



Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

**WARNING LETTER
VIA FEDERAL EXPRESS**

AUG 18 1999

Mr. C. S. Park
Managing Director
Dongkuk Techco Rubber Industries, Sdn. Bhd.
7th Floor Maybank Trust Building
3 Penang Street
10200 Penang
Malaysia

Dear Mr. Park:

During the Food and Drug Administration (FDA) inspection of your facility located in Kedah, Malaysia, conducted on June 21-24, 1999, the FDA investigator determined that your firm manufactures condoms. These products 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 may be adulterated under 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 Regulations (21 CFR), Part 820, as follows:

Failure to establish and maintain procedures for the identification, documentation, validation, or where appropriate verification, review and approval of design changes before their implementation as required by 21 CFR 820.30(i). For example, the investigator observed that your firm did not have change control procedures to address routine design changes to your condoms.

We are aware that you have notified FDA [REDACTED] your condoms, and that a clearance letter was issued on May 17, 1999. For your information, this clearance letter does not exempt you from design control requirements or any other aspects of Good Manufacturing Practices. Please be aware that design change procedures are required to be in place and must be used prior to implementing this [REDACTED] as well as any other routine design changes to your condoms.

As noted by the investigator, when designing a totally new device, the following elements of a design control system are required to ensure that specified design requirements are met: design and development planning; design input; design output; design review; design verification; design validation; design changes; design transfer, and design history file.

In addition to the above noted issues relating to the Quality Systems Regulation, we have reviewed the labeling collected by the investigator and have determined that the labeling of your condoms deviates from FDA requirements in the following respects:

1. The statement required by 21 CFR 801.1 is not present on the individual condom package (foil). This section requires the name and place of business of the manufacturer or distributor to be listed on the product label. Therefore your condoms are misbranded within the meaning of section 502(b) of the Act.
2. The statement required by 21 CFR 801.437(d) is not present on the individual condom package (foil). Therefore your condoms are misbranded within the meaning of 502(a) of the Act for failure to reveal consequences which may result from the use of the product as described in section 201(n). We also note that the outer retail packages of your condoms do not include the exact wording of this latex caution statement which should read “Caution: This Product Contains Natural Rubber Latex Which May Cause Allergic Reactions.”

We also recommend that the individual condom package (foil) include the statement: “If used properly, latex condoms will help to reduce the risk of transmission of HIV infection (AIDS) and many other sexually transmitted diseases.”

The noted deviations from the labeling requirements could result in your products being refused entry into the United States. You should correct these labeling deficiencies before attempting any further imports.

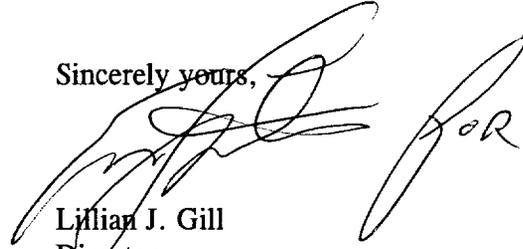
This letter is not intended to be an all-inclusive list of deficiencies at your facility. It is your responsibility to ensure adherence to each requirement of the Act and regulations. You are responsible for investigating and determining the causes of the violations identified by the FDA. If the causes 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.

Please notify this office in writing within 15 days regarding the specific steps you have taken, or intend to take, to correct the noted violations, including an explanation of each step being taken to identify and make necessary corrections to any underlying systems problems 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 the documentation is not in English, please provide an English translation to facilitate our review. Please send your response and any questions to Mr. Paul F. Tilton, Acting Chief, OB/GYN, Gastroenterology, & Urology Branch, at the letterhead address.

Page 3 – Mr. C. S. Park

Should you require any assistance in understanding the contents of this letter, do not hesitate to contact Mr. John Farnham at the letterhead address, at (301) 594-4616 or FAX (301) 594-4638.

Sincerely yours,

A handwritten signature in black ink, appearing to be "LJ Gill", written over the typed name.

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