

Purged



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

M33021

Food and Drug Administration
Rockville MD 20857

FEB 7 2000

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Mr. Allan Madsen, Managing Director
LR Plast A/S
Formervangen 14-16
Dk-2600 Glostrup
Denmark

Dear Mr. Madsen:

During an inspection of your firm located in Glostrup, Denmark on November 22 through 26, 1999, our investigator determined that your establishment is a contract sterilizer for medical 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 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 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 investigate the cause of nonconformities relating to product, processes, and the quality system, as required by 21 CFR 820.100(a)(2). For example, certain indicators of nonconformities were not documented and investigated to determine the cause of the nonconformity, as follows:
 - a. There was no investigation into the cause of the machine error that resulted in the failure of the tray separating two batches of medical devices [REDACTED] (NCR report [REDACTED] November 2, 1999).

As of this date, we have not received a response from you for this observation.

- b. There was no investigation into the cause of boxes of medical devices being reportedly incorrectly placed onto the conveyor (NCR report [REDACTED] October 13,

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1999). Retraining had been previously documented on October 6, 1999, for the same error (NCR # [REDACTED]).

As of this date, we have not received a response from you for this observation.

2. Failure to establish and maintain process control procedures that describe any process controls necessary to ensure conformance to specifications where deviations from device specifications could occur as a result of the manufacturing process, as required by 21 CFR 820.70(a). For example, process control procedures that describe the process controls necessary to ensure conformance to specifications are not defined and documented, as follows:

- a. The function of the [REDACTED] and its limitations are not described.

Your response, dated January 14, 2000, appears to be adequate.

- b. A list of the alarms, the allowable ranges for the alarms, and the rationale for establishing the alarm limits have not been documented in process control procedures.

Your response, dated January 14, 2000, is not adequate because the revised procedure did not define the allowable ranges for the alarms or the rationale for establishing the alarm limits. Your response did provide the list of alarms.

- c. There is no documentation of parameter settings for the accelerator in the process control procedures.

Your response, dated January 14, 2000, appears to be adequate.

3. Failure to validate a process with a high degree of assurance where the results of a process cannot be fully verified by subsequent inspection and test, as required by 21 CFR 820.75. For example, the validation report does not include a complete description of the sterilization system and its functions.

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As of this date, we have not received a response from you for this observation.

4. Failure to validate computer software for its intended use according to an established protocol when computers are used as part of production or the quality system, as required by 21 CFR 820.70(i). For example, the validation report does not include documentation to describe the functions (input/output) of the software controlling the sterilization process.

As of this date, we have not received a response from you for this observation.

5. Failure to establish and maintain procedures for the control of storage areas and stock rooms for product to prevent mixups, damage, deterioration, contamination, or other adverse effects pending use or distribution, as required by 21 CFR 820.150(a). For example, procedures were not followed to ensure that mixups, damage, or other adverse effects to products do not occur during handling. Specifically, temporary storage of products in areas not dedicated for the product was observed in 4 cases. Although procedure [REDACTED] allows temporary storage by exception in non-dedicated areas, the observed 4 cases appear to be a routine practice and not an exception.

As of this date, we have not received a response from you for this observation.

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 the FDA 483 issued at the conclusion 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 FDA. 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 January 14, 2000, concerning our investigator's observations noted on

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the form FDA 483. We have reviewed your response and have concluded that it is inadequate for the reasons cited above.

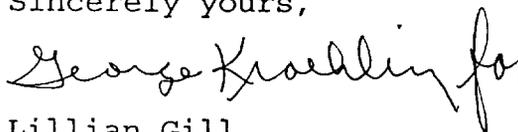
Federal agencies are advised of the issuance of all Warning Letters about devices so that they may take this information into account when considering the award of contracts.

You should take prompt action to correct these and any other manufacturing or quality systems deviations identified by your internal audits. Failure to promptly correct these deviations may be identified in a follow-up inspection, and may result in the detention of your device(s) without physical examination upon entry into the United States.

Please notify this office, in writing, within 15 working days of receipt of this letter, 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 the documentation is not in English, please provide a translation to facilitate our review.

Your response should be sent to Sarah Mowitt at the above letterhead address. If you have questions or need further assistance contact Mrs. Mowitt by telephone at (301) 594-4595 or by FAX at (301) 594-4636.

Sincerely yours,



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