

4/23/97
JFHAND DELIVEREDFood and Drug Administration
7200 Lake Ellenor Drive
Orlando, FL 32809WARNING LETTER

FLA-97-49

April 22, 1997

Jui Teng Lin, President
Photon Data, Inc.
7055 University Boulevard
Winter Park, Florida 32792

Dear Mr. Lin:

On February 20 and 21, 1997, the Food and Drug Administration (FDA) visited your firm, Photon Data, Inc. (PDI) in Winter Park, Florida. During this inspection, FDA determined that you manufacture and distribute the Scan-190 Excimer Laser System, which is a device within the meaning of section 201(h) of the Food, Drug and Cosmetic Act (the Act).

The excimer laser systems that you manufacture and distribute are adulterated under section 501(f)(1)(B) of the Act because they are class III devices under section 513(f), which are required to have in effect an approved application for premarket approval (PMA) under section 515(a) or an investigational device exemption (IDE) under section 520(g), and no such PMA or exemption is in effect for them. In addition, your excimer laser systems are also misbranded within the meaning of section 502(o) because a notice or other information respecting them was not provided as required by section 510(k).

FDA has evidence that you have distributed your excimer laser systems in the United States. Moreover, you have exported such systems to [REDACTED], [REDACTED], and [REDACTED] without complying with section 801(c)(2) or section 802 of the Act. Our records indicate that FDA denied three requests by PDI for approval to export Scan-190 excimer laser systems to other countries under section 801(e)(2) of the Act.

Because your laser systems are adulterated and misbranded as discussed above, any past domestic or international distribution of such devices was in violation of the Act. In addition, those devices that you have distributed are subject to regulatory action. Finally, any further domestic distribution of adulterated or misbranded devices would be in violation of the Act and future international distribution of such devices is a violation of the Act if you have not complied with section 801(e)(2) or section 802 of the Act.

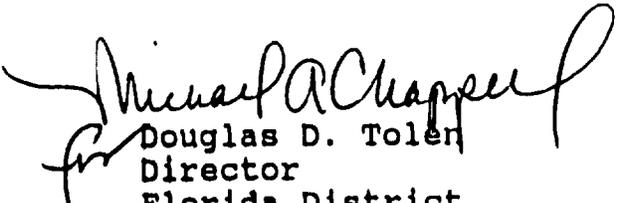
Mr. Jui Teng Lin
Page 2
April 22, 1997

Please note that federal agencies are advised of the issuance of all FDA Warning Letters, such as this one, so they may take the information set forth in the letters into account when considering the award of contracts.

This letter is not intended to be an all-inclusive list of violations of the Act or deficiencies at your facility. It is your responsibility to ensure adherence to each of the requirements of the Act and its implementing regulations. You are responsible for investigating and determining the causes of the violations identified by the FDA. You should take prompt action to correct these deviations. Failure to promptly correct these deviations may result in regulatory action being initiated by the Food and Drug Administration without further notice. These actions include, but are not limited to, seizure, injunction and/or civil penalties.

Please notify this office in writing within 15 working days of receipt of this letter, of specific steps you have taken to correct the noted violations, including: (1) each step that has or will be taken to correct the current violations; (2) the time frame within which the corrections will be completed; (3) the person responsible for effecting correction; and (4) any documentation indicating correction has been achieved. In addition, please report any action being taken to remove previously distributed product from use. If corrections cannot be completed within 15 working days, state the reason for the delay and the time frame within which corrections will be completed. Please direct your reply to Timothy J. Couzins, Compliance Officer, Food and Drug Administration, 7200 Lake Ellenor Drive, Ste. 120, Orlando, Florida 32809, telephone no. (407) 648-6823, ext. 264.

Sincerely,


for Douglas D. Tolen
Director
Florida District

cc: Chung L. Lee, Vice President
Photon Data, Inc.