DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE
PUBLIC HEALTH SERVICE
FOOD AND DRUG ADMINISTRATION
ROCKVILLE, MARYLAND 20857

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TO: All Manufacturers of Laser Diodes and Fiber Optic Communications Equipment

SUBJECT: Application Of the Federal Performance Standard for Laser Products to Laser Diodes in Fiber Optics Communications

BACKGROUND: Laser diodes/fiber optics are already well established in telephony, instrumentation, video and many military applications. This rapidly expanding field needs direction on the criteria employed by the BRH in classifying and applying the Federal performance standard for laser products (21 CFR 1040.10 and 1040.11) to these varied products.

GUIDANCE:

1. The standard defines a laser product as "any manufactured product or assemblage of components which constitutes, incorporates, or is intended to incorporate a laser or laser system. A laser or laser system which is intended for use as a component of an electronic product shall itself be considered a laser product." A laser is "any device which can be made to produce or amplify electromagnetic radiation in the wavelength range of greater than 250 nm but less than or equal to 13,000 nm primarily by the process of controlled stimulated emssion." A laser system is defined as "a laser in combination with an appropriate laser energy source with or without additional incorporated components." Laser energy sources are devices "intended for use in conjunction with a laser to supply energy for the operation of the laser. General energy sources such as electrical supply mains or batteries shall not be considered to constitute laser energy sources."

2. Converters or pulse generators sold individually but without a laser diode are not considered laser products and do not require certification.

3. Laser diodes and diode arrays are laser products but are only lasers, not laser systems. They must be certified unless sold only to original equipment manufacturers (OEM's). The manufacturer of the uncertified product must know it will be incorporated into an electronic product which will be certified. (Note: A fiber optic network may be the final certified product.) In the absence of this verification the manufacturer must certify the product prior to sale. Certified lasers do not have to meet those requirements of the standard applicable to laser systems only, i.e., remote control connector, emission delay and key control for

Classes III and IV, or emission indicator and beam attenuator for Classes II, III and IV but must have the protective housing and labeling required by the standard. The labeling required consists of product certification (Section 1010.2), identification of manufacturer (Section 1010.3), and warning logotype and aperture label (Section 1040.10(g)). Many manufacturers have requested alternate labeling as provided in 21 CFR 1040.10(g)(10) due to the small size of laser diodes.

4. A pulse generator with a compatible laser diode is also a laser but not a laser system and is, therefore, not subject to the performance features required of a laser system. However, it must be certified to meet all requirements for a laser or be sold OEM.

5. The combination of an AC or DC to DC converter with a pulse generator and a compatible laser diode is a laser system and must meet all the certification requirements of such systems or be sold OEM.

6. A converter and pulse generator sold together for a specified laser product application are considered a laser product and require certification or OEM sale (this combination is equivalent to a power supply and product intended to incorporate a laser).

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