DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

SEP 5 1996

TO: All Manufacturers and Importers of Laser Products

SUBJECT: Emitted Laser Beam as Emission Indicator for Class II and Class IIIa Laser Products.

BACKGROUND:

The Federal Performance Standard for Laser Products requires, (21 CFR 1040.10(f)(5)(i)), that Class II and Class IIIa laser systems incorporate an emission indicator that provides a visible or audible signal during emission of accessible laser radiation in excess of the accessible emission limits of Class I. Paragraph 1040.10(f)(5)(iv) requires that any visible signal used as an emission indicator be clearly visible through protective eyewear designated specifically for the wavelength(s).

It is often necessary for the operator to observe the emitted beams of certain types of visible laser products in order for the products to perform their intended functions, i.e. to observe the path of the beam when the product is used for leveling, pointing or aiming. It is also believed to be very unlikely that laser safety eyewear would be used in conjunction with Class II or Class IIIa laser products.

The Center for Devices and Radiological Health (CDRH) has made known that it intends to propose amendments to the standard under which neither beam attenuators nor emission indicators would be required for laser systems that are now classified in Class II or Class IIIa. This proposal would bring the CDRH standard into agreement with the standards of the International Electrotechnical Commission, IEC 825-1:1994, and the American National Standards Institute, ANSI Z136.1:1993, on this requirement. The administration of these requirements has been a burden to the industry and to the CDRH from which little or no significant protection of the public safety results.

POLICY:

The CDRH will not object to the use of the emitted laser beam as the indication of emission of visible laser radiation from Class II and Class IIIa laser products.

Comments are invited and should be addressed to: Electronic Products Devices Branch, HFZ-342, Division of Enforcement III, Office of Compliance, Center for Devices and Radiological Health, 2098 Gaither Road, Rockville, Maryland 20850.

Sincerely yours,

Lillian Gill

Lillian Gill
Director
Office of Compliance
Center for Devices and
Radiological Health

LASER NOTICE NO. 49