DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

MAY 22 1987

Rockville MD 20857

To: All Manufacturers and Importers of Laser Products

Subject: Importation of Certain Laser Products for Investigations and Evaluations

Federal regulations require that all imported electronic products for which applicable FDA radiation performance standards exist shall comply with these standards and shall bear certification of such compliance. Before these products can be permitted to enter the U.S., manufacturers and importers are required to submit with each shipment certain required import entry papers through the District Director, U.S. Customs Service to the appropriate FDA district office. Currently, imported laser products manufactured after August 2, 1976, must meet the requirements of the performance standard (21 CFR 1040.10 and 1040.11) or be detained.

Section 360B(b) of the Radiation Control for Health and Safety Act of 1968, provides for possible exemption from certification of electronic products for the purpose of research, investigations, studies, demonstrations, or training. Current FDA policy is that exemptions for such electronic products may be granted for a period of 180 days. During this period of time, the products remain in import detention status and are allowed in the country by means of a written declaration (Form FD 2877 "Affirmation C") filed with the FDA and through a Temporary Import Bond (TIB) filed with Customs. Liquidation of the Customs bond for these products is attained only through their exportation or destruction.

From our review of this process, it is now the opinion of the Center for Devices and Radiological Health that these procedures are unnecessarily restrictive for certain Affirmation C type laser products such as audio or video disc players that do not exceed the limits of Class I during any conditions of operation, maintenance or service. These shipments are usually of small quantity and are tested and evaluated under controlled conditions by technically trained individuals. These products pose no public health hazard as long as they are limited in number and kept out of commercial distribution.

Therefore, under the authority of Section 360B(b) of the Radiation Control for Health and Safety Act of 1968, laser products that do not exceed the limits of Class I during any conditions of operation, maintenance or service, that are imported for the purpose of research, investigations, studies, demonstrations, or training, and that consist of 10 or fewer units per shipment are hereby exempt from the performance standard for laser products. This exemption is granted on the condition that the following requirements are strictly adhered to by the manufacturer/importer:

1. Each laser product and its shipping carton bear a label which states "TESTING/EVALUATION Laser audio/or video disc players - NOT TO BE SOLD IN THE UNITED STATES. THIS PRODUCT HAS NOT BEEN TESTED FOR COMPLIANCE WITH THE U.S. FEDERAL PERFORMANCE STANDARD FOR LASER PRODUCTS."

2. Form FD 701, Importer's Entry Notice is filed with the FDA which describes the laser products as testing/evaluation laser audio video disc players and attests that the products will not be commercially distributed at any time. This form should be submitted before the shipment arrives, if possible. Shipments in excess of 10 units shall be subject to the normal bonding procedures unless a written exemption is obtained from the Director, Center for Devices and Radiological Health.

Movement in commerce of uncertified products imported under this exemption is a violation of Section 360B(a)(1) of the Act and violators shall be subject to civil penalties of $1,000 per violation up to a maximum of $300,000.

Any questions regarding this exemption or any imports procedure should be directed to the imports officer at the FDA District Office nearest you.

Sincerely yours,

John C. Villforth, Director
Center for Devices
and Radiological Health