



DEPARTMENT OF HEALTH & HUMAN SERVICES

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Food and Drug Administration

Dallas District
4040 North Central Expressway
Dallas, Texas 75204-3145

April 18, 2002

Ref: 2002-DAL-WL-14

WARNING LETTER

CERTIFIED MAIL
RETURNED RECEIPT REQUESTED

Mr. Ben J. Gallant, Chairman and CEO
American Dental Technologies, Inc.
5555 Bear Lane
Corpus Christi, Texas 78405

Dear Mr. Gallant:

On February 27 through March 1, 2002, our FDA investigators conducted an inspection of your device manufacturing facility located in Corpus Christi, Texas. Our investigators determined that your firm manufactures several dental device systems, such as the PulseMaster® 600-IQ and DioLase ST® Dental Laser System, PowerPAC® High Speed Curing Light System, KCP® 5 and 1000 Air Abrasive Kinetic Cavity Preparation System, and Ultracam® Intraoral Camera System. These products are medical devices as defined in Section 201(h) of the Federal Food, Drug, and Cosmetic Act (the Act).

At the conclusion of the inspection on March 1, 2002, Investigator Ellen Kleintop issued a list of Inspectional Observations (Form FDA-483) to you listing significant deviations from Current Good Manufacturing Practices (CGMP). Your 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 their manufacturing, packing, storage, or installation are not in conformance with the CGMP requirements of the Quality System Regulation, as specified in Title 21, Code of Federal Regulation (CFR), Part 820. Significant CGMP deviations include, but are not limited to, the following:

1. Failure to establish and maintain procedures for implementing corrective and preventive action [21 CFR 820.100] [FDA-483 Item 1]. For example:
 - (a) Your firm does not initiate a corrective or preventive action until product defects exceed a limit of [REDACTED] without providing a valid rationale to support the use of this limit or categorizing and classifying each type of product defect in relation to patient and user risks.

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- (b) Your firm failed to maintain records of device failure investigations, records of management approval, records of engineering change orders, records or reports of design verification or validation, for several design changes addressing quality problems in the PowerPAC® High Speed Curing Light System (i.e., [REDACTED]).
2. Failure to establish and maintain adequate complaint handling procedures [21 CFR 820.198] [FDA-483 Item 2]. For example:
- (a) Your firm's procedures do not call for evaluating each customer complaint and servicing report for a possible MDR reportable event and do not define MDR evaluation criteria; and
- (b) Complaint records lack a description of the nature and details of complaints.
3. Failure to establish and maintain adequate MDR procedures [21 CFR 803.17 and 803.20] [FDA-483 Item 3]. For example, your procedures do not:
- (a) Require for maintaining documentation of the information used to determine if an event was reportable;
- (b) Define the required reporting timeframes (i.e., 5 days and 30 days);
- (c) Use the correct reporting form for capturing and reporting MDR event information to FDA.
4. Failure to maintain adequate device master records [21 CFR 820.181] [FDA-483 Item 5]. For example, your firm did not maintain or refer to the location of the software engineering change records and software testing procedures.

Electro-Optics Specialist (EOS) Dennis Butcher participated in this inspection and issued another FDA-483 citing eleven observations of noncompliance from the Federal Laser Performance Standard (21 CFR Part 1040). The Center for Devices and Radiological Health (CDRH) is reviewing these observations and will follow-up with your firm in a separate letter.

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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 the GMP regulations. The specific violations noted in this letter and in the FDA-483 issued by FDA Investigator Kleintop at the close of the inspection 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 GMP violations identified by the FDA. 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.

You should take prompt action to correct these GMP violations. 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 penalties.

Please provide this office in writing within 15 working days of receipt of this letter a report of the specific steps you have taken, or will take to identify and correct any underlying systems problems necessary to assure that similar violations will not recur. If corrective action cannot be completed within 15 working days, state the reason for the delay and the time frame within which the corrections will be completed. Your reply should be directed to Thao Ta, Compliance Officer, at the above letterhead address.

Sincerely,



Michael A. Chappell
Dallas District Director

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