Procedure", #WEOP0224, dated 10/11/12, section 6.16 states a review of the risk analysis will be required if the device risk changes over time. It further states that a source of information that may indicate a change in risk includes post market information that indicates the device may be performing differently than at the time the risk analysis was performed. The three risk analyses for the OxyTOTE Regulators were not updated to include the potential for "ignition" after a complaint was received involving an ignite event.

Your response, dated, September 16, 2014, cannot be assessed at this time. Your response states that the Customer Complaint Procedure, Risk Analysis Procedure, and Risk Analysis documents for Valve Integrated Pressure Regulators will be revised by November 30, 2014.

Your response is not adequate regarding your retrospective review of complaints. You state all complaints from 2011 to the present will be reviewed to assure that all complaints have been processed and closed. In addition to this review, why is a review of all open complaints prior to 2011 not being conducted?

4. Failure to validate with a high degree of assurance, a process where the results cannot be fully verified by subsequent inspection and test, as required by 21 CFR 820.75(a). Specifically,

"Process Validation Procedure", #WEOP0827, dated 1/22/14 (initial release 8/19/11), section 4.4.1 states that "Established processes that have historically provided acceptable output without significant nonconformities are exempted from validation". There is no documented rationale as to why the 4 product families, which were being manufactured prior to 2011, have no processes that need to be validated. Additionally, these products appear to have processes that would require

validation, such as cleaning, lathing, milling, deburring and plating.

Your response, dated, September 16, 2014, cannot be assessed at this time. Your response states that your Process Validation Procedure will be revised. Additionally, a "Process Validation Matrix" has been developed for each product family and an assessment of the extent of validation required for each will be based upon the PFMEA and Risk Assessment that will be conducted. A Master Validation Plan and formal validation protocols will be developed and executed; and these activities will be documented. Your target completion date for the validation activities is December 31, 2015.

5. Failure to establish and maintain process control procedures that describe any process controls necessary to ensure conformance to specifications, as required by 21 CFR 820.70(a). Specifically,

The "Process Failure Mode and Effects Analysis (PFMEA) Procedure", #WEOP1012, dated 7/30/13, section 1.1 states that this procedure should be used on all new products. This procedure does not address existing products. There are no PFMEAs for the OxyTOTE, OxyTOTE NG, and the **(b)(4)** valve integrated pressure regulators (VIPR). In 2009, you made a change from a PTFE cylinder O-ring to an EPDM cylinder O-ring for all VIPR products. This change affected the manufacturing process. Additionally, the OxyTOTE NG product line was released in 2010 and no PFMEA was completed as required by your procedure, initial release date 9/22/09.

Your response, dated, September 16, 2014, cannot be assessed at this time. Your response states that PFMEAs will be conducted on all processes used for devices which have not been validated to identify risks associated with medical device manufacturing. The target completion date of the PFMEAs is June 30, 2015.

6. Failure to establish and maintain procedures to ensure that all purchased or otherwise received product and services conform to specified requirements, as required by 21 CFR 820.50. Specifically, your "Supplier Management Procedure", #WEOP0601, dated 4/1/14, has not been adequately established in that:

a) You have not considered test labs and consultants as suppliers, as required by section 1.1 of your procedure, which states that all suppliers and subcontractors providing materials, services, tools, or parts that affect the quality of the organization's end product or device are subject to this procedure". As a result, you have not ensured the received services conform to specified requirements.

b) The primary supplier of EDPM and PTFE O-rings; supplier of various medical components, such as the valve poppets and seat retainers; and the supplier of various medical gas cylinders, do not have a self-survey or a current

registration certification (i.e.: ISO certification), as required by section 4.7.3 of your procedure.

c) Your procedure is not adequate in that it allows for a supplier's quality rating to be as low as 60% and still be acceptable, because you combine the quality rating with the on-time delivery rating. For example, in August of 2013, one of your cylinder supplier's quality rating was 66.7% and the delivery rating was 100%. The overall rating for the month was 83.3%, which is above an 80% rating, which is considered the acceptable rating per your procedure. No further action was taken regarding the quality issues with this supplier.

d) Section 4 of this procedure regarding supplier approval levels and assigning risk levels is not being followed and the defined risk levels are not being consistently applied. For example, the O-rings used in many of the regulators are assigned different risk levels without any documented rationale.

Your response, dated September 16, 2014, cannot be assessed at this time. Your response states that your purchasing control procedures will be revised to add additional supplier types; to require that all suppliers must complete a self-survey; to define quality and delivery as two individual metrics; and to require the issuance of a Supplier Corrective Action Request whenever a supplier's quarterly quality rating drops below an 80%. The target completion date for these procedural changes is October 31, 2014.

Additionally, you have approved the suppliers discussed in 6(a) above and are reviewing all suppliers to determine if there are any similar test labs and consultants that have been omitted from the supplier approval process. You have received current Registration Certificates and self-surveys from the suppliers discussed in 6(b) above, and a database will be created to track expirations of supplier approvals. You are reviewing all medical device components to ensure that all these components are assigned a Risk Class 3. The target completion dates for these corrective actions are October 31, 2014, November 30, 2014, and December 31, 2014, respectively.

7. Failure to establish and maintain procedures to control product that does not conform to specified requirements, as required by 21 CFR 820.90(a).Specifically,

Your "Nonconforming product Control Procedure", #WEOP0863 is not being followed in that each nonconformance does not include documentation whether an investigation is needed, as required by the procedure.

For example, NMR #WO61113-1, dated 6/11/13, reported suction regulator bodies were received with "dents and dings that can cause leakage when assembled". No investigation or the reason for not conducting an investigation was documented. No SCAR was issued to the supplier. The regulators were just returned to the supplier.

Your response, dated, September 16, 2014, cannot be assessed at this time. Your response states that your Nonconforming Material Control Procedure will be revised by November 30, 2014 to include defined criteria for when an investigation shall be conducted, and a mechanism to document that an evaluation has been performed.

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 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 working days from the date you receive this letter of the specific steps that 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 the corrective actions cannot be completed within the timeframes specified in your response, state the reason for the delay and the time within which the corrections will be completed.

Your response should be sent to: Ms. Gina Brackett, Compliance Officer, Food and Drug Administration, 6751 Steger Drive, Cincinnati, Ohio 45237. If you have any questions about the content of this letter please contact Ms. Brackett at (513) 679-2700, ext. 2167, or by email at gina.brackett@fda.hhs.gov.

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 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,
/S/
Paul J. Teitell
District Director

Cincinnati District

CC:
Gary R. Heeman
Group President
Western/Scott Fetzer Company
875 Bassett Road
Westlake, OH 44145-1142

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