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Food and Drug Administration  
Center for Devices and  
Radiological Health  
2098 Gaither Road  
Rockville, MD 20850

**WARNING LETTER**  
**VIA FEDERAL EXPRESS**

OCT 12 2001

Mr. Patrice Luneau  
General Director  
Luneau S.A.  
B. P. 252, 28005 Chartres  
France

Dear Mr. Luneau:

During the Food and Drug Administration's (FDA) inspection of your firm, Luneau Gynecologic S.A. at 1 Avenue De Malaguet, Prunay Le Gillon, France, from June 18-21, 2001, our investigator determined that your firm manufactures optometry products, sterile disposable curettes, and obstetric examination chairs. These products are devices within the meaning of Section 201(h) of the Federal Food, Drug, and Cosmetic Act (the Act).

The above-stated inspection revealed that these devices are adulterated, in that the methods used in, or the facilities or controls used for the manufacture, packaging, storage, or installation are not in conformance with the Quality System Regulations, as specified in Title 21, Code of Federal Regulations (21 CFR), Part 820, as follows:

1. Failure to validate a process with a high degree of assurance where the results of the process cannot be fully verified by subsequent inspection and test, as required by 21 CFR § 820.75(a). For example:
  - a.) The validation study of the radiation sterilization process is inadequate in that it does not demonstrate that the recommended dose of 25 kGy will be effective in achieving a SAL of  $10^{-6}$  for your [REDACTED]. We agree that biological indicators are not required during the validation of a radiation sterilization process as discussed at the close of the inspection. However, we disagree with your belief, as reported by our investigator, that the objective of a sterilization study is to determine whether sterilization process has had an adverse effect on the device. Finished product performance testing is only one aspect of validating the sterilization process. Although historically, 25 kGy has been established as an efficient sterility dose, you must conduct a study in accordance with an established protocol, to show that your product can be effectively sterilized with that recommended dose. There is no documented evidence that such a study was performed.

b.) You did not validate the injection molding process including its regrinding procedure to assure that regrinding materials do not adversely effect the device's ability to meet all of its specifications, (i.e. purity, strength, flexibility, hardness). This observation was noted on the previous inspection but was not corrected as promised.

2. 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's [REDACTED] is computer-controlled. It uses software programs to record data from measurements of the radius of curvature and corneal refraction of the eye. However, your firm has not validated the software and computer system used to record this data for its intended uses. Your firm has no documentation to assure that they perform as intended. Also, there is no validation and documentation of subsequent changes to the software.

3. Failure to establish and maintain complaint handling procedures that ensure that all complaints are evaluated to determine whether a complaint represents an event which is required to be reported to FDA under Medical Device Reporting (MDR), as required by 21 CFR § 820.198(a)(3). For example, your complaint handling procedures entitled, "LIFE 065/05" are incomplete in that they do not include a requirement for making an MDR filing determination.

We acknowledge that a pen correction to the procedure to include making an MDR determination was made during the inspection and verified by the investigator. Please provide a copy of the revised procedure.

4. Failure to review and evaluate all complaints to determine whether an investigation is necessary as required by 21 CFR § 820.198(b). For example, complaint handling procedures do not require the review of post sales customer service and repair records for complaints, including out of box failures.

We acknowledge that you have made a correction to the procedure to include review of post sale customer service and repair records. Please provide a copy of the revised procedure.

5. Quality audits are inadequate 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. For example, your firm's quality audits did not document or justify your failure to validate the [REDACTED] software and the injection molding process.

As a manufacturer of medical devices, you are obligated to meet the requirements of the Medical Device Reporting (MDR) regulation of 21 CFR, Parts 803 and 804. The inspection revealed the following violations of 21 CFR § 803 of the MDR Regulation:

1. Failure to develop, maintain, and implement MDR procedures as required by 21 CFR § 803.17. Specifically, You have not established MDR procedures to ensure compliance with any of the requirements of MDR, Parts 803 or 804 which includes a standardized review process for identification, communication, and evaluation of events which meets the criteria for reporting.
2. Failure to establish and maintain MDR event files, as required by 21 CFR § 803.18. You do not have an MDR file, which is prominently identified as such, where MDR reportable events are maintained.

Also, during the FDA inspection it was discovered that electronic records are used to establish portions of your design output, 21 CFR § 820.30(d). However, there is no documentation to establish that these records meet the requirements of 21 CFR Part 11, Electronic Records; Electronic Signatures. The requirements of 21 CFR Part 11 are designed to ensure that electronic records are trustworthy, reliable, and generally equivalent to paper records.

For example, drawing [REDACTED] + [REDACTED] collection set is considered an electronic record. There is no documentation to establish that the system by which these records were produced has been properly validated. There is no ability to generate accurate and complete copies of records in human readable and electronic form. There is no protection of records to enable their accurate and ready retrieval. Access to your system has not been limited and there are other significant deficiencies as well. We strongly encourage you to perform a thorough and complete evaluation of all your electronic records in accordance with 21 CFR Part 11 as well as any guidance generated by the FDA to assure conformance to our requirements. Do not limit your evaluation solely to the example cited above. Only electronic records and electronic signatures that meet part 11 requirements may be used to satisfy record and signature requirements of 21 CFR §820.30(d), Design Output.

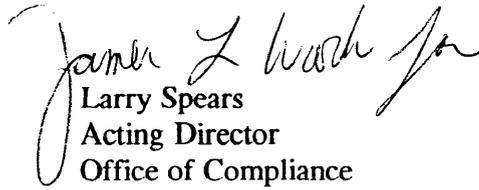
This letter is not intended to be an all-inclusive list of deficiencies at your facility. It is your responsibility to ensure adherence to each requirement of the Act and regulations. The specific violations noted in this letter and in the FDA 483 issued at the close of the inspection may be symptomatic 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. 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.

Please address your response and any questions to Paul F. Tilton, Chief, OB/GYN, Gastroenterology and Urology Branch, at the letterhead address. Should you require any assistance in understanding the contents of this letter, do not hesitate to contact Ms. Sharon Murrain-Ellerbe at the letterhead address or at (301) 594-4616 or FAX (301)594-4638.

Sincerely yours,

  
Larry Spears  
Acting Director  
Office of Compliance  
Center for Devices and  
Radiological Health