Inspections, Compliance, Enforcement, and Criminal Investigations

Omron (Dalian) Co., Ltd. Plant 1 2/14/12

Department of Health and Human Services

Public Health Service
Food and Drug Administration
Center for Tobacco Products
10903 New Hampshire Avenue
Silver Spring, MD 20993

FEB 14 2012

WARNING LETTER

VIA UNITED PARCEL SERVICE

Mr. Massaki Iida
General President
Omron (Dalian) Co., Ltd. (Plant 1)
No. 3 Song Jiang Road
Economic and Technical Development Zone
Dalian 116600
China

Dear Mr. Iida:

During an inspection of your firm located in Dalian, China, on October 17, 2011, through October 20, 2011, an investigator from the United States Food and Drug Administration (FDA) determined that your firm manufactures non-sterile blood pressure monitors. 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 they are intended 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 requirements of the Quality System regulation found at Title 21, Code of Federal Regulations (CFR), Part 820. We received a response from Mr. Xiaobo Shi, Quality Management Representative, dated November 7, 2011, concerning our investigator's observations noted on the Form FDA 483 (FDA 483), 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 adequate procedures for receiving, reviewing, and

evaluating complaints by a designated unit, as required by 21 CFR 820.198(a). For example, your firm's Complaint Handling Procedure, **(b)(4)**, does not require that complaints be evaluated to determine whether the complaint represents an event which is required to be reported to FDA under 21 CFR Part 803, Medical Device Reporting (MDR). Complaints 110322001 (dated March 22, 2011), 100816001 (dated August 16, 2010), and 100416001 (dated April 6, 2011), were among eleven complaints reviewed during the inspection. There was no evidence to indicate that an MDR evaluation occurred for any of these complaints.

We reviewed your firm's response and are unable to verify its adequacy at this time. Your firm indicated that a corporate level complaint handling procedure is being established and implemented by the parent company in Kyoto, Japan, however the new procedure was not submitted with your response.

2. Failure to validate computer software used as a part of production or the quality system for its intended use according to an established protocol, as required by 21 CFR 820.70 (i). For example, your firm could not provide any documentation to demonstrate that the software used for the 6111 PCB (Printed Circuit Board) check machine **(b)(4)** was validated for its intended use. Your firm's Department Manager of Regulatory Affairs stated that the software used for the PCB check machine has not been validated.

The adequacy of your firm's response cannot be determined at this time. Evidence of implementation of your firm's corrections and corrective actions referenced in your response were not provided.

3. Failure to establish and maintain adequate procedures, where appropriate, to ensure that specified requirements for in-process product are met, as required by 21 CFR 820.80(c). For example:

a. Your firm's **(b)(4)**, requires that functional tests be performed on each lot of PCBs assembled. On October 17, 2011, while in-process functional testing was being performed on two models of 6114D PCBs **(b)(4)**, it was observed that 4 out of the 8 PCBs tested for each model failed the functional testing. However, these failures were not documented by the operator and the operator was observed retesting the failed PCBs until they passed inspection.

b. A review of your firm's in-process PCB Sampling Inspection Records from October 4, 2011, through October 17, 2011, indicated that several lots were tested and accepted using the wrong sample size. For example, the following lots were accepted using the wrong sample size: **(b)(4)** for PCB Model no. 7117E dated October 4, 2011; **(b)(4)** for PCB Model no. 8705WM dated October 5, 2011; and **(b)(4)** for PCB Model no. 8705WM dated October 8, 2011.

We reviewed your firm's response and conclude that it is not adequate. For those PCB lots that were accepted using the wrong sample size, your firm did not provide evidence to indicate that a correction was implemented to re-sample the lots according to the established sampling procedure. In addition, your firm did not provide information to indicate that all PCB sampling inspection records were evaluated to determine whether any more PCB lots were accepted with improper sample size.

4. Failure to establish and maintain procedures to ensure that Device History Records (DHRs) for each batch, lot, or unit are maintained to demonstrate that the device is manufactured in accordance with the Device Master Record, as required by 21 CFR 820.184. For example, your firm's Department Manager of Regulatory Affairs stated that this facility has yet to establish a written DHR procedure. Also, **(b)(4)**, **(b)(4)**, and **(b)(4)**, for the blood pressure monitor model number HEM-6052-Z do not include or refer to the location of the primary identification label and labeling used for each production unit.

We reviewed your firm's response and are unable to determine its adequacy. It is unclear whether a procedure is being established to ensure that all required information is being maintained in a DHR. You did not provide a copy of the new procedure for our review to verify that DHRs contain or make reference to all required documents.

Our inspection also revealed that your firm's 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:

Failure to develop, maintain, and implement written Medical Device Reporting (MDR) procedures, as required by 21 CFR 803.17.

For example, your firm does not have a procedure for identification, evaluation, and communication of events that may be subject to MDR requirements.

The adequacy of your firm's response cannot be determined at this time. Your firm indicated that a corporate level complaint handling procedure is being established by the parent company located in Kyoto, Japan, however, a copy was not submitted for our review.

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. Please refer to the Unique Identification Number 273116 when replying. If you have any questions about the contents of this letter, please contact Mr. Joshua Simms at via telephone at (301) 796-5599 or via fax at (301) 847-8138.

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

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