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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

JUL 28 1997

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

WARNING LETTER

VIA FEDERAL EXPRESS

Mr. Sang-un W. Choi
Plant Manager and Dorector
Soehung Industrial Company, Ltd.
106-1, San 31
Yong gang-Ri Jeung Pyoung-eup
Koesan-gun
Choongbuk, South Korea

F.D.A.
Purged
JF 7/28/97

Dear Mr. Choi:

During an inspection of your firm located in Choongbuk, South Korea, on April 12-13, 1997, our Investigator determined that your firm manufactures Latex Surgical Gloves, Examination Gloves, Condoms, and Fingercots. 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 your 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 Practices (GMP) regulations of 1978, as specified in Title 21, Code of Federal Regulations (CFR), Part 820. The 1978 GMP regulation was superseded on June 1, 1997, by the Current Good Manufacturing Practice (CGMP) requirements as set forth in the Quality System Regulation, 21 CFR Part 820. The deficiencies noted during the inspection reference the 1978 GMP requirements, with a cross reference to the new 1997 Quality System Regulation.

1. Failure to establish and implement specification control measures to assure that the design basis for the device is correctly translated into approved specifications, as required by 21 CFR 820.100(a)(1). This would also be a violation of the Quality System Regulation, 21 CFR 820.75(a). For example, there is no written validation protocol for the latex manufacturing process dipping time, leaching time, speed, and temperature.
2. Failure to have written procedures describing any processing controls necessary to assure conformance to specifications, where deviations from device specifications could occur as a result of the manufacturing process itself, as required by 21 CFR 820.100(b)(1). This would also be a violation of the Quality System Regulation, 21 CFR 820.70(a) and 21 CFR 820.75(b). For example, there are no written process

controls for the latex manufacturing process dipping time, leaching time, speed, and temperature.

3. Failure to conduct processing control operations in a manner designed to assure that the device conforms to applicable specifications, as required by 21 CFR 820.100(b)(2). This would also be a violation of the Quality System Regulation, 21 CFR 820.70(a). For example, the latex manufacturing process is only committed to memory, and production line supervisors have authority to change process controls for the latex processing speed and temperature at will. (This was not listed on the FDA-483; however, this was discussed in the Establishment Inspection Report written by the Investigator.)
4. Failure to maintain a device history record to demonstrate that the device is manufactured in accordance with the device master record, as required by 21 CFR 820.184. This would also be a violation of the Quality System Regulation, 21 CFR 820.184(d). For example, the device history records have no provisions for noting changes that occur to latex manufacturing process parameters such as temperature, dipping time, leaching time, and speed. (This was not listed on the FDA-483; however, this was discussed in the Establishment Inspection Report written by the Investigator.)
5. Failure to inspect, sample, and test components for conformance to specifications where deviations from component specifications could result in the device being unfit for its intended use, as required by 21 CFR 820.80(a). This would also be a violation of the Quality System Regulation, 21 CFR 820.50. For example, there is no documentation to support the analysis for pre-formulated latex that is purchased under a [REDACTED] from manufacturers in [REDACTED]. (This was not listed on the FDA-483; however, this was discussed in the Establishment Inspection Report written by the Investigator.)

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. You also failed to establish and maintain MDR event files, as required by 21 CFR 803.18(a).

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.

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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 Soehung Industrial Company, Ltd., Choongbuk, South Korea, may be detained upon entry into the United States without physical examination until these violations are corrected.

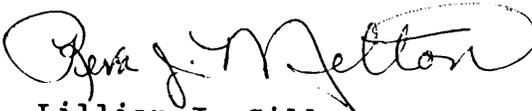
In order to remove the devices from detention, it will be necessary for you to provide a written response to the charges in this Warning Letter for our review. After we notify you that your response is adequate, it will be your responsibility to schedule an inspection of your facility. As soon as the inspection has taken place, the implementation of your corrections has been verified, 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 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.

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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 Joseph Salyer.

Sincerely yours,

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