



DEPARTMENT OF HEALTH & HUMAN SERVICES

HFZ-35  
95014d  
Food and Drug Administration

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

October 14, 2004

Ref: 2005-DAL-WL-1

**WARNING LETTER**

**CERTIFIED MAIL**  
**RETURNED RECEIPT REQUESTED**

Mr. David E. Lesh, President  
Dale Dental, Inc.  
1701 North Greenville Avenue, Suite 712  
Richardson, Texas 75081

Dear Mr. Lesh:

Our review of information collected during an inspection of your firm's manufacturing operations located at the above-referenced address on August 30 and 31, 2004, revealed that your firm repackages and relabels bulk porcelain powder, a device that is used to coat the coping (base of dental crown) and provide the appearance of a natural tool. This product is a device as defined in 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 their manufacturing, packing, or holding are not in conformance with the Current Good Manufacturing Practice (CGMP) requirements of the Quality System Regulations for medical devices, as specified in Title 21, Code of Federal Regulation (CFR), Part 820. At the close of the inspection, your firm was issued a Form FDA-483 (copy enclosed) which delineated a number of significant GMP inspectional observations which include, but are not limited to, the following:

1. Failure of management with executive responsibility to ensure that an adequate and effective quality system has been fully implemented and maintained at all levels of



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1. Failure of management with executive responsibility to ensure that an adequate and effective quality system has been fully implemented and maintained at all levels of

the organization [21 CFR 820.20] [FDA-483 Items 1 through 9]. For example, your firm has not established quality system procedures and instructions, including but not limited to, procedures for complaint handling, internal quality audit, purchasing controls, acceptance or rejection of incoming and finished products, repackaging and relabeling of porcelain powder, identification and disposition of nonconforming porcelain powder, and corrective and preventive actions.

2. Failure to maintain complaint files and to establish and maintain procedures for receiving, reviewing, and evaluating complaints by a formally designated unit [21 CFR 820.198(a)] [FDA-483 Item 2]. For example, your firm has not (a) established procedures to indicate how complaints are received, investigated, and documented; and (b) maintained complaint records.
3. Failure to establish and maintain procedures to ensure that all purchased or otherwise received product and services conform to specified requirements [21 CFR 820.50] [FDA-483 Item 4]. For example, your firm has not established purchasing documentation that clearly references product specifications and quality requirements that must be met by the suppliers and procedures describing your firm's quality assessments of the suppliers.
4. Failure to establish and maintain procedures for acceptance or rejection of incoming and finished product to ensure that each production run, lot, or batch of incoming and finished devices meets acceptance criteria [21 CFR 820.80(b), (d), and (e)] [FDA-483 Item 7]. For example, your firm has not established (a) procedures describing how incoming bulk porcelain powder is received, inspected, accepted or rejected; and (b) procedures describing how repackaged/re-labeled porcelain powder is inspected, accepted or rejected before shipment; and (c) records of acceptance results.
5. Failure to establish and maintain process control procedures to include documented instructions, standard operating procedures (SOPs), and methods that define and control the manner of production [21 CFR 820.70(a)] [FDA-483 Item 6]. For example, your firm has not established procedures for the repackaging and relabeling of bulk porcelain powder, quality inspection, and release of repackaged/re-labeled porcelain powder.
6. Failure to establish and maintain procedures to ensure that equipment is routinely calibrated, inspected, checked, and maintained and that calibration records are maintained [21 CFR 820.72(a) and (b)(2)] [FDA-483 Item 5]. For example, your firm has no procedures for performing calibration of the [REDACTED] electronic scale that is used to weight the porcelain powder during the repackaging process.

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Dale Dental, Inc.  
October 14, 2004

7. Failure to establish and maintain device history records that include or refer to any device identification(s) and control number(s) used [21 CFR 820.184(f)]. For example, lot numbers of the repackaged/re-labeled porcelain powder are not documented in the device history records or shipping records.
8. Failure to establish and maintain procedures for the control of storage areas and stock rooms for product to prevent mixups, damage, deterioration, contamination, or other adverse effects pending use or distribution [21 CFR 820.150(a)]. For example, your firm indicates to our investigator that bulk porcelain powder is sensitive to light but that has not established procedures to prevent this adverse effect.
9. Failure to establish and maintain procedures for identifying and documenting training needs and ensure that all personnel are trained to adequately perform their assigned responsibilities [21 CFR 820.25(b)]. For example, your firm reported to have provided staff training on the handling of incoming product and repackaging operations but did not document staff training.

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 regulations. The specific violations noted in this letter and in the Form 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 are responsible for investigating and determining the causes of the violations identified by the FDA. You also must promptly initiate permanent corrective action and preventative action on your quality system.

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.

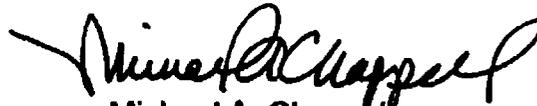
You should take prompt action to correct these violations. Failure to promptly correct these violations may result in regulatory action being initiated by the Food and Drug Administration without further notice. These actions include, but are not limited to, seizure, injunction, and/or civil penalties.

Should you need general information about FDA's requirements for medical device manufacturers, you may obtain information on the FDA's website at <http://www.fda.gov> or by contacting our Division of Small Manufacturers, International and Consumer Assistance (DSMICA) at (800) 638-2041.

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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,

A handwritten signature in black ink, appearing to read "Michael A. Chappel". The signature is fluid and cursive, with a large initial "M" and "C".

Michael A. Chappel  
Dallas District Director

MAC:txt

Enclosure