



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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9/9/97
J.S.

SEP -3 1997

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

WARNING LETTER

VIA FEDERAL EXPRESS

Mr. Holgar Soring, President
Soring GmbH
Justus-Von-Leibig-Ring #10
D-25451 Quickborn, Germany

Purged
9/18/97
J.S.

Dear Mr. Soring:

During an inspection of your firm located in Quickborn, Germany, on June 2-4, 1997, our Investigator determined that your firm manufactures ultrasonic-dissection/aspiration systems. 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 your 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 current good manufacturing practice (CGMP) requirements of the Quality System Regulation (QS Regulation), as specified in Title 21, Code of Federal Regulations (CFR), Part 820. The 1978 Good Manufacturing Practices (GMP) regulation was superseded on June 1, 1997, by the QS Regulation. Since the records reviewed were dated prior to June 1, 1997, the deficiencies noted during the inspection are cross referenced to the 1978 GMP's. We have not received a response from you regarding the observations noted in the FDA 483 by the Investigator.

1. Failure of the manufacturer to document any review, evaluation, and revalidation where appropriate when process changes occur, as required by 21 CFR 820.75(c). This would also be a violation of the Good Manufacturing Practices Regulation, 21 CFR 820.100(b)(3). For example, there is no documented validation test data to show that the new production specifications for the [REDACTED] will work effectively.
2. Failure to establish and maintain procedures for finished device acceptance to ensure that each production run, lot, or batch of finished devices meets its acceptance criteria, as required by 21 CFR 820.80(d). This would also be a violation of the Good Manufacturing Practices Regulation, 21 CFR 820.160. For example, [REDACTED] release dates for the [REDACTED] devices (Serial Numbers [REDACTED]) were not always documented in the systems test records as required.

3. Failure to document all activities, and their results, for corrective and preventative actions, as required by 21 CFR 820.100(b). This would also be a violation of the Good Manufacturing Practices Regulation, 21 CFR 820.162 and 21 CFR 820.198(c). For example, failure investigations concerning defective [REDACTED] were not documented.
4. Failure to establish and maintain procedures for receiving, reviewing, and evaluating complaints by a formally designated unit, as required by 21 CFR 820.198(a). This was not a requirement of the Good Manufacturing Practices Regulation. For example, a complaint handling procedure has not been established.
5. Failure of the formally designated unit to maintain a record of each investigation made under this section, as required by 21 CFR 820.198(e). This would also be a violation of the Good Manufacturing Practices Regulation, 21 CFR 820.198(c). For example, several written complaints concerning defective [REDACTED] resulting in modifications, were not documented nor referenced in the complaint forms as required. Also the complaint form does not include control numbers used, address and phone number of complainant, failure investigation information needed (nature and details of complaint), name of individuals (receiving, reviewing, and evaluating complaint), and status of investigation.
6. Failure to ensure that each device master record is prepared and approved in accordance with 21 CFR 820.40; and failure of the device master record to include, or refer to the location of, device specifications including appropriate drawings, composition, formulation, component specifications, and software specifications, as required by 21 CFR 820.181(a). This would also be a violation of the Good Manufacturing Practices Regulation, 21 CFR 820.181(a). For example:
 - a. The device master record does not specify the [REDACTED] for the newly designed [REDACTED] that were modified to [REDACTED]
 - b. The device master record has not been revised since [REDACTED] to specify the [REDACTED] for the newly designed [REDACTED]
 - c. The device master record for the [REDACTED] has not been revised since [REDACTED] for [REDACTED] of the [REDACTED] currently used in the new [REDACTED] for the newly designed [REDACTED]

- d. The device master record does not trace the history of [REDACTED]. The [REDACTED] numbers were not changed following multiple modifications made to the [REDACTED] since [REDACTED]; and the [REDACTED] were overwritten or lost after each [REDACTED] change.
7. Failure to ensure that each device master record is prepared and approved in accordance with 21 CFR 820.40; and failure of the device master record to include, or refer to the location of, production process specifications including the appropriate equipment specifications, production methods, production procedures, and production environmental specifications, as required by 21 CFR 820.181(b). This would also be a violation of the Good Manufacturing Practices Regulation, 21 CFR 820.181(b). For example, the device master record has not been revised since [REDACTED] to specify the [REDACTED] procedure used in [REDACTED] the newly designed [REDACTED].
8. Failure to ensure that each device master record is prepared and approved in accordance with 21 CFR 820.40; and failure of the device master record to include, or refer to the location of, quality assurance procedures and specifications including acceptance criteria and the quality assurance equipment to be used, as required by 21 CFR 820.181(c). This would also be a violation of the Good Manufacturing Practices Regulation, 21 CFR 820.181(c). For example, the device master record does not specify the acceptance criteria for the [REDACTED] for the newly designed [REDACTED] that were modified to [REDACTED].
9. Failure to analyze processes, work operations, concessions, quality audit reports, quality records, service records, complaints, returned product, 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). This would also be a violation of the Good Manufacturing Practices Regulation, 21 CFR 820.20(a)(3). For example, rework records of various [REDACTED] have not been reviewed nor analyzed to identify existing and potential causes of quality problems.
10. Failure to establish procedures for quality audits and conduct such audits to assure that the quality system is in compliance with the established quality system requirements and to determine the effectiveness of the quality system, as required by 21 CFR 820.22. This would also be a violation

of the Good Manufacturing Practices Regulation, 21 CFR 820.20(b). For example, since the [REDACTED] used for a [REDACTED] is still in draft form and has not been approved.

11. Failure to establish and maintain procedures for identifying product during all stages of receipt, production, distribution, and installation to prevent mixups, as required by 21 CFR 820.60. This would also be a violation of the Good Manufacturing Practices Regulation, 21 CFR 820.80. For example:
 - a. There is no serial number or other control identifications to trace [REDACTED] to the finished device. (This was not listed on the FDA-483, but was included in the Establishment Inspection Report by the Investigator.)
 - b. The [REDACTED] numbers were not changed following multiple modifications made to the [REDACTED]
12. Failure to document the acceptance or rejection of incoming product, as required by 21 CFR 820.80(b). This would also be a violation of the Good Manufacturing Practices Regulation, 21 CFR 820.80(a). For example, the quantity of acceptance and rejections for the incoming inspections of various [REDACTED] have not been documented.
13. Failure to establish and maintain procedures for rework, to include retesting and revalidation of the nonconforming product after rework, to ensure that the product meets its current approved specifications; and failure to document rework and reevaluation activities, as required by 21 CFR 820.90(b)(2). This would also be a violation of the Good Manufacturing Practices Regulation, 21 CFR 820.115(a). For example:
 - a. There is no written rework procedure for the [REDACTED] that failed the [REDACTED] testing.
 - b. There are no documented acceptance test results to show if each reworked [REDACTED] passed the retesting.

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 form FDA 483 issued at the close of the inspection may be symptomatic of

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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 (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.

In order to facilitate the FDA in making the determination that such corrections have been made and thereby enabling FDA to withdraw its advisory to other federal agencies concerning the award of government contracts, we are requesting that you submit to this office on the schedule below, certification by an outside expert consultant that it has conducted an audit of your firm's manufacturing and quality assurance systems relative to the CGMP requirements of the QS Regulation (21 CFR, Part 820). You should also submit a copy of the consultant's report, and certification by your firm's CEO (if other than yourself) that your firm has initiated or completed all corrections called for in the report. The enclosed guidance may be helpful in selecting an appropriate consultant.

The certification of audits and corrections should be submitted to this office by the following date:

- Initial certification by an outside expert consultant no later than March 31, 1998.

Given the serious nature of these violations of the Act, all devices manufactured by Soring GmbH, Quickborn, Germany, may be detained upon entry into the United States without physical examination 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 for our review, and have an outside consultant certify your compliance with the QS Regulation no later than March 31, 1998. After we notify you that your response is adequate, it will be your responsibility to schedule an inspection of your facility. As soon as the inspection has taken place, the implementation of your corrections has been verified, your products may resume entry into this country.

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,

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should be included with your response to this letter. If documentation is not in English, please provide a 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, HFZ-323, 2098 Gaither Road, Rockville, MD 20850, to the attention of Joseph L. Salyer.

Should you require any assistance in understanding the contents of this letter, do not hesitate to contact Mr. Salyer at the above address or at (301)-594-4595, Ext.175 or fax (301)-594-4636.

Sincerely yours,



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

Enclosure: Selecting a Consultant?

CC: 