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Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

MAR 20 1998

WARNING LETTER
VIA EXPRESS

Mr. Tu Chuan Jian
General Manager
Suzhou Huanqiu Acupuncture
Medical Appliance Company Ltd.
218-Daoqian Street
Suzhou, China 215002

Dear Mr. Jian:

During an inspection of your firm located in Suzhou, China, on January 19-22, 1998, our investigator determined that your firm manufactures single-use acupuncture needles. These acupuncture needles 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 Quality System Regulation, as specified in Title 21, Code of Federal Regulation (CFR), Part 820, as follows:

1. 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:
 - a. there are no established procedures for formulation of ultrasonic wash and disinfection water;
 - b. there is no established procedure for depyrogenation of glassware;
 - c. there is no established procedure/specifications for the operation of the blister packaging machine for single-use needles; and
 - d. SOP PO-11:1988, Blister/Packing/Perforating provides instructions for aluminum foil packaging; however, no instructions are provided for the packaging of used paper packaging.

Your response to these observations appears to be adequate.

2. Failure to establish and maintain procedures to adequately control environmental conditions where these conditions could reasonably be expected to have an adverse effect on product quality, as required by 21 CFR 820.70(c). For example:

- a. there are no established procedures for monitoring, testing, and changing of the air filters;
- b. no studies have been conducted during operation of the cleanroom to determine areas of high particulate counts;
- c. no environmental monitoring is conducted in the window/channel between the Q.C. inspection room and the outside environment, or in the Q.C. inspection room;
- d. there is no established procedure for testing the effectiveness of UV lights; and
- e. the procedure QI-05:1998 does not specify allowed operating range for relative humidity.

Your response to items 2.a, 2.b., 2.c., and 2.e appears to be adequate. However, your response to item 2.d. is not adequate. The SOP which was submitted is incomplete. It states that if the CFU count is the same before and after the UV sterilization, then the UV light must be changed. However, the SOP doesn't say what to do if the CFU count is greater or less than the count prior to UV sterilization.

3. Failure to establish and maintain requirements for the health, cleanliness, personal practices, and clothing of personnel if contact between such personnel and product or environment could reasonably be expected to have an adverse effect on product quality, as required by 21 CFR 820.70(d). For example, on January 20-21, 1998, between five and ten packaging employees had hair protruding from their hair coverings.

Your response to this observation is not adequate. Please submit documentation of employee training for cleanroom hygiene.

4. 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). For example:
 - a. cleaning solutions for the ultrasonic washing step and disinfection of hands are formulated outside the cleanroom in an open containers which are carried through the untreated factory environment and brought back into the cleanroom;
 - b. there is no established procedure for use of the window/channel located between the cleanroom Q.C. inspection room and the hallway which is open to the outside of the factory;
 - c. there is no definition of "clean" and "dirty" sides in the changing room at the cleanroom entrance; and
 - d. on January 20-21, 1998, the water hose on the blister-packaging machine for single-use needles leaked onto the cleanroom floor and stayed there as operators walked through it.

Your response to these observations appears to be adequate.

5. Failure to establish and maintain schedules for the adjustment and other maintenance of equipment and to document maintenance activities, including the date and individual performing the maintenance activities, as required by 21 CFR 820.70(g)(1). For example:

- a. equipment repairs are not documented; and
- b. there is no established schedule for regular repair/adjustment of molds in the drawing workshop.

Your response to these observations appears to be adequate.

6. Failure to establish and maintain procedures, including inspecting, testing, or otherwise verifying conformance to specified requirements, for acceptance of incoming product, as required by 21 CFR 820.80(b). For example, no tests are conducted on in-coming paper which is supplied by a company not included on the approved supplier list.

Your response to this observation appears to be adequate.

7. 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. the SOP for sterility testing requires use of [REDACTED]; however, [REDACTED] is used; and
- b. there is no established procedure for testing the seal in the blister-pack for single-use needles.

Your response to these observations appears to be adequate.

8. Failure to maintain procedures for the control of storage areas for product to prevent deterioration, contamination, or other adverse effects pending use or distribution. For example, SOP QI-04:1998 requires storage of media at [REDACTED] however, there is no thermometer in the refrigerator used for storing media.

Your response to this observation appears to be adequate.

9. Failure to maintain a device master record which includes packaging and labeling specifications, as required by 21 CFR 820.181(d). For example, there are no established specifications for paper used in blister-packaging of single-use needles.

Your response to this observation appears to be adequate.

10. Failure to maintain device history records to demonstrate that the device is manufactured in accordance with the device master record, as required by 21 CFR 820.184. For example, there is no evidence that tests are conducted according to test requirements.

Your response to this observation appears to be adequate.

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 conclusion 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.

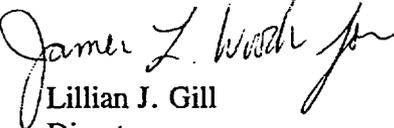
Federal agencies are advised of the issuance of all Warning Letters concerning devices so that they may take this information into account when considering the award of contracts. Additionally, no requests for Certificates For Products For Export will be approved until the violations related to the subject devices have been corrected.

We acknowledge that you have submitted to this office a response dated February 5 and 27, 1998, concerning our investigator's observations noted on the form FDA-483. Please notify this office in writing within 15 days of receipt of this letter, of the specific steps you have taken to correct the noted violations which have not been adequately addressed, 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 documentation is not in English, please provide an English translation to facilitate our review. Please address your response and any questions to the Food and Drug Administration, Center for Devices and Radiological Health, Office of Compliance, Division of Enforcement II, General Hospital Devices Branch, HFZ-333, 2098 Gaither Road, Rockville, Maryland 20850, to the attention of Ms. Carolyn Niebauer.

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Should you require any assistance in understanding the contents of this letter, do not hesitate to contact Ms. Dorsey at the letterhead address or at (301) 594-4618, ext. 115.

Sincerely yours,

A handwritten signature in cursive script, appearing to read "Lillian J. Gill".

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