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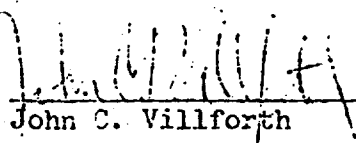
TO: ALL LASER PRODUCT MANUFACTURERS

SUBJECT: Approval of Alternative Wording for Labels Involving Visible Laser Radiation Only.

BACKGROUND: In response to requests from some manufacturers, the Bureau of Radiological Health has approved the substitution of the words "Laser Light" for "Laser Radiation" in the label required by 21 CFR 1040.10(g)(1)(i) for certain Class IIa laser products. The bases of these approvals are that the accessible laser radiation is visible light only, that the word light more understandably describes the nature of the radiation, and that there is less likelihood of confusion with ionizing, particulate or other electromagnetic radiation.

Upon further consideration, the Bureau believes that this same reasoning can be applied without compromise of safety to all labels and warnings required by the laser product performance standard where the warnings are related to laser radiation in the visible wavelength range from 400 to 710 nanometers only.

GUIDANCE: In accordance with 21 CFR 1040.10(g)(10) approval is hereby given for the substitution of the words "Laser Light" for "Laser Radiation" in all labels and warnings required by 21 CFR 1040.10 and 1040.11 providing that all laser radiation exceeding the limits of Class I requiring such labels is within the visible wavelength range from 400 to 710 nanometers.



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