



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

Food and Drug Administration
Nashville District Office
297 Plus Park Blvd.
Nashville, TN 37217

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*Completed 8/4/99
JED*

August 4, 1999

CERTIFIED - RETURN RECEIPT REQUESTED

Mr. Harry L. Johnson
Owner
TMED, Inc.
915 Carters Creek Pike
Columbia, TN 38401

WARNING LETTER - 99-NSV-19

Dear Mr. Johnson:

During an inspection of your firm located in Columbia, Tennessee, on July 1 and 6-8, 1999, our investigators determined that your firm manufactures sterile urinary drainage bags. Under the Federal Food, Drug, and Cosmetic Act (the Act), these products are considered to be medical devices because they are used to diagnose or treat a medical condition or to affect the structure or function of the body.

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, manufacture, packing, storage or installation are not in conformance with the Current Good Manufacturing Practice (CGMP) regulations of the Quality System Regulation, as specified in Title 21, Code of Federal Regulations (CFR), Part 820. The 1978 Good Manufacturing Practices (GMP) for Medical Device Regulations were superseded on June 1, 1997, by the Quality System Regulation.

The inspection revealed inadequate validation of your Ethylene Oxide Sterilization procedure, no procedures for conducting quality audits, inadequate Device Master Records (DMR), and deviations from your protocol in the sterilization of your drainage bags.

This inspection also revealed that you have distributed cases of Urinary Drainage Bags, product No. 1000, Lot No. 063097 and cases of Urinary Leg Bags, Product No. 1265, Lot No. 063097 which were labeled as sterile. Our inspection revealed that these products were distributed without being sterilized by a valid sterilizer procedure. Please notify this office in regard to your intentions concerning these products.

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 Form 483 issued at the closure 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.

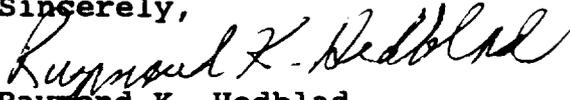
Federal agencies are advised of the issuance of all warning letters about devices so that they may take this information into account when considering the award of contracts. Additionally, no premarket submission for devices to which the GMP deficiencies are reasonably related will be cleared until the violations have been corrected. Also, no request for Certificate for Products to 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 promptly correct these deviations 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 fifteen (15) working days 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 system problems necessary to ensure that similar violations will not recur. If corrective action cannot be taken within fifteen (15) working days, state the reason for the delay and the time within which the corrections will be completed.

Your reply should be addressed to the attention of Joseph E. Hayes, Compliance Officer, Food and Drug Administration, 297 Plus Park Boulevard, Nashville, Tennessee 37217.

Sincerely,


Raymond K. Hedblad
Director, Nashville District

RKH/kl

Enclosures:

Form FDA-483
21 CFR Part 820

cc: Betty J. McPeak
Quality Assurance Manager