Guidance on the Department of Defense Exemption from the FDA Performance Standard for Laser Products; Guidance for Industry and FDA

(Laser Notice No. 52)

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U.S. Department Of Health and Human Services
Food and Drug Administration
Center for Devices and Radiological Health

Electronic Product Devices Branch
Division of Enforcement III
Office of Compliance

Preface

Public Comment

Comments and suggestions may be submitted at any time for Agency consideration to Dockets Management Branch, Division of Management Systems and Policy, Office of Human Resources and Management Services, 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.

For questions regarding the use or interpretation of this guidance contact Jerome E. Dennis at (301) 594-4654, ext. 135, or by electronic mail at mailto:jxd@cdrh.fda.gov.

Additional Copies

Additional copies are available from the Internet at: http://www.fda.gov/cdrh/comp/guidance/1412.html, or CDRH Facts-On-Demand. In order to receive this document via your fax machine, call the CDRH Facts-On-Demand system at 800-899-0381 or 301-827-0111 from a touch-tone telephone. Press 1 to enter the system. At the second voice prompt, press 1 to order a document. Enter the document number 1412 followed by the pound sign (#). Follow the remaining voice prompts to complete your request.

Guidance on the Department of Defense Exemption from the FDA Performance Standard for Laser Products (Laser Notice No. 52)

This document is intended to provide guidance. It represents the Agency'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 the Food and Drug Administration (FDA) or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statute and regulations.

Purpose

This guidance clarifies and updates the conditions of FDA exemption no. 76EL-01DOD granted in 1976 to the U.S. Department of Defense (DoD) for laser products procured for combat or combat training or that are classified for reasons of national security. This guidance supplements Laser Notice Nos. 9 and 15 and identifies the current resources in the military services for the administration of this exemption.

Issue

The U.S. Department of Defense established a joint services group, the Laser Systems Safety Working Group (LSSWG), to coordinate laser safety issues within the DoD. The LSSWG requested FDA to reissue its earlier guidance to industry on the subject of the DoD exemption. The LSSWG request was based on a concern that laser products not in compliance with the FDA standard are offered to various DoD purchasing authorities and procured without appropriate control measures implemented to assure the safest possible use.

Background

Laser products sold in or imported into the United States must comply with the Federal Performance Standard for Laser Products issued by the Food and Drug Administration (FDA), Center for Devices and Radiological Health (CDRH), in Title 21, Code of Federal Regulations, Subchapter J, Parts 1040.10 and 1040.11[1]. The Federal Laser Standards require laser products to incorporate certain safety features, which may include warning lights, warning labels, and housing interlocks.

In 1976, the FDA Commissioner allowed the Department of Defense (DoD) or its components to exempt certain military laser products from the provisions of the Federal Laser Standard and associated reporting and recordkeeping requirements. This exemption applies to DoD lasers used for actual combat or combat training or those

[1] See 21 CFR 1040.10 (a) for details on the applicability of the FDA standard and exceptions from applicability.

classified in the interest of national security. The exemption was granted with the following provisions:

- Laser product specifications must include, to the extent practicable, the safety features required by the FDA standard;
- Laser product specifications will be supplemented with safety controls specified by DoD; and
- DoD exempted laser products will be clearly identified through labeling.

An example of how the DoD exemption may be applied is to exempt a military laser product from the FDA requirements for laser radiation emission indicators and warning labels. These visible or audible emission indicators and brightly-colored labeling are inappropriate for products intended for use in a combat environment where camouflage and concealment are necessary.

The Least Burdensome Approach

The issues identified in this guidance document represent those we believe need to be addressed before your product can be marketed. In developing the guidance, we carefully considered the relevant statutory criteria for Agency decision-making. We also considered the burden that may be incurred in your attempt to comply with the guidance and address the issues we have identified. We believe that we have considered the least burdensome approach to resolving the issues presented in the guidance document. If, however, you believe that there is a less burdensome way to address the issues, you should follow the procedures outlined in the "A Suggested Approach to Resolving Least Burdensome Issues" document. It is available on our Center web page at: http://www.fda.gov/cdrh/modact/leastburdensome.html.

Guidance

The manufacturer must obtain an exemption letter from an authorized DoD procuring agency to allow the use of the DoD exemption for a specific product. The manufacturer must obtain the DoD exemption letter prior to sale and retain it for subsequent sales to any DoD agency. Any subsequent modification to a "military exempt" laser product by the manufacturer requires a new DoD exemption letter. The DoD exemption letter may specify a number of units, an armed service, and/or a period of time.

A manufacturer violates Federal law if it sells a laser system not in compliance with the FDA standard to the DoD or falsely labels a laser product as exempt without a written DoD exemption letter. Several laser system manufacturers market laser products that are labeled as "military exempt." Many of these systems lack written documentation of DoD exemption. An appropriate DoD laser safety representative must evaluate all "military exempt" laser products to determine compliance with relevant military or Federal requirements. Manufacturers of "military exempt" laser products should not assume the DoD exemption applies to its product unless DoD provides an exemption letter.

Once the DoD exemption is applied to a specific laser system, the system cannot be sold, surplused, or distributed to organizations outside the DoD, unless the laser system is

brought into full compliance with the FDA standard, certified, and reported in accordance with FDA regulations.

For further information on this process, contact an appropriate DoD laser safety representative.

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Getting More Information

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

If you have questions about this guidance, contact Jerome Dennis, CDRH, Office of Compliance (HFZ-342), 2094 Gaither Rd., Rockville, MD 20850, FAX 301-594-4672, or e-mail jxd@cdrh.fda.gov.

Sincerely yours,

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