Inspections, Compliance, Enforcement, and Criminal Investigations

Weartech International Inc. 9/29/09

Department of Health and Human Services

Public Health Service
Food and Drug
Administration
Los Angeles District
Pacific Region
19701 Fairchild
Irvine, CA 92612-2506
Telephone: 949-608-2900
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WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

September 29, 2009

W/L 29-09

Mr. Sankar P. Iyer
President
Weartech International Inc.
13032 Park Street
Santa Fe Springs, California 90670

Dear Mr. Iyer:

During an inspection of your firm located in Santa Fe Springs, California on June 24, 2009, through July 16, 2009, an investigator from the United States Food and Drug Administration (FDA) determined that your film manufactures dental alloy products. 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 (C.F.R.), Part 820. We received a response from Micol Coppock, Quality Manager dated July 28, 2009, concerning our investigator's observations noted on the Form FDA 483, List of Inspectional Observations that was issued to you. 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 procedures to control the design of the device in order to ensure that specified design requirements are met, as required by 21 CFR 820.30(a). For example, there are no design control procedures for the dental alloy products.

2. Failure to establish and maintain a design history file (DHF) for each type of device. The DHF shall contain or reference the records necessary to demonstrate that the design was developed in accordance with the approved design plan and the requirements of this part, as required by 21 CFR 820.300). For example, there is no design history file for the Dentaflex and Dentalbond dental alloys.

3. Failure to adequately ensure that when the results of a process cannot be fully verified by subsequent inspection and test that the process shall be validated with a high degree of assurance and approved according to established procedure, as required 21 CFR 820.75(a). For example, the following processes do not have established procedures for
validation activities and results, nor documented validations: (a) cleaning and polishing of the dental alloys; (b) cutting the dental alloys; and (c) the mold process for the dental
alloys.

4. Failure to adequately establish and maintain procedures for implementing corrective and preventive action, as required by 21 CFR 820.100(a). For example, the corrective and
preventative actions procedures are inadequate in they do not require the verification or validation of corrective and preventive actions.

5. Failure to adequately establish and maintain procedures for receiving, reviewing, and evaluating complaints which shall ensure complaints are evaluated to determine whether
the complaint represents an event which is required to be reported to FDA under part

803 of this chapter, Medical Device Reporting (MDR), as required by 21 CFR 820.198(a)(3).
For example, your firm's complaint procedures do not require the evaluation of complaints for MDR reportable determination.

6. Failure to adequately establish and maintain procedures for rework, to include retesting and reevaluation of the nonconforming product after rework, to ensure that the product
meets its current approved specifications. Rework and reevaluation activities, including a determination of any adverse effect from the rework upon the product, shall be
documented in the device history record (DRR), as required by 21 CFR 820.90(b)(2). For example, your firm's SOP 7.3, Product Control, Rev. B, dated May 5, 2008, does not
clearly state to retest and reevaluate rework products.

7. Failure to adequately conduct periodic inspections in accordance with established procedures to ensure adherence to applicable equipment maintenance schedules, as required by 21 CFR 820.70(g)(2). For example, your firm failed to follow WI-032 Daily Scale Verification, Revision A, dated July 27, 2007, that requires daily verification of
five scales used in the production of your dental alloys. Your firm's records indicate that this daily verification activity was last completed in April 2009. There are no records of
this daily verification activity of the five scales in June 2009 or July 2009.

8. Failure to validate computer software for its intended use according to an established protocol, as required by 21 CFR 820.70(i). For example, your firm uses off-the-shelf
software that generates the labels for the dental alloys. The off-the-shelf software has not been validated for this use.

9. Failure to adequately establish and maintain procedures to control all documents that are required by this part, as required by 21 CFR 820.40. For example, your firm has no

adequate procedure to control all documents required be the Quality System regulation.

10. Failure to maintain records of changes to documents which include a description of the change, identification of the affected documents, the signature of the approving
individual(s), the approval date, and when the change becomes effective, as required by 21 CFR 820.40(b). For example, records documenting changes to your firm's procedures

are not adequately established and maintained. Your firm has a listing of revisions but this listing does not indicate the implementation dates or a description of the changes.

11. Failure to adequately establish and maintain records of acceptable suppliers, contractors, and consultants, as required by 21 CFR 820.50(a)(3). For example, the vendors of the coolant, soap, and ceramic used for manufacturing the dental alloys are not listed to the firm's approved vendor list.

12. Failure to adequately establish procedures for identifying training needs and ensure that all personnel are trained to adequately perform their assigned responsibilities. Training
shall be documented, as required by 21 CFR 820.25(b). For example, there is no documentation of employee training for your firm's numerous procedures and work instructions that are necessary for your employees to perform their assigned responsibilities.

13. Failure to adequately establish procedures for quality audits and conduct such audits to assure that the quality system is in compliance with the established quality system
requirements and to determine the effectiveness of the quality system, as required by 21 CFR 820.22. For example, your firm has not conducted monthly internal audits as required by your firm's SOP No. 8.1, Revision D, dated February 2, 2009, and WI-033, Monthly Quality Audits, dated August 23, 2007. Your firm in discussion with the
investigator indicated that your firm does not conduct monthly audits.

14. Failure to establish and maintain procedures to control labeling activities, as required by 21 CFR 820.120. For example, there are no labeling procedures established for your
firm's dental alloy devices.

15. Failure to adequately maintain device master records (DMR's). Each manufacturer shall ensure that each DMR is prepared and approved in accordance with 21 CFR 820.40, as
required by 21 CFR 820.181. For example, the DMR for the Dentabond and Dentaflex dental alloys does not contain the following: packaging procedures and specifications; label procedures and specifications; procedures and specifications for manufacturing materials (coolant and ceramics).

Our inspection also revealed that your dental alloy 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 C.F.R. Part 803 - Medical Device Reporting

(MDR) regulation. Significant deviations include, but are not limited to, the following: Failure to develop written MDR procedures, as required by 21 CFR 803.17.

We have reviewed your response to all of the Observations listed on the FDA 483 and have concluded that it is inadequate. Your firm did not provide any documented evidence of effectively implemented corrections and corrective actions taken on the deficiencies observed during the inspection. Your firm only provides approximate completion dates. Your firm also did not note to the LOS-DO your plan to prevent the observations from recurring.

You should take prompt action to correct the violation(s) addressed in this letter. Failure to promptly correct these violation(s) 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 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 violation(s), or similar violation(s), 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. A follow up inspection will be required to assure that corrections are adequate.

Your response should be sent to:

Mr. James Stumpff
Acting Director, Compliance Branch
Food and Drug Administration
19701 Fairchild
Irvine, California 92612

If you have any questions about the content of this letter please contact: Mr. Marco Esteves at (949) 608-4439.

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.

Sincerely yours,
/S/

Alonza E. Cruse
District Director
Los Angeles District