DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE
PUBLIC HEALTH SERVICE
FOOD AND DRUG ADMINISTRATION
ROCKVILLE, MARYLAND 20852

REF:DOC:4021:MA

AUG 5 1976

TO: ALL MANUFACTURERS AND POTENTIAL MANUFACTURERS OF LASER PRODUCTS

SUBJECT: Applicability of Viewing Optics Performance Requirements to a Sighting Telescope of a Surveying Laser Product, 21 CFR 1040.10(f)(8)

BACKGROUND AND QUESTION: A manufacturer of a surveying laser product incorporates into the product a sighting telescope that is intended to be used to aim the product and to view the laser light diffusely reflected from a target. When used as intended by the manufacturer the maximum level of laser radiation accessible through the telescope is well below the maximum accessible level for viewing optics despite emission from the laser product being well in excess of this level. The manufacturer is aware that users may employ retroreflective or specular mirror targets with the product, in which case the level of laser radiation accessible through the telescope may approach the level of the laser itself. The manufacturer is reluctant to utilize a lower power laser so that the product could be Class I since viewing of the reflected laser light from a diffuse target under normal daylight background conditions would be impossible. The manufacturer asks whether it is the intent to consider such sighting telescopes as viewing optics under 21 CFR 1040.10 and 1040.11.

RESPONSE: The telescope is intended for viewing the reflection of the laser light. Therefore the function of the telescope and the target is that of a viewing optic, and the performance of the unit must conform to 21 CFR 1040.10(f)(8).

If the manufacturer supplies or specifically recommends a diffusely reflecting target for use with the laser product, and provides instructions and warnings to use only that target, then if the viewing optic attenuates the beam reflected from the target to the level of Class I under all possible uses, the product would be compliant with the requirements of 21 CFR 1040.10(f)(8). The target in this case may be considered an integral part of the viewing optics system and of the laser product.

A specific warning not to use a target which would give a specular reflection or a retroreflection would be required in the instructions as being necessary for adequate safety information. A supplemental warning not to view the radiation in conjunction with mirror-like targets may be added to the warning logotype required to be on the exterior of the laser product pursuant to 21 CFR 1040.10(g)(2) and (3).

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Policy Statement #8