



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

Purged 8/19/99 man
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Food and Drug Administration
Nashville District Office
297 Plus Park Blvd.
Nashville, TN 37217

July 27, 1999

CERTIFIED MAIL—RETURN RECEIPT REQUESTED

Bruno E. Wuest
President/Chief Executive Officer
Wuestec Medical, Inc.
PO Drawer 190037
Mobile, AL 36619-0037

Warning Letter No. 99-NSV-18

Dear Mr. Wuest:

During an inspection of your firm located at 5600 Commerce Blvd. East, Mobile, Alabama, on May 17-28, 1999, our investigators determined that your firm manufactures diagnostic x-ray equipment. 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 Practices (CGMP) regulations of the Quality System Regulation, as specified in title 21, Code of Federal Regulations (CFR), Part 820. The 1978 Good Manufacturing Practice (GMP) for Medical Device regulations were superceded on June 1, 1997, by the Quality System Regulation.

The inspection revealed inadequate complaint and Medical Device Reporting procedures (MDRs), incomplete design control and preventive action procedures, inadequate labeling procedures, incomplete master records and inadequate Device History Records.

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.

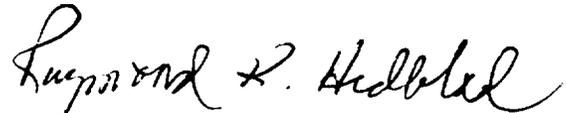
Federal agencies are advised of the issuance of all warning letters about devices so that they may take this information into account when considering the award of contracts. Additionally, no premarket submission for devices to which the GMP deficiencies are reasonably related will be cleared until the 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 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 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 Blvd., Nashville, TN 37217.

Sincerely,



Raymond K. Hedblad
Director, Nashville District

JEH:RKH:man

Enclosure:

21 CFR Part 820