Inspections, Compliance, Enforcement, and Criminal Investigations

Arnold Tuber Industries Dba Sci-Dent, Inc 11/10/09

Department of Health and Human Services

Public Health Service
Food and Drug
Administration
New York District
158-15 Liberty Ave.
Jamaica, NY 11433

November 10, 2009

WARNING LETTER NYK-2010-05

VIA FEDERAL EXPRESS

Michael L. Tuber, President
Arnold Tuber Industries, LLC
Dba Sci-Dent, Inc.
97 Main Street
Hamburg, New York 14075-4904

Dear Mr. Tuber:

During an inspection of your firm on July 27 through July 31, 2009, investigators from the United States Food and Drug Administration (FDA) determined your firm manufactures aspirating dental injection syringes of various sizes and colors. As defined pursuant to 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 a 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 these devices are adulterated within the meaning of section 501(f)(1)(B) of the Act [21 U.S.C. § 351(f)(1)(B)], because you do not have an

approved application for premarket approval (PMA) in effect pursuant to section 515(a) of the Act [21 U.S.C. § 360e(a)], or an approved application for an investigational device exemption (IDE) under section 520(g) of the Act [21 U.S.C. § 360j(g)]. The device is also misbranded under section 502(0) the Act [21 U.S.C. § 352(o)], because you did not notify the agency of your intent to introduce the device into commercial distribution, as required by section 510(k) of the Act [21 U.S.C. § 360(k)]. For a device requiring premarket approval, the notification required by section 510(k) of the Act [21 U.S.C. § 360(k)], is deemed satisfied when a PMA is pending before the agency 21 CFR 807.81(b). The kind of information you need to submit in order to obtain approval or clearance for your device is described on the Internet at http://www.fda.gov /cdrh/devadvice/3122.html. The FDA will evaluate the information you submit and decide whether your product may be legally marketed.

Our inspection also revealed these devices are adulterated within the meaning of section 501(h) of the Act [21 U.S.C. § 351 (h)], because 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 a response from you dated August 12, 2009, concerning our investigator's observations listed on the Form FDA 483, List of Inspectional Observations 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) You have failed 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).

Specifically, there were no procedures to control the design of the aspirating dental injection syringes that were designed by the firm in 2004 and then manufactured and shipped to the customer in **(b)(4)** from December 2004 to present.

2) You have failed to establish and maintain procedures for the identification, documentation, validation or where appropriate verification, review, and approval of design changes before their implementation, as required by 21 CFR 820.30(i).

Specifically, a change was implemented for the design of the hub on the **(b)(4)** aspirating dental injection syringe because the hubs were falling off and the needles would not stay on. However, there is no data or documentation supporting the verification, review, and approval of design change.

3) You have failed to adequately establish and maintain the procedures for receiving, reviewing, and evaluating complaints by a formally designated unit, as required by 21 CFR 820.198(a).

Specifically, the procedure **(b)(4)** and the corresponding form **(b)(4)** used to handle customer complaints, is not complete and the procedure lacks the definition of a complaint,
requirement of a record when no investigation is made, requirements that complaints be reviewed by a formally designated unit and whether an investigation is necessary.

4) You have failed to review, evaluate, and investigate any complaint involving the possible failure of a device to meet any of its specifications, as required by 21 CFR 820.198(c).

Specifically, the corrective/Preventive Action Reports **(b)(4)** (needle won't stay on) **(b)(4)** tarnished plunger and tubes), **(b)(4)** (hub fell off), **(b)(4)** and **(b)(4)** (bad threading) identifies different problems with the device. However, the reports failed to document the investigation into the failure of the device to meet specifications.

5) You have failed to establish and maintain procedures for finished device acceptance to ensure that each production, run, lot or batch of finished devices meets acceptance criteria, as required by 21 CFR 820.80(d).

Specifically, during the inspection it was noted that your firm lacks procedures for acceptance or rejection of finished device production run, lots or batches.

6) You have failed to validate computer software for its intended use according to an established protocol, when computers or automated data processing systems are used as part of the production or the quality system, as required by 21 CFR 820.70(i).

Specifically, there is no record of validation for software in the **(b)(4)** which is used to make components for the aspirating dental injection syringes.

7) You have failed to document maintenance activities, including the date and individuals performing those activities, as required by 21 CFR 820.70(g)(1).

Specifically, the firm's representative stated that the firm performs maintenance according to the manufacturer's maintenance schedule. However, there is no documented
maintenance activities for the **(b)(4)** used to make thumb ring, grasp and body components for the aspirating dental injection.

8) You have failed to establish and maintain adequate procedures to ensure that device history records for each batch, lot, or unit are maintained to

demonstrate that the device is manufactured in accordance with the device master record, as required by 21 CFR 820.184.

Specifically, the firm's device history record for the aspirating dental injection syringes is the"Syringe Job Traveler" implemented in 2008. However, only 3 travelers exist **(b)(4)** for all syringe products manufactured and shipped from 12/2004-07/2009

9) You have failed to maintain a device master record to include device specifications, as required by 21 CFR 820.181(a).

Specifically, the device master record for the aspirating dental injection failed to include information about the type of dental glue used for the assembly of the Hub and extension
components and the master approved top level drawings for **(b)(4)**

10) You have failed to 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.

Specifically, the inspection determined that the firm does not have procedures to perform internal quality audits and no internal quality audits were performed by the firm.

11) You have failed to appoint and document such appointment of a member of management who, irrespective of other responsibilities, ensures that quality system requirements are effectively established and effectively maintained and reports on the performance of the quality system to management with executive responsibility, as required by 21 CFR 820.20(b)(3).

Specifically, during the inspection, you stated that the firm had not appointed a management representative to the firm's quality system, to ensure the quality system requirements were met.

12) Your management with executive responsibility failed to review the suitability and effectiveness of the quality system at defined intervals and with sufficient frequency according to established procedures to ensure that the quality system satisfies the requirements of this part and the manufacturer's established quality policy and objectives. The dates and results of quality system reviews shall be documented, as required by 21 CFR 820.20(c).

Specifically, the firm does not have procedures for management review and management has not reviewed the suitability and effectiveness of the quality system at defined intervals and with sufficient frequency.

13) Failure to provide adequate resources including the assignment of trained personnel, for management, performance of work, and assessment activities, including internal quality audits, as required by 21 CFR 820.20(b)(2).

Specifically, the current inspection demonstrated that there is no documentation to show that personnel performing the assembly and inspection of the aspirating dental injection syringe were trained. In addition, there are no personnel trained to conduct internal quality audits.

We have reviewed your responses and have concluded that they are inadequate. Your firm promised to correct the deficiencies without providing evidence of implementation of the correction, corrective action and proposed preventive action.

Our inspection also revealed that your aspirating dental injection syringes are misbranded within the meaning of section 502(t)(2) of the Act [21 U.S.C. § 352(t)(2)], because your firm failed or refused to furnish material or information regarding the device that is required by or under section 519 of the Act [21 U.S.C. § 360i], and 21 CFR Part 803 Medical Device Reporting (MDR) regulation. Specifically, your firm failed to develop, maintain, and implement written MDR procedures for the following:

a) Internal systems that provide for:

1) Timely and effective identification, communication, and evaluation of events that may be subject to MDR requirements;
2) A standardized review process or procedure for determining when an event meets the criteria for reporting under this part; and
3) Timely transmission of complete medical device reports to manufacturers or to us, or to both if required.

b) Documentation and record keeping requirements for:

1) Information that was evaluated to determine if an event was reportable;
2) All medical device reports and information submitted to manufacturers and/or us;
3) Any information that was evaluated for the purpose of preparing the submission of annual reports; and
4) Systems that ensure access to information that facilitates timely follow-up and inspection by us (21 CFR 803.17).

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 ill 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 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 IS 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 violations and to bring your products into compliance.

Your response should be sent to Compliance Officer Dean Rugnetta, U.S. Food and Drug Administration, 300 Pearl Street, Suite100, Buffalo,NY 14202. If you have any questions about the content of this letter please contact Compliance Officer Dean Rugnetta at 716-541-0324, or dean.rugnetta@fda.hhs.gov.
Arnold Tuber Industries, LLC

Sincerely yours,

/S/

Laurence D. Daurio
Acting District Director
New York District