Inspections, Compliance, Enforcement, and Criminal Investigations

Woo Young Medical 1/14/13

Department of Health and Human Services

Public Health Service
Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

JAN 14 2013

WARNING LETTER

VIA UNITED PARCEL SERVICE

Mr. Young-Gyu Lee
CEO
Woo Young Medical Co., Ltd
374-3 Sangshin-ri, Jincheon-eup
Jincheon-gun Chungcheongbuk-do, Korea

Dear Mr. Lee:

During an inspection of your firm located in Jincheon-gun Chungcheongbuk-do, Korea,on September 10, 2012, through September 13, 2012, an investigator from the United States Food and Drug Administration (FDA) determined that your firm manufactures elastomeric infusion pumps. Under section 201(h) of the Federal Food, Drug, and Cosmetic Act (the Act), 21 U.S.C. § 321(h), these products are a device 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 the elastomeric infusion pumps 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, its 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 **(b)(6)**, dated September 25, 2012, concerning our investigator's observations noted on the Form FDA 483 (FDA 483), List of Inspectional Observations, that was issued to your firm. We address this response below, in relation to each of the noted violations. These violations include, but are not limited to, the following:

1. 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). For example:

There is no documentation or evidence indicating that controls were used to verify sterility of the sterile water used for washing components of the device. Additionally, a review of the bioburden test procedure **(b)(4)** for sterile water revealed that a negative control is required to be incubated with each test sample.

We reviewed your firm's response and conclude that it is not adequate. Your firm has not provided sterility testing for lot #CDHAN103. Also, evidence demonstrating that a systemic corrective action was performed by verifying that this same issue has or will not occur with other lots was not provided. Additionally, there is no evidence to support that sterility testing has been conducted for the sterile water.

2. Failure to establish and maintain procedures for finished device acceptance to ensure that each production run, lot or batch of finished devices meets acceptance criteria, as required by 21 CFR 820.80(d). For example:

There is no documentation or evidence indicating that controls were used to verify sterility of the finished device, which is labeled sterile. Additionally, the sterility test report for lot CDHAN103 has a section for controls; however, there is no documentation of controls being used for fungi testing.

We reviewed your firm's response and conclude that it is not adequate. Your firm has not provided sterility testing for lot #CDHAN103. Also, evidence demonstrating that a systemic corrective action was performed by verifying that this same issue has or will not occur with other lots was not provided.

3. Failure to validate computer software for its intended use according to an established protocol when computers or automated data processing systems are used as part of production or the quality system, as required by 21 CFR 820.70(i). For example:

There is no evidence that validation was completed for the **(b)(4)** software used by your firm to provide the customer with the graphic representation of the flow rate of the device. **(b)(6)**, indicated that your firm did not have user requirements, input, or output requirements for the **(b)(4)** software.

We reviewed your firm's response and conclude that it is not adequate. Your firm promised to conduct a retrospective validation. Your firm would also confirm and verify the following: requirements for the data logger program/software, the test method to verify requirements, and program credibility through data collected. Your firm also stated that the internal quarterly inspection of the electronic balance would be scheduled and executed. Also, your firm has stated that a relevant procedure and appropriate education will be offered to the person responsible for maintaining the record. However, your firm has not provided evidence of these corrections and your firm has not provided evidence of training on the new procedure. Additionally, your firm has not indicated that it would retrospectively review software validation activities for other software products to ensure those products were properly validated.

4. Failure to establish and maintain requirements for the health, cleanliness, personal practices, and clothing of personnel if contact between such personnel and product or environment could reasonably be expected to have an adverse effect on product quality, as required by 21 CFR 820.70 (d). For example:

Approximately 9 out of 82 employees were observed not using the disinfectant prior to entering the production area as required by procedure **(b)(4)**.

We reviewed your firm's response and conclude that it is not adequate. Your firm has stated that employees have been retrained on hand washing and that one or more additional hand washers will be installed in order for workers to wash their hands before the end of their break time.

However, your firm has not considered a systemic corrective action, for example, conducting a thorough review and documenting whether other production areas are/are not affected.

5. Failure to establish and maintain procedures to ensure that equipment is routinely calibrated, inspected, checked, and maintained, as required by 21 CFR 820.72(a). For example:

The final testing of the flow rate is **(b)(4)**. The flow rate testing is one of the tests required for finished devices prior to release for distribution. During the inspection, it appeared that your firm had no provisions for preserving the integrity of the data of the flow rate testing since access to **(b)(4)** was not limited to authorized personnel.

We reviewed your firm's response and conclude that it is not adequate. While your firm has stated that access to the flow rate test will be **(b)(4)**, your firm has not provided training records indicating that such training of employees has taken place. Additionally, your firm has provided no evidence to support that it has conducted a retrospective review of the test systems to ensure that the testing equipment is checked and maintained, as required.

6. Failure to store labeling in a manner that provides proper identification and is designed to prevent mixups, as required by 21 CFR 820.120(c). For example:

Bulk labels are stored on open shelves in the warehouse and production area where access is not limited.

We reviewed your firm's response and conclude that it is not adequate. Your firm promised to **(b)(4)**. You firm also indicated that it would educate the employees on the updated procedure. However, this information could not be verified since the completion date was November 11, 2012. Also, your firm has not indicated why the labels will not be locked in a designated area immediately. Additionally, your firm has not indicated that it would review storage of other labels to ensure that they were being stored under adequate controls.

7. Failure to control labeling and packaging operations to prevent labeling mixups, as required by 21 CFR 820.120(d). For example:

Access to the labeling machine is not limited to authorized personnel, since neither keys nor passwords are required to operate it. Additionally, the labeling equipment is not limited to authorized personnel, since it is located in the production area that is not restricted to authorized personnel.

We reviewed your firm's response and conclude that it is not adequate. Your firm promised to **(b)(4)**. Your firm also indicated that it would educate the employees on the updated procedure. However, this information could not be verified since the completion date was November 11, 2012. Additionally, your firm has not indicated that other labeling and packaging operations would be reviewed to ensure adequate controls.

U.S. 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 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 business days from the date you receive this letter of the specific steps your firm has taken to correct the noted violations, including 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 action (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. Please provide a translation of documentation not in English to facilitate our review.

Your firm's response should be sent to: Food and Drug Administration, Center for Devices and Radiological Health, Office of Compliance, Field Operations Branch, White Oak Building 66, Rm 2609, 10903 New Hampshire Ave., Silver Spring, MD 20993. Refer to CMS case #386118 when replying. If you have any questions about the contents of this letter, please contact: Carl Fischer at 301-796-5770.

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

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

Page Last Updated: 02/21/2013
Note: If you need help accessing information in different file formats, see Instructions for Downloading Viewers and Players.