DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

FEB 5 1985

TO: All Manufacturers and Potential Manufacturers of Laser Products

SUBJECT: Reproduction of Hazard Warnings in User Instructions

BACKGROUND: 21 CFR 1040.10(h)(1)(iii) requires that the user instructions or operation manual for laser products contain legible reproductions (color optional) and indicate locations of all labels and hazard warnings that are required by 21 CFR 1040.10(g) and 1040.11 to be affixed to the product. Some manufacturers have enclosed their laser product protective housings within additional external "cosmetic" enclosures. Such enclosures are intended to preserve the aesthetic integrity of the products and to discourage users from opening the products. Since protective housing warning labels are covered by the "cosmetic" enclosures and are not visible in operation and maintenance configurations, manufacturers have asked whether operation or maintenance manuals need to contain reproductions of these labels.

POLICY: CDRH will not object to the omission of reproductions of those labels and hazard warnings required by 21 CFR 1040.10(g)(6) or (g)(7) from operation and maintenance information provided such labels are not visible in any operation or maintenance configuration. However, such labels and warnings must be visible during service and must be reproduced in service literature in the manner specified in 21 CFR 1040.10(h)(2)(ii).

INVITATION TO COMMENT: The Center for Devices and Radiological Health intends to propose an amendment to the Federal performance standard for laser products which will clearly permit the conditions specified above. In the meantime, the Food and Drug Administration will not take action under Section 359, 360B, or 360C of the Radiation Control for Health and Safety Act of 1968 if certified laser products deviate from the requirements of 21 CFR 1040.10(h)(1)(iii) for the reproduction and locations of certain labels and hazard warnings required by 21 CFR 1040.10(g) in user instructions, since such deviation, while technically noncompliant with the present performance standard, does not compromise the public health and safety. Comments on this policy are invited.

James S. Benson

James S. Benson
Deputy Director
Center for Devices
and Radiological Health

Laser Notice #35