Accordingly, on July 28, 1997, we called you to notify you that use of your excimer laser to treat patients would violate the Act and requested that, if you are presently using the laser to treat patients, you immediately cease doing so. To enable FDA to complete its review of your IDE application, we also requested that you provide the agency with the following additional information: a written statement that, as of the close of business on July 28, 1997, you are not using your excimer laser system to treat patients. Please complete the enclosed statement and transmit it to:

Morris Waxler, Ph.D.
Food and Drug Administration
Center for Devices and Radiological Health
Office of Device Evaluation
Document Mail Center (HFZ401)
9200 Corporate Blvd.
Rockville, MD 20850

You may submit the statement by facsimile to (301) 480-4201, provided that you also send the original statement to the address above. This statement must be submitted within three (3) business days of the receipt of this letter.

You should be aware that FDA's regulations provide that an IDE application may be disapproved if "[t]here has been a failure to comply with any requirement of [21 C.F.R. Part 812] or the Act . . . ," 21 C.F.R. § 812.30(b)(1); thus, any previous use of an excimer laser system for which no PMA or IDE is in effect would be grounds for disapproval of an applicant's IDE. However, the agency, in an exercise of its enforcement discretion, does not intend to consider your previous use, if any, of such a device to be grounds for disapproval of your IDE. Nevertheless, FDA does intend to consider any use of your laser to treat patients after the close of business July 28, 1997 unless and until the agency approves an IDE for your device to be grounds for disapproval of your IDE. In addition, please note that failure to "respond to a request for additional information within the time prescribed by FDA" also would be grounds for disapproval of your IDE. 21 C.F.R. § 812.30(b)(3).

Furthermore, if you are, in fact, using an unapproved laser, failure to cease treating patients with the laser immediately also may result in regulatory action against you or the device by FDA without further notice. These actions include, but are not limited to, seizure, injunction, and civil money penalties.