



DEPARTMENT OF HEALTH & HUMAN SERVICES

94852d  
Food and Drug Administration

June 15, 2004

Chicago District  
550 West Jackson Blvd., 15th Floor  
Chicago, Illinois 60661  
Telephone: 312-353-5863

**WARNING LETTER**  
**CHI-14-04**

**CERTIFIED MAIL**  
**RETURN RECEIPT REQUESTED**

Mr. Les Vinney, Chief Executive Officer  
Steris Corporation  
5960 Heisley Road  
Mentor, OH 44060

Dear Mr. Vinney:

During inspections of Steris Isomedix Services, 2500 Commerce Drive, Libertyville, IL ("Libertyville South" or "LS"), from January 20, 2004 through February 13, 2004, and Steris Isomedix Services, 1880 Industrial Drive, Libertyville, IL ("Libertyville North" or "LN"), from January 13, 2004 through February 13, 2004, Food and Drug Administration (FDA) investigators determined that both firms perform as contract sterilizers of products that are devices as defined by Section 201(h) of the Federal Food, Drug, and Cosmetic Act (the Act).

The inspections 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 by the manufacturing, packing, storage, or installation are not in conformance with the Quality System Regulations (QSR), Title 21, Code of Federal Regulations (CFR), Part 820. Under the QSR, firms that perform the function of contract sterilization are manufacturers. 21 CFR 820.3(o)

The deficiencies noted include the following:

1. Failure to establish and maintain procedures for implementing corrective and preventive action (CAPA), as required by 21 CFR 820.100(a)(4). Both inspections found that procedures that address the verification or validation of corrective and preventive actions have not been established. Procedure SOP 3107, entitled "Nonconformance – Investigation, Corrective and Preventive Action" does not include a discussion of parameters for addressing the verification and validation of corrective actions. For example, the inspection of the Libertyville South facility revealed that Deviation Report DR-3-062 was issued due to an [REDACTED] As a corrective action, the specification for the [REDACTED] This change

was implemented without verification or validation. Three of the next [REDACTED] runs of product code [REDACTED] resulted in [REDACTED] (documented in Deviation Reports DR3-068, DR4-005, and DR4-006). The newly implemented [REDACTED] was used in all runs.

A second example is the change in the [REDACTED] specification from [REDACTED] for product code 16-42846 for production run 03-0352. The specification change was not verified or validated before its implementation. Production run 03-0352 resulted in a [REDACTED] documented in Deviation Report DR3-069. (LS FDA 483, items #1&10, LN FDA 483 item #5).

2. Failure to establish and maintain procedures for implementing corrective and preventive action, as required by 21 CFR 820.100(a). The inspections found that both facilities fail to follow SOP 3107, "Nonconformance – Investigation, Corrective and Preventive Action," which requires that all investigations of complaints should determine root cause, corrective actions, preventive actions and effectiveness. (LS FDA 483, item # 11, LN FDA 483 item #6)
3. Failure to establish and maintain process control procedures necessary to ensure conformance to specifications, including documented instructions, standard operating procedures (SOPs) and methods that define and control the manner of production as required by 21 CFR 820.70(a)(1). For example, SOP 1400, "Process Qualification and Routine Process Control Policy" does not differentiate between which parameters are pertinent to product [REDACTED]. A second example is SOP 1079LV "Product Processing" is used for processing product [REDACTED] applicable to the [REDACTED]. The Libertyville South facility does not have a Product Processing procedure for processing product on the [REDACTED] (LS FDA 483, item # 8, LN FDA 483 item #4)
4. Failure to develop, conduct, control and monitor production processes to ensure that a device conforms to its specifications as required by 21 CFR 820.70(a). For example, the inspection of the Libertyville North facility revealed that SOP 1103IL, "Procedure for Establishing Cycle Time," does not document or refer to instructions for how to use the [REDACTED]. Deviations DR 3-014 and DR3-032 were a result of [REDACTED] chosen from the [REDACTED] file by the Production Planner. (LN FDA 483 item #1)

5. Failure to fully document process validation activities and results as required by 21 CFR 820.75(a). For example, SOP 1285LV "Product Qualification" does not describe the final adjustment made to determine the [REDACTED] or the calculations that are used for the [REDACTED] Product Qualification. (LS FDA 483 item #3)
6. Failure to document the evaluation and any investigation of nonconforming product as required by 21 CFR 820.90(a). For example, Deviation Reports DR3-088, DR4-005 and DR4-006 list the cause of [REDACTED]. The investigations do not contain documentation to support this fact as the cause for the [REDACTED] which were described in these deviations. (LS FDA 483 item #5)
7. Quality audits are not being conducted by individuals who do not have direct responsibility for the matters being audited as required by 21 CFR 820.22. For example, the Quality Systems/Regulatory Compliance (QS/RC) Manager for the Libertyville North facility conducted all [REDACTED] of the firm's internal audits for 2003. The QS/RC manager is listed as a Department Manager on the Internal Audit cover letters for all five areas which include Quality Management System, Management Responsibility, Resource Management, Product Realization, and Measurement, Analysis and Improvement. (LN FDA 483 item #8)

This letter is not intended to be an all-inclusive list of deficiencies at these facilities. It is your responsibility to ensure adherence to each requirement of the Act and regulations. Federal agencies are advised to 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 deviations and to establish procedures to prevent their recurrence. Failure to promptly correct these deviations may result in regulatory action being initiated by FDA without further notice. These actions include, but are not limited to, seizure, injunction, and/or civil penalties. Additionally, no premarket submissions for Class III devices to which Quality System/GMP deficiencies are reasonably related will be cleared or approved until the violations have been corrected. Also, no requests to for Certificates to Foreign Governments will be approved until the violations related to the subject devices have been corrected and verified.

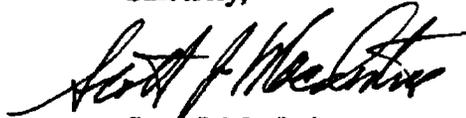
We acknowledge receipt of the undated written responses to the FDA Form 483s that were submitted by Jerry Kriebel, Director, Midwest Plant Operation. We find the responses to be inadequate because there was no documentation provided demonstrating that corrective actions have been implemented and are effective.

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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 (1) the time frames within which the corrections will be completed, (2) any documentation indicating that the corrections have been achieved, and (3) 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 occur.

Your response should be sent to the attention of Compliance Officer George F. Bailey at the address listed above.

Sincerely,

A handwritten signature in black ink, appearing to read "Scott J. MacIntire". The signature is written in a cursive style with a large, sweeping initial "S".

Scott J. MacIntire  
District Director

cc: Mr. Jerry Kriebel,  
Director of Midwest Plant Operations,  
Steris Isomedix Services  
2500 Commerce Drive  
Libertyville, IL 60048-2403