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VIA FEDERAL EXPRESS

Food and Drug Administration
Center for Devices and
Radiological Health
2098 Gaither Road
Rockville, MD 20850

WARNING LETTER

Mr. Qian Jun
Director
Textus Ningbo Manufacturing Company, Ltd.
Baidu Fenghua City
Zhejiang, China 315558

Dear Mr. Jun:

During an inspection of your firm located in Zhejiang, China on April 30 through May 3, 2000, our investigator determined that your firm manufactures sterile gauze and bandage compresses. These 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 manufacturing, packing, storage, or installation are not in conformance with the good manufacturing practice (GMP) requirements of the Quality System Regulation, as specified in Title 21, Code of Federal Regulations (CFR), Part 820, as follows:

1. Failure of the management with executive responsibility to establish and implement a quality policy and objectives for ensuring that the Quality System Regulation requirements are met; and failure of the management with executive authority to ensure that the quality policy is understood, implemented and maintained at all levels of the organization, as required by 21 CFR 820.20(a). For example:
 - a. Your firm has no written quality policy that includes objectives and procedures for management review, quality policy and quality plan.
 - b. Key employees are not aware of a quality policy.
2. Failure to establish an organizational structure to ensure that devices are designed and produced according to the Quality System Regulation, as required by 21 CFR 820.20(b). For example, there is no organizational structure that describes the functional areas or people responsible for performing certain task.

3. Failure to document the management representative's authority and responsibility for reporting on the performance of the quality system to management with executive responsibility for review, as required by 21 CFR 820.20(b)(3)(ii). For example, the appointed management representative for your firm is not documented, and there is no documentation showing his approval and sign-off of processing records (device history records, quality control records, and lot acceptance records) from [REDACTED].
4. Failure to establish procedures for quality audits and conduct such audits to assure that the quality system is in compliance with the established quality system requirements and to determine the effectiveness of the quality system, as required by 21 CFR 820.22. For example, an internal quality audit of your firm has not been conducted.
5. Failure to establish procedures for identifying training needs and ensure that all personnel are trained to adequately perform their assigned responsibilities, as required by 21 CFR FR 820.25. For example, there are no records to document that a training program has been established and provided to employees.
6. Failure to validate with a high degree of assurance and approved according to established procedures, a process where the results cannot be fully verified by subsequent inspection and test, as required by 21 CFR 820.75(a). For example:
 - a. The packaging process has not been validated.
 - b. The vacuum and heat sealing machines [REDACTED] and [REDACTED] installed by the firm in 1997 have not been validated.
7. Failure to conduct, control and monitor production processes to ensure the approval of process equipment as required by 21 CFR 820.70(a); failure of your firm to ensure that all equipment used in the manufacturing process meets specified requirements, as required by 21 CFR 820.70(g); and failure of your firm to establish and maintain schedules for the cleaning and maintenance of equipment to ensure that manufacturing specifications are met, as required by 21 CFR 820.70(g)(1). For example, there are no records documenting the cleaning and preventive maintenance of the vacuum and heat sealing machines [REDACTED]. This equipment was purchased and installed in the manufacturing facility in 1997.

8. Failure to document environmental control activities to ensure that environmental conditions do not adversely effect product quality, as required by 21 CFR 820.150. For example:
 - a. There are no records to indicate that rodent and pest control has been performed.
 - b. There is an approximate three-inch space between the storage room door and the floor that could facilitate potential rodent contamination in the area where raw materials are stored.

9. Failure to establish and maintain procedures, and document acceptance or rejection of incoming product, as required by 21 CFR 820.80(b); and failure to establish and maintain procedures for finished device acceptance to ensure that each production run, lot, or batch of finished devices meets acceptance criteria, as required by 21 CFR 820.80(d). For example,
 - a. There are no written procedures for acceptance of incoming product and unacceptable raw materials received from suppliers are not documented.
 - b. There are no package seal integrity acceptability parameters based on valid statistical rationale.

10. Failure to identify by suitable means the acceptance status of product to indicate the conformance or nonconformance of product with acceptance criteria, as required by 21 CFR 820.86. For example, the acceptance of [redacted] rolls [redacted] of non-adherent pads located in the incoming goods storage room could not be determined.

11. Failure to establish and maintain procedures for identifying valid statistical techniques required for establishing, controlling, and verifying the acceptability of process capability and product characteristics, as required by 21 CFR 820.250(a). For example:
 - a. There is no formal sampling plan for testing incoming raw materials.
 - b. There is no formal sampling plan for testing the seal integrity of pre-sterile packages of product.

12. Failure to establish and maintain procedures to control product that does not conform to specified requirements, as required by 21 CFR 820.90. For example, there are no written procedures describing what action(s) to be taken when packaging process deviations are found.

13. Failure to establish and maintain procedures for implementing corrective and preventive action that includes requirements for complaints, as required by 21 CFR 820.100(a)(1). For example, there is no complaint handling procedure or complaint file system to identify quality problems.
14. Failure to maintain complaint files, and establish procedures for receiving, reviewing, and evaluating complaints by a formally designated unit, as required by 21 CFR 820.198. For example, complaints received by your firm through electronic mail or telephone are not maintained or documented.
15. Failure to document the approval, including the date and signature of the individual(s) approving the device master records (DMR's), as required by 21 CFR 820.40. For example, DMR's for Bandage Compress, Gauze Compress and Gauze Roller Bandage have not been signed and dated as reviewed and approved by a designated individual.
16. Failure to ensure that device history records (DHR's) for each lot are maintained to demonstrate that the device is manufactured in accordance with the DMR and the Quality System Regulation, as required by 21 CFR 820.184. For example, no management review was performed for Bandage compress, lot [REDACTED] Roller gauze bandage, lot [REDACTED] and Gauze compress, and lot [REDACTED] 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 form FDA 483 issued at the closeout 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 Food and Drug Administration. 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.

Given the serious nature of these violations of the Act, all devices manufactured by Textus Ningbo Manufacturing Company, Ltd., Baidu Fenghua City, Zhejiang, China, may be detained without physical examination upon entry into the United States (U.S.) until these violations are corrected.

In order to remove the devices from detention, it will be necessary for you to provide a written response to the charges in this Warning Letter for our review. After we notify you that the

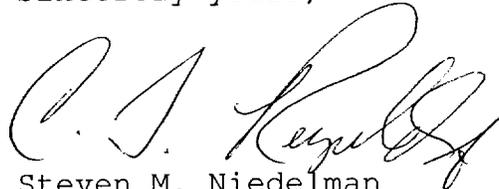
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response is adequate, a re-inspection will be required to verify that your corrective actions have been implemented. As soon as the inspection has taken place, and the implementation of your corrections has been verified, your products may resume entry into this country.

Please notify this office, in writing, 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. Please include any and all documentation to show that adequate correction has been achieved. In the case of future corrections, an estimated date of completion, and documentation showing plans for correction, should be included with your response to this letter. If the documentation is not in English, please provide an English translation to facilitate our review.

Your response should be sent to the Food and Drug Administration, Center for Devices and Radiological Health, Office of Compliance, Division of Enforcement I, General Surgery Devices Branch, 2098 Gaither Road, Rockville, Maryland 20850. If you have questions or need further assistance contact Peggy C. Mayo by telephone at (301) 594-4595 or by FAX at (301) 594-4636.

Sincerely yours,



Steven M. Niedelman
Acting Director
Office of Compliance
Center for Devices and
Radiological Health

cc:

Mr. Doug Smith
Textus USA Inc.
1621 W. Chanute Road
Peoria, Illinois 61615