DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Purged: P.C. Mayo 7/9/99

M7774n

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

VIA FEDERAL EXPRESS

JUL - 8 1999

WARNING LETTER

Mr. Joram Hirsch
President
Medigloves, Inc.
33/3 Moo 2 Tivanont Road
Panthumthani 12000, Thailand

Dear Mr. Hirsch:

During an inspection of your firm located in Panthumthani, Thailand on March 29 through April 2, 1999, our investigator determined that your firm manufactures surgical and examination latex 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) requirements of the Quality System Regulation, as specified in Title 21, Code of Federal Regulations (CFR), Part 820, as follows:

1. Failure to validate with a high degree of assurance and approve according to established procedures, a process where the results cannot be fully verified by subsequent inspection and test, as required by 21 CFR 820.75(a). For example:

    a. The compounding process has not been validated.

    Your response of April 30, 1999, is not adequate. You did not address the compounding process validation.

    b. The Dipping Line Validation Protocol/Report does not include the date and signature of the individuals approving the validation.

Your response of April 30, 1999, is not adequate. You provided validation reports for the dipping process, but the individuals approving the validation did not include the date of approval.

c. The [redacted] Sterilization Validation Report does not include the date of approval.

Your response of April 30, 1999, is not adequate. You did not provide the [redacted] Sterilization Validation report documenting the date of approval for our review.

d. The Dipping Line Validation Protocol/Report does not include the identification of the processing line or lots validated.

Your April 30, 1999, response is adequate.

e. The Dipping Line Validation/Report conclusions are not defined in that the specifications for the measured parameters are not provided for comparison with the validation results.

Your April 30, 1999, response is adequate.

f. The equivalency of the [redacted] product used during validation of the sterilization process and the actual product has not been determined.

Your April 30, 1999, response did not address this observation.

g. [redacted] have not been conducted on the [redacted] sterilization chamber."

Your response is adequate.

2. Failure to establish and maintain process control procedures that describe any process controls necessary to ensure conformance to specifications; and failure to verify or validate process changes to specifications before implementation of the change, as required by 21 CFR 820.70. For example:

a. There are no manufacturing process control procedures to identify, control, and monitor the compounding, dipping, sterilization, and packaging processes.

Your April 30, 1999, response is not adequate. You included a comprehensive listing of the critical manufacturing process control procedures; however, you did not include any procedures for significant processes such as compounding, dipping, sterilization and packaging for our review.

b. The Control Cards [(Nos. ,] and [)] do not identify the standard operating procedures used for each process listed.

Your April 30, 1999, response is adequate.

c. The Documentation and Change Control Procedure [()] does not include a verification and/or validation requirement for process specification changes.

Your response is not adequate. You did not provide a revised Documentation and Change Control Procedure [()] for our review.

3. Failure of the device master record (DMR) to include or refer to the location of the device specifications, production process specifications, quality assurance specifications, and packaging and labeling specifications, as required by 21 CFR 820.181. For example, the [] [] Gloves DMR did not refer to the location of the device specifications, production process specifications, quality assurance procedures, or the packaging and labeling specifications.

Your April 30, 1999, response may be adequate. You stated that the MDR was amended to include the reference and location of process specifications; however, the amended MDR for the [ ]

[2 words] Gloves was not provided for our review.

4. Failure to establish and maintain procedures to control all documents that provide for a description of the change, the identification of the affected documents, and the date of approval by the individual approving the document, as required by 21 CFR 820.40(b). For example:

   a. Documentation and Change Control Procedure [ ] dated 10/31/96, was not dated with an approval date; the reason for the change was unclear; and the affected documents were not identified.

   b. The Controlled Document Request (Change Records), Request Nos. [ ] and [ ], were not dated with an approval date; the changes were not evaluated; the affected records were not identified; and the reason for the change was unclear.

      Your April 30, 1999, response is adequate.

   c. The device master record (DMR) for the [ ] Gloves contained handwritten changes that had no approval date or the signature of the person authorizing the change.

      Your April 30, 1999, response is adequate.

5. Failure to identify by suitable means the acceptance status of product to indicate the conformance or nonconformance of product with acceptance criteria, as required by 21 CFR 820.86. For example:

   a. The [ ] Report, Lot [ ] did not indicate whether the lot was accepted.

   b. The [ ] Report, Lot [ ] did not indicate whether the lot met specifications or was accepted.

c. The [redacted] Report, Lot [redacted,] did not meet specifications and was rejected; however, the disposition of the lot was not identified.

Your April 30, 1999, response is adequate.

6. Failure to document corrective and preventive action activities to include analysis of other sources of quality data to identify existing and potential causes of nonconforming product; failure to identify the action(s) needed to correct and prevent recurrence of nonconforming product; and failure to verify or validate the corrective and preventive action to ensure that such action is effective and does not adversely affect the finished device, as required by 21 CFR 820.100. For example:

   a. There were no documents connecting the Change Request [redacted] with the Corrective Action Request [(redacted)] dated 9/24/98.

   b. Corrective and preventive actions were not documented on Change Request [redacted.]

   c. Change Request [redacted,] approved on 10/14/98, was not verified or validated.

   Your April 30, 1999, response is adequate.

7. Failure to ensure that all inspection, measuring, and test equipment is suitable for its intended purposes and is capable of producing valid results; and failure to include in the calibration procedure specific directions and limits for accuracy and precision, and provisions for remedial action when accuracy and precision limits are not met, as required by, as required by 21 CFR 820.72. For example:

   a. The dipping line (D/L No. [redacted] dated 11/9/98) calibration records did not show the method or tools used to calibrate the equipment or an evaluation of the calibration results.

   Your April 30, 1999, response is adequate.

b. The calibration records for the dipping line (D/L No.[redacted] dated 11/9/98) did not include the limits for accuracy and precision.

Your April 30, 1999, response is adequate.

c. The [redacted] Nos. [redacted] and [redacted] provided by [redacted], [redacted], [redacted], did not indicate if the equipment was calibrated with accuracy, and if not, if any remedial action was taken.

Your April 30, 1999, response is adequate.

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 closeout 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.

We acknowledge that you have submitted a response dated April 30, 1999, concerning our investigator's observations noted on the form FDA 483. We have reviewed your response and have concluded that it is inadequate. Detailed comments on your response are cited above.

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 surgical and examination gloves manufactured by Medigloves, Inc. of Panthumthani, Thailand, may be detained upon entry into the United States (U.S.) 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 where we judged your April 30, 1999, response less than adequate. 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 has been verified, your products may resume entry into this country.

Please notify this office in writing 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 an English translation to facilitate our review.

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, 2098 Gaither Road, Rockville, Maryland 20850, to the attention of Peggy C. Mayo.

Sincerely yours,

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

cc:

[redacted]