Inspections, Compliance, Enforcement, and Criminal Investigations

P.M.T. Corp, 12/3/09

Department of Health and Human Services

Public Health Service
Food and Drug Administration
Minneapolis District Office
Central Region
250 Marquette Avenue, Suite 600
Minneapolis, MN 55401
Telephone: (612) 758-7133
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December 3, 2009

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Refer to MIN 10 - 07

Alfred A. Iversen
President
PMT Corporation
P.O. Box 610
Chanhassen, Minnesota 55317-0610

During an inspection of PMT Corporation, located at 1500 Park Road Chanhassen, Minnesota 55317-0610, on July 22 through August 4, 2009, investigators from the United States Food and Drug Administration (FDA) determined that your firm manufactures breast expanders, tissue expanders, neurosurgical electrodes, traction systems, cervical collars, and gel shapes for scar treatment. 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 (21 CFR), Part 820. At the close of the inspection, our investigators issued a Form FDA 483 (copy enclosed) citing a number of quality system observations, which included the following:

1. Failure to adequately validate processes (whose results cannot be fully verified by subsequent inspection and test) as required by 21 CFR 820.75(a). Specifically:

   A. Biological indicators used in the establishment of the sterilization process were not placed in the most difficult to sterilize location within the load.

   B. The validation of the sterilization process did not evaluate the extent to which variation in load configuration and load size affects the process.

   C. **(b)(4)** testing results for the Depthalon Electrode In-Line Interconnection System failed to meet the acceptance criteria of the validation plan (TR 204-001, 11/24/2004). **(b)(4)** of **(b)(4)** samples tested at **(b)(4)**, which is less than the **(b)(4)** acceptance criteria. The validation plan required design mitigation and retesting for validation failures, but this was not done.

2. Failure to adequately document the justification for use of nonconforming product, which is required by 21 CFR 820.90(b){1). Specifically, a biological indicator (BI) for box # **(b)(4)** tested positive in sterile load #2011-03B. **(b)(4)** devices in box # **(b)(4)** were repackaged, relabeled, and re-sterilized; but **(b)(4)** other boxes in the same sterile load were released for distribution without re-sterilization and without justification for use.

3. Failure to analyze data from quality sources to identify existing and potential causes of non-conforming product and other quality problems, which is required by 21 CFR 820.100(a)(1). Specifically, non-conforming product and rework documented on Rework Tracer Sheets (Document Number 12204-001) are not captured in failure mode quality trending. This includes the sterility related failure cited above in item #2.

4. Failure to perform complete risk analysis as required by 21 CFR 820.30(g). Specifically, risk analysis of the neurological electrode products does not include the risk effect to the patient for the failure mode of electrode separation.

5. Failure to fully investigate a complaint involving the possible failure of a device to meet its specifications, which is required by 21 CFR 820.198(c). Specifically, complaint number N07-001 reported unsealed inner packages for ring sets for a halo system. Investigation was limited to a review of the device history record.

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 FDA 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 received responses from Eric Caille, Regulatory Manager, dated September 1 and September 28, 2009, concerning the observations noted on the Form FDA 483. The responses appear to be adequate with one exception. For item # 1 above (also # 1 on the Form FDA 483), Corrective Action Requests (CARs) were provided to the investigators during the inspection. The CARs described plans for corrective action; however, the written responses to the 483 did not provide any further information about the implementation and status of the corrections. A follow-up inspection will be necessary to ensure that all corrective actions are fully implemented and effective.

The July 22 through August 4, 2009, inspection also revealed deficiencies in your firm's implementation of Medical Device Reporting (MDR) procedures. (See enclosed Form FDA 483, observation #4.) In particular, your firm failed to submit MDRs for two reportable events:

1.) Complaint number N06-020, which reported that a Depthalon electrode fell apart during removal. Two contacts remained inside the patient and were removed later under x-ray.

2.) Complaint Number N09-009, which reported that a sheath slipped off an electrode and was unintentionally left in the patient's scalp.

During the inspection, your firm filed MDRs for those two complaints (and one additional reportable event) and promised to retrain employees in the MDR procedures. Corrective actions appear to adequately address the deficiencies, Implementation and effectiveness of these corrective actions will be evaluated further during your next inspection.

Please notify this office in writing within 15 working days from the date you receive this letter to acknowledge receipt of this Warning Letter and to provide an update on the specific steps taken by your firm to correct the five violations noted above. Include an explanation of how you plan to prevent these violations, or similar violations, from occurring again. If not already provided in your 483 responses, include documentation of the corrective actions 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.

Your response should be sent to Timothy G. Philips, Compliance Officer, at the address on this letterhead. If you have any questions about the content of this letter please contact Mr. Philips at (612) 758-7133.

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, issued at the conclusion 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 violations and to bring your products into compliance.

Sincerely,

/s

W. Charles Becoat
Director
Minneapolis District

TGP/ccl
Enclosure: Form 483, 8/4/09