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

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TO: ALL MANUFACTURERS AND POTENTIAL MANUFACTURERS OF LASER PRODUCTS

SUBJECT: Wording of Required Warning Labels For Dye Laser and Other Multiple Wavelength Lasers, 21 CFR 1040.10(g)

BACKGROUND: A laser is capable of emitting, at the discretion of the user, laser radiation in a number of ranges in the visible and invisible portions of the electromagnetic spectrum. The laser manufacturer asks what wording should be provided on the required warning logotype which would fulfill the requirements of 21 CFR 1040.10(g)(5) and (8) and be appropriate to the product. The manufacturer comments that the following problems exist: (1) A listing of all possible wavelengths would not accurately indicate the particular hazard that might be present at any given time, and (2) in the case of dye lasers, the maximum output of the pumped laser is also dependent on the laser used for pumping which cannot be controlled by the dye laser manufacturer.

POLICY: If a laser could be made to produce either visible or invisible laser radiation and perhaps both visible and invisible laser radiation simultaneously, it would be acceptable for a manufacturer to appropriately precede the word "radiation" on the required warning labels with the words "visible and/or invisible". The Bureau would not object to the addition of a note on warning labels refering the user to the operation or instruction manual for further information.

Since no specific wording is required for the radiation output information on the warning logotype (21 CFR 1040.10(g)(5)), the following statements of laser medium or wavelength of emitted laser radiation might be used at position 2 of the required warning logotype of a dye laser:

"DYE LASER - VARIOUS ULTRAVIOLET, VISIBLE OR INFRARED WAVELENGTHS MAY BE EMITTED. CONSULT INSTRUCTION MANUAL."; or

"DYE LASER - WAVELENGTHS EMITTED MAY RANGE FROM _____nm to _____nm. CONSULT INSTRUCTION MANUAL."

A similar statement would be used for other types of multiple wavelength lasers as appropriate.

Since the maximum output level of a dye laser is dependant upon and limited to that of the input radiation, a statement to this effect would be adequate, for example:

"MAXIMUM OUTPUT DEPENDS ON DYE, MIRRORS AND PUMPING LASER - CONSULT INSTRUCTION MANUAL AND LABEL ON PUMPING LASER FOR MAXIMUM POWER."

This statement would serve to direct the attention of the reader of this information to the warning logotype of the pumping laser.

INVITATION TO COMMENT: The Bureau is considering an amendment to the performance standard for laser products which may provide an opportunity in the future for manufacturers to seek greater flexibility in the wording of warning logotypes and other required labels. In the interim, the above policy shall apply to the circumstances as described. Comments on this policy are invited.

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