DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration

Chicago District
550 West Jackson Blvd., 15th Floor
Chicago, Illinois 60661
Telephone: 312-353-5863

January 18, 2008

WARNING LETTER
CHI-1-08

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Mr. Isao Ogino
President and CEO
Omron Healthcare, Inc.
1200 Lakeside Drive
Bannockburn, IL 60015-1243

Dear Mr. Ogino:

During an inspection of your firm located in Bannockburn, Illinois, conducted from January 25 through February 16, 2007, an investigator from the United States Food and Drug Administration (FDA) determined that your firm is an initial importer and distributor of various diagnostic and therapeutic foreign manufactured medical devices.

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 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 (CGMP) requirements of the Quality System (QS) regulation found at Title 21, Code of Federal Regulations (CFR), Part 820. We received your response letters dated March 20, 2007, April 20, 2007, and November 6, 2007, concerning our investigator's observations noted on the FDA 483, 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 establish and maintain procedures for implementing corrective and preventive action that include requirements 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) and (a)(1).

- For example, according to your Operational Procedures, Corrective and Preventive Action (CAPA), the Quality Manager will identify the investigation plan to uncover the potential root cause of device issues (any written, electronic, or oral communications that allege deficiencies related to identity, quality, durability, reliability, safety, effectiveness, or performance).

    -- An investigational plan has not yet been identified for six CAPAs from 2005.

    -- Nine other CAPAs have not yet been assigned for evaluation.

  Your April 20, 2007 response to this observation appears to be adequate pending verification. Although your firm stated that all CAPAs referenced were appropriately assigned, you submitted no documentation showing that this action was completed.

- CAPA # 34, requested 4/5/2005, described the HEM-907-CL19 Blood Pressure Monitors as having Units Malfunction and Inaccurate Readings. Quality data relating to CAPA #34 has not been adequately analyzed. For example:

    -- Only HEM-907 Blood Pressure Monitors received in August 2004 were evaluated.

    -- Lot numbers for model HEM-907-CL19 were never documented.

2. Failure to maintain a record of an investigation of a complaint by a formally designated unit that includes any corrective action taken, as required by 21 CFR 820.198(e)(7).

- For example, in ten of the thirteen complaints reviewed concerning the device model HEM-907-XL IntelliSence Digital Blood Pressure Monitor, the "Complaint Resolved By" field was annotated as "Pending Resolution," although some repairs have been completed and your firm considers the complaints closed.

3. Failure to review, evaluate and investigate complaints involving the possible failure of a device, as required by 21 CFR 820.198(a) and (c). (This is a repeat observation from the last FDA inspection completed in July 2003.)

- For example, on 2/12/2007 a model HEM-705CPN was sent in for repair. It was switched out and a new one was sent out. There was no investigation done, however, to determine the cause of the failure.

- Data was not forwarded to the foreign manufacturer so that it could investigate the cause of the failure.

4. Failure to include in your complaint investigation records the devices' control numbers and the nature and details of the complaints, as required by 21 CFR 820.198(e)(3) and 21 CFR 820.198(e)(5), respectively.

- For example, serial numbers were not entered for complaints #123350 and #55308.

- Six of 13 complaint records reviewed did not contain documented information on the nature and details on how the devices were used.

Your November 6, 2007 response to this observation is not adequate because the new [redacted] third party complaint call center will not be operational until February 1, 2008.

5. Failure to adequately validate computer software used in an automated process for its intended use according to an established protocol, as required by 21 CFR 820.70(i).

- For example, no person from your firm reviewed or approved the third party approval test results for the original "[redacted] Complaint System Validation" used in your firm's quality system.

  Your November 6, 2007 response to this observation is not adequate because the new [redacted] third party complaint call center will not be operational until February 1, 2008. In addition, your response does not address plans for your firm to review and approve the third party approval test results for the [redacted] validation, which system will replace the [redacted] Complaint System.

6. Failure to establish and maintain procedures for acceptance of incoming product, and to inspect, test, or otherwise verify incoming product as conforming to specified requirements, as required by 21 CFR 820.80(b).

- For example, your firm's procedure entitled "Device Master Record" is an index of documentation required for procurement of materials and components, and evaluation of the devices. Your firm has not completed this form for any of the foreign manufactured devices initially distributed by your firm.

  Your April 20, 2007 response to this observation appears to be adequate. The document entitled "Verification of Purchased Products" appears to address this concern.

7. Failure of management with executive responsibility to appoint and document such appointment of, a member of management who, irrespective of other responsibilities, shall have established authority over and responsibility for ensuring that quality system requirements are effectively established, as required by 21 CFR 820.20(b)(3).

- For example, no one has been appointed as having this authority since the previous Quality Manager left your firm on 01/19/2007.

8. Failure to establish and maintain procedures to ensure that all purchased or otherwise received product and services conform to specified requirements, including quality requirements that must be met by suppliers, contractors, and consultants, as required by 21 CFR 820.50(a).

- For example, your firm has not identified for [redacted] (contract repair facility) the type of quality requirements that must be met.

9. Failure to establish and maintain procedures to control all required documents, as required by 21 CFR 820.40.

- For example, in your firm's operational procedure entitled "Control of Documents," there is no explanation of the information that is to be included in the "Document Status" field. That procedure does not have the required approving/releasing authority, the new effective date, and the new alphanumeric revision level document as required by your firm's Operational Procedure titled "CONTROL OF DOCUMENTS" (QOP-42-03, effective 12/19/05, revision A).

10. Failure to have documents established that meet the requirements of 21 CFR 820.40(a). Documents must be available at all locations for which they are designated, used, or otherwise necessary, and to promptly remove all obsolete documents from all points of use.

- For example, an obsolete version of the Quality System Manual Index and revision Status Revision C, effective 12/23/2005, was on your firm's network. The current Revision F, effective 5/18/2006, includes a list of ***Inspectional Guidance Sheets*** (IGS) not included in the obsolete version and which was not available from your firm's in-house computer network.

- The following obsolete documents were used by a repair technician at [redacted]

-- The Repair Department Work Instruction entitled "Digital Blood Pressure Monitor Power-on Test," document No. RDWI-018, Revision 3, issued 2/10/2005. New Repair Department Work Instruction document No. RDWI-018, Revision 3, originated on 4/19/2005, was not issued to the Repair Department.

-- The repair Department Work Instruction entitled "Calibration Test and Repair for Digital BPM," document No. RDWI-019, Revision 1, issued 2/10/2005. Instruction document No. RDWI-019, Revision 1, originated on 4/19/2005, was not issued to the Repair Department.

-- The Repair Department Work Instruction entitled, "Check Console For SYS/DIA/PULSE/DEFLATION Rate" document No. RDWI-028, Revision 2, issued 2/10/2005. Document No. RDWI-028, Revision 2, originated on 4/20/2005, was not issued to the Repair Department.

-- The Repair Department Work Instruction entitled, "Test Cuff - Digital BPM," document No. RDWI-033, Revision 1, issued 6/21/1997. Document No. RDWI-033, Revision 2, originated on 2/10/2005, was not issued to the Repair Department.

11. Failure to have approved changes communicated to the appropriate personnel in a timely manner, as required by 21 CFR 820.40(b).

- For example, revisions to the following lists of "Repair Department Work Instructions" were approved by the Quality Manager, but the Repair Supervisor was unaware of them:

  -- RDWI-018 issued 4/19/2005 Revision 3

  -- RDWI-019 issued 4/19/2005 Revision 1

  -- RDWI-028 issued 4/20/2005 Revision 2

  -- RDWI-033 issued 4/20/2005 Revision 2

Our inspection also revealed that your firm's MC-600 Thermometer and Omron HEM-630 Blood Pressure Monitor devices are misbranded under Section 502(t)(2) of the Act, 21 U.S.C. 352(t)(2), in that your firm failed to or refused to furnish material or information respecting the devices that is required by or under Section 519 of the Act, 21 U.S.C. 360i, and 21 CFR Part 803 – the Medical Device Reporting (MDR) regulation. Significant deviations include, but are not limited to, the following:

1. Failure to submit a report to FDA, and a copy of this report to the manufacturer, as soon as is practicable but no later than 30 calendar days after the day that your firm receives or otherwise becomes aware of information from any source, including user facilities, individuals, or medical or scientific literature, whether published or unpublished, that reasonably suggests that one of your marketed devices may have caused or contributed to a death or serious injury, as required by CFR 21 803.40(a).

- For example, on 8/15/2005, your firm was made aware of an event that alleged that an MC-600 thermometer had caused a burn on an eight month old baby girl's underarm. Your firm did not send a FDA Form 3500A for this event to FDA until 9/29/2005.

2. Failure to include complete information in the above report, if the information is known or should be known to you, as described in 21 CFR 803.40, containing the information required by 21 CFR 803.42 (which corresponds generally to the format of FDA Form 3500A).

- For example, Section F of the FDA Form 3500A was incomplete (numbers 2-14) and did not state whether a copy of the report had been sent to the manufacturer.

- Sections G and H of the FDA Form 3500A were incorrectly completed, implying that your firm was the manufacturer of the MC-600 thermometer

Your April 20, 2007 response to these observations appears to be adequate.

3. Failure to submit a report to the manufacturer as soon as practicable, but no later than 30 calendar days after the day that your firm receives or otherwise becomes aware of information from any source, including user facilities, individuals, or through your firm's own research, testing, evaluation, servicing, or maintenance of one of your firm's devices, that reasonably suggests that one of your firm's devices has malfunctioned, and that this device or similar device that your firm markets would be likely to cause or contribute to a death or serious injury if the malfunction were to recur, as required by 21 CFR 803.40(b).

- For example, the following two voluntary Medwatch Reports were received by FDA and forwarded to your firm. There is no documented evidence that your firm reviewed these reports for MDR reportability and your firm never sent these reports to the corresponding foreign manufacturer through an FDA Form 3500A within the 30 calendar days:

-- MedWatch report dated 3/22/2004, regarding model HEM-630, a digital wrist blood pressure monitor. When this digital wrist blood pressure monitor was compared to a standard arm cuff, it was consistently 15 and 20 mm higher than the standard cuff. This device deficiency was never reported to the foreign manufacturing firm.

-- MedWatch report dated 09/04/2001, regarding model HEM-630, a digital wrist blood pressure monitor. The reading from that monitor was moderately elevated when used to monitor a patient's blood pressure in his home and office. When the readings were later compared to several different instruments used in his office and the office of his internist, the digital wrist monitor instrument consistently gave a higher reading with the magnitude of the differences varying considerably. In addition, we have no information showing that your firm reviewed the above referenced MedWatch reports to determine whether you should submit them to the manufacturer.

We have reviewed your April 20, 2007, response and have concluded that it is not adequate because your firm's draft revised MDR procedures are not complete and have not been implemented, and your firm has not completed training on the procedures.

4. Failure to develop, maintain, and implement complete written medical device reporting (MDR) procedures, as required by 21 CFR 803.17.

- For example, your QMS Operational Procedure QOP-85-05 entitled "Medical Device Reporting (MDR)," does not address the handling of information you become aware of whereby a device has malfunctioned and if such device or similar device marketed by the manufacturer or distributor would be likely to cause or contribute to a death or serious injury, if the malfunction were to recur.

  We have reviewed your April 20, 2007 response and have concluded that it is not adequate because your firm's draft revised MDR procedures are not complete and they have not been implemented, and your firm has not completed training on the procedures. In reviewing these procedures, however, we noted the following:

  - Page 3 of 6, item 3.3.2, the definition of a reportable malfunction should be inserted at the top of the list of Reportable Malfunction, i.e., the requirement in 21 CFR 803.40(b).

  - Page 4 of 6, item 3.3.4, 3rd bullet, "health care professional" language should be replaced with the language in the regulation; refer to 21 CFR 803.20(c)(2). This language includes "physicians, nurses, risk managers, and biomedical engineers" and is, therefore, not limited to health care professionals.

- Page 4 of 6, items 3.4 and 3.5, MedWatch Form 3500 needs to be changed to 3500"A" in both items.

Please note that page 2 of 6, items 2.1 – 2.2, of your firm's draft revised MDR procedures, "10 working days" could be changed to "30 calendar days" to comply with 21 CFR 803.40(a).

Please note that, once finalized, written MDR procedures cannot be verified until the next inspection, since the regulation requires that you "develop, maintain, and implement" the procedures.

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 15 working days from the date you receive this letter of the specific steps 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 your planned corrections will occur over time, please include a timetable for implementation of those corrections. If corrective action cannot be completed within 15 working days, state the reason for the delay and the time within which the corrections will be completed.

Finally, you should know that this letter is not intended to be an all-inclusive list of the violation(s) at your facility. It is your responsibility to ensure compliance with applicable laws and regulations administered by FDA. The specific violation(s) noted in this letter and in the Inspectional Observations, Form FDA 483 (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 violation(s), and take prompt actions to correct the violation(s) and to bring your products into compliance.

Please note that the November 2, 2004 letter your firm submitted for Recall # Z-0382-05 (Medication Bottle for NE-U22 Nebulizer) appears to have followed the reporting guidelines in 21 CFR Part 7, Subpart B (Recalls). Since this recall was classified Class II, your firm should have also submitted a Removal Report (21 CFR Part 806). The information your firm submitted, including additional information submitted in a November 8, 2004, letter, did not include a Removal Report number and the device's expected life [21 CFR 806.10(c)(1) and (c)(10)].

Please also note that the October 13, 2005 letter your firm submitted for Recall # Z-0466-06 (3-way Instant Thermometer) appears to have also followed the reporting guidelines in 21 CFR Part 7, Subpart B. This recall was classified Class II. While your firm later submitted a Removal Report number, your firm did not submit the marketing status of the device, the device listing number, a related Medical Device Reporting (MDR) number, and the device's expected life [21 CFR 806.10(c)(4), (8) and (10)].

Please be aware that your firm is required to submit for Class I and II recalls a Corrections and Removal report under 21 CFR 806.10(b) within 10 working days of initiating such correction or removal, and that the report must contain the items listed in 21 CFR 806.10(c). If the required information is not immediately available, your firm must provide a statement as to why the missing/incomplete information is not available and state when the missing/incomplete information will be submitted to the appropriate FDA District Office [CFR 806.10(c)(13)].

In addition, if your firm decides that a correction/removal is not subject to reporting under 21 CFR 806.10, your firm is required to comply with the provisions of 21.CFR 806.20(a) and (b).

Your response to this letter should be sent to Matthew J. Sienko, Compliance Officer, at the above address. If you have any questions about the content of this letter please contact Mr. Sienko at (312) 596-4213.

Sincerely,

Scott J. MacIntire
District Director