Criticare Technologies Inc 4/21/17

U.S. FOOD & DRUG ADMINISTRATION

New England District Office
(NWE-DO)
One Montvale Avenue, 4th floor
Stoneham, MA 02180
Phone 781.587.7500

WARNING LETTER
CMS # 523101

UNITED PARCEL SERVICE
OVERNIGHT DELIVERY

April 21, 2017

Neeraj Jha, CEO
Criticare Technologies Inc.
125 Commerce Park Rd
North Kingstown, RI 02852-8420

Dear Mr. Jha:

The United States Food and Drug Administration (FDA) conducted an inspection of your firm's medical device operations at 125 Commerce Park Road, North Kingstown,

RI, from March 6 through 29, 2017. During the inspection, an FDA investigator determined that your firm is a manufacturer of patient vital sign monitors, including the eQuality and nGenuity systems. 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.

Your significant violations are as follows:

1. Failure to establish and maintain procedures for receiving, reviewing, and evaluating complaints by a formally designated unit, as required by 21 CFR 820.198(a). For example:

- During the inspection, we observed that 1385 complaints, received from January 2016 to February 2017, were still open and have not yet been investigated. Your own complaint procedure, CTI212 – Servicing Activities requires customer complaints be analyzed.

2. Failure to review, evaluate and investigate any complaint involving the possible failure of a device, labeling or packaging to meet any of its specification, as required by 21 CFR 820.198(c). For example,

- Six out six complaint records reviewed during the inspection, (CT1409, CT1439, CT1450, CT1460, CT1475, and CT1480), revealed that your firm failed to document required complaint information, including the nature and details of the complaint, and whether a patient was harmed.

3. Failure to establish and maintain procedures for implementing corrective and preventive actions, as required by 21 CFR 820.100(a). For example:

- Your firm has not analyzed any of your 1385 open complaints received since January 2016 to identify any existing or potential causes of nonconforming product, or other quality problems.
- Your firm failed to investigate and identify any actions needed to evaluate the impact of the **(b)(4)**, ID # C5003 after a calibration service provider reported it “failed as found”. This flow meter was used in routine device acceptance activities to calibrate the **(b)(4)** adjustments of your Criticare patient monitors.

During the inspection we observed that your firm had not yet taken any actions to address your only CAPA, CTI CA1000, initiated on August 1, 2016.

4. Failure to establish and maintain procedures to control product that does not conform to specified requirements, and to address the identification, documentation, evaluation, segregation, and disposition of nonconforming product, as required by 21 CFR 820.90(a). For example:

- During the inspection, we observed that you initiated in-process testing of the **(b)(4)** subassembly due to an increase in complaints related to the subassembly. It was explained that if the **(b)(4)** module failed during the in-process testing; it was sent back to the assembly station to be reworked. Your firm was not initiating any nonconforming product reports (NCR's) for these failures nor were you documenting the in-process test results, the related rework, or test results after rework.
- Your firm failed to initiate a NCR for Criticare nGenuity S/N **(b)(4)** when it failed the **(b)(4)** test during finished device testing, as required by your procedure.

5. Failure to establish and maintain procedures to ensure that all received product conforms to specified requirements, as required by 21 CFR 820.50(a). For example, your firm has not evaluated or selected potential suppliers on the basis of their ability to meet specified requirements, including quality requirements. You do not have any quality agreements or contracts for any of your suppliers, including contract manufacturers.

6. Failure to establish and maintain procedures for acceptance activities that include inspections, tests, or other verification activities, as required by 21 CFR 820.80(a). For example, a review of acceptance testing performed at your facility revealed the following inconsistencies:

- Seven out of seven material inspection reports were reviewed during the inspection: **(b)(4)**. All 7 reports did not include required functional/ mechanical fit, dimensional and visual inspection test results.
- Your firm lacked a procedure for in-process test and inspection of the Criticare nGenuity **(b)(4)** (subassemblies).
- Your firm was unable to locate and provide the contract manufacturer's certificate of conformance for the following received and accepted materials: **(b)(4)** and **(b)(4)**.

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.

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 (which must address systemic problems) 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.

Please send your reply to the Food and Drug Administration, Attention: Karen N. Archdeacon, One Montvale Avenue, Stoneham, MA 02180. If you have questions regarding any issues in this letter, please contact Ms. Archdeacon at 781-587-7491 or at karen.archdeacon@fda.hhs.gov.

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/
Joseph Matrisciano, Jr.
District Director
New England District Office

Cc:
Mr. Vinod Ramani
CEO and Chairman
Opto Circuits (India)

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Contact FDA