



AUG 3 2004

WARNING LETTERFood and Drug Administration
Center for Devices and
Radiological Health
2098 Gaither Road
Rockville, MD 20850VIA FEDERAL EXPRESSJohan Gjemre Olsen
CEO/Leader of the Board
Ola Olsen Eftf. A/S
Postboks 52
Stavanger, Norway

Dear Mr. Olsen:

During an inspection of your facility located in Stavanger, Norway, on March 1, 2, and 5, 2004, our investigator determined that your firm manufactures Sea Tangle Laminaria Tents (cervical dilators). These products are devices within the meaning of Section 201(h) of the Federal Food, Drug, and Cosmetic Act (the Act)(21 U.S.C. § 321(h)).

This inspection revealed that these devices appear to be adulterated within the meaning of section 501(h) of the Act (21 U.S.C. § 351(h)), in that the methods used in, or the facilities or controls used for, their manufacture, packing, storage, or installation are not in conformity with applicable Current Good Manufacturing Practice (CGMP) requirements, which are set forth in FDA's Quality System (QS) regulation, codified at Title 21, Code of Federal Regulations (CFR), Part 820. Significant deviations include, but are not limited to, the following:

1. Failure to validate with a high degree of assurance, and to approve according to established procedures, a process whose results cannot be fully verified by subsequent inspection and test, as required by 21 CFR 820.75(a). Specifically, the pouch sealing process using [REDACTED] brand heat sealer was not validated. During pouch sealing a worker operating the device verbally counts from [REDACTED] to [REDACTED] then presses on a foot pedal to achieve a sealing dwell time of [REDACTED], as no machine [REDACTED] was installed on the heat sealer or placed near the machine to eliminate variations between verbal counts. Although the seal dwell time and temperature were defined, no validation data exist to show that, at the mentioned set process parameters, it resulted in a seal that met the firm's final acceptance criteria.
2. Failure to establish and maintain procedures for implementing corrective and preventive action, as required by 21 CFR 820.100(a), and to document these activities and their results, as required by 21 CFR 820.100(b). Specifically, your firm has no procedures including requirements for analyzing sources of quality data, such as complaints and returned product. Also, your firm failed to employ appropriate statistical methodology where necessary to detect recurring quality problems.

3. Failure to write and base sampling plans on a valid statistical rationale; and, failure to establish and maintain procedures to ensure that sampling methods are adequate for their intended use and to ensure that, when changes occur, the sampling plans are reviewed, as required by 21 CFR 820.250(b). Specifically, during the final QC inspection, 3 laminaria tents are collected from a batch size of 10 to 15 pieces. However, if one or more tents do not conform to the final specification, additional tents are removed from the batch for further inspections until all samples are found acceptable. There is no fixed sampling plan established based on a valid statistical rationale.
 4. Failure to establish quality system procedures and instructions, as required by 21 CFR 820.20(e). Specifically, no quality manual or high level document containing procedures identifying quality system requirements, quality policy, quality plan, and instructions for performing management reviews, handling design changes, evaluating suppliers and contractors, approving and distributing documents, inspecting laminaria tents, monitoring production activities; identifying the breakdown of device identification codes (lot numbers), calibrating measurement instruments, handling non-conformities, performing corrective and preventative actions and handling a review of product labeling, were maintained.
 5. Failure to establish and maintain procedures for the identification, documentation, validation or where appropriate verification, review, and approval of design changes before their implementation, as required by 21 CFR 820.30(i).
 6. Failure to establish and maintain procedures to ensure that all purchased or otherwise received product and services conform to specified requirements, as required by 21 CFR 820.50. Specifically, no procedures for evaluating suppliers and contractors were maintained.
 7. Failure to establish and maintain procedures to control all documents that are required by the QS Regulation, as required by 21 CFR 820.40.
 8. Failure to establish and maintain procedures to control product that does not conform to specified requirements, as required by 21 CFR 820.90(a). Specifically, no procedures for handling non-conformities were maintained.
 9. Failure of management with executive responsibility to review the suitability and effectiveness of the quality system at defined intervals and with sufficient frequency according to established procedures to ensure that the quality system satisfies the requirements of the QS Regulation, as required by 21 CFR 820.20(c).
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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.
11. Failure of management with executive responsibility to appoint, and document such appointment of, a member of management who, irrespective of other responsibilities, shall have established authority over and responsibility for ensuring that quality system requirements are effectively established and effectively maintained in accordance with the QS Regulation, and reporting on the performance of the quality system to management with executive responsibility for review, as required by 21 CFR 820.20(b)(3).
12. Failure to establish and maintain procedures, for receiving, reviewing, and evaluating complaints by a formally designated unit, which ensure that all complaints are processed in a uniform and timely manner; oral complaints are documented upon receipt; and complaints are evaluated to determine whether the complaint represents an event which is required to be reported to FDA, as required by 21 CFR 820.198(a).
13. Failure to document the equipment identification, calibration dates, the individual performing each calibration, and the next calibration date for inspection, measuring, and test equipment, as required by 21 CFR 820.72(b)(2). Specifically, calibration of the temperature control for the ~~XXXXXX~~ heat sealer was not documented.
14. Failure of the device history record to include, or refer to the location of, the primary identification label and labeling used for each production unit, as required by 21 CFR 820.184(e). Specifically, a copy of the pouch or unit cardboard box (with printed lot number) was not maintained as part of the device history record, and the device history record did not refer to the location of the pouch or box.
15. Failure to establish and maintain procedures to control labeling activities, as required by 21 CFR 820.120. Specifically, no procedures were established to require visual inspection of printed information on product inserts, unit boxes, and individual pouches against master copies to confirm all relevant information (including lot number) be legible.
16. Failure of management with executive responsibility to establish its policy and objectives for, and commitment to, quality, and to ensure that the quality policy is understood, implemented, and maintained at all levels of the organization, as required by 21 CFR 820.20(a).

The above-stated inspection also revealed that your firm failed to develop, maintain, and implement written MDR procedures, as required by 21 CFR 803.17.

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 applicable requirement of the Act and of FDA regulations. The specific violations noted in this letter and in the Form FDA 483 provided to you at the closet 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 FDA. If the causes are determined to be systems problems, you must promptly initiate permanent corrective actions.

You should take prompt action to correct these deviations. Failure to do so may result in FDA regulatory action without further notice. Under Section 801(a) of the Act, for example, your devices could be detained without physical examination upon entry into the United States on the ground that they appear to be adulterated under Section 501(f)(1)(B). To remove your devices from this detention, it would be necessary for you to provide a written response to the charges in this Warning Letter for our review. As soon as the implementation of your corrections has been verified, and you are notified that your corrections are adequate, your devices would be removed from detention without physical examination.

In addition, United States federal agencies are advised of the issuance of all Warning Letters about medical devices so that they may take this information into account when considering the award of contracts, and pending export approval requests may not be approved until the above violations are corrected.

Our office was informed that your response to the FDA 483 was received by our Field Programs Branch on May 10, 2004. On June 2, 2004, we notified Mr. Knud Jensen by email and FAX that we could not locate that response within our immediate office, and requested that a response be re-sent to us. On June 14, 2004, Mr. Jensen indicated via email that the FDA 483 response had been re-sent. Our office responded on June 15, 2004, that we have not yet received that response. When that response is finally received, we will review it and communicate our comments to you.

Please notify this office in writing within fifteen (15) working days from the date you receive this letter of the specific steps you have taken to correct the noted violations, including an explanation of how you plan to prevent these violations, or similar violations, from occurring again. Include all documentation of the corrective action you have taken. If you plan to make any corrections in the future, include those plans with your response to this letter as well. If the 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 A, OB/GYN, Gastroenterology, and Urology Device Branch, 2098 Gaither Road, Rockville, Maryland 20950 USA, to the attention of Mr. Paul Tilton.

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If you need help in understanding the contents of this letter, please contact Mr. Paul Tilton at the above address or at (301) 594-4616 or FAX (301) 594-4638.

Sincerely yours,

A handwritten signature in black ink that reads "Larry D. Spears for". The signature is written in a cursive style with a large initial "L" and a checkmark at the end.

Timothy A. Ulatowski
Director
Office of Compliance
Center for Devices and
Radiological Health

