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

AUG 25 1980

TO: MANUFACTURERS AND POTENTIAL MANUFACTURERS OF LASER PRODUCTS

SUBJECT: Alternate Wording of Caution Statement in User Information (21 CFR 1040.10(h)(1)(iv))

The warning statement, "Caution - use of controls or adjustments or performance of procedures other than those specified herein may result in hazardous radiation exposure" required by 21 CFR 1040.10(h)(1)(iv) to be provided in the user information with laser products has been found to be inappropriate or misleading for certain products. Such instances occur when there are no controls available to the user or there are no adjustments or procedures which the user could reasonably perform during conditions of operation or maintenance which could result in hazardous radiation exposure. Some Class I laser products that have evidenced this condition are business machines, and sealed consumer products.

The Bureau of Radiological Health will not object to the use of alternative warnings to the statement required by 21 CFR 1040.10(h)(1)(iv) under the following conditions:

1. The required warning statement must be inappropriate in the context of the design or use the product.

2. The alternative warning statement(s) must be more appropriate than the required statement.

3. The alternative warning statement(s) must be related to the laser hazard possible as a result of procedures other than those given in the user instructions, e.g. removal of protective housing, attempting to defeat nondefeatable interlocks, etc.

Under 21 CFR 1040.10(g)(10) as amended the Director, Bureau of Radiological Health may approve on the Director's own initiative or upon written application by the manufacturer alternate means or wording. Manufacturers are requested to apply for approval of alternate labeling in advance of use of alternate labeling. In cases where a manufacturer substitutes approved alternative warnings, it is also requested that the alternative warnings be specifically identified in the initial or model change report on the product.

Sincerely yours,

Robert G. Britain
Director
Division of Compliance
Bureau of Radiological Health

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