

Inspections, Compliance, Enforcement, and Criminal Investigations

OST Medical, Inc.



Department of Health and Human Services

Public Health Service
Food and Drug Administration
New England District
One Montvale Avenue
Stoneham, Massachusetts
02180
(781) 596-7700
FAX: (781) 596-7896

WARNING LETTER

NWE -13-10W

VIA FEDERAL EXPRESS

January 27, 2010

Mr. Peter J. Sacchetti
President/Owner
OST Medical, Inc.
11 Knight Street, Building F23
Warwick, RI 02886-1281

Dear Mr. Sacchetti:

The Food and Drug Administration (FDA) recently performed an inspection on November 23 through December 31, 2009 of your medical device manufacturing facility located at 11 Knight Street, Warwick, RI and determined that you manufacture Sentinel enteral feeding pumps and distribute both the pumps and disposable delivery sets. Under a United States law, the Federal Food, Drug and Cosmetic Act, (the Act), all of these above mentioned products are considered to be medical devices under 201(h) of the Act (21 U.S.C. § 321(h)) because they are used to diagnose or treat a medical condition.

The recent FDA inspection found that the devices manufactured at your facility are adulterated under 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, the manufacture, packing, storage or installation

are not in conformance with the Current Good Manufacturing Practice (CGMP) requirements for medical devices which are set forth in the Quality System regulation, as specified in Title 21 Code of Federal Regulations, (21 CFR), Part 820. FDA has found ongoing systemic violations in the quality management system employed to ensure the safety and effectiveness of the medical devices you distribute. Significant deviations from the QS regulations include, but are not limited to, the following:

1. Failure to establish and maintain procedures to ensure that all received product conforms to specified requirements, as required by 21 CFR 820.50. For example, your firm has not performed testing for 3 out of 4 incoming lots received by one of your suppliers of disposable delivery sets, **(b) (4)**

Your firm also receives disposable delivery sets from **(b) (4)**. This firm is not on your approved supplier list and you did not have adequate documentation upon receipt to demonstrate that these incoming sets met required specifications.

Also, your firm contracted with an unapproved supplier to print out labels for the Sentinel pumps, which included serial numbers. Your firm did not perform any incoming inspection of the printed labels to demonstrate that they met required specifications. As a result, your firm received two complaints that the labels were smudging and chipping off.

2. Failure to maintain a device history record (DHR) that includes acceptance records which demonstrate that the device is manufactured in accordance with the DHR, as required by 21 CFR 820.184(d). For example, four DHR's for pumps (8010, 8036, 8039 and 14029) were missing documentation of the "Acceptance Test report and Burn-In Test sheet" for these devices.

3. 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 C.F.R. § 820.198(c). For example, your complaint files for complaints # 96, 98, 99, 104, 105, 108 did not have any documentation demonstrating that an investigation was completed prior to closing the complaints.

4. 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, the firm has no procedure describing the review of service calls for potential complaints.

5. Failure to establish and maintain procedures for verifying or validating the corrective and preventive action, to ensure that such action is effective and does not adversely affect the finished device, as required by 21 CFR 820.100(a)(4). For example, CAPA 76 did not contain any record that a validation or verification of your corrective action was performed prior to closure. CAPA 78, opened on 6/11/08 and CAPA 79, opened on 9/22/08 remain open with no corrective action verified or documented. Also, CAPA 82 notes that the CAPA was verified and closed by a person who was not employed by OST. During the inspection your firm was not able to explain how this was considered to be an acceptable practice.

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.

We are requesting that you submit to this office on the schedule below, certification by an outside expert consultant that he/she has conducted an audit of your establishment's manufacturing and quality assurance systems relative to the requirements of the device QS regulation (21 CFR, Part 820). You should also submit a copy of the consultant's report, and certification by your establishment's Chief Executive Officer (if other than yourself) that he or she has reviewed the consultant's report and that your establishment has initiated or completed all corrections called for in the report. The initial certifications of audit and corrections and subsequent certifications of updated audits and corrections (if required) should be submitted to this office by the following dates:

- Initial certifications by consultant and establishment – July 27, 2010
- Subsequent certifications – January 27, 2011 and January 27, 2012

Please notify this office in writing within fifteen (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 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 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 violations, and take prompt actions to correct the violation(s) and to bring your products into compliance.

We also want to remind you of your obligations as a medical device manufacturer to submit a written report to FDA of any correction or removal of a device initiated by the manufacturer to reduce a risk to health posed by the device, as required by 21 CFR 806.10(a)(1). During our inspection we observed you to contact a number of customers with updates regarding your devices. Please be aware that if any future corrections are conducted to reduce a risk to health, then you will need to report these to FDA as Corrections or Removals.

Please direct your response or any questions you may have to Karen Archdeacon, Compliance Officer, Food and Drug Administration, One Montvale Avenue, 4th Floor,

Stoneham, Massachusetts 02180. Her telephone number is (781) 596-7707.

Sincerely,

/S/

John R. Marzilli

District Director

New England District