EUROMI S.A. 6/22/15

Department of Health and Human Services

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

WARNING LETTER
JUN 22, 2015

VIA UNITED PARCEL SERVICE

Marc Dauvister
Managing Director
Euromi S.A.
Z.I. De Lambermont
151, Rue Des Ormes
4800 Verviers
Belgium

Dear Mr. Dauvister:

During an inspection of your firm located in Verviers, Belgium on January 12, 2015, through January 15, 2015, an investigator from the United States Food and Drug Administration (FDA) determined that your firm manufactures the EVA Sp Liposuction System. 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.

Your firm 's response to the Form FDA 483 (FDA 483), dated April 29, 2015, was not reviewed because it was not received within fifteen business days of issuance of the FDA 483. The response will be evaluated along with any other written material provided in response to the violations cited in this Warning Letter. These violations include, but are not limited to, the following:

1. 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. For example, your firm's contract sterilizer, **(b)(4)**, has not validated the sterilization of the disposable tubing sets used with the EVA Sp6 liposuction device.

2. 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). For example:

a. Your firm's procedure, "**(b)(4)**," does not include requirements to ensure that:

i. Complaints are processed in a uniform and timely manner;

ii. Oral complaints are documented upon receipt;

iii. Complaint investigation records include the name of the device, the date the complaint was received, any device identifications, the name, address, and phone number of the complainant, the dates and results of the investigation, and any reply to the complainant;

iv. When no investigation is made, the manufacturer maintains a record that includes the reason no investigation was made and the name of the individual responsible for the decision not to investigation; and

v. Complaints are evaluated for MDR reportability.

b. Complaint files 105 and 132, representing events where tips of cannulas broke and remained lodged in patients, were not investigated and evaluated for MDR reportability.

3. Failure to establish and maintain procedures for implementing corrective and preventive action, as required by 21 CFR 820.100(a). For example:

a. Your firm's "Corrective Actions/Preventive Actions" procedure does not include requirements for:

i. Analyzing quality data to identify existing and potential causes of nonconforming product or other quality problems, using appropriate statistical methodology, where necessary; and

ii. Verifying and validating corrective and preventive actions to ensure such actions are effective and do not adversely affect the finished devices.

b. CAPA files for complaints 105 and 132, regarding cannulae breaking and fragments remaining in the patient, did not identify corrective or preventive actions.

c. The CAPA file for nonconformance 108 (for bending problems on 2.0 mm and 2.5 mm infiltration cannulas), did not identify the batch records of the device used for testing, or a statistical rationale for testing **(b)(4)** for a wall thickness evaluation. Additionally, your firm did not verify or validate that the corrective actions were effective.

4. Failure to establish and maintain procedures for validating the device design, as required by 21 CFR 820.30(g). For example:

a. Your firm's "Conception and Development" procedure does not include requirements to ensure that:

i. Devices conform to defined user needs and intended uses, and to include testing of production units under actual or simulated use conditions.

ii. Acceptance criteria are established prior to performance of validation activities.

b. The model used in design validation testing, the design validation test methods, and the acceptance criteria were not recorded in the "**(b)(4)**" for the EVA Sp6 liposuction device design project.

5. Failure to establish and maintain procedures to control product that does not conform to specified requirements, as required by 21 CFR 820.90(a). For example, your firm's "Corrective Actions/Preventive Actions" procedure does not include requirements that address the identification, documentation, evaluation, segregation, and disposition of nonconforming product as well as rework requirements.

Specifically, the identification, investigation, and disposition of affected devices were not documented for nonconforming cannulas described in Nonconformance **(b)(4)**.

6. Failure to ensure that all inspection, measuring, and test equipment, including mechanical, automated, or electronic inspection and test equipment, is suitable for its intended purposes and is capable of producing valid results, as required by 21 CFR 820.72(a). For example:

a. Your firm's calibration procedure, "**(b)(4)**," does not include requirements which ensure that all applicable inspection, measuring, and test equipment is capable of producing valid results.

b. The **(b)(4)** used to test PCB boards, and the tester used to test cannula flow, contain measuring devices which have not been calibrated or checked to ensure the test equipment is capable of producing valid results.

7. Failure to establish and maintain procedures for verifying the device design, as required by 21 CFR 820.30(f). For example, in testing for the Sp6 design project:

a. The identification of the software version and **(b)(4)** versions installed in the prototype were not adequately identified in electromagnetic compatibility (EMC) and ISO 60601 testing.

b. No production records were available for the prototype used in the verification testing.

c. No design verification test results were available for the in house testing conducted by your firm on the prototype.

8. Failure to establish and maintain procedures to ensure that formal documented reviews of the design results are planned and conducted at appropriate stages of the device's design development, as required by 21 CFR 820.30(e). For example:

a. Your firm's procedures "**(b)(4)**," do not include requirements to ensure that:

i. Participants at each design review include representatives of all functions concerned with the design stage being reviewed;

ii. An individual who does not have responsibility for the design stage being reviewed as well as any specialists needed; and

iii. Design review results are documented in the DHF.

b. Additionally, there was no documentation of attendees or identification of design

records for design reviews related to the EVA Sp6 design project.

9. Failure to establish and maintain procedures to control all documents that are required by 21 CFR 820, as required by 21 CFR 820.40. For example, "**(b)(4)**" does not include requirements to ensure that all obsolete documents are promptly removed from all points of use or otherwise prevented from unintended use, and that documentation includes approval dates and signatures. Specifically:

a. Obsolete versions of procedures were printed and not identified as obsolete; and

b. The approval of "**(b)(4)**" by the responsible person and the Director were not documented, as required by the procedure.

10. Failure to establish and maintain procedures to control labeling activities, as required by 21 CFR 820.120. For example:

a. Your firm's labeling control procedures do not include requirements to ensure that:

i. Labeling has been examined for accuracy by a designated individual prior to storage or use;

ii. The release of labeling is documented; and

iii. Labeling/packaging operations are controlled to prevent labeling mixups.

b. Batch history records for the EVA Sp6 1402217, EVA Sp1 1403306, and Cannulas 14ADHA423 did not include the primary identification labeling or the review and approval of labeling.

11. 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. For example, your firm's "Quality Audit" procedures do not include requirements that:

a. Define which quality system areas are to be audited; and

b. Ensure that auditors are independent of the areas being audited.

Our inspection also revealed that the EVA Sp Liposuction System is misbranded under Section 502(t)(2) of the Act, 21 U.S.C. § 352(t)(2), in that your firm failed or refused to furnish material or information regarding the devices that is required by or under Section 519 of the Act, 21 U.S.C. § 360i, and 21 CFR Part 803 - Medical

Device Reporting. Significant deviations include, but are not limited to:

12. Failure to adequately develop, maintain, and implement written MDR procedures, as required by 21 CFR 803.17. For example, after reviewing your firm's MDR procedure, titled "**(b)(4)**", Ref: Copy (1,) **(b)(4)**, dated 2/19/2014, the following issues were noted:

a. "**(b)(4)** does not establish internal systems that provide for timely and effective identification, communication, and evaluation of events that may be subject to MDR requirements. For example, there are no definitions of what your firm will consider to be a reportable event under 21 CFR Part 803. The exclusion of definitions from 21 CFR 803.3 for the terms "become aware," "caused or contributed," "malfunction," "MDR reportable event," and "serious injury," and the definition for the term "reasonably suggests," found in 803.20(c)(1) may lead your firm to make an incorrect reportability decision when evaluating a complaint that may meet the criteria for reporting under 21 CFR 803.50(a).

b. "**(b)(4)** does not establish internal systems that provide for timely transmission of complete medical device reports. Specifically, the following are not addressed:

i. The procedure does not contain or refer to instructions for how to obtain and c;:omplete the FDA 3500A form.

ii. The circumstances under which your firm must submit supplemental report and the requirements for such reports.

iii. How your firm will submit all information reasonably known to it for each event.

iv. The procedure does not include the address for where to submit MDR reports: FDA, CDRH, Medical Device Reporting, P.O. Box 3002, Rockville, MD 20847-3002.

c. "**(b)(4)** does not describe how your firm will address documentation and record-keeping requirements, including:

i. Documentation of adverse event related information maintained as MDR event files.

ii. Information that was evaluated to determine if an event was reportable.

iii. Documentation of the deliberations and decision-making processes used to determine if a device-related death, serious injury, or malfunction was or was not reportable.

iv. Systems that ensure access to information that facilitates timely follow-up and inspection by FDA.

The eMDR Final Rule requiring manufacturers and importers to submit electronic Medical Device Reports (eMDRs) to FDA was published on February 13, 2014. The requirements of this final rule will take effect on August 14, 2015. If your firm is not currently submitting reports electronically, we encourage you to visit the following web link for additional information about the electronic reporting requirements:

http://www.fda.gov/ForIndustry/FDAeSubmitter/ucm107903.htm

If your firm wishes to discuss MDR reportability criteria or to schedule further communications, it may contact the Reportability Review Team by email at ReportabilityReviewTeam@fda.hhs.gov

Given the serious nature of the violations of the Act, EVA Sp Liposuction devices manufactured by your firm are subject to refusal of admission under section 801 (a) of the Act, 21 U.S.C. § 381 (a), in that they appear to be adulterated. As a result, FDA is taking steps to refuse entry of these devices into the United States, known as "detention without physical examination," until these violations are corrected. In order to remove the devices from detention, your firm should provide a written response to this Warning Letter as described below and correct the violations described in this letter. We will notify you regarding the adequacy of your firm's response and the need to re-inspect your firm's facility to verify that the appropriate corrections and/or corrective actions have been made.

Also, 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.

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 actions (which must address systemic problems) 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 Inspections Support Branch, White Oak Building 66, Rm 2622, 10903 New Hampshire Ave., Silver Spring, MD 20993. Refer to CMS case #456931 when replying. If you have any questions about the contents of this letter, please contact: Mr. Daniel Walter, Branch Chief, Foreign Enforcement Branch, at 301-796-5587 (telephone) or 301-847-8139 (fax).

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/
Jan B. Welch, MHS, MT (ASCP) SBB
Acting Director
Office of Compliance
Center for Devices and
Radiological Health

- FDA Archive
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