U.S. Food and Drug Administration
Protecting and Promoting *Your* Health

F.P. Rubinstein Y Cia SRL 5/5/16

Department of Health and Human Services

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

WARNING LETTER
MAY 5, 2016

VIA UNITED PARCEL SERVICE

Federico Rubinstein
Director
F.P. Rubinstein Y Cia SRL
Calle David Luque 519
X5004AKM Cordoba
Argentina

Dear Mr. Rubinstein:

During an inspection of your firm located in Cordoba, Argentina, on December 14, 2015, through December 17, 2015, an investigator from the United States Food and Drug Administration (FDA) determined that your firm manufactures laser powered surgical instruments. 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 for implementing corrective and preventive action (CAPA), as required by 21 CFR 820.100(a). For example:

a. CAPA **(b)(4)** , opened to address the lack of validation records for **(b)(4)**, is incomplete. Your firm closed this CAPA without performing validation of the **(b)(4)**.

b. CAPA **(b)(4)** was opened because a **(b)(4)**). One correction was to update the **(b)(4)**. However, your firm has not validated the change in the **(b)(4)**.

This is a repeat observation from the inspection ending in October 17, 2014.

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. Complaint cases 001-00003023 and 001-00003542, associated with patients burnt due to high voltage output related to circuit board failures, do not include adequate complaint investigations. Specifically, your **(b)(4)** the circuit board failures. However, no investigation into the potential causes of circuit board failures occurred.

b. Eight out of eight complaints sampled by the investigator do not include MDR evaluations.

c. Four complaints do not have the phone number of the complainant or the description of the complaint.

This is a repeat observation from the inspection ending in October 17, 2014.

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

a. Your firm has not performed software validation **(b)(4)**. These programs are used in the Starlight laser product family.

b. The software validation for **(b)(4)** is inadequate, in that the **(b)(4)**. This message occurs when either the maximum voltage (6V) is exceeded, or the actual voltage is higher than the reference voltage associated with the intensity selected by the operator.

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

a. The verification test for radiation emission does not confirm that design outputs meet design inputs. The verification test for radiation emission from IEC 60601-1-2:2007 for the Starlight laser powered surgical instrument did not pass.

b. No verification testing is performed on packaging to ensure the Starlight lasers can withstand stresses encountered during shipping. Several complaints associated with printed circuit board failures shortly after the customer received the product are related to shipping damage.

5. Failure to ensure that where the results of a process cannot be fully verified by subsequent inspection and test, the process shall be validated with a high degree of assurance and approved according to established procedures, as required by 21 CFR 820.75(a). For example, your firm does not have process validation procedures. Additionally, your firm has not validated the process for **(b)(4)**, used when these supplied parts need rework.

6. 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 has not validated the following software used in its quality system:

a. **(b)(4)**, used for complaint handling;
b. **(b)(4)**, used for complaint handling by your firm's sales force; and
c. **(b)(4)**, used for data analysis.

7. Failure to establish and maintain procedures to control environmental conditions, where they could reasonably be expected to have an adverse effect on product quality, as required by 21 CFR 820.70(c). For example, operators are not wearing **(b)(4)**.

8. 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:

a. Your firm has not documented the qualifications of its suppliers, consultants, or contractors.

b. Your firm's approved supplier list does not include three contractors/consultants used for software development and internal audits.

c. The approved supplier list lacks revision numbers, dates, and signatures.

9. 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, your firm's procedures require measuring equipment to be calibrated annually. However, your firm could no provide calibration records for two pieces of measuring equipment **(b)(4)**.

This is a repeat observation from the inspection ending in October 17, 2014.

10. Failure 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 21 CFR 820 and the manufacturer's established quality policy and objectives, as required by 21 CFR 820.20(c). For example, management with executive responsibility did not attend the management review meeting in 2015.

11. Failure to maintain device history records (DHRs), as required by 21 CFR 820.184. For example, DHRs for the Starlight laser powered surgical instrument do not show that the device is manufactured in accordance with the Device Master Record:

a. Documentation of circuit board testing for **(b)(4)** includes quality results **(b)(4)**. This finding affects **(b)(4)** DHRs total, including **(b)(4)**.

b. DHRs do not include primary identification labeling.

This is a repeat observation from the inspection ending in October 17, 2014.

In addition, FDA has noted nonconformances with regards to Subchapter C of the Act, Electronic Product Radiation Control, the requirements at 21 CFR 1000-1005, and the performance standards at 21 CFR 1010, 1040.10, and 1040.11. These nonconformanes include, but are not limited to, the following:

12. Failure to classify the laser product, as required by 21 CFR 1040.10(c). For example, the Starlight label states Class Ill but this classification is according to UNE-EN60601-2-57 2012. Your firm's Technical Director indicated that the classification is Class IV. There is no documentation on how your firm determined the product to be Class Ill.

13. Failure to affix to each laser the Warning logotype label, as required by 21 CFR 1040.10(g). For example, each Class IV laser product does not have affixed a label bearing the DANGER logotype specified in the regulation and bearing the wording "LASER RADIATION - AVOID EYE OR SKIN EXPOSURE TO DIRECT OR SCATTERED RADIATION" in the position specified in the regulation and bearing the wording "CLASS IV LASER PRODUCT" in the position specified in the regulation.

14. Failure to submit Annual reports for each year, as required by 21 CFR 1002.13. For example, your firm has not submitted Annual reports for 2013-2014 or 2014-2015.

15. Failure to submit Product reports for the Starlight dermatology laser prior to introduction into U.S. commerce, as required by 21 CFR 1002.10. For example, your firm has not submitted a Product report for the Starlight laser but shipped products.

Given the serious nature of the violations of the Act, the devices manufactured by your firm, including the laser powered surgical instruments, 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 responses 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 Ill 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, Room 3540, 10903 New Hampshire Ave., Silver Spring, MD 20993. Refer to CMS case #491271 when replying. If you have any questions about the contents of this letter, please contact Daniel Walter, Chief, Foreign Enforcement Branch, at feb@fda.hhs.gov (email), +1 (240) 402-4020 (telephone), or +1(301) 847-8138 (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 your,
/S/
Robin W. Newman
Office Director
Office of Compliance
Center for Devices and
Radiological Health

More in 2016 (/ICECI/EnforcementActions/WarningLetters/2016/default.htm)