



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

VIA FEDERAL EXPRESS

WARNING LETTER

Mr. Wilson Wu
General Manager
P.T. Saptindo Surgica
JL. Raya Serang Km. 65
Cikande-Serang, Jawa Barat
Indonesia

Dear Mr. Wu:

During an inspection of your firm located in Cikande-Serang, Jawa Barat, Indonesia on July 15, 1999, our investigator determined that your firm manufactures latex surgical gloves. These 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 Regulations (CFR), Part 820, as follows:

1. Failure of management with executive responsibility to implement and maintain a quality policy and objectives, and to appoint a member of management who, irrespective of other responsibilities, shall have authority over and responsibility for quality planning and quality system procedures, as required by 21 CFR 820.20. For example:
 - a. A quality policy and objectives have not been implemented.
 - b. A management representative has not been appointed.
 - c. Quality plans have not been established.
 - d. Quality system procedures have not been established.
2. Failure to, where the results of a process cannot be fully verified by subsequent inspection and test, validate the process with a high degree of assurance and approve that process according to established procedures, as required by 21 CFR 820.75(a). For example:

- a. The manufacturing process for the surgical latex gloves has not been validated, particularly for the latex dipping and leaching activities.
 - b. The [REDACTED] sterilization process for the surgical latex gloves has not been validated.
 - c. The surgical latex gloves have a [REDACTED] expiration date. Stability studies have not been conducted to validate this expiration date.
 - d. The effectiveness of the addition of the agents, [REDACTED] and [REDACTED] to the starch slurry mixture has not been validated.
3. Failure to develop, conduct, control, and monitor production processes to ensure that a device conforms to its specifications, and to establish and maintain process control procedures that describe any process controls necessary to ensure conformance to specifications, as required by 21 CFR 820.70(a). For example:
- a. The latex feeding and dipping tanks temperature is repeatedly out of specification (above [REDACTED]). The specified temperature is [REDACTED] for the feeding tank.
 - b. The leaching tank heating element is not working since [REDACTED] and therefore the leaching water temperature [REDACTED] has not been achieved.
 - c. The coagulant tank's temperature is regularly out of specification ([REDACTED] or less). The specification is [REDACTED].
 - d. The starch slurry total solid content is regularly out of specification (over [REDACTED]). The specification for TSC is [REDACTED].
 - e. The latex compound is regularly out of specification for total solid content (TSC [REDACTED] to [REDACTED]). The specification for TSC for the latex compound (dip and feeding tank) is [REDACTED].
4. Failure to maintain a device master record prepared, dated, and signed by a designated individual for each type of device, including or referring to production process specifications including appropriate equipment specifications, production methods, production procedures, and production environmental specifications, as required by 21 CFR 820.181(b). For example:

- a. [REDACTED] sterilization operating parameters have not been established.
 - b. There are no procedures for the formulation of the starch slurry.
 - c. There are no procedures for monitoring the dusting powder tank.
 - d. There is no procedure for adjusting the concentration of the [REDACTED] agents, [REDACTED] and [REDACTED] when replenishing the starch slurry.
 - e. There is no procedure for bioburden control.
 - f. There is no specification for moisture content of the finished surgical latex gloves.
5. Failure to investigate the cause of non-conformities relating to product, processes, and the quality system, as required by 21 CFR 820.100(a)(2). For example, quality problems or nonconforming product are not [REDACTED] evaluated/investigated to determine the root cause and correct the problem. The quality problems noted in the "INSPECTION REPORT-QC" for 1999, document over a rejection rate for surgical latex gloves' [REDACTED] such as [REDACTED] No corrective action was taken.
6. Failure to establish procedures for quality audits and to conduct such audits to assure that the quality system is in compliance with the established quality system requirements, as required by 21 CFR 820.22. For example, the quality system has not been audited since [REDACTED]
7. Failure to establish and maintain procedures to ensure that all inspection, measuring, and test equipment, including mechanical, automated, or electronic inspection and test equipment is routinely calibrated, inspected, checked, and maintained, as required by 21 CFR 820.72(a). For example, the viscometer, analytical balance, laboratory balance, and laboratory water bath should be checked or calibrated every six (6) months. The calibration record indicates they have not been checked or calibrated since [REDACTED]
8. Failure to establish and maintain procedures to control all documents required by this part with procedures that provide for review and approval of changes to documents by an individual(s) in the same function or organization that performed the original review and approval, unless specifically designated otherwise, as required by 21 CFR 820.40(b). For example, change control procedures [REDACTED]

have not been implemented in accordance with the device master record showing the date the procedures were approved, when the change became effective, and the reason for the change.

9. Failure to establish and maintain procedures implementing corrective and preventive action including requirements for analyzing processes, quality records, and other sources of quality data to identify existing and potential causes of nonconforming product or other quality problems, as required by 21 CFR 820.100(a)(1). For example, corrective and preventive action system procedures have not been defined and documented, and data sources have not been identified and analyzed to identify product and quality problems that require corrective/preventive action.
10. Failure to establish that calibration standards used for inspection, measuring, and test equipment shall be traceable to national or international standards, or in-house standards established should standards not be practical or available, as required by 21 CFR 820.72(b)(1). For example, the calibration records do not include the calibration standards used to assure that they are traceable to national or international standards.

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.

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 devices manufactured by P.T. Saptindo Surgica, JL. Raya Serang KM. 65 Cikande-Serang, Jawa Barat, Indonesia may be detained without physical examination 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

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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 Carol Shirk.

Sincerely yours,



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