DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

APR 30 2009

Mr.

The Center for Devices and Radiological Health (CDRH) has determined, from your internet web sites http://.com and http://.com that manufactures, assembles or distributes laser products and has introduced such products into commerce in the United States.

A review of the website leads us to believe the laser products offered for sale on this site may not be compliant with applicable provisions of the regulations of the Federal performance standard for laser products contained in 21 CFR 1002.1, 1040.10 and 1040.11. Please provide clarification for the following concerns and questions:

1. Specifications included on your internet web site for laser pointer products indicate they can be purchased with a power output ranging from greater than 5 mW to 250 mW. Specifically, these products are described as Blu-ray and Red Lasers and Laser kits. These laser products are surveying, leveling and alignment laser products. Part 21 CFR 1040.11(b) of the laser standard limits the maximum output power of surveying, leveling and alignment laser products to no more than 5 milliwatts (mW). These products exceed the Class IIIa power limit of 5 mW for laser products that are surveying, leveling and alignment laser products.

2. Our records failed to show that has submitted any laser product reports for these products. If they have been certified as Class IIIb laser products and reported by another manufacturer, identify that firm and provide the accession or reference number of the report(s) submitted for these products. If the original manufacturer private labels these units for provide the original manufacturers' model number and the corresponding model number for the units as sold by

Be advised that, by authority of the Federal Food, Drug, and Cosmetic Act, Chapter V, Subchapter C - Electronic Product Radiation Control (formerly the Radiation Control for Health and Safety Act of 1968), these laser products are subject to all the applicable requirements of the Federal Performance Standard for laser products, in Title 21, Code of Federal Regulations (CFR), Part 1040.10 and 1040.11, as well as the

reporting requirements in 21 CFR Part 1002 and the certification requirements in 21 CFR Part 1010.2.

You are requested to apprise CDRH of the following within 30 working days from the date of this letter:

(a) which models you currently have in stock;
(b) which models and how many of each model were shipped from your place of manufacture;
(c) whether each unit was certified as required by 21 CFR 1010.2; and
(d) the full address of where the products are manufactured.

You are also advised that 21 CFR 1002.10 requires submission of a Radiation Safety Product Report prior to introduction into commerce of any products that are subject to the standard.

Please address your response to:

Chief, Electronic Products Branch (HFZ-240)
Division of Mammography Quality and Radiation Programs
Office of Communication, Education, and Radiation Programs
Center for Devices and Radiological Health
1350 Piccard Drive
Rockville, Maryland 20850

Copies of the Federal Performance Standards, compliance guides, radiation safety product report guides, and other documents related to laser products are available on FDA's web site at:

http://www.fda.gov/cdrh/radhealth/

If you have any questions, please contact Dan Hewett of my staff by voice at (240)276-3268, facsimile at (240)276-3272, or internet electronic mail at daniel.hewett@fda.hhs.gov.

Sincerely yours,

Robert Doyle, Chief
Electronic Products Branch
Division of Mammography Quality and
Radiation Programs
Office of Communication, Education,
and Radiation Programs
Center for Devices and
Radiological Health