



DEPARTMENT OF HEALTH AND HUMAN SERVICES

g. 4245d  
Food and Drug Administration

Atlanta District Office  
60 Eighth Street N.E.  
Atlanta, GA 30309

Telephone: 404-253-1161  
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August 28, 2003

**VIA FEDERAL EXPRESS**

Joseph Davant III  
President  
Rx Textiles, Inc.  
3107 Chamber Drive  
Monroe, NC 28110

**WARNING LETTER**  
(03-ATL- 25)

Dear Mr. Davant:

Our review of information collected during an inspection of your firm located at the above-referenced address on July 16-24, 2003, revealed that your firm manufactures and distributes surgical drapes, elastic bandages, cast liners and stockinettes. These products are devices as defined by Section 201(h) of the Federal Food, Drug, and Cosmetic Act (the Act).

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 their manufacturing, packing, storage, or installation are not in conformance with the Current Good Manufacturing Practice (CGMP) requirements of the Quality System Regulations for medical devices, as specified in Title 21, Code of Federal Regulation (CFR), Part 820. At the close of the inspection, you were issued a Form FDA-483 which delineated a number of significant GMP inspectional observations which include, but are not limited to, the following:

1. Failure to fully validate and approve a process whose results cannot be fully verified by subsequent inspection and test, as required by 21 CFR 820.75 (a). For example, the radiation sterilization process for sterile stockinettes is not currently validated. The pre-dosing process of [REDACTED] also has not been verified as acceptable for the sterile stockinette. Your firm does not have any documentation that the bioburden level for any of the cotton products has been evaluated.
2. Failure of management with executive responsibility to ensure that an adequate and effective quality system has been fully implemented and maintained at all levels of the organization, as required by 21 CFR 820.20. For example your firm has not established a quality unit. Prior to the start of our inspection, your firm did not have anyone in charge of quality assurance.
3. Failure to establish and maintain a design history file as well as failure to demonstrate that the design was developed following the approved design plan and the design control requirements, as required by 21 CFR 820.30 (j). For example, your firm did not have an established design development or design plan prior to production and distribution of the sterile devices. Your firm did not have records of design and development, risk analysis, or design validation/verification.

4. Failure to establish, define, document, and implement procedures to ensure that mix-ups, damage, or other adverse effects to product do not occur during handling, as required by 21 CFR 820.140. For example, there were incomplete procedures for handling or storing stockinettes after pre-dosing by the contract sterilizer, for the product's return to the firm, and the shipment of the product to the contract manufacturer. Your firm failed to establish control over non-sterile product and pre-dosed product. There were no controls, i.e., instructions to employees on how to handle/store product that has been pre-dosed, or a physical separation of the non-sterile and pre-dosed stockinettes
5. Failure to establish and implement procedures for acceptance activities, as required by 21 CFR 820.80 (a). For example, your firm did not define the acceptance criteria for devices and components. You failed to review the sterilization certification (pre-dosing), and there was no inspection or testing prior to release of the products to the contract manufacturer.
6. Failure to establish and implement procedures to ensure that equipment is routinely calibrated, as required by 21 CFR 820.72 (a). For example, there were no procedures or calibration schedules set for the scales, tensile tester, and yardage counters used in production. The investigator noted that the available equipment calibration stickers indicated that all of the equipment was out of calibration.
7. Failure to maintain complete complaint files, as required by 21 CFR 820.198 (a). For example, your firm did not maintain documented complaint files prior to 7/9/03. Even though complaints were received, they were not formally documented.
8. Failure to establish and maintain procedures for the evaluation, disposition, and investigation of nonconforming product, as required by 21 CFR 820.90 (a). For example, there were no established procedures for handling non-conformances.

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-483 issued at the close 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 causes of the violations identified by the FDA. You also must promptly initiate permanent corrective and preventative action on your quality system.

We acknowledge that you have already initiated a voluntary recall of your sterile stockinettes which were not gamma irradiated to reduce the bioburden prior to packaging and sterilization.

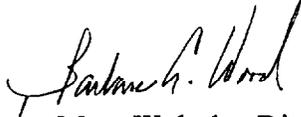
Federal agencies are advised of the issuance of all warning letters about devices so that they may take this information into account when considering the award of contracts. Additionally, no premarket submissions for devices to which the Quality System/GMP deficiencies are reasonably related will be cleared until the violations have been corrected. Also, no request for Certificates For Export will be approved until the violations related to the subject devices have been corrected.

You should take prompt action to correct these violations. Failure to promptly correct these violations may result in regulatory action being initiated by the FDA without further notice. These actions include, but are not limited to, seizure, injunction, and or civil penalties.

Please provide this office in writing within fifteen (15) working days of receipt of this letter a report of the specific steps you have taken, or will take to identify and 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 actions cannot be completed within fifteen (15) working days, state the reason for the delay and the time within which the corrections will be completed.

Please send your response to the attention of Serene A. Kimel, Compliance Officer at the address noted in the letterhead. If you have any questions about this letter, you can contact Ms. Kimel at 404-253-1296.

Sincerely,

  
for Mary Woleske, Director  
Atlanta District