Contains Nonbinding Recommendations

Guidance for Industry and FDA Staff

Approval of Alternate Means of Labeling for Laser Products (Laser Notice 53)

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U.S. Department of Health and Human Services
Food and Drug Administration
Center for Devices and Radiological Health
Electronic Products Branch
Division of Mammography Quality and Radiation Programs
Office of Communication, Education, and Radiation Programs

Preface

Public Comment

Written comments and suggestions may be submitted at any time for Agency consideration to the Division of Dockets Management, Food and Drug Administration, 5630 Fishers Lane, Room 1061, (HFA-305), Rockville, MD, 20852. When submitting comments, please refer to the exact title of this guidance document. Comments may not be acted upon by the Agency until the document is next revised or updated.

Additional Copies

Additional copies are available from the Internet at: http://www.fda.gov/radhealth/products/lasers.html. You may also send an e-mail request to dsmica@fda.hhs.gov to receive an electronic copy of the guidance or send a fax request to 240-276-3151 to receive a hard copy. Please use the document number (**1633**) to identify the guidance you are requesting.

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This guidance represents the Food and Drug Administration's (FDA's) current thinking on this topic. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. You can use an alternative approach if the approach satisfies the requirements of the applicable statutes and regulations. If you want to discuss an alternative approach, contact the FDA staff responsible for implementing this guidance. If you cannot identify the appropriate FDA staff, call the appropriate number listed on the title page of this guidance.

Introduction

Under current radiological health regulations, the Center for Devices and Radiological Health (CDRH) may approve alternate means for manufacturers of laser products to provide required certification, identification, and warning labeling in cases where it is not feasible to provide the labeling as specified in the regulations (21 CFR 1010.2, 1010.3, 1040.10(g)). CDRH may approve alternate means of providing the certification and identification upon the manufacturer's application (21 CFR 1010.2(d), 1010.3(b)). CDRH on its own initiative or in response to a manufacturer's written application may approve either alternate means of providing the labels or alternate wording for the warning labeling required under 1040.10(g).

CDRH is issuing this guidance to inform manufacturers that the FDA intends to exercise enforcement discretion, under certain circumstances described later, as to its current regulations governing the provision of certification, identification, and warning labeling for laser products and obtaining approval of alternate means of providing this information.

FDA's guidance documents, including this guidance, do not establish legally enforceable responsibilities. Instead, guidances describe the Agency's current thinking on a topic and should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited. The use of the word *should* in Agency guidances means that something is suggested or recommended, but not required.

The Least Burdensome Approach

We believe we should consider the least burdensome approach in all areas of medical device and electronic product regulation. This guidance reflects our careful review of the relevant scientific and legal requirements and what we believe is the least burdensome way for you to comply with those requirements. However, if you believe that an alternative approach would be less burdensome, please contact us so we can consider your point of view. You may send your written comments to the contact person listed in the preface to this guidance or to the CDRH Ombudsman. Comprehensive information on CDRH's Ombudsman, including ways to contact him, can be found on the Internet at http://www.fda.gov/cdrh/ombudsman/.

1. Issue

The applicable regulations in 21 CFR 1010.2, 1010.3, and 1040.10(g) require that manufacturers provide certification, identification, and warning labeling in a specified manner. However, the regulations contain provisions for CDRH to approve alternate means of providing the required labeling in cases where it is not feasible to provide the labeling as specified in the regulation, often due to size. Alternate means may be approved by CDRH upon application by the manufacturer (21 CFR 1010.2, 1010.3, and 1040.10(g)). However, due to the increasing numbers of laser products of small size and the overall increase in the number of manufacturers and minimal risk to public health, CDRH intends to exercise enforcement discretion, under certain circumstances, and permit manufacturers of laser products to use alternate means of providing the required information without applying to and receiving approval from CDRH.

2. Guidance

Under what circumstances may manufacturers use alternate means of providing the required certification, identification, or warning labeling, without applying to and receiving approval from CDRH?

Alternate means of labeling may be used without applying to and receiving approval from CDRH when

- size
- configuration
- design
- function
- sterilization

or other considerations make the placement of the labels as required by the regulations and performance standard impractical.

What are some examples of alternate means of providing required labeling?

Examples of alternate means of providing required labeling include

- Placement of labels on packaging
- Placement of labels in user instructions
- Placement of labels on alternate portions of the product

What should manufacturers do if using alternate means without applying to and receiving approval from CDRH?

As is currently the case, manufacturers who use alternate means—whether they applied for and received approval for the alternate means from CDRH or based on this guidance--should document this in the product report and retain in-house the justification for use of alternate means for review upon CDRH request.

If, in its review of a manufacturer's product report, CDRH believes a particular laser product should have been labeled in accordance with the regulations, CDRH may notify the manufacturer and require recall of the product for relabeling or a change in the labeling in future production in accordance with 21 CFR 1003 and 1004.

Manufacturers also may contact CDRH to discussion whether this guidance applies to their product. Please note, however, that CDRH does not act as an intermediary between manufacturers and testing laboratories from which the manufacturer may have sought independent certification of conformance.

3. Getting More Information

You can get more information about our requirements for lasers from our electronic product radiation control web page http://www.fda.gov/cdrh/radhealth/.

If you have any questions about this guidance, contact Jerome Dennis, Center for Devices and Radiological Health (HFZ-240), Food and Drug Administration, 1350 Piccard Drive, Rockville, Maryland 20850 or jerome.dennis@fda.hhs.gov.