Inspections, Compliance, Enforcement, and Criminal Investigations

FSSB Chirurgische Nadeln Gmbh 1/29/13

Department of Health and Human Services

Public Health Service
Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

WARNING LETTER

January 29, 2013

VIA UNITED PARCEL SERVICE

Henry Frenzel
Chief Executive Officer
FSSB Chirurgische Nadeln GMBH
Allmendweg 2
Jestetten, Germany 79798

Dear Mr. Frenzel:

During an inspection of your firm located in Jestetten, Germany on September 17, 2012, through September 20, 2012, an investigator from the United States Food and Drug Administration (FDA) determined that your firm manufactures a wide variety of sterile and non-sterile needles and sutures. Under section 201(h) of the Federal Food, Drug, and Cosmetic Act (the Act), 21 U.S.C. § 321(h), these products are devices because they are intended for use in the diagnosis of disease or other conditions or in the cure, mitigation, treatment, or prevention of disease, or to affect the structure or function of the body.

This inspection revealed that these devices are 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 the current good manufacturing practice requirements of the Quality System regulation found at Title 21, Code of Federal Regulations (CFR), Part 820. These violations include, but are not limited to, the following:

1. Failure to establish and maintain procedures to control product that does not conform to specified requirements and that set forth the review and disposition process, as required by 21 CFR 820.90. For example, your firm has a procedure for handling nonconforming material, "Lenkung von Fehlern, Ruckmeldesystem bei Qualitatsproblemen", VA-Nr.: VA 9.3/1, Revision 2, dated 5/29/2010, a procedure for internal errors in production, and a form, FB 8.3-04, to document nonconformances during production. Your firm stated that it does not use the form and that it has had several nonconformances during needle production, but that they are not documented. Your firm also stated that it is hard to count the tiny needles, but that it disposes of all the nonconforming needles without conducting any evaluations or implementing corrective or preventive actions. Additionally, this disposition process is not

controlled or documented and there is no tracking of nonconforming needles.

2. Failure to ensure that complaints are evaluated to determine whether the complaint represents an event which is required to be reported to FDA under 21 CFR 803, Medical Device Reporting, as required by 21 CFR 820.198(a)(3). For example, your firm has a complaint procedure, VA-Nr.: VA 8.3/1, Rev 2, dated 05/28/2010, and a complaint work instruction, Nr. AA 8.3/02, Rev 2, dated 03/12/2009. However, the combination of these documents does not contain the requirement to evaluate complaints to determine if they represent events that should be submitted as a Medical Device Report.

3. Failure to validate computer software for its intended use according to an established protocol when computers or automated data processing systems are used as part of production or the quality system, as required by 21 CFR 820.70(i). For example, your firm uses custom automatic machines in the needle production process. Your firm stated that it performed software validation for the automatic machines and that the software protocol was tested, but these validation activities were not documented.

4. Failure to establish and maintain procedures for identifying valid statistical techniques required for establishing, controlling, and verifying the acceptability of process capability and product characteristics, and to ensure that sampling methods are adequate for their intended use, as required by 21 CFR 820.250. For example, your firm stated that it does not have a procedure for sampling in-process products. Your firm stated that it **(b)(4)** for inspection. This sampling plan is not written and it is not based on a valid statistical rationale to ensure that the sampling methods are adequate for their intended use.

U.S. federal agencies may be advised of the issuance of Warning Letters about devices so that they may take this information into account when considering the award of contracts. Additionally, premarket approval applications for Class III devices to which the Quality System regulation deviations are reasonably related will not be approved until the violations have been corrected. Requests for Certificates to Foreign Governments will not be granted until the violations related to the subject devices have been corrected.

Please notify this office in writing within fifteen business days from the date you receive this letter of the specific steps your firm has taken to correct the noted violations, including an explanation of how your firm plans to prevent these violations, or similar violations, from occurring again. Include documentation of the corrections and/or corrective action (including any systemic corrective actions) that your firm has taken. If your firm's planned corrections and/or corrective actions will occur over time, please include a timetable for implementation of those activities. If corrections and/or corrective actions cannot

be completed within fifteen business days, state the reason for the delay and the time within which these activities will be completed. Please provide a translation of documentation not in English to facilitate our review.

Your firm's response should be sent to: Food and Drug Administration, Center for Devices and Radiological Health, Office of Compliance, Field Operations Branch, White Oak Building 66, Rm 2609, 10903 New Hampshire Ave., Silver Spring, MD 20993. Refer to CMS case # 390140 when replying. If you have any questions about the contents of this letter, please contact: LaShanda Long at
301- 796-5465 or fax at 301-847-8137.

Finally, you should know that this letter is not intended to be an all-inclusive list of the violations at your firm's facility. It is your firm's responsibility to ensure compliance with applicable laws and regulations administered by FDA. The specific violations noted in this letter and in the Inspectional Observations, FDA 483, issued at the close of the inspection may be symptomatic of serious problems in your firm's manufacturing and quality management systems. Your firm should

investigate and determine the causes of the violations, and take prompt actions to correct the violations and bring the products into compliance.

Sincerely yours,
/S/
Steven D. Silverman
Director
Office of Compliance
Center for Devices and
Radiological Health

Page Last Updated: 02/04/2013
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