



DEPARTMENT OF HEALTH & HUMAN SERVICES

94701d

New York District

Food & Drug Administration
158-15 Liberty Avenue
Jamaica, NY 11433

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Thomas G. Miller, President
TGM Products, Inc.
88 Rome Street
Farmingdale, NY 11735-6604

May 3, 2004

Ref: NYK-2004-14

Dear Mr. Miller:

During an inspection of your establishment located at the above address on April 1 and 5, 2004, our investigator determined that your firm manufactures dental forceps, orthodontics pliers, clip forceps, and cholangiography instruments. These products are devices 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 manufacturing, packing, storage, or installation are not in conformance with the Quality System regulation for medical devices, as specified in Title 21, *Code of Federal Regulations* (CFR), Part 820. The deficiencies include, but are not limited to, the following:

1. You failed to prepare, approve, and maintain device master records as required by 21 CFR 820.181. For example, you did not have any device master records for dental forceps, cholangiogram clamps, and certain orthodontic pliers that you manufacture. Further, your device master records for clip forceps and certain cholangiography instruments were inadequate in that they lacked production process specifications including appropriate equipment specifications, production methods, and production procedures. They also lacked quality assurance procedures and specifications including acceptance criteria.
2. You failed to maintain device history records to demonstrate that devices are manufactured in accordance with their device master records as required by 21 CFR 820.184. For example, you did not have any device history records for dental forceps, orthodontic pliers, clip forceps, and cholangiography instruments that you manufacture.

3. You failed to establish quality system procedures and instructions as required by 21 CFR 820.20(e). For example, you lacked established procedures for the following:
 - A. Receiving, reviewing and evaluating complaints including those complaints required to be reported to the FDA as required by 21 CFR 820.198.
 - B. Incoming, in-process, and finished product acceptance activities including inspections, tests, or other verification activities as required by 21 CFR 820.80.
 - C. Conducting 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.
 - D. Calibrating and maintaining inspection, measuring, and test equipment to ensure its suitability for its intended purpose as required by 21 CFR 820.72.
 - E. Implementing corrective and preventive action as required by 21 CFR 820.100.

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 its implementing regulations. The specific violations noted in this letter and in the Form FDA 483 (copy enclosed) issued to and discussed with you at the conclusion of the inspection may be symptomatic of serious underlying problems in your firm's quality system. You are responsible for investigating and determining the causes of the violations identified by the Food and Drug Administration (FDA). You also must promptly initiate permanent corrective and preventive 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. Additionally, no premarket submissions for Class III devices to which the Quality System/Good Manufacturing Practice deficiencies are reasonably related will be cleared or approved until the violations have been corrected. Also, no requests for Certificates to Foreign Governments will be approved until the violations related to the subject devices have been corrected.

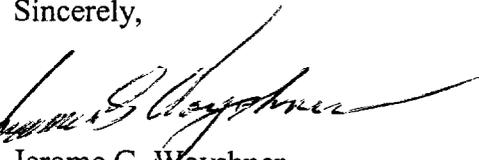
You should take prompt action to correct these deviations. Failure to promptly correct these deviations may result in regulatory action being initiated by the FDA without further notice. These actions include, but are not limited to, seizure, injunction, and/or civil penalties.

Please notify this office in writing within 15 working days of 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 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 within which the corrections will be completed.

TGM Products, Inc.
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Your response should be sent to Bruce A. Goldwitz, Compliance Officer, Food and Drug Administration, 158-15 Liberty Avenue, Jamaica, NY 11433, Tel. 718-340-7000 ext. 5582.

Sincerely,

A handwritten signature in black ink, appearing to read "Jerome G. Woysner", written in a cursive style.

Jerome G. Woysner
District Director

Enclosure: Form FDA 483 dated April 5, 2004