



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

D1255B

1-15 I-35 - 3/12/97

Food and Drug Administration  
2098 Galther Road  
Rockville MD 20850

MAR 12 1997

**WARNING LETTER**  
**VIA EXPRESS**

Mr. Mokhtar Ali  
General Manager  
Crocker Industrial Resources Sdn. Bhd.  
PLO 38, Senai Industrial Area Phase II  
81400 Senai, Johor, Malaysia

Dear Mr. Ali:

During an inspection of your firm located in Senai, Johor, Malaysia, on December 16-19, 1996, our investigator determined that your firm manufactures non-sterile powdered and non-powdered latex 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 Good Manufacturing Practice (GMP) for Medical Devices Regulation, as specified in Title 21, Code of Federal Regulation (CFR), Part 820, as follows:

1. Failure of the device master record to include production process specifications and quality assurance procedures and specifications, as required by 21 CFR 820.181. For example, you have standard operating procedures, component specifications, blue-prints of some equipment, packaging specifications, forms used for documentation and quality assurance techniques; however, the device master record does not contain or reference the majority of the required information, such as, quality assurance procedures and specifications.
2. 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. For example, there is no device history record which ensures that the products are manufactured in accordance with the device master record.
3. Failure to have facilities which provide adequate space to prevent mix-ups and to assure orderly handling of finished devices and devices which have been rejected, as required by 21 CFR 820.40. For example, all types of gloves are stored [REDACTED]

4. Failure of the quality assurance program to identify, recommend, or provide solutions for quality assurance problems and verify the implementation of such solutions, as required by 21 CFR 820.20(a)(3). For example:
  1. Some of the polybags which contained finished product were torn or open.
  2. Several polybags lacked the QA-1&2 tag which is applied to display the acceptance/rejection status of the devices.
5. Failure to have a system to assure that the oldest approved devices are distributed first, where a device's fitness for use or quality deteriorates over time, as required by 21 CFR 820.150. For example, newer production lots were being released prior to older production lots.

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 system. 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. Additionally, no premarket submissions for devices to which the GMP deficiencies are reasonably related will be cleared until the violations have been corrected.

Given the serious nature of these violations of the Act, all non-sterile powdered and non-powdered latex examination gloves manufactured by Crocker Industrial Resources Sdn. Bhd. of Johor, Malaysia may be detained upon entry into the United States (U.S.) until these violations are corrected.

In order to remove the devices from this 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 response is adequate, it will be your responsibility to schedule an inspection of your facility. As soon as the inspection has taken place, and the implementation of your corrections have been verified, your products may resume entry into this country.

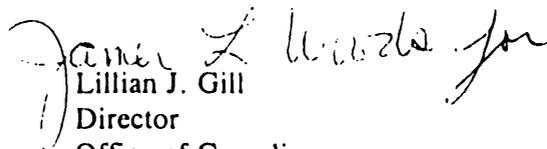
Please notify this office in writing within 15 days of the specific steps you have taken to correct the noted violations, including an explanation of each step being taken to identify and make correction to any underlying systems problems necessary to assure that similar violations will not recur. Please include any and all documentation to show that adequate correction has been achieved. In the case of future corrections, an estimated date of

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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.

Should you require any assistance in understanding the contents of this letter, do not hesitate to contact Ms. Diane Goldsberry at the letterhead address or at (301) 594-4618 or FAX (301)594-4638.

Sincerely yours,

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