



Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

MAR 13 1998

WARNING LETTER
VIA EXPRESS

Mr. Edward R. Markovic
QA/Regulatory Manager
Tillotson Healthcare Corporation, USA
360 Route 101
Bedford, NH 03110

Dear Mr. Markovic:

During an inspection of your firm located in Melaka, Malaysia, on November 27 - December 2, 1997, our investigator determined that your firm manufactures powdered and powder-free non-sterile examination gloves. These gloves 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 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, the temperature of the latex tank was not set at the specified range.

Your response to this observation appears to be adequate.

2. Failure to carry out procedures for implementing corrective and preventive action, as required by 21 CFR 820.100(a). For example:
 - a. the root cause of problems are not investigated;
 - b. the corrective/preventive action is not always identified;
 - c. the effectiveness of the corrective/preventive action is not verified/validated; and
 - d. the corrective/preventive action control procedure is not being followed when corrective action is done by the receiving department.

Your response to this observation appears to be adequate.

3. Failure to document all corrective and preventive actions and their results, as required by 21 CFR 820.100(b). For example, under Section 2.0 of the procedure B41402, Rev. 0, 6/1/97, it states that every corrective action report shall be registered into the CAR Log; however, this has not been done.

Your response to this observation appears to be adequate.

4. Failure to develop, conduct, and monitor production processes to ensure that a device conforms to its specifications, as required by 21 CFR 820.70(a). For example, chain speed and dipping time have not been formally verified.

Your response to this observation appears to be adequate.

5. Failure to ensure that all equipment used in the manufacturing process meets specified requirements and is appropriately designed, constructed, placed, and installed to facilitate maintenance, adjustment, cleaning, and use, as required by 21 CFR 820.70(g). For example, manufacturing equipment, such as ovens and tumblers have not been formally qualified.

Your response to this observation is not adequate. You failed to qualify the equipment installation to verify the equipment is capable of consistently operating within established limits and tolerances.

6. Failure to establish and maintain procedures for changes to a specification, method, process, or procedure, and verifying, or where appropriate validating according to Sec. 820.75, before implementation, as required by 21 CFR 820.70(b). For example, the coagulant was changed due to contamination without product evaluation.

Your response to this observation appears to be adequate.

7. Failure to implement schedules for the cleaning of equipment to ensure that manufacturing specifications are met, as required by 21 CFR 820.70(g)(1). For example, the dipping process was started without proper cleaning of the formers.

Your response to this observation appears to be adequate.

8. Failure to establish procedures to control all documents, as required by 21 CFR 820.40. For example, the document and data control procedure is inadequate in that it lacks the identification of the affected documents, approval date, and effective date.

Your response to this observation is not adequate. The identity of the affected document is not included in the change control form.

9. Failure to include, in document change records, a description of the change, identification of the affected documents, the approval date, and when the change becomes effective, as required by 21 CFR 820.40(b). For example, the change control form lacked the title of the document being changed, approval date, effective date, and the effect which the proposed change may have on other procedures, documents, and products.

Your response to this observation appears to adequate.

10. Failure to establish and maintain procedures for acceptance activities, as required by 21 CFR 820.80(b). For example, all parameters of the raw materials are not being tested during the receiving inspection.

Your response to this observation appears to be adequate.

11. Failure to document the justification for use of nonconforming product, as required by 21 CFR 820.90(b). For example, nonconforming products are being accepted without any justification or rational.

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 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

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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.

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,



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

cc:

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