



DEPARTMENT OF HEALTH & HUMAN SERVICES

11330317

New York District

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

WARNING LETTER

February 3, 2000

REF: NYK-2000-31

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Mr. Allen J. Tower
President
Numed, Inc.
280 Main Street
Hopkinton, New York 12965

Dear Mr. Tower:

During an inspection of your firm located in Hopkinton, New York, conducted on October 4-15, 1999, our investigator determined that your firm manufactures and distributes a variety of dilatation catheters including those under the Tyshak, Z-Med and Ghost brand names. These are devices within the meaning of section 201(h) of the Federal Food, Drug, and Cosmetic Act (the Act).

The Tyshak, Z-Med and Ghost brand dilatation catheters 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 good manufacturing practice, as specified in Title 21, Code of Federal Regulations (CFR), Part 820, Quality System Regulation for Medical Devices, as follows:

1. Failure to validate processes as required by 21 CFR 820.75. During the inspection our investigator observed the validation data of the Ethylene Oxide sterilization process, approved on 1/12/99, is deficient in that:
 - (a) The biological indicators (BIs) used during the validation were not placed in the portion of the device which is most difficult to sterilize. The BIs were placed into a self-sealing single pouch and no data is available to show that this pouch is an equal or greater challenge than BIs placed in the device which are packaged in a double tyvek pouch.
 - (b) The validation did not demonstrate repeatability in that only 1 validation half-cycle was performed and pre-conditioning temperatures and aeration times/temperatures were not

the same as the Canadian validation performed, which was used as the basis for comparison.

2. Failure to take adequate corrective and preventive action for nonconforming product as required by 820.100 in that:
 - (a) In the case of the BI sterility test failure for sterilization load ST-238, your firm failed to employ all possible sources of quality data to identify existing and potential causes of the process indicator failure or potential product quality problems in that the investigation report contains no indication that the sterilization process was reviewed, evaluated, or considered for revalidation.
 - (b) The investigation report for the above failure concluded the source of the problem was the BI, however, the report contains insufficient information to support this conclusion.
 - (c) The investigation report failed to identify any action needed to correct and prevent a recurrence of nonconforming product and other quality problems in that there was no consideration of the sterilization process through review, evaluation and possible revalidation.
3. Failure to hold finished devices in quarantine or otherwise adequately controlled until released as required by 21 CFR 820.80 in that Sterilization lot ST-238 was released for distribution prior to the completion of all tests. The Biological Indicator Sterility Test, completed on 1/30/99, reported growth of 1 biological indicator. A total of 302 of 416 catheters contained in this load were distributed from 1/25-28/99.

This letter is not intended to be an all inclusive list of deficiencies at your facility. You should examine your firm's operations and determine if such conditions relate to other products manufactured and distributed by your firm. 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 close out 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 submissions for devices to which 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 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 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. Your response should include your intentions with regard to the catheters which have been shipped in domestic commerce. If corrective action cannot be completed within 15 working days, state the reason for the delay and the time within which corrections will be completed.

Your response should be sent to Lillian C. Aveta, Compliance Officer, Food and Drug Administration, 158-15 Liberty Avenue, Jamaica, New York 11433. If you have any questions, Ms. Aveta's telephone number is 718-340-7000 x 5576.

Sincerely,



Brenda J. Holman
District Director