



MA97617

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

WARNING LETTER VIA FEDERAL EXPRESS

SEP 27 1999

Mr. Seah Boon Ngee
Managing Director
LS Rubber, SDN, BHD
PLO 22, Senai Industrial Estate
81400 Senai, Johor
Malaysia

Dear Mr. Ngee:

During the Food and Drug Administration (FDA) inspection of your facility located in Johor, Malaysia, conducted on June 14-17, 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 the following nonconformances with the Act and implementing regulations.

1. Failure to develop supporting data for shelf life claims as described in 21 CFR 801.435(d). For example:
 - a) Paragraph 1 of the above section requires aging for 7 days at 70° C in order to allow a tentative expiration date to be provided on the label. Our review of the data provided to the investigator indicates that no 7-day, 70° C data has been established for the following types of condoms exported to the U. S. under the LS Rubber 510(k)'s:
 - [REDACTED] condom [REDACTED]
 - [REDACTED] condom [REDACTED]
 - [REDACTED] condom [REDACTED]
 - [REDACTED] condom [REDACTED]
 - [REDACTED] condom [REDACTED]
 - b) Paragraph 2 of the above section requires aging for 90 days at 40-50° C in order to allow a tentative expiration date to be provided on the label. Our review of the data provided to the investigator indicates that no 90-day, 40-50° C data has been established for the following types of condoms exported to the U. S. under the LS Rubber 510(k)'s:

- [REDACTED] condom [REDACTED]
- [REDACTED] condom [REDACTED]
- [REDACTED] condom [REDACTED]
- [REDACTED] condom [REDACTED]

Additionally, for the two condom types ([REDACTED]) that do have 90-day data, it appears that the data has been developed at ambient temperature rather than at 40-50° C as required by this paragraph.

- c) Paragraph 3 of the above section requires real-time aging studies to confirm the tentative expiration date provided on the label. Our review of the data provided to the investigator indicates no real-time data has been established for the following types of condoms exported to the U. S. under the LS Rubber 510(k)'s:

- [REDACTED] condom [REDACTED]

- d) For those condom types that have some of the required data, the data appears to track only one lot, rather than the minimum of three lots required by this section of the regulation.

We recognize that your firm has now reduced its shelf life claim to three years for [REDACTED] condoms, and two years for [REDACTED] condoms. However, you must still submit the missing 7-day, 70° C, and 90-day, 40-50° C data (for the condoms listed above) in order to establish the temporary basis for even these reduced claims. You should also confirm in writing that you have established real-time studies for all applicable condom types in order to verify the claimed shelf life. Without this data your condoms could be considered misbranded under section 502(f)(1) of the Act and could be denied entry to the U. S.

We also note that your "Shelf-life Test for [REDACTED] shows that [REDACTED] condoms [REDACTED] (batch number [REDACTED]) had three air burst pressure failures out of 80 pieces tested at 45 days, and again at 60 days. This would constitute a failure of the International Standards Organization (ISO) ISO 4074 air burst acceptance criteria that your firm employs as a standard. Please explain whether you have investigated these interim test failures. Failure to investigate and explain such test failures could invalidate the claimed expiration date for these condoms, and they could be considered adulterated under section 501(h), and misbranded under section 502(f)(1) of the Act.

2. Nonconformance of product labeling with applicable requirements. The labeling collected by the investigator during the inspection included several samples of your firm's individual condom (foil) and retail package labels. We have reviewed these labels and have found the following deviations:

- a) The statement required by 21 CFR 801.1 is not present on the individual condom package (foil) of “Maxima” brand condoms. This section requires the name and place of business of the manufacturer or distributor to be listed on the product label. Therefore these condoms are misbranded within the meaning of section 502(b) of the Act.
- b) The statement required by 21 CFR 801.437(d) [i. e. “Caution: This Product Contains Natural Rubber Latex Which May Cause Allergic Reactions”] is not present on the individual condom package (foil) of “Maxima” and “Premium” brand condoms. We note that the outer retail packages of “Maxima” condoms also lack this required statement. Therefore these 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 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.” This statement is missing from the foils of “Maxima” condoms.

It is also noted that the “Premium” foils are black in color. Please provide samples of “Premium” foils that have been stamped with the expiration date so we can verify that the date is visible on the black background.

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.

3. Introduction of products into U. S. commerce without a finding of substantial equivalence. For example, during the inspection the investigator noted that your firm had made numerous shipments of flavored condoms to the U. S. before March 12, 1999, the date the clearance letter for the 510(k) submission (K980964) for these products was issued. Additionally we have reviewed the shipping records and have noted several shipments of colored, spermicidally lubricated condoms that were apparently exported to the U. S. before March 15, 1999, the date the clearance letter for the 510(k) submission (K981955) for these products was issued.

While we recognize that your firm has now obtained 510(k) clearance for these products, at the time these shipments were made these devices were adulterated within the meaning of section 501(f)(1)(B)(i) of the Act

Your response that you “overlooked” this aspect of the Act and regulations, is not adequate. We note that your firm currently makes various condoms which are not cleared for market in the U. S., such as [REDACTED] condoms. We recommend that prior to shipping condoms to the U. S. that a check should be

performed to confirm that the products being shipped have received 510(k) clearance. A record of this check should be made and an authorizing signature recorded. Please comment on this recommendation.

4. Failure to maintain process control procedures as required by 21 CFR 820.70(a). For example, the investigator observed that your firm compounded 27 batches of latex between June 13, 1998, and June 27, 1998, using [REDACTED] that did not meet the [REDACTED] specification. The investigator also observed that your firm had not investigated the condoms made with these latex batches to determine whether quality had been affected by the failure to maintain the [REDACTED] specification.

Your response to this item is not complete. You have now investigated the latex condom lots that were produced using the out-of-specification [REDACTED]. The only condom lot rejections/reworks observed in these lots were due to defects not apparently related to the [REDACTED] of the [REDACTED] used in the latex. You have not, however, identified any corrective actions that address how you intend to prevent similar failures to maintain process control specifications in the future.

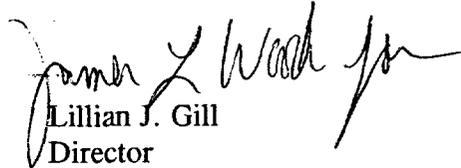
This letter is not intended to be an all-inclusive list of deficiencies at your facility. It is your responsibility to ensure adherence to each requirement of the Act and regulations. You are responsible for investigating and determining the causes of the violations identified by the FDA. If the causes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

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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 read "Lillian J. Gill". The signature is fluid and cursive, with a long horizontal flourish extending to the right.

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