LASIK, bilateral surgery, and treatment of astigmatism or greater degrees of myopia have not currently been supported by the data, the agency is aware that practitioners are engaging in these off-label uses with their patients. Although the term "practice of medicine" covers discussions and decisions between the practitioner and the patient, it does not allow the advertising of the device for such off-label uses. The agency believes that the best data and protection of patients are achieved when these unapproved uses are studied under an FDA approved investigational device exemption.

The agency is aware of and is currently investigating unapproved lasers manufactured as one-of-a-kind by the owner, by someone else for the owner, or by a corporate entity. Practitioners who use these lasers are not operating within the legal requirements of the Federal Food, Drug, and Cosmetic Act (the act) unless they have an IDE that has been submitted to and approved by the agency. Also the IDE regulations (21 CFR Part 812; based in Part 50; and Part 56 of the act) mandate that human subjects must not be used in clinical investigations without their knowledge and consent. A grace period will be given to owners of these unapproved lasers to identify themselves to FDA, to obtain information about the IDE application process, and to submit an IDE application to FDA. These IDE applications must be submitted with an investigational plan adequate to generate data for submission in a PMA for an FDA determination of reasonable assurance of safety and effectiveness for the laser.

Additionally, FDA is also aware of the importation of lasers for use in refractive surgery which have characteristics different from those specified in the PMAs approved by FDA. Owners of imported lasers originally manufactured by the holder of a PMA approved by the FDA have two choices. The first option is for the owner of such a laser to submit certification to FDA that the imported laser is identical in all relevant aspects to the approved ones, e.g., ablation zone size, software, calibration, and labeling. The alternative is to submit an IDE application for a clinical trial for these unapproved investigational devices. Owners of imported lasers who choose to submit certification should do so quickly. If FDA determines that the owner's certification is inadequate, then the owner will have to submit an IDE application to FDA before this deadline of January 15, 1997.

Please note that an IDE application should be submitted to FDA by January 15, 1997 to take advantage of the enforcement grace period. We, therefore, advise all potential applicants to identify themselves to FDA as soon as possible. If you are the owner of an investigational laser for refractive correction without an IDE application approved by FDA, please call our Division of Small Manufacturers Assistance at 1-301-443-6597 or 1-800-638-2041. FDA has information to send to you on how to file an IDE application and on what technical and scientific information you should submit in your application for an IDE study of lasers for refractive correction. You may choose to submit your IDE application as an individual, or you may choose to submit your application jointly with others who own comparable lasers under a single sponsorship. A one day training session will take place on both November 14 and 15, 1996 for those who wish to submit an IDE and require further assistance. Similarly, if you are an owner of an imported laser and wish to submit a cerification for your laser which may include third-party engineering certification, please call our Division of Small Manufacturers Assistance at the number(s) above to obtain additional information on certification. As with the IDE application the deadline is January 15, 1997. Note: This information can also be obtained by accessing CDRH Facts-On-Demand at 1-800-899-0381.

In summary, the end of the grace period is January 15. 1997. After this deadline your laser may be used to treat patients only if adequately certified by you or, alternatively, you have submitted an IDE study to protect the health and rights of human subjects. The grace period does not apply to individuals who have received Warning Letters or other regulatory communications from the FDA or who are importers of lasers currently under detention.

We should like to thank you for your cooperation in this matter.

Sincerely yours.

Susan Alpert, Ph.D., M.D.
Director
Office of Device Evaluation

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