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JUN 29 2004

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

WARNING LETTER

FEDERAL EXPRESS

Mr. Giovanni Piazza
President and Chief Executive Officer
Dental Manufacturing S.P.A.
Via Ca Mignola Nuova 1699
Badia Polesine, Italy

Dear Mr. Piazza:

During an inspection of your firm located in Badia Polesine, Italy on April 13-15, 2004, our investigator determined that your firm manufactures preformed plastic denture teeth. These products are devices within the meaning of section 201(h) of the Federal Food, Drug, and Cosmetic Act (the Act) (21 U.S.C. § 321(h)).

This inspection revealed that these devices appear to be 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 (CFR), Part 820. Significant 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, design control procedures were not established at the time that the ACRY PLUS artificial resin teeth were released for commercial distribution in or about February 2001.
2. Failure to establish and maintain procedures for verifying the device design to confirm that the design output meets the design input requirements, as required by 21 CFR 820.30(f). For example:
 - (a) all design verification test requirements were not established for the ACRY PLUS artificial resin teeth prior to completion of design activities and there is no justification for not conducting all of the tests performed on earlier design versions. The cytotoxicity, intracutaneous reactivity, sensitization biocompatibility testing, and the ISO 3336:1993 tests were not completed. Additionally, there is no approved formulation documentation relating to the initial design transferred to production.

- (b) manufacturing records for samples used in design verification testing conducted on either ACRY PLUS or equivalent designs, are not always available.
3. Failure to maintain device history records (DHR's) to ensure that DHR's 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. For example, records relating to the _____ process for the artificial teeth are not maintained.
 4. Failure of management to establish its policy and objectives for, and commitment to, quality, as required by 21 CFR 820.20(a). For example, a written quality policy has not been established by executive management.
 5. Failure of management 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, as required by 21 CFR 820.20(c). For example, the management review procedure states that reviews are to be conducted as necessary. The minimum frequency for management reviews has not been established.

Additionally, the above-stated inspection revealed that your devices are misbranded under section 502(t)(2) of the Act, in that your firm failed or refused to furnish any material or information as required by or under section 519 respecting the device and 21 CFR 803 – Medical Device Reporting (MDR) regulation. Your firm failed to develop, maintain, and implement written MDR procedures as required by 21 CFR 803.17.

This letter is not intended to be an all-inclusive list of deficiencies at your facility. It is your responsibility to ensure compliance with applicable laws and regulations administered by the United States Food and Drug Administration (FDA). The specific violations noted in this letter and in the Inspectional Observations, Form FDA 483 (FDA 483), issued at the close of the inspection may be symptomatic of serious underlying 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.

You should take prompt action to correct these deviations. Failure to promptly correct these deviations may result in regulatory action without further notice, which may include the refused entry of your affected products until the corrections are completed.

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,

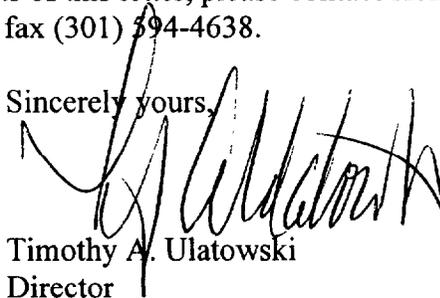
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from occurring again. Include all documentation of the corrective action you have taken. If you plan to make any corrections in the future, include those plans with your response to this letter as well. If the documentation is not in English, please provide a translated copy to facilitate our review.

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, and Ophthalmic Devices Branch, 2098 Gaither Road, Rockville, Maryland 20850 USA, to the attention of Keisha Thomas.

If you need help in understanding the contents of this letter, please contact Keisha Thomas at the above address or at (301) 594-4613 or fax (301) 594-4638.

Sincerely yours,

A handwritten signature in black ink, appearing to read 'Timothy A. Ulatowski', written over the 'Sincerely yours,' text.

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