



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Minneapolis District Office
Central Region
212 3rd Avenue South
Minneapolis, MN 55401
Telephone: (612) 334-4100
FAX: (612) 334-4134

February 2, 2007

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Refer to MIN 07 - 10

Mark St. Michel
President
Medical Concepts Development
2500 Ventura Drive
Woodbury, Minnesota 55125

Dear Mr. St. Michel:

During an inspection of your firm located in Woodbury, Minnesota, on October 25 through November 8, 2006, an investigator from the United States Food and Drug Administration (FDA) determined that your firm manufactures surgical drapes. Under section 201(h) of the Federal Food, Drug, and Cosmetic Act (the Act), 21 U.S.C. 321(h), these products are devices because they are intended for use in the diagnosis of disease or other conditions or in the cure, mitigation, treatment, or prevention of disease, or are intended to affect the structure or function of the body.

This inspection revealed that these devices are adulterated within the meaning of section 501(h) of the Act [21 U.S.C. 351(h)], in that the methods used in, or the facilities or controls used for, their manufacture, packing, storage, or installation are not in conformity with the Current Good Manufacturing Practice (CGMP) requirements of the Quality System (QS) regulation found at Title 21, Code of Federal Regulations (CFR), Part 820. These violations include, but are not limited to, the following:

1. Failure to implement procedures for corrective and preventive actions as required by 21 CFR 820.100(a). Specifically, a corrective action was not initiated to address the problem of bioburden levels exceeding action/alert levels.
2. Failure to document corrective and preventive action activities, including investigations of causes of nonconformities, which is required by 21 CFR 820.100(b). Specifically:
 - a. Corrective Actions 078, 087, 106, and 146 are incomplete. "Corrective action," "root cause," "completed by," "verified by," and "closed by" are left blank.
 - b. Corrective Action 170, is [REDACTED] could not be found.

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3. Failure to implement procedures for monitoring and control of process parameters for validated processes as required by 21 CFR 820.75(b). Specifically, when bioburden levels exceeded the action/alert limits, no action was taken as required by Procedure for Environmental Monitoring, QP-19. A [REDACTED] and there was no formal investigation into manufacturing processes.
4. Failure to validate a process whose results cannot be fully verified by subsequent inspection and test according to established procedures, which is required by 21 CFR 820.75(a). Specifically, the Procedure for Validation of Sterilization Processes, QP-25, requires annual re-validation of the sterilization process. Re-validation was not performed in 2004.
5. Failure to investigate complaints involving the possible failure of a device to meet its specifications as required by 21 CFR 820.198(c). Specifically, complaint 2006-0051 reported "[REDACTED]." The investigation summary stated that this is an "isolated incident;" however, numerous other complaints of [REDACTED] had been received (15 complaints in 2006 and 12 complaints in 2005).
6. Failure to establish process control procedures that describe any process controls necessary to ensure conformance to specifications as required by 21 CFR 820.70(a). Specifically, procedures that describe the process of packaging non-sterile product into boxes with labels indicating the boxes have undergone the sterilization process have not been established to assure that non-sterile devices are not distributed to customers.
7. Failure to document employee training, which is required by 21 CFR 820.25(b). Specifically, employee training was held on new lab coat procedures, but the training procedures are not dated or formally controlled, there is no date on the employee signature list, and it was not clear if one employee whose signature was not on the list had taken the training.
8. Failure to establish procedures for identifying training needs as required by 21 CFR 820.25(b). Specifically, Cleanliness and Safety Tenets, procedure MM-E-01, has not been updated to include new lab coat procedures and training.

You should take prompt action to correct the violations addressed in this letter. Failure to promptly correct these violations 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 money penalties. Also, 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, premarket approval applications for Class III devices to which the Quality System regulation deviations are reasonably related will not be approved until the violations have been corrected. Requests for Certificates to Foreign Governments will not be granted until the violations related to the subject devices have been corrected.

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Please notify this office in writing within 15 working days from the date you receive this letter of the specific steps you have taken to correct the noted violations, including an explanation of how you plan to prevent these violations, or similar violations, from occurring again. Include documentation of the corrective action you have taken. If your planned corrections will occur over time, please include a timetable for implementation of those corrections. 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 Timothy G. Philips, Compliance Officer, at the address on this letterhead. If you have any questions about the content of this letter please contact Mr. Philips at (612)758-7133.

Finally, you should know that this letter is not intended to be an all-inclusive list of the violations at your facility. It is your responsibility to ensure compliance with applicable laws and regulations administered by FDA. The specific violations noted in this letter and in the Inspectional Observations, Form FDA 483, issued at the close-out of the inspection may be symptomatic of serious problems in your firm's manufacturing and quality assurance systems. You should investigate and determine the causes of the violations and take prompt actions to correct the violations and to bring your products into compliance.

Sincerely,



W. Charles Becoat
Director
Minneapolis District

TGP/ccl