DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

DEC 1 8 2012

WARNING LETTER

Edward C. Wade, M.D.
Partner and Co-Founder
Eye Center of Texas
6565 W. Loop S.
Suite 650
Bellaire, Texas 77401

Dear Dr. Wade:

The Food and Drug Administration (FDA) has learned that the Eye Center of Texas is promoting on its website (www.eyecenteroftexas.com) the VISX laser in violation of the Federal Food, Drug, and Cosmetic Act (the Act). This excimer laser is a device within the meaning of section 201(h) of the Act, 21 U.S.C. § 321(h), 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. As described below, the Eye Center of Texas' promotion of the VISX laser misbrands the device under sections 502(a) and (q) of the Act, 21 U.S.C. §§ 352(a) and (q).

Lasers, such as the VISX laser, that are used in refractive procedures are restricted devices pursuant to section 515(d)(1)(B)(ii) of the Act, 21 U.S.C. § 360e(d)(1)(B)(ii). Section 502(a) of the Act provides that a device is misbranded if its labeling is false or misleading in any particular. Section 502(q) of the Act provides that a restricted device is misbranded if its advertising is false or misleading in any particular. According to section 201(n) of the Act, 21 U.S.C. § 321(n), in determining whether a device's labeling or advertising is misleading, the extent to which the labeling or advertising fails to reveal material facts, including the consequences which may result from the use of the device, must be taken into account.[1] It is a prohibited act under section 301(k) of the Act, 21

[1] On September 23, 2011, FDA issued a letter to eye care professionals regarding the promotion and advertising of FDA-approved lasers used during refractive procedures, including LASIK. *See* http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/SurgeryandLifeSupport/LASIK/ucm272960.htm. In this letter, FDA emphasized the importance of providing adequate risk information in the advertising and promotion of FDA-approved

U.S.C. § 331(k), to do any act with respect to a device, if such act is done while the device is held for sale after shipment in interstate commerce, and results in the device being adulterated or misbranded.[2]

The Eye Center of Texas's webpage entitled "Lasik FAQ," available at http://www.eyecenteroftexas.com, states:

> More Lasik procedures have been done with this VISX CustomVue laser than any other in the US. It is the only laser that uses the advanced CustomVue treatment to allow for Custom Lasik vision correction with measurement precision 25 times greater than conventional Lasik. It has an eye tracker that follows the eye during the Lasik procedure eliminating problems associated with eye movements during the treatment. It is the only laser that tracks the eye in all three dimensions and the only laser that adjusts for the rotation of the eye when people lie down using advanced iris registration technology.

Moreover, the website states:

> **What are the side effects?**
> The most common side effects are dry eyes, a "halo" effect, and some glare at night around lights. However, these problems are no worse than what most contact lens and eyeglass wearers often experience and usually diminish or disappear within 4-6 months of surgery.

However, the Eye Center of Texas' website is misleading because it minimizes and fails to reveal material facts, including relevant risk information associated with the use of the VISX laser. While dry eye syndrome, halos, and glare are risks associated with the VISX laser, the website minimizes these risks by failing to disclose that these symptoms may be severe or debilitating and may persist long term, and by claiming, without adequate substantiation, that these risks are no worse than those associated with glasses or contact

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lasers used in refractive procedures and directed eye care professionals to additional relevant information. As explained in the letter, lasers used in refractive procedures are restricted devices and are misbranded under the Act if their labeling or advertising is false or misleading. FDA also issued letters to the American Society of Cataract and Refractive Surgery and the American Academy of Ophthalmology. *See* http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/SurgeryandLifeSupport/LASIK/ucm297512.htm; http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/SurgeryandLifeSupport/LASIK/ucm297514.htm.

[2] A clinic's use of a device in patient treatment constitutes "holding for sale." *See, e.g., United States v. Diapulse Corp. of Am.*, 514 F.2d 1097, 1098 (2d Cir. 1975).

lenses. The website also omits other important risk information such as the possible need for glasses or contact lenses after surgery and the risk of loss of vision.

It is critical to disclose risk information appropriately and effectively to consumers in all advertising and labeling concerning a restricted device such as the VISX laser. Risk information may include contraindications, warnings, precautions, and adverse events. FDA has available on its website background and risk information that may be helpful when developing advertisements and promotional materials concerning FDA-approved lasers used in LASIK procedures. *See* http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/SurgeryandLifeSupport/LASIK/default.htm. The approved labeling for each laser approved for LASIK, including the VISX laser (P930016 and P990010), can be found at http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/SurgeryandLifeSupport/LASIK/ucm192109.htm. In addition, information on the most common risks associated with refractive lasers intended for LASIK procedures is available at FDA's LASIK website at http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/SurgeryandLifeSupport/LASIK/ucm061354.htm. As noted on that website, common risks include the risks of dry eye syndrome, which can be severe; the possible need for glasses or contact lenses after surgery; visual symptoms including halos, glare, starbursts, and double vision, which can be debilitating; and the loss of vision.

FDA requests that the Eye Center of Texas immediately cease promoting the VISX laser in violation of the Act. The 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 FDA without further notice. These actions may include, but are not limited to, seizure, injunction, and civil money penalties.

Please notify this office in writing within fifteen business days from the date that you receive this letter of the specific steps that 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 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 sent to:

Toni Stifano
Food and Drug Administration
Center for Devices and Radiological Health
Office of Compliance
10903 New Hampshire Avenue
WO66-3654
Silver Spring, MD 20993

Finally, you should know that this letter is not intended to be an all-inclusive list of the firm's violations. It is your firm's responsibility to ensure compliance with applicable laws and regulations administered by FDA.

Sincerely yours,

Steven Silverman
Director
Office of Compliance
Center for Devices and
Radiological Health