DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

JUL 7 2011

Morris Waxler, Ph.D.
Waxler Regulatory Consultancy LLC
1920 Arlington Place
Madison, WI 53726-4002

Re: FDA-2011-P-0022

Dear Dr. Waxler:

I am writing to inform you that the Food and Drug Administration (FDA) has not yet resolved the issues raised in your petition filed on January 7, 2011, and referenced above. Your petition requests that the agency withdraw FDA approval for all LASIK devices and issue a Public Health Advisory with a voluntary recall of LASIK devices in an effort to stop permanent eye injury caused by lasers and microkeratomes used for LASIK eye surgery.

FDA has been unable to reach a decision on your petition because it raises issues requiring further review and analysis by agency officials. This interim response is provided in accordance with FDA regulations on citizen petitions (21 CFR 10.30(e)(2)). We will respond to your petition as soon as we have reached a decision on your request.

Sincerely,

Nancy Slade
Deputy Director for Policy
Center for Devices and
Radiological Health