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

JUN 12 1978

TO: ALL MANUFACTURERS AND POTENTIAL MANUFACTURERS OF LASER PRODUCTS

SUBJECT: Modified Aperture Label For Laser Product Used For Patient Positioning and Alignment, 21 CFR 1040.10(g)(4)

BACKGROUND AND QUESTION: The Bureau of Radiological Health has observed that laser radiation at levels less than the limits of Class II is being used for the positioning or alignment of patients relative to certain medical devices. A manufacturer of a laser product for this function has requested relief from the requirement in 21 CFR 1040.10(g)(4) that the laser aperture label include the words "avoid exposure" and permission to use a label bearing the wording "Laser Aperture" as allowed by 21 CFR 1040.11(a)(3) for medical laser products. The manufacturer claims that although the laser products are not medical laser products since they are not "manufactured, designed, intended or promoted for purposes of in vivo diagnostic, surgical, or therapeutic laser irradiation of any part of the human body", the required warning is inconsistent with the purpose of the laser radiation, namely, exposure of the patient.

POLICY: Laser products that are medical devices utilizing visible lasers for patient illumination in aiming or patient positioning may in lieu of the aperture label specified by 21 CFR 1040.10(g)(4) utilize an aperture label with the following statement: "Laser Aperture - Do not stare into beam", providing that the level of laser radiation emitted through the aperture exceeds the limits of Class I but does not exceed the limits of Class II. The Bureau of Radiological Health concurs that, under these circumstances, the wording required by 21 CFR 1040.10(g)(4) is inconsistent with the function of the radiation and could cause unnecessary anxiety to the patient. The Bureau believes if the patient is exposed to levels for which a specific warning is appropriate, that the warning should be visible to the patient on the product. Since this caution should have already been communicated to the patient by the staff, the label should only be a reinforcement and not cause any undue anxiety to the patient. Users of such products should be cautioned to avoid ocular exposure in the user instructions furnished.

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