



g1165d

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

APR 16 2001

Food and Drug Administration  
Center for Devices and  
Radiological Health  
2098 Gaither Road  
Rockville, MD 20850Director  
Hiyi Export Company  
5F-13, No. 1, Lane 126  
Fu-Hsing S. Road Sec. 1  
Taipei, Taiwan**Re: Entry # H41-3086356-0**

Dear Sir or Madam:

Based on a Food and Drug Administration (FDA) laboratory analysis of the above identified shipment, as well as analyses of previous shipments, we have reason to believe that there may be deficiencies in the method by which you manufacture, inspect, test, package, store, or ship patient examination gloves. Patient examination gloves are medical devices as defined by section 201(h) of the Federal Food, Drug, and Cosmetic Act (the Act).

You received notification from FDA that your device shipments had been found to be violative for defects by FDA analysis, placing you on level 1 and level 2 detention. You were previously notified on June 30, 2000, by FDA of the requirements of the Quality System (QS) regulation and the potential for problems if these requirements are not given serious attention. It is your responsibility to ensure adherence to each requirement of the Act and its implementing regulations. The letter also discussed the importance of complying with the QS Regulation, and informed you that failure to comply could result in increased levels of detention.

The current FDA analyses, as well as previous analyses, documents continuing violations. Your patient examination gloves are, therefore, 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, packaging, storage or installation are not in conformance with current Good Manufacturing Practice (GMP) requirements as set forth in the Quality System Regulation, specified in Title 21, Code of Federal Regulations (21 CFR, Part 820).

Because your firm has had three glove shipments fail testing in the last 24 months, your firm is now considered to be on level 3 detention. At level 3 detention, analytical evidence alone may not be sufficient to show that the gloves have been manufactured to meet minimum quality standards. Further evidence, such as an inspection by FDA (or by a qualified third party, in some instances) to assess conformance with the QS regulation may be needed for a firm to be removed from level 3 detention. As a first step, you should undertake a comprehensive review of your manufacturing procedures and practices to assure conformance with the requirements of the QS regulation. You are responsible for determining the cause of the violations identified by FDA. If the causes are determined to be systems problems, you must initiate permanent corrective actions and you must respond to FDA as described below.

Page 2 - Director

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 the violations of the Act, all patient examination gloves shipped by Hiyi Export Company, may be detained without physical examination upon entry into the United States until the violations are corrected.

After performing a comprehensive review of your manufacturing procedures, it will be necessary for you to provide a written response to the charges in this Warning Letter. Please notify this office, in writing, of the specific steps you have taken to correct GMP 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.

Your response should include programs/procedures currently in place at your firm for all medical gloves you manufacture at least in the following areas:

- 1)Written Standard Operating Procedures
- 2)Production and Process Controls
- 3)Process Validation
- 4)Corrective and Preventative Action
- 5)Contamination/Environmental Controls

If documentation is not in English, please provide a translation to facilitate our review.

Your response should be sent to, The U.S. Food and Drug Administration, Center for Devices and Radiological Health, Office of Compliance, Division of Enforcement II, General Hospital Devices Branch, HFZ-333, at the letterhead address, to the attention of Carolyn B. Niebauer, Chief.

We strongly recommend that you obtain the services of a consultant to review your manufacturing operations and work with you to provide information/records documenting that Quality System Requirements for Good Manufacturing Practices have been put in place and are being followed.

If you have more specific questions about the contents of this letter, please feel free to contact Rebecca Keenan, at the address indicated above, or at (301) 594-4618, or you may FAX her at (301) 594-4638.

Sincerely yours,

*Kimber Richter for*

Larry D. Spears  
Acting Director  
Office of Compliance  
Center for Devices and Radiological Health