Grams Medical Inc. 3/17/16

Department of Health and Human Services

Public Health Service
Food and Drug Administration
Los Angeles District
19701 Fairchild
Irvine, California 92612-2506
Telephone (949) 608-2900
Fax (949) 608-4415

VIA UNITED PARCEL SERVICE
SIGNATURE REQUIRED

March 17, 2016

WL # 24-16

Mr. Guenter A. Grams, Owner
Grams Medical Products
2443 Norse Avenue
Costa Mesa, California 92627

Dear Mr. Grams:

During the inspection of Grams Medical Products, Inc., located in Costa Mesa, California, conducted from September 14 through September 25, 2015, an investigator from the United States Food and Drug Administration (FDA) determined that your firm manufactures the Grams Aspirator S-300. Under section 201(h) of the

Federal Food, Drug, and Cosmetic Act (the Act), 21 U.S.C. § 321(h), this product is a device because it is 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 any function of the body.

This inspection revealed that your 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.

Our investigator issued the Form FDA483, List of Inspectional Observations, to you at the conclusion of the inspection on September 25, 2015. The violations listed on the Form FDA483 include, but are not limited to, the following:

1) Failure to adequately validate a process whose results cannot be fully verified by subsequent inspection and test according to established procedures, as required by 21 CFR 820.75(a).

For example, your firm has not validated a cleaning and sterilization process for the reusable cannula tips used in conjunction with the Grams Aspirator S-300. These tips are stored, unwrapped in open wooden bins in a packaging and shipping room. No baseline bioburden has been established for these cannula tips, no studies have been performed to ensure specific sterilization processes will not adversely affect these tips, and no cleaning or sterilization processes have been validated to ensure sterility of these tips before they are used in an operative setting, or to ensure their sterility after use in an operative setting, and prior to their being re-used.

2) Failure to adequately maintain a device master record, as required by 21 CFR 820.181.

For example, you did not maintain documentation of device specifications, component specifications, production process specifications, production methods and procedures, production environment specifications, quality assurance equipment, procedures and specifications including acceptance criteria, packaging and labeling instructions for the Grams Aspirator S-300 devices and their accessories.

3) Failure to establish procedures for device history records, as required by 21 CFR 820.184.

For example, you did not establish procedures to ensure that device history records were maintained to demonstrate that the devices are manufactured in accordance with an established device master record and 21 CFR 820.

4) Failure of management with executive responsibility to review the suitability and effectiveness of the quality system at defined intervals and with sufficient frequency, as required by 21 CFR 820.20(c).

For example, your Quality Manual, FSP-14, Revision A requires annual management reviews of the quality system. Your firm has not performed any management reviews.

5) Failure to perform quality audits at defined intervals and at sufficient frequency to determine whether the quality system activities and results comply with quality system procedures, as required by 21 CFR 820.22.

For example, your firm's quality manual Quality Manual, FSP-14, Revision A, references that internal audits are to be conducted and documented. The frequency and/or intervals are not defined, and your firm has not performed any quality audits.

Our inspection also revealed that the Grams Aspirator S-300is 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:

6) Failure to develop, maintain and implement written MDR procedures, as required by 21 CFR 803.17. Your firm has not developed an MDR procedure.

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 were effective 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.

Your firm should take prompt action to correct the violations addressed in this letter. Failure to promptly correct these violations may result in regulatory action being initiated by the FDA without further notice. These actions include, but are not limited to, seizure, injunction, and civil money penalties. Also, 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 violations 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, as well as 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 (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. Your firm's response should be comprehensive and address all violations included in this Warning Letter. Include special identifier FEI: 2021743 on all correspondence.

Your response should be sent to:

CAPT Daniel Cline
Acting Director, Compliance Branch
Food and Drug Administration
19701 Fairchild
Irvine, CA 92612-2506

If you have any questions about the content of this letter please contact: Dr. William Vitale, Compliance Officer at 949-608-2919.

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,
/S/
Steven Porter
Acting District Director
Los Angeles District

Cc:

David M. Mazzera, Ph.D.
Chief, Food and Drug Branch
California Department of Public Health
Food and Drug Branch
1500 Capitol Avenue, MS-7602
Sacramento, CA 95899-7413

More in 2016

Page Last Updated: 05/02/2016
Note: If you need help accessing information in different file formats, see Instructions for Downloading Viewers and Players.

U.S. Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993
1-888-INFO-FDA (1-888-463-6332)

Contact FDA