DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

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

January 23, 2015

Dr. Morris Waxler
President
Waxler Regulatory Consultancy LLC
1920 Arlington Place
Madison, WI 53726-4002

Re: Reconsideration Petition – Docket Number FDA-2011-P-0022/PRC

Dear Dr. Waxler:

This is an interim response to your Reconsideration Petition dated July 22, 2014, filed by the Food and Drug Administration (FDA) on September 4, 2014. In the petition, you request FDA to reconsider its decision in the June 23, 2014 letter from Nancy K. Stade denying your Citizen Petition, FDA Docket No. FDA-2011-P-0022, in which you requested the Food and Drug Administration to withdraw PMA approvals for all LASIK excimer laser devices and to issue a public advisory with a voluntary recall of the devices.

FDA has been unable to reach a decision on your petition because it raises issues requiring further review and analysis by Agency officials. We will respond to your petition as soon as we have reached a decision on your request.

If you have any questions about this interim response, please contact John Maiers of our Regulations Staff at (301) 796-0343.

Sincerely yours,

William H. Maisel, MD, MPH
Deputy Director for Science
Center for Devices and
Radiological Health