



DEPARTMENT OF HEALTH & HUMAN SERVICES

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Public Health Service

APR 4 1998

Food and Drug Administration  
2098 Gaither Road  
Rockville MD 20850

WARNING LETTER

VIA FEDERAL EXPRESS

Mr. Zhang Guang Yu  
President  
Nantong International Medical Material Co. Ltd.  
18 Baochang Road, North  
Libao Town, Haian County  
Jiangsu Province  
CHINA

Dear Mr. Yu:

During an inspection of your firm located in Libao Town, on January 12-15, 1998, our Investigator determined that your firm manufactures laparotomy sponges and surgical towels. These are medical 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 Current Good Manufacturing Practice (CGMP) requirements as set forth in the Quality System Regulation, as specified in Title 21, Code of Federal Regulations (CFR) Part 820. We have not received a response from your firm regarding the observations noted in the FDA 483 by the Investigator.

1. Failure to establish and maintain procedures for implementing corrective and preventative action; and failure of the procedures to include requirements for analyzing processes, work operations, concessions, quality audit reports, quality records, service records, complaints, returned product, and other sources of quality data to identify existing and potential causes of nonconforming product, or other quality problems, as required by 21 CFR 820.100(a)(1); and failure of the procedures to include requirements to identify the action(s) needed to correct and prevent recurrence of nonconforming product and other quality problems, as required by 21 CFR 820.100(a)(3); failure of the procedures to include requirements on submitting relevant information on identified quality problems, as well as corrective and preventative actions, for management review, as required by 21 CFR 820.100(a)(7).  
For example:

- a. There is no established procedure for [REDACTED]

- [REDACTED]
- b. There is no established criteria for [REDACTED]
- [REDACTED]
- c. There is no established procedure for management review of quality problems.
2. Failure to document all activities, and their results, for corrective and preventative actions, as required by 21 CFR 820.100(b). For example:
- a. No records are maintained documenting [REDACTED]
- b. There is no record of a [REDACTED]
3. 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 is no established procedure for quality assurance review and approval of [REDACTED]
- b. There is no established procedure for formal review and approval of [REDACTED]
4. Failure to establish and maintain procedures for receiving, reviewing, and evaluating complaints by a formally designated unit, as required by 21 CFR 820.198(a). For example, the procedure for receiving complaints from their [REDACTED] does not include definitions of responsibility of [REDACTED] and Nantong.
5. Failure to establish and maintain procedures to ensure that complaints are evaluated to determine whether the complaint represents an event which is required to be reported to the FDA under 21 CFR parts 803 or 804, Medical Device Reporting,

as required by 21 CFR 820.198(a)(3). For example, there is

6. 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, there is no justification for
7. Failure to maintain device master records; and failure to ensure that each device master record is prepared and approved in accordance with 21 CFR 820.40; and failure of the device master record to include, or refer to the location of device specifications including component specifications, production process specifications, and quality assurance procedures and specifications including acceptance criteria, as required by 21 CFR 820.181. For example:
  - a. There are system-wide
  - b. Quality control test
  - c. There is no comprehensive established document of specifications for
8. Failure to develop, conduct, control, and monitor production processes to ensure that a device conforms to its specifications, as required by 21 CFR 820.70(a). For example, there is no established procedure for frequent, regular monitoring and recording
9. Failure to establish and maintain procedures for acceptance activities, including inspections, tests, or other verification activities, as required by 21 CFR 820.80(a). For example, the established procedures

[REDACTED]

10. Failure to establish and maintain acceptance procedures, where appropriate, to ensure that specified requirements for in-process product are met; and failure to ensure that in-process product is controlled until the required inspection and tests or other verification activities have been completed, or necessary approvals are received, and are documented, as required by 21 CFR 820.80(c). For example:

a. [REDACTED] instances were noted on documents from [REDACTED]

b. There are no records to verify that [REDACTED]

11. Failure to establish and maintain procedures for rework, to include retesting and reevaluation of the nonconforming product after rework, to ensure that the product meets its current approved specifications; and failure to document rework and reevaluation activities, as required by 21 CFR 820.90(b)(2). For example:

a. There are no records maintained for [REDACTED]. There is no definition or documentation of the types of defects noted or corrective actions.

b. Failure to follow the quality control requirements for [REDACTED]

12. Failure to establish and maintain procedures to ensure that sampling methods are adequate for their intended use, and based on valid statistical rationale, as required by 21 CFR 820.250(b). For example, there are discrepancies in the [REDACTED]

13. Failure to establish and maintain procedures to prevent contamination of equipment or product by substances that could reasonably be expected to have an adverse effect on product quality, as required by 21 CFR 820.70(e) [REDACTED]

14. Failure to establish and maintain procedures to adequately control environmental conditions, where the environmental conditions could reasonably be expected to have an adverse effect on product quality, as required by 21 CFR 820.70(c). For example, failure to follow the manufacturer's instructions for calculations.

Additionally, the above-stated inspection revealed that your devices are misbranded under section 502(t)(2) of the Act, in that your firm failed to develop, maintain, and implement written Medical Device Reporting (MDR) procedures, as required by 21 CFR 803.17.

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 the form 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 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 Nantong International Medical Material Co. Ltd., 18 Baochang Road, North, Libao Town, Haiyan County, Jiangsu Province, China, may be detained without physical examination upon entry into the United States 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 your response is adequate, it will be your responsibility to schedule another FDA inspection of your facility. As soon as the inspection has taken place, the implementation of your corrections has been verified, and you are notified that your corrections are adequate, your products may resume entry into this country.

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

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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 documentation is not in English, please provide a 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, HFZ-323, 2098 Gaither Road, Rockville, MD 20850, to the attention of Mr. Joseph L. Salyer.

You may obtain general information about FDA's requirements for manufacturers of medical devices by contacting our Division of Small Manufacturers Assistance at 800-638-2041 or through the Internet at <http://www.fda.gov>.

If you have more specific questions about the contents of this letter, please feel free to contact Mr. Joseph L. Salyer at the above address or at (301)-594-4595, Ext.175 or FAX (301)-594-4636.

Sincerely yours,

*Lillian J. Gill*  
for Lillian J. Gill  
Director  
Office of Compliance  
Center for Devices and  
Radiological Health

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