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DEC 11 2003

Food and Drug Administration
Center for Devices and
Radiological Health
2098 Gaither Road
Rockville, MD 20850

VIA FEDERAL EXPRESS

WARNING LETTER

Dr. Scott Bakos
President
Smith Sterling Dental Laboratory, Inc.
4531 Deleon Street, Suite 205
Ft. Myers, Florida 33907

Dear Dr. Bakos:

During an inspection of your facility, Laboratorios Dentales Zona Franca S.A., located in Cartago, Costa Rica, on July 28-29, 2003, our investigator determined that your firm manufactures dental prostheses. This product is a medical device as defined by section 201(h) of the Federal Food, Drug, and Cosmetic Act (the Act).

The above-stated inspection revealed that these devices are adulterated within the meaning of section 501(h) of the Act, in that the methods used in, or the facilities or controls used for, its manufacture, packing, storage, or installation are not in conformance with the Current Good Manufacturing Practice (CGMP) requirements of the Quality System regulation, as specified in Title 21, Code of Federal Regulations (CFR), Part 820. Significant deviations include, but are not limited to, the following:

1. Failure to establish and maintain procedures for implementing corrective and preventive action (CAPA), as required by 21 CFR § 820.100(a). Your firm's procedure for implementing corrective and preventive actions (CAPA) does not include requirements for the following:
 - a. Analyzing processes, work operations, complaints, returned product and other sources of quality data to identify existing and potential causes of nonconforming product;
 - b. Investigating the cause of nonconformities relating to product, processes, and the quality system;
 - c. Identifying the actions needed to correct and prevent recurrence of nonconforming product and other quality problems;
 - d. Verifying or validating the CAPA to ensure that such action is effective and does not adversely affect the finished device;

- e. Ensuring that information related to quality problems or nonconforming product is disseminated to those directly responsible for assuring the quality of such product or the prevention of such problems; and
 - f. Submitting relevant information on identified quality problems and CAPA for management review.
2. 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).
 3. Failure to conduct quality 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, there is no written procedure for quality audits. For example, quality audits are not routinely conducted to ensure that dental prostheses such as crowns and bridges, are manufactured in compliance with the established Quality System requirements and to determine the effectiveness of the Quality System.
 4. Failure to establish and maintain an adequate organizational structure to ensure that your medical devices are designed and produced in accordance with the requirements of 21 CFR Part 820, as required by 21 CFR § 820.20(b). Specifically, at the time of the inspection your firm did not have a management representative appointed.
 5. Failure to establish and maintain procedures to control all documents that are required by 21 CFR § 820.40. Specifically, no procedure exists for document control. In addition, documents such as the Quality Policy and procedures related to the manufacture of dental prostheses are not controlled, and do not bear approval signatures or effectiveness dates. For example, there is no system to ensure that the most current version of a document and/or procedure is used.
 6. Failure of management with executive responsibility 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).
 7. Failure to establish and maintain procedures for acceptance activities, as required by 21 CFR § 820.80(a). For example,

there is no record for in-process or final inspection of dental implants prior to distribution.

8. Failure to have sufficient personnel with the necessary education, background, training, and experience to assure that all activities are correctly performed, as required by 21 CFR § 820.25. For example, management was unable to produce personnel documentation required by this part.

This letter is not intended to be an all-inclusive list of deficiencies at your facility. It is your responsibility to ensure adherence to each requirement of the Act and regulations. The specific violations noted in this letter may be symptomatic of serious underlying problems in your firm's manufacturing and quality assurance systems. You are responsible for investigating and determining the causes of the violations identified by the Food and Drug Administration. If the causes are determined to be systems problems, you must promptly initiate permanent corrective actions. 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.

We received a response from Mike Lomax, General Manager dated October 24, 2003, concerning our investigator's observations noted on the FDA-483. It appears that the response is adequate. However, a follow-up inspection will be required to assure that corrections are adequate. We will contact the appropriate people and request an establishment re-inspection. An FDA trip planner will be in touch with you to arrange a mutually convenient date for this inspection. If the implementation of your corrections is verified during the re-inspection, you will be notified that your corrections are adequate. If it is determined during the re-inspection that your corrections are inadequate, all devices manufactured by Laboratories Dentals Zone Franca SEA., Cartage, Costa Rica, will be detained without physical examination upon entry into the United States (U.S.) until these violations are corrected.

Please notify this office in writing within 15 working days from the date you receive this letter, the specific steps you have taken to correct the noted violations, including an explanation of each step being taken to identify and make corrections to any underlying systems problems necessary to assure that similar violations will not recur. Please include any and all documentation to show that adequate correction has been achieved. In the case of future corrections, an estimated date of completion, and documentation showing plans for correction, should be included with your response to this letter.

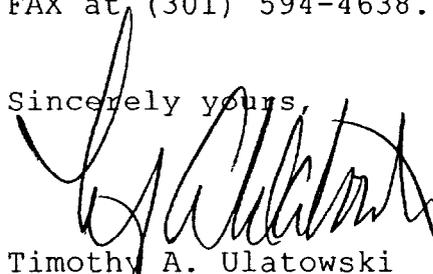
If documentation is not in English, please provide an English translation to facilitate our review.

Page 4 - Dr. Scott Bakos

Your response should be sent to the Food and Drug Administration, Center for Devices and Radiological Health, Office of Compliance, Division of Enforcement A, Dental, ENT, & Ophthalmic Devices Branch, 2098 Gaither Road, Rockville, Maryland 20850, to the attention of Mr. Ronald L. Swann, Chief.

Should you require any assistance in understanding the contents of this letter, do not hesitate to contact Mr. Ernest N. Smith, Consumer Safety Officer, at the letterhead address or via telephone at (301) 594-4613 or via FAX at (301) 594-4638.

Sincerely yours,

A handwritten signature in black ink, appearing to read "Timothy A. Ulatowski". The signature is fluid and cursive, with a large initial "T" and "U".

Timothy A. Ulatowski
Director
Office of Compliance
Center for Devices and
Radiological Health