DALE

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

SEP 5 1996

To: All Manufacturers of Laser Products

Subject: Identification Labels for Certain Class I Laser Products

BACKGROUND AND QUESTION

The regulations for electronic products require each electronic product for which a standard has been promulgated to be identified with the name and address of the manufacturer (21 CFR 1010.3). This identification is to be on a tag or label permanently affixed to the product. Identification of the product is required so the product may be traced for recall in the event there is a defect in the product or the product is found to be noncompliant. This requirement is applicable to all laser products certified as complying with the Federal performance standard for laser products, 21 CFR 1040.10 and 1040.11.

A manufacturer of certain types of laser products that are Class I under all circumstances of operation, maintenance, service or failure has requested that its company name not appear on the identification label. The products are certified and may be, for example, compact disc players or CD ROM units that will be integrated into other products such as music systems, automobiles, or computers. The manufacturer (the integrator) of the music system, automobile or computer is intended to be the primary contact for service rather than the manufacturer of the laser product. The laser product manufacturer wishes to hold large quantities of products as ready-to-ship inventory that can be sold to any integrator without having to be relabeled. The regulations already permit, under 21 CFR 1010.3(a)(1), labeling a certified product with a brand name other than that of the manufacturer as long as the Center for Devices and Radiological Health (CDRH) is advised of the true identity of the affected product.

POLICY

The CDRH will not object to the name of the original laser product manufacturer not appearing as part of the identification label when the following criteria are met:

1. The certified product is not modified in any aspect of performance or intended use,

2. The level of laser radiation accessible during any conditions of operation, maintenance, service or single failure does not exceed the accessible emission limits of Class I.

3. The identification label required by 21 CFR 1010.3 contains a code in lieu of the name and address of the manufacturer, such as: FDA/CDRH ID: XXXX. This code will be assigned by the CDRH to the manufacturer of the certified product upon application, as permitted under 21 CFR 1010.3(b).

Comments are invited and should be addressed to the Electronic Products Branch, HFZ 342, Office of Compliance, Division of Enforcement III, Center for Devices and Radiological Health, 2098 Gaither Road, Rockville, MD 20850.

Sincerely yours,

Lillian J. Gill
Director
Office of Compliance
Center for Devices and
Radiological Health

Laser Notice No. 48