



April 10, 2000

Chicago District
300 S. Riverside Plaza, Suite 550 South
Chicago, Illinois 60606
Telephone: 312-353-5863

WARNING LETTER
CHI-15-00

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Mr. Werner Mittermeier, President
Manan Medical Products, Inc.
2200 Carlson Drive
Northbrook, IL 60062

Dear Mr. Mittermeier:

During an inspection of your establishment located in Northbrook, IL, from January 6 to January 26, 2000, our investigator, Tamara Brey, determined that your establishment manufactures oncology needles, epidural needles, guide wire/introducer needles, procedure needles, biopsy needles, and gastroenterology catheters. These products are devices as defined by Section 201(h) of the Federal Food, Drug, and Cosmetic Act (the Act).

This 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, as follows:

1. Failure to adequately validate manufacturing processes. For example, your firm's validation study for injection molding of 12F catheter hubs, dated September 8, 1998, contains the following deficiencies:
 - a. Identification of worst-case operating conditions is not documented;
 - b. Identification of the duration of individual process runs (typical vs. validation) is not documented;
 - c. The study does not contain evidence that assures the process parameters remain within specifications and the process produces parts within specification throughout an entire process run. For example, the study protocol requires your firm sample product only at the beginning of the validation run, once it determines the process "will still produce acceptable parts."
 - d. The study does not identify statistical methods for data collection and provide justification the sampling method chosen. The study does not identify statistical methods of analysis.

- e. The study protocol does not identify the individuals that will perform the validation study and their responsibilities.
2. Failure to establish procedures to review and evaluate the molding process to determine the cause of non-conforming product, take corrective/preventive action, and perform revalidation where appropriate, when the process produces nonconforming product. For example, Specification 3-03, *Plastic Molding Parameters*, allowed injection-mold machine set-up personnel to change the mold machine's process parameters, during routine injection-mold production, outside those parameters specified in the process specification and supported by validation, when the process produces nonconforming product. Specification 3-03 lacked a requirement that the firm determine the following: the need for an investigation to determine cause of the nonconforming product, the need for corrective/preventive action, and need for revalidation.
3. Failure to establish adequate procedures to implement corrective and preventive action. For example, your firm did not analyze service records for the Manan™ Pro-Mag Automatic Biopsy System to identify quality problems that require corrective or preventive action.

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 conclusion of the inspection may be symptomatic of serious underlying problems in your establishment'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 requests for Certificates to Foreign Governments will be approved until the violations related to the subject devices have been corrected and verified.

We acknowledge that your firm responded by letter, dated February 15, 2000, to our Investigator's FDA-483. We do not consider your firm's response adequate because of the following:

- The validation report submitted in response to FDA-483 Observation #1 contains the deficiencies regarding process validation listed above in Point #1.
- Your firm's response to FDA-483 Observation #2 contains the deficiencies listed above in Point #2.

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We request that you 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. 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 the attention of Michael A. Lang, Compliance Officer at the above address.

Sincerely,

\s\
Raymond V. Mlecko
District Director