-

Nevyas Eye Associates 6/5/12

Department of Health and Human Services

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

June 5, 2012

WARNING LETTER

VIA UNITED PARCEL SERVICE

Herbert J. Nevyas, M.D.
Medical Director
Nevyas Eye Associates
Two Bala Plaza PL-33
333 E. City Avenue
Bala Cynwyd, Pennsylvania 19004-1501

Dear Dr. Nevyas:

During an inspection of your firm located in Bala Cynwyd, Pennsylvania, on March 19-28, 2012, an investigator from the United States Food and Drug Administration (FDA) determined that your firm is a medical device user facility that is subject to the statutory reporting requirements of the Medical Device Reporting (MDR) regulation, found at Title 21, Code of Federal Regulations (CFR), Part 803.

The ophthalmic laser used at your facility to perform Laser-Assisted In Situ Keratomileusis procedures is a medical device under Section 201(h) of the Federal Food, Drug, and Cosmetic Act (the Act), 21 U.S.C. § 321(h), because it is intended for the 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.

Our inspection revealed that this device is misbranded under section 502(t)(2) of the Act, 21 U.S.D. § 352(t)(2), in that your firm failed or refused to furnish material or information respecting the device 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 violations include, but are not limited to, the following:

Failure to develop, maintain, and implement written MDR procedures, as required by 21 CFR 803.17. For example, the investigator asked the medical director and refractory consultants if the facility had written MDR procedures and they confirmed that they did not and did not know what events would be considered serious injuries and reportable to manufacturers. The investigator reviewed some of the adverse events identified in the assignment guidance with them and they confirmed that these types of events have occurred at their facility. They explained that they inform their patients through the consenting process that they may have vision-threatening complications following the surgery.

We reviewed your firm's response dated April 2, 2012, and concluded that it is not adequate because it did not include a copy of your firm's MDR procedures.

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.

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.

Your firm's response should be sent to: Food and Drug Administration, Center for Devices and Radiological Health, Office of Surveillance and Biometrics, MDR Policy Branch, White Oak Building 66, 10903 New Hampshire Avenue, Room 3208, Silver Spring, Maryland 20993. Refer to the Unique Identification Number #306398 when replying. If you have any questions about

the contents of this letter or wish to discuss MDR reportability criteria or schedule further communications, please contact: MDR Policy Branch at (301) 796-6670 or by email at MDRPolicy@fda.hhs.gov.

Finally, you should know that this letter is not intended to be an all-inclusive list of the violations at your firm. 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, Form FDA 483, issued at the close of the inspection, may be symptomatic of serious problems in your firm. Your firm should investigate and determine the causes of the violations and take prompt actions to correct the violations and bring the device into compliance.

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

Links on this page:

Page Last Updated: 06/22/2012
Note: If you need help accessing information in different file formats, see Instructions for Downloading Viewers and Players.