

During the inspection, Mr. Stokes also discussed with you the need to have advertisements related to your IDE study approved by the reviewing IRB. A transcript of a radio advertisement that had aired for several weeks was included with the inspection report (copy enclosed). This advertisement refers to laser vision correction at the Delaware Valley Laser Surgery Institute. According to Mr. Stokes, the only laser at your Bala Cynwyd office used for refractive surgery is your IDE laser. While your Marlton, New Jersey site has a Summit laser, the advertisement does not specify a location. Future advertisements should specify the location(s) of approved lasers, as the enclosed advertisement would not be appropriate for soliciting subjects for your IDE study. All promotional materials designed to solicit participants or to inform subjects about the IDE study need to be approved by the reviewing IRB.

No further response is necessary. For further information concerning the Bioresearch Monitoring program, please visit our internet homepage at <http://www.fda.gov/cdrh/comp/bimo.html>. Valuable links to related information are included at this site. If you have any questions, feel free to contact Jean Toth-Allen, Ph.D. at (301) 594-4723, ext. 141.

Sincerely yours,



Viola Sellman

Chief

Program Enforcement Branch II  
Division of Bioresearch Monitoring  
Office of Compliance  
Center for Devices and  
Radiological Health

Enclosure