DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
1390 Piccard Drive
Rockville MD 20850

JUN - 7 1993

To: Manufacturers and Importers of Laser Products

Subject: Beam Attenuators and Emission Indicators for Class II and IIIa Laser Systems

BACKGROUND: The 1985 amendments to the Federal Performance Standard for Laser Products gave the Director, Office of Compliance and Surveillance, Center for Devices and Radiological Health (CDRH) authority to approve, upon written application by the manufacturer, alternate means to accomplish the radiation protection provided by the beam attenuator (21 CFR 1040.10(f)(6)(ii)). This amendment recognized that for many laser products, a beam attenuator, usually a shutter, provides little if any improved safety, especially for laser systems that have short beam recovery times and can readily be turned off by their operators. Many approvals have been granted since the amendment became effective. When, through its review of product reports or inspectional findings, the CDRH becomes aware of noncompliance with the requirement for a beam attenuator, notification to the manufacturer is required to be given in accordance with 21 CFR 1003.11. In many cases, the notification results in an application from the manufacturer for approval of an alternate means of safety, usually a power switch, and for exemption in accordance with 21 CFR 1003.30 from the notification to affected persons as required by 21 CFR 1003.21. These cases are most common for Class II and Class IIIa visible laser products.

Similarly, the performance standard requires Class II and Class IIIa visible laser systems to incorporate an indicator that provides a visible or audible indication of emission. The standard does not give the director the authority to approve alternate means of providing an indication except through the procedures for variances in 21 CFR 1010.4. Many variances have been requested and granted for battery operated products that emit low powers of visible laser radiation and that incorporate normally off, momentary on switches for emission control. It is understood that a normally off, momentary on switch is on only while physical pressure is applied. The CDRH in granting variances, has accepted the reasoning that an active light or sound indication would only provide indication to the immediate user who certainly should be aware of the tactile indication provided by the physical pressure necessary to activate a momentary power control switch.

In addition, the CDRH has made known that it intends to propose new amendments to the standard under which neither beam attenuators nor emission indicators would be required for visible laser systems that are now classified in Class II or Class IIIa. The administration of these applications has been of considerable burden to the industry and to the Center from which little or no significant protection of the public safety results.

POLICY; The CDRH will not object to:

1. The omission of a beam attenuator on a Class II or Class IIIa laser product that is a visible laser system and that incorporates a specific, suitable means of emission control such as a switch, or

2. The omission of a visible or audible indication of emission from a Class II or Class IIIa laser product that is a visible laser system and that incorporates, as the control for laser emission, a normally off, momentary on switch that provides a clear, tactile indication of emission.

The CDRH intends to incorporate this policy into amendments that it plans to propose. Comments are invited and should be addressed to the Non-Medical Radiological Devices Branch, HFZ-312, Division of Enforcement III, Center for Devices and Radiological Health, 1390 Piccard Drive, Rockville, Maryland 20850

Sincerely yours,

Ronald M. Johnson
Director
Office of Compliance
and Surveillance
Center for Devices and
Radiological Health