

HFI-35

Reviewed 11/25/96
N.L. Rose

11/26/96
ajf

D1512b

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration

Refer to: CFN 1124851

Baltimore District
900 Madison Avenue
Baltimore, Maryland 21201
Telephone: (410) 962-4040

November 18, 1996

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Mr. Abdul Q. Tabusum, President
Dentomed, Incorporated
4936 C Eisenhower Avenue
Alexandria, Virginia 22304

Dear Mr. Tabusum:

During a Food and Drug Administration (FDA) inspection of your medical device manufacturing facility, conducted October 24 through November 13, 1996, our investigator determined that your firm manufactures dental instruments. Dental instruments are devices as defined by Section 201(h) of the Federal Food, Drug, and Cosmetic Act (the Act).

The inspection revealed that these medical 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 Good Manufacturing Practice (GMP) for Medical Devices Regulation, as specified in Title 21, Code of Federal Regulations (CFR), Part 820, as follows:

1. Failure to establish specifications for the finished dental devices.
2. Failure to maintain Quality Audit procedures or records to document that such audits were performed.
3. Failure to maintain testing and release records for your finished dental devices.
4. Failure to maintain records or written procedures for the reprocessing of returned dental devices.

Mr. Abdul Q. Tabusum

Page 2

November 18, 1996

5. Failure to maintain records or specifications for the finished product labeling. For example, the [REDACTED] was used to label dental instruments with "DENTOMED STAINLESS," but there were no approved written specifications for this labeling, no approved procedures for use of the machine in labeling the instruments, and no records to show which dental instruments had been labeled.

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.

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 pre-market submissions for devices to which the GMP deficiencies are reasonably related will be cleared until the violations have been corrected. Also, no requests for Certificates for Products for Export 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 do so 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 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.

Your response should be sent to Gerald W. Miller, Compliance Officer, U.S. Food and Drug Administration, 101 West Broad Street (Suite 400), Falls Church, Virginia 22046-4200.

Sincerely yours,



Kenneth C. Shelin
Director, Baltimore District