DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
1390 Piccard Drive
Rockville, MD 20850

DEC 18 1989

TO: ALL MANUFACTURERS AND POTENTIAL MANUFACTURERS OF LASER PRODUCTS

SUBJECT: Clarification of Compliance Requirements for Certain Manufacturers Who Incorporate Certified Class I Laser Products into Their Products

BACKGROUND:

Numerous questions have arisen regarding the applicability of 21 CFR 1040.10(i), Modification of a Certified Product, in those situations in which a firm purchases a certified Class I laser product and incorporates it into another product for sale. Examples of this practice include certified Class I optical disc drive units incorporated into computers, compact disc players installed in home entertainment centers, and compact disc players installed in automobiles.

POLICY:

The Center for Devices and Radiological Health (CDRH) will consider firms incorporating certified Class I laser products into another product to be distributors of laser products certified and reported by other manufacturers provided the following conditions are met:

1. No modification of performance or intended use of the certified product is made and incorporation of the certified laser product results only in concealment of the original manufacturer's certification and identification labels required by Part 1010; and

2. The labeling requirements of 21 CFR 1010 and 1040.10(g) for the Class I laser product would be met when the certified product is removed from the product into which it had been incorporated; and

3. The labeling requirements of 21 CFR 1040.10(g) for the Class I laser product would be met in any service configuration of the certified laser product, even when that product could be serviced without removal from the incorporating product; and

4. The laser safety information provided by the certifying manufacturer is distributed with the final product.

Distributors of laser products must only comply with the recordkeeping requirements of Part 1002. Distributors need not submit initial and annual reports described in Part 1002 nor apply new certification and identification labels to the outside of the final product.

Edwin A. Miller

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