DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

AUG 15 1995

To: Manufacturers and Importers of Laser Products

Subject: Labeling of Laser Products

BACKGROUND:
The Federal Performance Standard for Laser Products specifies in 21 CFR 1040.10(g) safety related labels for laser products. Logotype labels are specified for laser products in Classes II, III and IV. The logotypes are based on designs found in the American National Standards Institute (ANSI) Z535 series.

However, laser products intended for export are often required to be labeled in accordance with the standard, Document 825-1 of the International Electrotechnical Commission (IEC 825-1)[1]. This standard requires similar information to be provided but specifies a different configuration of the logotype labels. This requirement for dual labeling presents additional cost and confusion for manufacturers and has prompted several requests for permission to use labels as specified in IEC 825-1. It is further noted that the ANSI standard, Z136.1-1993[2] for the safe use of lasers permits labeling in accordance with IEC 825-1.

However, there are differences between the Federal standard and IEC 825-1 in how measurements of laser power and energy are made for the purposes of classification, in the accessible emission limits of the classes, and in the numerical designations of the classes.

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[1] Safety of Laser Products - Part 1: Equipment classification, requirements and user's guide, International Electrotechnical Commission, International Standard IEC 825-1, 1993. Available from American National Standards Institute (ANSI), 11 West 42nd Street, New York, NY 10036.

[2] American National Standard for the Safe Use of Lasers, ANSI Z136.1-1993. Available from Laser Institute of America, 13434 Research Parkway, Suite 130, Orlando, FL 32826.

POLICY:
The Center for Devices and Radiological Health (CDRH) believes that the different geometries of the ANSI and IEC warning logotype designs have little or no effect on the safety of the product. Therefore, the CDRH will not object to the use of the labeling specified in IEC 825-1 providing that the classification is determined and shown as specified in the CDRH standard, 21 CFR 1040.10(c), (d), (e) and (g). The CDRH will also not object to the classifications being show as determined according to both standards if the standards result in differing classifications. For example, a 4 milliwatt visible laser may be designated as:

Class IIIa laser product (CDRH)
Class 3B laser product (IEC).

The CDRH has announced its intention to consider amendment of its standard to permit this concession in the interests of international harmonization. Comments are welcome and should be addressed to the Nonmedical Radiological Devices Branch (HFZ-342), Office of Compliance, Center for Devices and Radiological Health, 2098 Gaither Rd., Rockville MD 20850.

Sincerely yours,

Paul L. Leggett, Jr.

for Lillian J. Gill, Director
Office of Compliance
Center for Devices and
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