DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

MAY 14 1997

TO: Manufacturers and Importers of Consumer Electronic Products

SUBJECT: Date of Manufacture Label for Electronic Products Subject to Radiation Standards

ISSUE

The Consumer Electronics Manufacturers Association has requested that the Food and Drug Administration (FDA), Center for Devices and Radiological Health (CDRH), exempt manufacturers of electronic products from the required label providing the date of manufacture or to permit date coding.

BACKGROUND

Manufacturers of electronic products are required to comply with radiation performance standards promulgated under Section 534(a)(1) of the Electronic Product Radiation Control provisions of the Federal Food, Drug, and Cosmetic Act (the Radiation Control for Health and Safety Act of 1968). The regulations, 21 CFR 1010.3, specify that an identification label or tag must be affixed to each product with the date of manufacture.

On March 7, 1996, the Consumer Electronics Manufacturers Association (CEMA), a sector of the Electronic Industries Association, requested a change in the date format specified in the regulations and then subsequently questioned the need for providing a date on the label at all. The original intent of the label was to identify which products are subject to a standard (as opposed to ones manufactured prior to the effective date) and to identify products subject to differing requirements when the performance standards are amended. Since the television and microwave oven standards have not been amended since 1983 and the laser standard is seldom amended in any manner that affects the consumer product industries, CEMA asks that the requirement for the label be exempted until any future amendments to these standards are promulgated. The change is expected to reduce the tracking resources and paperwork burden on industry, with negligible impact on FDA or public health.

GUIDANCE

The CDRH concurs that there is little need for the date of manufacture on the identification label at this time and failing to provide the information does not impact public health. As permitted by Section 539(d) of the Act, the CDRH

will not object to manufacturers omitting the date of manufacture from the identification label required by 21 CFR 1010.3 from consumer (non-medical) electronic products under the following conditions:

1. Each product is marked with a serial number or other identification by which the manufacturer may identify the date of manufacture in case of any regulatory action or investigation.

2. The date of manufacture is included on the label within 30 days after a final rule to amend an applicable standard is published in the Federal Register, if the amendment adds or amends (not reduces or eliminates) any aspect of performance to which that electronic product must comply.

Failure to comply with an applicable standard is a violation of Section 538(a)(1) of the Act. Violations will result in disallowing this guidance by the responsible parties and are subject to civil penalties not to exceed $1000 per violation and $300,000 maximum. Providing false information to the U.S. government is a violation of the U.S. Code, Title 18, and subject to criminal prosecution.

In accordance with FDA's Good Guidance Practices, comments are invited. This guidance document represents the agency's current thinking on date of manufacture labeling on consumer electronic products. It does not create or confer any right for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statute and/or regulations.

Any comments or questions should be directed to the Electronic Products Branch at the address above, by telephone at 301-594-4654 or by facsimile at 301-594-4672.

Sincerely yours,

Lillian J. Gill

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