



DEPARTMENT OF HEALTH & HUMAN SERVICES  
PUBLIC HEALTH SERVICE  
FOOD AND DRUG ADMINISTRATION

PHILADELPHIA DISTRICT

900 U.S. Customhouse  
2nd and Chestnut Streets  
Philadelphia, PA 19106

Telephone: 215-597-4390

WARNING LETTER

CERTIFIED MAIL  
RETURN RECEIPT REQUESTED

December 1, 1998

Mr. Otto W. Voit III  
President & Chief Financial Officer  
T & S Dental and Plastics Manufacturing Co.  
52 West King Street  
P.O. Box 264  
Myerstown, PA 17067-0264

Dear Mr. Voit:

On October 15-29, 1998, Food and Drug Administration (FDA) Investigator, Michael A. Taylor conducted an inspection at your Myerstown, PA facility. Your firm manufactures saliva ejectors which are devices as defined by section 201(h) of the Federal Food, Drug, and Cosmetic Act (the Act). As such these devices are subject to the requirements of Title 21 Code of Federal Regulations (21 CFR), including, but not limited to the Quality System Regulation, set forth at 21 CFR part 820. At the conclusion of the inspection a Form FDA-483 List of Inspectional Observations was issued to and discussed with you listing deviations to the Quality System Regulation.

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 the manufacture, packing, storage, or installation, are not in conformance with the Quality System Regulation, as follows:

Failure to validate the manufacturing process of your saliva ejector.

In absence of an inspection and testing procedure which can verify that a manufacturing process does what it is expected to do, every time, the process must be fully validated. We feel that your current inspection and testing procedures are not sufficient to assure that the saliva ejectors are manufactured in accordance to specifications, because failures, such as tips separating from the stems, continue to occur after distribution. This demonstrates a need for process validation.

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Failure to identify the action(s) necessary to correct and prevent recurrence of non-conforming product.

When your firm finds that the tips are not adhering to the stem, as evidenced in your complaints, in-process and finished product testing, your only attempt to correct the problem is through adjustments to equipment, specifically to the [REDACTED]. While the adjustments to the [REDACTED] are an attempt to correct the problem, it only does so temporarily; therefore, you have failed to take adequate corrective and preventative action. You have not determined the root cause of the failures in an effort to prevent recurrence of devices that do not meet specifications.

Additionally, when product testing finds poor adhesion of the tip to the stem, you test a small number of additional samples. If they (additional samples) meet specifications, the portion of the production run tested is released. We believe that the number of units tested is far too low for the size of the lot. The number of units tested should be based on a statistically sound sampling plan.

During the inspection the Investigator expressed his concern with regard to tip-separation complaints not being reported under the Medical Device Reporting Regulation (MDR). It is the Agency's position that if a malfunction has never led to a death or a serious injury, and a firm can document this conclusion, it is not MDR reportable. This rule applies unless there is a compelling clinical evaluation to indicate that the event would be likely to cause or contribute to a death or serious injury, even though previous deaths or serious injury had not occurred.

At the conclusion of the inspection, you promised to make corrections to the items listed the FDA-483. We acknowledge receipt of your letter dated November 3, 1998, and your representations concerning corrective actions. Your corrective activities will be evaluated during the next inspection of your facility.

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 and in the FDA-483 issued at the closeout 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. If the causes are determined to be systems problems, you must promptly initiate permanent corrective actions.

You should take prompt action to correct any manufacturing or quality systems deviations identified by your internal audits. Failure to promptly correct these deviations may be identified in a later comprehensive follow-up inspection, and may result in regulatory action being initiated by the Food and Drug Administration without further notice. These actions include, but are not

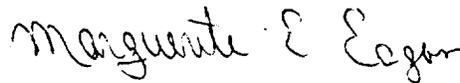
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limited to, seizure, injunction, and/or civil penalties.

Please notify this office in writing with fifteen (15) working days upon receipt of this letter, of 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 the 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 within which the corrections will be completed.

Your reply should be sent to the attention of Richard C. Cherry, Compliance Officer, at the address noted above.

Sincerely,



Marguerite E. Eagan  
Acting District Director  
Philadelphia District

cc: Pennsylvania State Department of Health  
132 Kline Plaza, Suite A  
Harrisburg, PA 17104  
Attention: Robert E. Bastian, Director  
Division of Primary Care and  
Home Health Services