EXEMPTIONS
From
Electronic Product Regulations

A Compilation of Exemptions for Electronic Products Found in 21 CFR Chapter I, Sub-Chapter J -- Radiological Health Parts 1000 – 1050

January 5, 2010

INTRODUCTION

Exemption provisions are found throughout the Code of Federal Regulations (CFR) for Electronic Products – Parts 1000-1050. They are typically found within the specific regulation to which they apply. Other types of exemptions and special provisions going back to 1976 are contained in agency letters and Laser Notices. As a result, it is often difficult to find all the exemptions which may apply to a given product.

Exemptions are granted for a wide variety of reasons and many are granted to other branches of the federal government such as the Department of Defense (DOD). Often, being exempt is misinterpreted by manufacturers to mean exempt from any and all of CFR Parts 1000-1050 – this is not correct; exemptions are limited to specified provisions of the CFR. In addition, to have a valid DOD exemption for example, a manufacturer must meet the exemption provisions of the DOD and receive a written notice of same.

To simplify the process of finding all the exemptions provided for in the CFR Parts 1000-1050 and those granted by an agency letter or Laser Notice, this document has been assembled. It is a compilation of all exemptions which relate to the regulations for electronic products found in 21 CFR Parts 1000-1050. The document is organized by Part beginning with a summary section followed by the applicable Part with the word "exemption" highlighted within the text. Agency letters and Laser Notices are also provided as references to the summary sections.

If you have any comments or questions concerning this compilation of electronic product exemptions please contact CDR Patrick Hintz at 301-796-6927 or patrick.hintz@fda.hhs.gov.

21 CFR Chapter I, Sub-Chapter J -- Radiological Health
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PART 1002 RECORDS AND REPORTS

SUMMARY:

Subpart A – General Provisions

Part 1002 describes the requirements of manufacturers of electronic products with respect to records and reporting. The general provisions state that manufacturers, dealers, and distributors are subject to the provisions of Part 1002 as set forth by Table 1 – "Records and Reporting Requirements by Product".

Manufacturers may be granted an exemption by the Director, CDRH from the provisions of Part 1002 under 1002.50 and 1002.51, found in Subpart F – Exemptions from Records and Reports Requirements.

However, all manufacturers are subject to 1002.20, "Reporting of accidental radiation occurrences". There are no exemptions from this section, unless exempted by the Director of CDRH (see Subpart F).

Subpart F – Exemptions from Records and Reports Requirements

Section 1002.50 states that a manufacturer can request an exemption from any records and reporting requirements listed in Table 1, but the request must specify each requirement from which an exemption is requested along with a justification and supporting documentation showing that the product does not pose a public health risk. The manufacturer must also ensure that their product meets at least one of the four criteria found in this section.

The Director, CDRH has the authority to deny or grant exemption requests from all or part of the provisions of Part 1002 provided they are in keeping with the purposes of the Act, and must provide written notification of it. Written notification of granted exemptions must include the product or products for which the exemption was granted, the requirements from which the product is exempted, and conditions of the exemption necessary to protect public health.

The Director may also exempt certain classes of products from the requirements found in Table 1, provided the exemption is in keeping with the purposes of the Act.

Manufacturers of electronic products for which there are no applicable performance standards are also exempt from records and reporting requirements if:

1) The product was granted clinical, investigational device exemption (IDE) under Section 812.30, or

2) The product is a medical device and was granted a premarket approval (PMA) in accordance with Section 814.449(d).

There are three sections of Subchapter J which discuss exemptions for manufacturers of products intended for the U.S. Government. Section 1002.1(c)(3) states that the requirements of Part 1002 as specified in Table 1 of that section are *not applicable* to manufacturers of electronic products that are intended for use by the U.S. Government and whose function or design cannot be divulged by the manufacturer for reasons of national security, as evidenced by government security classification.

Section 1002.51 states that a manufacturer may be granted an exemption from the records and reporting requirements for an electronic product intended for sole or predominant use by departments or agencies of the US government with prescribed procurement provisions which govern product radiation emissions.

Section 1010.5 specifically exempts electronic products or classes of products from provisions of performance standards for electronic products intended for use by departments or agencies of the United States. The exemption may be granted to manufacturers, but is typically granted to U.S. Government departments or agencies, who then administer this exemption to their vendors. This will be discussed in more detail in Part 1010.

PART 1002 RECORDS AND REPORTS

Subpart A—General Provisions

Sec. 1002.1 Applicability.

The provisions of this part are applicable as follows:

(a) All manufacturers of electronic products are subject to 1002.20.

(b) Manufacturers, dealers, and distributors of electronic products are subject to the provisions of part 1002 as set forth in Table 1 of this section, unless excluded by paragraph (c) of this section, or unless an ***exemption*** has been granted under 1002.50 or 1002.51.

Subpart F – Exemptions From Records and Reports Requirements

Sec. 1002.50 Special exemptions.

(a) Manufacturers of electronic products may submit to the Director a request, together with accompanying justification, for exemption from any requirements listed in table 1 of 1002.1. The request must specify each requirement from which an exemption is requested. In addition to other information that is required, the justification must contain documented evidence showing that the product or product type for which the exemption is requested does not pose a public health risk and meets at least one of the following criteria:

(1) The products cannot emit electronic product radiation in sufficient intensity or of such quality, under any conditions of operation, maintenance, service, or product failure, to be hazardous;

(2) The products are produced in small quantities;

(3) The products are used by trained individuals and are to be used by the same manufacturing corporation or for research, investigation, or training.

(4) The products are custom designed and used by trained individuals knowledgeable of the hazards; or

(5) The products are produced in such a way that the requirements are inappropriate or unnecessary.

(b) The Director may, subject to any conditions that the Director deems necessary to protect the public health, exempt manufacturers from all or part of the record and reporting requirements of this part on the basis of information submitted in accordance with paragraph (a) of this section or such other information which the Director may possess if the Director determines that such exemption is in keeping with the purposes of the Act.

(c) The Director will provide written notification of the reason for any denial. If the exemption is granted, the Director will provide written notification of:

(1) The electronic product or products for which the exemption has been granted;

(2) The requirements from which the product is exempted; and

(3) Such conditions as are deemed necessary to protect the public health and safety. Copies of exemptions shall be available upon request from the Center for Devices and Radiological Health, Office of Communication, Education, and Radiation Programs (HFZ-240), 9200 Corporate Blvd., Rockville, MD 20850.*

(d) The Director may, on the Director's own motion, exempt certain classes of products from the reporting requirements listed in table 1 of 1002.1, provided that the Director finds that such exemption is in keeping with the purposes of the Act.

(e) Manufacturers of products for which there is no applicable performance standard under parts 1020 through 1050 of this chapter and for which an investigational device exemption has been approved under 812.30 of this chapter or for which a premarket approval application has been approved in accordance with 814.44(d) of this chapter are exempt from submitting all reports listed in table 1 of 1002.1.

Sec. 1002.51 Exemptions for manufacturers of products intended for the U.S. Government.

Upon application therefore by the manufacturer, the Director, Center for Devices and Radiological Health, may exempt from the provisions of this part a manufacturer of any electronic product intended for use by departments or agencies of the United States provided such department or agency has prescribed procurement specifications governing emissions of electronic product radiation and provided further that such product is of a type used solely or predominantly by departments or agencies of the United States.

* The Center for Devices and Radiological Health, Office of Communication, Education, and Radiation Programs is now located at 10903 New Hampshire Avenue, Silver Spring, MD 20993

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PART 1003 NOTIFICATION OF DEFECTS OR FAILURE TO COMPLY

SUMMARY:

Subpart B—Discovery of Defect or Failure to Comply

If the Secretary, DHHS determines that an electronic product fails to comply with 21 CFR or has a defect, he or she shall immediately notify the manufacturer in writing detailing the nature of the discovery and the methods used to detect it. The manufacturer may present its views and evidence to rebut the notice, and will also be given an opportunity for a regulatory hearing on the matter.

Upon receiving the notice, the manufacturer must provide production and distribution numbers of the products in question. If after the time period specified by the notice the Secretary finds that the manufacturer is still not in compliance with 21 CFR or there is a defect, the manufacturer must notify affected people as per Section 1003.21 in 14 days unless the manufacturer has applied for an exemption from the time period specified in notification.

Subpart D – Exemptions From Notification Requirements

The Secretary may exempt a manufacturer from the original time period to present its views and present evidence in rebuttal to the notification if he or she finds that the application for a time extension is based on reasonable grounds.

If within the time extension the manufacturer proves to the Secretary's satisfaction that the defect or failure to comply does not create a significant risk of injury, including genetic injury, to any person, the Secretary shall issue an exemption from the requirement of notification to the manufacturer and shall notify the manufacturer in writing.

PART 1003 NOTIFICATION OF DEFECTS OR FAILURE TO COMPLY

Subpart B—Discovery of Defect or Failure to Comply

Sec. 1003.11 Determination by Secretary that product fails to comply or has a defect.

(a) If, the Secretary, through testing, inspection, research, or examination of reports or other data, determines that any electronic product does not comply with an applicable Federal standard issued pursuant to the Act or has a defect, he shall immediately notify the manufacturer of the product in writing specifying:

(1) The defect in the product or the manner in which the product fails to comply with the applicable Federal standard;

(2) The Secretary's findings, with references to the tests, inspections, studies, or reports upon which such findings are based;

(3) A reasonable period of time during which the manufacturer may present his views and evidence to establish that there is no failure of compliance or that the alleged defect does not exist or does not relate to safety of use of the product by reason of the emission of electronic product radiation.

The manufacturer shall have an opportunity for a regulatory hearing before the Food and Drug Administration pursuant to part 16 of this chapter.

(b) Every manufacturer who receives a notice under paragraph (a) of this section shall immediately advise the Secretary in writing of the total number of such product units produced and the approximate number of such product units which have left the place of manufacture.

(c) If, after the expiration of the period of time specified in the notice, the Secretary determines that the product has a defect or does not comply with an applicable Federal standard and the manufacturer has not applied for an ***exemption***, he shall direct the manufacturer to furnish the notification to the persons specified in 1003.10(b) in the manner specified in 1003.21. The manufacturer shall within 14 days from the date of receipt of such directive furnish the required notification.

Subpart D – ***Exemptions*** From Notification Requirements

Sec. 1003.30 Application for exemption from notification requirements.

(a) A manufacturer may at the time of giving the written confirmation required by 1003.20 or within 15 days of the receipt of any notice from the Secretary pursuant to 1003.11(a), apply for an ***exemption*** from the requirement of notice to the persons specified in 1003.10(b).

(b) The application for ***exemption*** shall contain the information required by 1003.20 and in addition shall set forth in detail the grounds upon which the exemption is sought.

Sec. 1003.31 Granting the exemption.

(a) If, in the judgment of the Secretary, the application filed pursuant to 1003.30 states reasonable grounds for an ***exemption*** from the requirement of notice, the Secretary shall give the manufacturer written notice specifying a reasonable period of time during which he may present his views and evidence in support of the application.

(b) Such views and evidence shall be confined to matters relevant to whether the defect in the product or its failure to comply with an applicable Federal standard is such as to create a significant risk of injury, including genetic injury, to any person and shall be presented in writing unless the Secretary determines that an oral presentation is desirable. Where such evidence includes nonclinical laboratory studies, the data submitted shall include, with respect to each such study, either a statement that the study was conducted in compliance with the requirements set forth in part 58 of this chapter, or, if the study was not conducted in compliance with such regulations, a brief statement of the reason for the noncompliance. When such evidence includes clinical investigations involving human subjects, the data submitted shall include, with respect to each clinical investigation either a statement that each investigation was conducted in compliance with the requirements set forth in part 56 of this chapter, or a statement that the investigation is not subject to such requirements in accordance with 56.104 or 56.105, and a statement that each investigation was conducted in compliance with the requirements set forth in part 50 of this chapter.

(c) If, during the period of time afforded the manufacturer to present his views and evidence, the manufacturer proves to the Secretary's satisfaction that the defect or failure to comply does not create a significant risk of injury, including genetic injury, to any person, the Secretary shall issue an ***exemption*** from the requirement of notification to the manufacturer and shall notify the manufacturer in writing specifying:

(1) The electronic product or products for which the ***exemption*** has been issued; and

(2) Such conditions as the Secretary deems necessary to protect the public health and safety.

(d) Any person who contests denial of an ***exemption*** shall have an opportunity for a regulatory hearing before the Food and Drug Administration pursuant to part 16 of this chapter.

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PART 1010—PERFORMANCE STANDARDS FOR ELECTRONIC PRODUCTS: GENERAL

SUMMARY:

Subpart A – General Provisions

This part describes the general performance standards for electronic products including manufacturer certification labeling of products and identification labeling of products, and instructions for determining the applicability and application for variances to the performance standards. Performance standards for specific types of electronic products are found in Parts 1020, 1030, 1040, and 1050 for ionizing radiation emitting products, microwave and radio frequency-emitting products, light-emitting products, and sonic, infrasonic, and ultrasonic radiation-emitting products; respectively.

Section 1010.5, describes the criteria, means, application procedures, and amendment procedures for obtaining exemptions for electronic products or class of products from the provisions of performance standards for electronic products intended for United States Government use. The Director, CDRH may grant exemptions from any performance standard under Subchapter J of Chapter I for an electronic product or a class of electronic products when he or she determines that they are intended for sole or predominant use by departments or agencies of the United States provided:

1) The procuring agency prescribes procurement specifications for the product or class of products governing emissions of electronic radiation and these products, or

2) The product or class of products is intended for research, investigations, studies, demonstration, or training, or for reasons of national security.

This section also recommends that the US Government department or agency which intends to procure or manufacture an electronic product which must deviate from FDA regulations or standards consult with CDRH about the exemption being sought as early as possible in the development of the specifications for the product. The application for exemption must be very specific and include certain applicable elements found in this section. Among those 13 elements is a time limit for the exemption. Should a time limit extension or an amendment to the exemption be necessary, these can be requested through a separate application process. Once the Director has granted an exemption, a written notice specifying the exemptions and all conditions or terms will be sent to the requesting department or agency. The department or agency will be the administrator of the exemption to the vendors. The Director also has the authority to amend or withdraw

any exemption whenever he or she determines that action is necessary to protect public health and communicated immediately to the department or agency holding the exemption. Any equipment covered by the exemption shall also bear a specific caution label or tag stating that the equipment has been granted an exemption from 21 CFR. See 1010.5(f) for specific language.

Subpart C--Exportation of Electronic Products

The performance standards of Part 1010 do not apply to electronic products intended solely for export, which meet all applicable requirements of the export country, and is properly labeled for export as per this section.

GOVERNMENT EXEMPTION DISCUSSION:

While government departments have been granted exemptions for laser products on a case by case basis, these will not be discussed in detail here. This discussion will provide examples of exemptions given to departments and agencies of the United States, which have resulted in these departments and agencies administering their own exemptions for a range of laser products. Laser industry notices which highlight key points as to their granting and enforcement will also be discussed.

Department of Defense Exemption. The first exemption granted by the Director of the Bureau of Radiological Health (predecessor to Center for Devices and Radiological Health) was under *1010.5 Exemptions for products intended for United States Government use*, and it was granted to the Department of Defense (DOD) in July 1976 (see Attachments 1 and 2). It is identified specifically as Exemption No. 76EL-01DOD and found in Policy Statement #9, which is currently disseminated to the laser industry as *FDA Notices to the Laser Industry No. 9, "Exemption of Certain Military Laser Products from the FDA Radiation Safety Performance Standard for Laser Products"* (see Attachment 3). The DOD exemption was from the provisions of 21 CFR 1040.10 and 1040.11, the laser performance standards and the provisions of 21 CFR 1002, records and reporting requirements. However, the exemption did not include 1002.20 Reporting of accidental radiation occurrences (ARO).

The basis for the request for exemption was due to labeling requirements of the laser, which did not lend themselves to DOD camouflage requirements or covert operations. The exemption was limited only to those laser products used for combat, combat training, and classified interests of national defense. The exemption would not apply to other laser products such as those used in classroom training, demonstrations, industrial operations, scientific investigations, and medical purposes. The Director also accepted the DOD laser user safety and control procedures as adequate.

Therefore, the exemption was granted with the following additional conditions:

1) DOD must establish monitoring procedures to assure that:

   a. Only laser products designed, purchased, made, and classified by the DOD for combat, combat training operations, or in the interests of national defense conform to conditions of the exemption,

   b. Permanent records will be maintained of the status of all exempted laser products, including their final disposition, and

   c. The exempted products will not be disposed of through excess or surplus property channels without advance authorization by the FDA,

2) DOD will provide an annual report to FDA summarizing the internal records maintained on the exempted products identifying types of laser products and manufacturers,

3) DOD procurement specifications for such exempted products will include the radiation safety provisions of 21 CFR 1040.10 and 1040.11 to the extent practical,

4) Any substantive amendments to the radiation safety and control procedures accepted by the Director will be submitted to the FDA for review,

5) All exempted products must be clearly identified either by a specific caution label or other means as found in Attachments 2 and 3, and that a list of products identified by other than the specified caution label be included in the annual report (from DOD) along with the alternate means and the bases for such alternate means.

The exemption may be withdrawn or amended if any of these terms are not adhered to or if other information becomes available indicating that the public's health and safety are not adequately protected from radiation emitted from exempted electronic products.

DOD Exemption in Practice. Five months later in December 1976, it became known to FDA that manufacturers of certain laser products for the DOD were claiming exemptions from 21 CFR 1410.10 and 1410.11 citing Policy Statement #9 (Attachment 3). Upon contacting the DOD, FDA learned that procedures for processing exemptions had not been implemented as of December 7, 1976 nor had DOD authorized an exemption for any laser product.

Therefore, FDA issued Policy Statement #15, which is currently disseminated to the laser industry as *FDA Notices to the Laser Industry No. 15, "Exemption of Certain Military Laser Products from the FDA Radiation Safety Performance Standard for Laser Products"* (see Attachment 4). In this statement, manufacturers were instructed to secure a written confirmation of their exemption from the DOD along with terms of the

exemption for their specific laser products. All non-exempted laser products manufactured on or after August 2, 1976 had to be certified by their manufacturers in compliance with 21 CFR 1040.10 and 1040.11. Manufacturers in violation of these requirements may have been subjected to penalties described by Section 360C (most likely updated to Section 303) of the Act. The statement also ordered that the introduction of all military laser products into general commerce which were not in compliance with the Federal standard be terminated immediately until an exemption authorization was secured from DOD.

DOD Exemption Amendment. In January 1986, DOD requested an amendment to exemption 76EL-01DOD, which would eliminate the annual report requirement. At the time the exemption was granted, the performance standard for light-emitting products (Section 1040) had not yet been in effect, and the Director retained the annual report requirement as a prudent measure to assure public health without being able to reasonably foresee the magnitude of potential problems and challenges associated with the performance standard.

After 10 years of experience administering these regulations and receiving 9 annual reports from DOD, the Director decided that annual reports were no longer needed as a monitoring tool and revoked the annual report requirement effective September 1, 1985. However, while annual reports were no longer required, the information contained in the annual reports must still be collected and maintained, as this information may be requested by FDA to verify manufacturer DOD exemption claims (See Attachment 5).

2002 DOD Exemption Guidance. In July 2002, a guidance document was written to laser manufacturers regarding DOD exemption 76EL01DOD and was disseminated to the laser industry as *FDA Notices to the Laser Industry No. 52, "Guidance on the Department of Defense Exemption from the FDA Performance Standard for Laser Products (Guidance for Industry and FDA"* (see Attachment 6). The purpose of this guidance document was to clarify and update the conditions for the DOD guidance procured for combat or combat training, or that are for reasons of national security. This guidance was directed specifically to manufacturers regarding the DOD exemption, supplements Laser Notices #9 and #15, and identifies the current military services resources for the administration of this exemption.

The coordinating group for laser safety issues within the DOD is the Laser Systems Safety Working Group (LSSWG). The LSSWG was concerned that laser products were offered to various DOD purchasing authorities and procured without appropriate control measures implemented to assure the safest possible use.

The guidance consists of three basic precepts:

1) Manufacturers must obtain an exemption letter from an authorized DOD procurement office and retain it for subsequent sales.

2) Any subsequent modification to a military exempt laser product by the manufacturer requires a new DOD exemption letter. Any manufacturer selling a product that is not FDA compliant to the DOD or falsely labels a laser product as exempt without a DOD exemption letter is in violation of Federal law; and

3) Once the DOD exemption is applied to a laser system, the system cannot be sold, surplused, or distributed to organizations outside the DOD, unless it fully complies with FDA regulations in 21 CFR.

DOE and NOAA Exemptions. Robert Britain, Director of Compliance, Bureau of Radiological Health approved an exemption for the Department of Energy (DOE) in 1978 and the National Oceanic and Atmospheric Administration (NOAA) in 1979 under Section 1010.5. These exemptions were identified specifically as Nos. 78EL-01DOE, and 79EL-01NOAA for DOE and NOAA, respectively. Both exemptions were the subject of Policy Statement #25, which was disseminated as a memorandum to the laser industry as *FDA Notices to the Laser Industry No. 25, "Exemption of Certain Laser Products Used Exclusively by the Department of Energy or Its Contractors, and by the National Oceanic and Atmospheric Administration, U.S. Department of Commerce"* (see Attachment 7). These exemptions are for exclusive use by NOAA and DOE or its contractors at DOE designated, government-owned, contractor-operated facilities in unique research applications or as components in larger research and development systems. The exemptions are from the provisions of the laser products performance standard, 21 CFR 1040.10 and 1040.11 and associated reporting and recordkeeping requirements of 21 CFR 1002 with the exception of 1002.20 relating to accidental radiation occurrences.

As conditions of the exemptions, all exempted products are to be clearly identified by legible labels or inscriptions upon final assembly as per wording set forth in the exemption letter. Additionally, DOE and NOAA will report annually to FDA on the type of devices procured under the exemption and their manufacturers. Finally, the exemption may be withdrawn or amended if any of the terms of the agreement between FDA and these agencies are not adhered to.

GOVERNMENT EXEMPTION CONCLUSION:

Exemptions have been granted to the Government departments and agencies who requested them under 1010.5, and DOD, DOE, and NOAA became the administrators of their exemptions to the vendors from whom electronic products would be procured. The DOD exemption letter is readily available, and it outlines the conditions under which their exemption is granted. Laser Notices 9, 15, and 52 communicate information about the DOD exemption and how it affects manufacturers. Similarly, Laser Notice 25 communicates updated information about the DOE and NOAA exemptions to manufacturers.

One item missing from both the DOD exemption request letter and the FDA letter granting the exemption was the period of time the exemption was to be in effect, but the inference from the letter was that it would be indefinite.

Evidence to date states that all original exemptions contain language requiring these Government agencies and departments to furnish annual reports summarizing the internal records maintained on the exempted products, identifying types of laser products and manufacturers (including those manufactured by the government departments and agencies) as well as a list of those products which are identified by means other than the label and wording specified by the exemption, and if different, information that forms the basis for different means of identification. Additionally, any substantive amendments to the radiation safety procedures enclosed in the exemption request letter must be submitted to FDA for review.

PART 1010—PERFORMANCE STANDARDS FOR ELECTRONIC PRODUCTS: GENERAL

Subpart A – General Provisions

Sec. 1010.5 Exemptions for products intended for United States Government use.

(a)Criteria for ***exemption***. Upon application by a manufacturer (including assembler) or by a U.S. department or agency, the Director, Center for Devices and Radiological Health, Food and Drug Administration, may grant an ***exemption*** from any performance standard under subchapter J of this chapter for an electronic product, or class of products, otherwise subject to such standard when he determines that such electronic product or class is intended for use by departments or agencies of the United States and meets the criteria set forth in paragraph (a) (1) or (2) of this section.

(1) The procuring agency shall prescribe procurement specifications for the product or class of products governing emissions of electronic product radiation, and the product or class shall be of a type used solely or predominantly by a department or agency of the United States.

(2) The product or class of products is intended for research, investigations, studies, demonstration, or training, or for reasons of national security.

(b)Consultation between the procuring agency and the Food and Drug Administration. The United States department or agency that intends to procure or manufacture a product or class of products subject to electronic product radiation safety standards contained in this subchapter should consult with the Center for Devices and Radiological Health, Food and Drug Administration, whenever it is anticipated that the specifications for the product or class must deviate from, or be in conflict with, such applicable standards. Such consultation should occur as early as possible during development of such specifications. The department or agency should include in the specifications all requirements of such standards that are not in conflict with, or are not inappropriate for, the special or unique uses for which the product is intended. The procuring agency should indicate to the Center for Devices and Radiological Health if it desires to be notified of the approval, amendment, or withdrawal of the ***exemption***.

(c)Application for ***exemption***. If you are submitting an application for ***exemption***, or for amendment or extension thereof, you must submit an original and two copies to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. For an ***exemption*** under the criteria prescribed in paragraph (a)(1) of this section, the application shall include the information prescribed in paragraphs (c)(1) through (c)(13) of this section. For an ***exemption*** under the criteria prescribed in paragraph (a)(2) of this section, the application shall include the information prescribed in paragraphs (c)(3) through (c)(13) of this section. An application for ***exemption***, or for amendment or extension thereof, and correspondence relating to such application shall be made available for public disclosure in the Division of Dockets Management, except for

confidential or proprietary information submitted in accordance with part 20 of this chapter. Information classified for reasons of national security shall not be included in the application. Except as indicated in this paragraph, the application for ***exemption*** shall include the following:

(1) The procurement specifications for the product or class of products that govern emissions of electronic product radiation.

(2) Evidence that the product or class of products is of a type used solely or predominantly by departments or agencies of the United States.

(3) Evidence that such product or class of products is intended for use by a department or agency of the United States.

(4) A description of the product or class of products and its intended use.

(5) An explanation of how compliance with the applicable standard would restrict or be inappropriate for this intended use.

(6) A description of the manner in which it is proposed that the product or class of products shall deviate from the requirements of the applicable standard.

(7) An explanation of the advantages to be derived from such deviation.

(8) An explanation of how means of radiation protection will be provided where the product or class of products deviates from the requirements of the applicable standard.

(9) The period of time it is desired that the ***exemption*** be in effect, and, if appropriate, the number of units to be manufactured under the ***exemption***.

(10) The name, address, and telephone number of the manufacturer or his agent.

(11) The name, address, and telephone number of the appropriate office of the United States department or agency purchasing the product or class of products.

(12) Such other information required by regulation or by the Director, Center for Devices and Radiological Health, to evaluate and act on the application. Where such information includes nonclinical laboratory studies, the information shall include, with respect to each nonclinical study, either a statement that each study was conducted in compliance with the requirements set forth in part 58 of this chapter, or, if the study was not conducted in compliance with such regulations, a statement that describes in detail all differences between the practices used in the study and those required in the regulations. When such information includes clinical investigations involving human subjects, the information shall include, with respect to each clinical investigation, either a statement that each

investigation was conducted in compliance with the requirements set forth in part 56 of this chapter, or a statement that the investigation is not subject to such requirements in accordance with 56.104 or 56.105 and a statement that each investigation was conducted in compliance with the requirements set forth in part 50 of this chapter.

(13) With respect to each nonclinical laboratory study contained in the application, either a statement that the study was conducted in compliance with the requirements set forth in part 58 of this chapter, or, if the study was not conducted in compliance with such regulations, a brief statement of the reason for the noncompliance.

(d)Amendment or extension of an ***exemption***. An ***exemption*** is granted on the basis of the information contained in the original application. Therefore, if changes are needed in the radiation safety specifications for the product, or its use, or related radiation control procedures such that the information in the original application would no longer be correct with respect to radiation safety, the applicant shall submit in advance of such changes a request for an amendment to the ***exemption***. He also shall submit a request for extension of the ***exemption***, if needed, at least 60 days before the expiration date. The application for amendment or extension of an ***exemption*** shall include the following information:

(1) The ***exemption*** number and expiration date.

(2) The amendment or extension requested and basis for the amendment or extension.

(3) If the radiation safety specifications for the product or class of products or the product's or class of products' use or related radiation control procedures differ from the description provided in the original application, a description of such changes.

(e)Ruling on an application.

(1) The Director, Center for Devices and Radiological Health, may grant an ***exemption*** including in the written notice of ***exemption*** such conditions or terms as may be necessary to protect the public health and safety and shall notify the applicant in writing of his action. The conditions or terms of the ***exemption*** may include specifications concerning the manufacture, use, control, and disposal of the excess or surplus ***exempted*** product of class of products as provided in the Code of Federal Regulations, title 41, subtitle C. Each ***exemption*** will be assigned an identifying number.

(2) The Director, Center for Devices and Radiological Health, shall amend or withdraw an ***exemption*** whenever he determines that such action is necessary to protect the public health or otherwise is justified by provisions of the act or this subchapter. Such action shall become effective on the date specified in the written notice of the action sent to the applicant, except that it shall become effective immediately when

the Director determines that it is necessary to prevent an imminent health hazard.

(f)Identification of equipment covered by ***exemption***. The manufacturer of any product for which an ***exemption*** is granted shall provide the following identification in the form of a tag or label permanently affixed or inscribed on such product so as to be legible and readily accessible to view when the product is fully assembled for use or in such other manner as may be prescribed in the ***exemption***:

Caution
This electronic product has been ***exempted*** from Food and Drug Administration radiation safety performance standards prescribed in the Code of Federal Regulations, title 21, chapter I, subchapter J, pursuant to ***Exemption*** No. ___, granted on _____

Subpart C--Exportation of Electronic Products

Sec. 1010.20 Electronic products intended for export.

The performance standards prescribed in this subchapter ***shall not apply*** to any electronic product which is intended solely for export if:

(a) Such product and the outside of any shipping container used in the export of such product are labeled or tagged to show that such product is intended for export, and

(b) Such product meets all the applicable requirements of the country to which such product is intended for export.

21 CFR Chapter I, Sub-Chapter J -- Radiological Health
Electronic Products Exemptions Found in Parts 1000 – 1050

PART 1020 – PERFORMANCE STANDARDS FOR IONIZING RADIATION EMITTING PRODUCTS

SUMMARY:

Sec. 1020.30 Diagnostic x-ray systems and their major components.

(q) Modification of certified diagnostic x-ray components and systems.

Certified diagnostic x-ray comp components and systems in accordance with 1010.2 of this chapter may only be modified if a variance has been granted or an exemption under Section 534(a)(5) or 538(b) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) has been granted (see Attachment 8).

Sec. 1020.31 Radiographic equipment.

This exemption is for radiation therapy simulation systems from the visual definition requirement of this section.

Sec. 1020.32 Fluoroscopic equipment.

(a)Primary protective barrier

Radiation therapy simulation systems shall be exempt from the limitation of useful beam requirement provided the systems are intended only for remote control operation and the manufacturer sets forth instructions for assemblers with respect to control location as part of the information, and the manufacturer provides precautions concerning the importance of remote control operation to users.

(d)Air kerma rates.

Fluoroscopic radiation therapy simulation systems are exempt from the requirements set forth in this section.

PART 1020 – PERFORMANCE STANDARDS FOR IONIZING RADIATION EMITTING PRODUCTS

Sec. 1020.30 Diagnostic x-ray systems and their major components.

(q)*Modification of certified diagnostic x-ray components and systems*.

(1) Diagnostic x-ray components and systems certified in accordance with 1010.2 of this chapter shall not be modified such that the component or system fails to comply with any applicable provision of this chapter unless a variance in accordance with 1010.4 of this chapter or an ***exemption*** under section 534(a)(5) or 538(b) of the Federal Food, Drug, and Cosmetic Act has been granted.

Sec. 1020.31 Radiographic equipment.

The provisions of this section apply to equipment for radiography, except equipment for fluoroscopic imaging or for recording images from the fluoroscopic image receptor, or computed tomography x-ray systems manufactured on or after November 29, 1984.

(d)*Field limitation and alignment for mobile, portable, and stationary general purpose x-ray systems*. Except when spot-film devices are in service, mobile, portable, and stationary general purpose radiographic x-ray systems shall meet the following requirements:

2)*Visual definition*.

(ii) When a light localizer is used to define the x-ray field, it shall provide an average illuminance of not less than 160 lux (15 footcandles) at 100 cm or at the maximum SID, whichever is less. The average illuminance shall be based on measurements made in the approximate center of each quadrant of the light field. Radiation therapy simulation systems are ***exempt*** from this requirement.

Sec. 1020.32 Fluoroscopic equipment.

The provisions of this section apply to equipment for fluoroscopic imaging or for recording images from the fluoroscopic image receptor, except computed tomography x-ray systems manufactured on or after November 29, 1984.

(a)Primary protective barrier –

(1)Limitation of useful beam. The fluoroscopic imaging assembly shall be provided with a primary protective barrier which intercepts the entire cross section of the useful beam at any SID. The x-ray tube used for fluoroscopy shall not produce x-rays unless the barrier is in position to intercept the entire useful beam. The AKR due to transmission through the barrier with the

attenuation block in the useful beam combined with radiation from the fluoroscopic image receptor shall not exceed 3.34*10-3percent of the entrance AKR, at a distance of 10 cm from any accessible surface of the fluoroscopic imaging assembly beyond the plane of the image receptor. Radiation therapy simulation systems shall be ***exempt*** from this requirement provided the systems are intended only for remote control operation and the manufacturer sets forth instructions for assemblers with respect to control location as part of the information required in 1020.30(g). Additionally, the manufacturer shall provide to users, under 1020.30(h)(1)(i), precautions concerning the importance of remote control operation.

(d)*Air kerma rates*. For fluoroscopic equipment, the following requirements apply:

(4)***Exemptions***. Fluoroscopic radiation therapy simulation systems are ***exempt*** from the requirements set forth in paragraph (d) of this section.

21 CFR Chapter I, Sub-Chapter J -- Radiological Health
Electronic Products Exemptions Found in Parts 1000 – 1050

PART 1030 – PERFORMANCE STANDARDS FOR MICROWAVE AND RADIO FREQUENCY EMITTING PRODUCTS

SUMMARY:

Sec. 1030.10 Microwave ovens.

(c) Requirements

(6) Warning labels.

Upon application, the Director, CDRH may grant an exemption from one or more of the statements (radiation safety warnings) specified in this paragraph and it must be based upon a determination by the Director that the microwave oven model for which the exemption is sought should continue to comply with paragraphs (c) (1), (2), and (3) of this section under the adverse condition of use addressed by such precautionary statement(s).

PART 1030 – PERFORMANCE STANDARDS FOR MICROWAVE AND RADIO FREQUENCY EMITTING PRODUCTS

Sec. 1030.10 Microwave ovens.

(c)Requirements –

(6)Warning labels. Except as provided in paragraph (c)(6)(iv) of this section, microwave ovens shall have the following warning labels:

(iv) Upon application by a manufacturer, the Director, Center for Devices and Radiological Health, Food and Drug Administration, may grant an ***exemption*** from one or more of the statements (radiation safety warnings) specified in paragraph (c)(6)(i) of this section. Such ***exemption*** shall be based upon a determination by the Director that the microwave oven model for which the ***exemption*** is sought should continue to comply with paragraphs (c) (1), (2), and (3) of this section under the adverse condition of use addressed by such precautionary statement(s). An original and two copies of applications shall be submitted to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Copies of the written portion of the application, including supporting data and information, and the Director's action on the application will be maintained by the Branch for public review. The application shall include:

(a) The specific microwave oven model(s) for which the ***exemption*** is sought.

(b) The specific radiation safety warning(s) from which ***exemption*** is sought.

(c) Data and information which clearly establish that one or more of the radiation safety warnings in paragraph (c)(6)(i) of this section is not necessary for the specified microwave oven model(s).

(d) Such other information and a sample of the applicable product if required by regulation or by the Director, Center for Devices and Radiological Health, to evaluate and act on the application.

Attachment 1

Request letter to Mr. John Villforth, Director Bureau of Radiological Health from George Marienthal, Deputy Assistant Secretary of Defense (Environment and Safety)

ASSISTANT SECRETARY OF DEFENSE

Mr. John Villforth 2 Jul 1976
Director
Bureau of Radiological Health
Rockville, Maryland 20852

Dear Mr. Villforth:

This is in response to 21 CFR Part 1010 rule changes that the Commissioner of the Food and Drug Administration proposed on September 4, 1974. The changes add a new section 1010.5 and provide for exemptions from standards for electronic products, primarily laser products.

Military laser products have special field-use considerations, such as weight, survivability, camouflage requirements, covert operations, which do not lend themselves to full compliance with all the standards promulgated under PL 90-602, Radiation Control for Health and Safety Act. In most instances, the specified defense mission requirements could not be satisfied if total compliance was accomplished.

I, therefore, propose that an exemption be granted for all military laser electronic products used exclusively by Department of Defense components and designed expressly for actual combat operations, combat training operations, and laser products classified in the interest of national defense. The exemption would not apply to laser products intended primarily for use in indoor classroom training and demonstration, industrial operations, scientific investigations, and medical laser products.

Because of the difficulties to achieve complete product safety with military hardware, the DoD components require proper laser user safety procedures in regulations and user guidance documents. Within the U.S. Army, they are: AR 40-5, Health and Environment, 25 September 1974; AR 40-46, Control of Health Hazards

from Lasers and Other High Intensity Optical Sources, 6 February 1974; TB MED 279, Control of Hazard to Health from Laser Radiation, 30 May 1975. The user guidance document for the U.S. Air Force is AF Manual 161-32, Laser Health Hazards Control, 20 April 1973. Those documents are enclosed. The ANSI 136. 1, 1973, American National Standard for Safe Use of Lasers, was adopted by the U.S. Navy. Additional control procedures include operator training in the safe use of tactical equipment, performing an in-depth hazard analysis of such equipment during various stages of its life cycle, as well as a hazard analysis of training and testing sites, and routine surveys of such equipment located at military installations.

The Department of Defense will establish monitoring procedures to assure that:

- Only products which meet criteria in the third paragraph of this letter will be procured or manufactured by the DoD pursuant to the requested exemption.

- The DoD will maintain a permanent record of the status of exempted laser products, including their ultimate disposition. The products will not be disposed through excess or surplus property channels without advance authorization by the FDA. All exempted products will be clearly identified, either by labeling as set forth below, or by other means.

CAUTION

This electronic product has been exempted from FDA radiation safety performance standards prescribed in the Code of Federal Regulations, Title 21, Chapter I, Subchapter J, pursuant to Exemption No. _____issued on _____. This product should not be used without adequate protective devices or procedures.

- Procurement specifications for such exempted products will include, to the extent practicable. the radiation safety provisions of the applicable Federal standard (21 CFR 1040.10; 1040.11) unless adequate alternative controls are to be provided by the Department of Defense. Any substantive amendments to the radiation safety procedures will be submitted to the FDA for review.

The Department of Defense will provide an annual report to FDA summarizing the internal records maintained on the exempted products, identifying types of laser products and manufacturers. Reporting and record keeping requirements prescribed in 21 CFR Part 1002, except for paragraph 1002.20, should be waived by the FDA.

I appreciate the time that you and your staff spent to assist the DOD to resolve a potential problem area. It is most gratifying to see this spirit of interagency cooperation.

Sincerely,

/S/

George Marienthal
Deputy Assistant Secretary of Defense
(Environment and Safety)

Enclosures

Attachment 2

Response letter to George Marienthal, Deputy Assistant Secretary of Defense (Environment and Safety) from Mr. John Villforth, Director Bureau of Radiological Health

Mr. George Marienthal July 29, 1976
Deputy Assistant Secretary of Defense
Environment and Safety
Department of Defense
Washington, D.C. 20301

This letter will respond to your letter of July 2,1976, to the Director of the Bureau of Radiological Health of the Food and Drug Administration requesting an exemption from the FDA radiation safety performance standard for laser products (21 CFR §§ 1040.10 and 1040.11) which becomes effective on August 2, 1976.

Under the authority delegated to me by the Assistant Secretary for Health of the Department of Health, Education, and Welfare (21 CFR ~ 5.1), pursuant to sections 358 and 360B of the Public Health Service Act, as amended by the radiation Control for Health and Safety Act of 1968 (42 U.S.C. § 263f and 263j), I hereby exempt from the provisions of 21 CFR §§ 1040.10 and 1040.ll, and from the provisions of 21 CFR Part 1002 (except § l002.20), laser products that are used exclusively by Department of Defense components and that are designed for actual combat or combat training operations or are classified in the interest of national security.

It is my understanding that this exemption is necessary because laser products that are to be used by the military for the purposes stated above require capabilities which do not lend themselves to full compliance with all provisions of the laser standard promulgated under the Act. Your request for exemption acknowledges that in most instances the specified defense mission for which the products are intended could not be fulfilled if total compliance with the standard were required.

In recommending that your request for exemption be granted, the Bureau of Radiological Health considered the laser user safety and control proce¬dures utilized by the Department of Defense. These include: for the U.S. Army, AR 40-5, Health and Environment, 25 September 1974; AR 40-46, Control of Health Hazards from Lasers and Other High Intensity Optical Sources, 6 February 1974; TB MED 279, Control of Hazard to Health from Laser Radia¬tion, 30 May 1975; for the U.S. Air Force, AF Manual l6l-32, Laser Health Hazards Control, 20 April 1973; and for the U.S. Navy ANSI 136.1, 1973, American National Standard for Safe Use of Lasers. Additional control procedures utilized by the Department of Defense include: operator training in the safe use of tactical

equipment, performing an in-depth hazard analysis of such equipment during various stages of its life cycle, a hazard analysis of training and testing sites, and routine surveys of such equipment located at military installations.

The granting of this exemption is also based upon the understanding that the Department of Defense will establish monitoring procedures to assure that (1) only laser products designed expressly for actual combat opera¬tions or combat training operations and laser products classified in the interest of national defense will be procured or manufactured by the Department of Defense pursuant to the requested exemption, and (2) the Department of Defense will maintain a permanent record of the status of all exempted laser products, including their ultimate disposition. The products will not be disposed of through excess or surplus property channels without advance authorization by the FDA.

As a further condition of this exemption, the Department of Defense has also agreed to provide an annual report to FDA summarizing the internal records maintained on the exempted products, identifying types of laser products and manufacturers. Furthermore, Department of Defense procurement specifications for such exempted products will include, to the extent practicable, the radiation safety provisions of the applicable Federal standard (21 CFR 1040.10; 1040.11) unless adequate alternative controls are to be provided by the Department of Defense. Any substantive amendments to the radiation safety procedures enclosed with your letter of July 2,1976 will be submitted to the FDA for review.

All exempted products are also to be clearly identified either by the label set forth below, or by other means;

CAUTION

This electronic product has been exempted from FDA radiation safety performance standards prescribed in the Code of Federal Regulations, Title 21, Chapter I, Subchapter J, pursuant to Exemption No. _____ issued on _____. This product should not be used without adequate protective devices or procedures.

We request, as a term of this exemption, that the Department of Defense list in the annual report to this Agency all exempted products which are identified by a means other than by the above label, and provide detailed information as to the alternative means of identification provided, and the bases for such alternative means of identification.

This exemption is granted upon the understanding that all of the above commitments, set forth in your letter of July 2. 1976, are fulfilled by the Department of Defense. The exemption may be withdrawn or amended if any of those terms are not adhered to, or if other information becomes available that indicates that the public health and safety are not adequately protected from electronic product radiation emitted by products exempted pursuant to this authorization.

This exemption shall be referred to as Exemption No. 76EL-OlDOD issued on July 26. 1976, and any correspondence concerning its implementation should be directed to the Director of the Bureau of Radiological Health. A copy of your July 2. 1976 letter requesting the exemption (with attachments) and this notice of approval will be filed in the FDA Public Records and Documents Center, Room 4-62, 5600 Fishers Lane, Rockville, MD.

We appreciate your cooperation in this matter.

Sincerely yours,

/S/

Sherwin Gardner
Acting Commissioner of Food and Drugs

Attachment 3

FDA Notices to the Laser Industry No. 9

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE
PUBLIC HEALTH SERVICE
FOOD AND DRUG ADMINISTRATION
ROCKVILLE, MARYLAND 20852

REF:DOC:4026-MA

AUG 23 1976

TO: ALL LASER PRODUCT MANUFACTURERS AND POTENTIAL MANUFACTURERS OF LASER PRODUCTS

SUBJECT: Exemption of Certain Military Laser Products from the FDA Radiation Safety Performance Standard for Laser Products.

The purpose of this memorandum is to notify all laser product manufacturers of an exemption granted for all laser products which are manufactured after August 2, 1976, and used exclusively by DOD agencies, and which are designed for actual combat or combat training operations or are classified in the interest of national defense (Reference FDA Docket No. 76P-0335). The exemption does not apply to laser products intended primarily for use in indoor classroom training and demonstration, industrial operations, and scientific investigations; and medical laser products. The exemption is from the FDA performance standard for laser products in 21 CFR Part 1040.10 and 1040.11 and the associated reporting and record keeping requirements of 21 CFR Part 1002, except for paragraph 1002.20 relating to accidental radiation occurrences.

Mr. Sherwin Gardner, Acting Commissioner of Foods and Drugs, announced the exemption in a letter dated July 29, 1976, to Mr. George Marienthal, Deputy Assistant Secretary of Defense. The exemption was granted on the grounds that the special military requirements for such devices preclude full compliance with the FDA performance standard. However, DOD procurement specifications will prescribe compliance with the FDA standard to the extent practicable and will be supplemented with safety controls and procedures utilized by DOD. All exempted products are also to be clearly identified either by the label set forth below, or by other approved means:

"CAUTION

This electronic product has been exempted from FDA radiation safety performance standards prescribed in the Code of Federal Regulations, Title 21, Chapter I, Subchapter J, pursuant to Exemption No. 76EL-01DOD issued on July 26, 1976. This product should not be used without adequate protective devices or procedures."

In addition, DOD will restrict surplus disposal of these devices and report annually to FDA on the types of devices procured under the exemption, their manufacturers, and means of identification if different than the above label.

Policy Statement #9

The exemption may be withdrawn or amended if any of the terms of the agreement between the Food and Drug Administration and Department of Defense are not adhered to, or if other information becomes available that indicates that the public health and safety are not adequately protected from electronic product radiation emitted by products exempted pursuant to this exemption.

Correspondence concerning the exemption should be directed to the Office of the Assistant Secretary of Defense (Installations and Logistics), Deputy Assistant Secretary of Defense for Environment and Safety, Pentagon Building, Washington, D.C. 20301; the office phone number is (703) 695-0221.

Robert G. Britain
Director
Division of Compliance
Bureau of Radiological Health

Attachment 4

FDA Notices to the Laser Industry No. 15

DEPARTMENT OF HEALTH, EDUCATION AND WELFARE
PUBLIC HEALTH SERVICE
FOOD AND DRUG ADMINISTRATION
ROCKVILLE, MARYLAND 20857

REF:DOC:9090 -MA

DEC 8 1976

TO: All Manufacturers and Potential Manufacturers of Laser Products.
SUBJECT: Exemption of Certain Military Laser Products From the FDA Radiation Safety Performance Standard for Laser Products.

A number of manufacturers of laser products for the Department of Defense have informed representatives of the Food and Drug Administration that certain of their products are exempted from the Federal performance standard for laser products, 21 CFR 1040.10 and 1040.11. The basis for the exemption is stated to be the agreement of July 1976, between Mr. Sherwin Gardner, Acting Commissioner of the Food and Drug Administration and Mr. George Marienthal, Deputy Assistant Secretary of Defense, whereby an exemption from the performance standard for certain military laser products was granted to the DOD. However the Food and Drug Administration has contacted the Office of the Assistant Secretary of Defense (Installation and Logistics) and found that procedures for processing exemptions have not been implemented by the Department of Defense as of December 7, 1976, nor has DOD authorized an exemption for any laser product.

The exemption to the Department of Defense was granted on the grounds that the special military requirements for such products preclude full compliance with the FDA standard. In granting this exemption the Department of Defense agreed to establish procedures to assure that (1) only laser products designed expressly for actual combat operations or combat training operation and laser products classified in the interest of national defense will be procured or manufactured by the Department of Defense pursuant to the requested exemption, and (2) a permanent record of the status of all exempted laser products, including their ultimate disposition will be maintained. Furthermore, it was agreed that Department of Defense procurement specification for such exempted products are to include, to the extent practicable, the radiation safety provisions of the Federal standard (21 CFR 1040.10; 1040.11) unless adequate alternative controls are provided by the Department of Defense.

Manufacturers of military laser products who have not secured in writing a confirmation of their exemption from the Department of Defense along with the terms of the exemption for their specific laser product will not be considered exempt by the Food and Drug Administration and therefore are required by the Radiation Control for Health and Safety Act of 1968, to furnish reports, maintain records on such products and to comply with performance standards as applicable. All laser products manufactured on or after August 2, 1976 and which have not been specifically exempted, must be certified by their manufacturers as in compliance with 21 CFR

1040.10 and 1040.11. Manufacturers who have violated these requirements may be subject to the penalties prescribed by Section 360C of the Act. Introduction of military laser products into commerce which are not certified as being in compliance with the Federal standard must be terminated immediately until an exemption authorization is secured from the Department of Defense.

Manufacturers of a laser product for the Department of Defense who believe their product is eligible for an exemption should contact their contracting officer, as soon as possible, or they may contact the Office of the Assistant Secretary of Defense (Installations and Logistics), Deputy Assistant Secretary of Defense for Environment and Safety, Pentagon Building, Washington, D.C. 20301; the office phone number is (202) 695-0221. The Department of Defense will then determine whether the product can be exempted and will inform the manufacturer in writing as to whether the exemption is authorized.

-/S/-

_____

Robert G. Britain
Director
Division of Compliance
Bureau of Radiological Health
Policy Statement #15

Attachment 5

Response letter to George W. Siebert, Director of Safety and Occupational Health Policy, Office of the Assistant Secretary of Defense from Mr. John Villforth, Director Center for Devices and Radiological Health regarding the elimination of annual report requirement

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service
Food and Drug Administration
Rockville, MD 20857

Mar 18 1986

George W. Siebert
Director of Safety and
Occupational Health Policy
Office of the Assistant Secretary of Defense
Washington, D.C. 20301-4000

Ref. Doc.: 76EL-0IDoD

Dear Mr Siebert:

This letter is in response to your January 6, 1986 request for amendment of exemption 76EL-01DoD to eliminate the requirement for an annual report. Under this exemption, laser products which are intended to be used in combat or in training for combat were exempted, as necessary, from the performance standard for laser products as provided in 21 CFR 1010.5. These products were also exempted from the reporting requirements of 21 CFR 1002.10 and 1002.12 under the authority provided in 1002.51.

At the time this exemption was granted, the performance standard for laser products was not yet in effect, and the Agency could not reasonably anticipate the type or magnitude of problems which would be encountered, or the efficacy of the various mechanisms provided in the standard in addressing these problems. The Agency elected at that time to maintain what was considered the minimal regulatory position consistent with its responsibility for Public Health, and, therefore, the annual reporting requirements was retained. Now the Center has almost ten years of experience in administering these Regulations, and has received nine annual reports from your department. At this point in time, it is my judgment that these reports on exempted products are no longer needed as a monitoring tool.

Therefore, as provided by 21 CFR 1010.5(e) (2), the Department of Defense (DoD) exemption is hereby amended to revoke the requirement for an annual report. The effective date of this amendment is September 1, 1985. Please note that while DoD will no longer need to submit the subject annual reports, it will still be expected to maintain the types of records on which this report was based. This information may be requested when we need to confirm a manufacturer's claim that he is producing laser products for DoD procurement and that his products are indeed subject to exemption. Your continued close cooperation in providing pertinent information upon request is recognized and appreciated, and, of course, such requests will be limited to information which does not impact on national security.

I trust that this resolution of the issues satisfactorily addresses your concerns.

Sincerely yours,

/S/

John C. Villforth
Director
Center for Devices and
Radiological Health

Attachment 6

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 Ad ministration (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.

US Army Center for Health Promotion and Preventive Medicine
ATTN: MCHB DC-OLO
Aberdeen Proving Ground, Maryland 21010-5422
Commercial (410) 436 3932

Naval Surface Warfare Center, Dahlgren Division
Code G73
17320 Dahlgren Road, Dahlgren, VA 22448-5100
Commercial (540) 653-1060/1149

Air Force Research Laboratory
Human Effectiveness Directorate; Optical Radiation Branch
Brooks City-Base, Texas 78235 5128
Commercial (210) 536 4784
Email: laser.safety@brooks.af.mil

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,
Phillip J. Frappaolo
Acting Director
Office of Compliance
Center for Devices and Radiological Health

Attachment 7

FDA Notices to the Laser Industry No. 25

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE
PUBLIC HEALTH SERVICE
FOOD AND DRUG ADMINISTRATION
ROCKVILLE, MARYLAND 20857

SEP 14 1979

TO: ALL LASER PRODUCT MANUFACTURERS AND POTENTIAL MANUFACTURERS OF LASER PRODUCTS

SUBJECT: Exemption of Certain Laser Products Used Exclusively by the Department of Energy or Its Contractors, and by the National Oceanic and Atmospheric Administration, U.S. Department of Commerce

The purpose of this memorandum is to notify all laser product manufacturers of exemptions granted for laser products intended for U.S. Government use (21 CFR 1010.5). These laser products may not be the same as models that are certified and sold or leased commercially. They are to be used exclusively by (1) the National Oceanic and Atmospheric Administration, U.S. Department of Commerce or by (2) the Department of Energy or by its contractors at DOE designated, government-owned contractor-operated (GOCO) facilities in unique research applications or as components in larger research and development systems. The exemption is from the FDA performance standard for laser products, 21 CFR 1040.10 and 1040.11, and the associated reporting and recordkeeping requirements, 21 CFR Part 1002, except for paragraph 1002.20 relating to accidental radiation occurrences.

The exemptions were approved by the Director, Bureau of Radiological Health, by letters dated May 26, 1978, to Mr. James Liverman, Acting Assistant Secretary for Environment, Department of Energy and June 4, 1979 to Mr. Ferris Webster, Assistant Administrator for Research and Development, National Oceanic and Atmospheric Administration, U.S. Department of Commerce.

The exemptions apply to all Department of Energy and to all National Oceanic and Atmospheric Administration, U.S. Department of Commerce, contracts and sub-contracts. However, DOE and NOAA procurement specifications will prescribe compliance with the FDA standard to the extent practicable and will be supplemented with safety controls and procedures utilized by DOE and NOAA.

All exempted products are to be clearly identified by labels permanently affixed to or inscribed on each such product so as to be legible and readily accessible to view when each product is fully assembled for

operation. The labels shall contain the wordings set forth below for DOE and for NOAA respectively:

Department of Energy

CAUTION

This electronic product has been exempted from FDA laser radiation safety performance standards prescribed in the Code of Federal Regulations, Title 21, Chapter 1, Subchaper J, pursuant to Exemption No. 78EL-01DOE issued on May 26, 1978. This product should not be used without adequate protective devices or procedures nor disposed of through excess or regular surplus property channels.

National Oceanic & Atmospheric Administration:

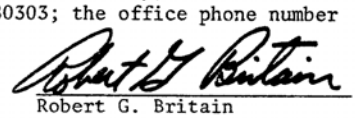
CAUTION

This electronic product has been exempted from FDA laser radiation safety performance standards prescribed in the Code of Federal Regulations, Title 21, Chapter 1, Subchapter J, under Exemption No. 79EL-01 NOAA issued on June 4, 1979. This product should not be used without adequate protective devices or procedures nor disposed of through excess or regular surplus property channels.

In addition DOE and NOAA will report annually to FDA on the type of devices procured under the exemption, and their manufacturers.

The exemption may be withdrawn or amended if any of the terms of the agreement between the Food and Drug Administration and these agencies are not adhered to, or if other information becomes available indicating that the public health and safety are not adequately protected from electronic product radiation emitted by products exempted pursuant to these exemptions.

Correspondence concerning the DOE exemption should be directed to Mr. Kenneth R. Baker, United States Department of Energy, MS E301 Washington, D.C. 20545; the office phone number is (202) 353-5615. Correspondence concerning the NOAA exemption should be directed to Dr. Freeman Hall, Chief of Coherent Lidar and Wave Propagation Laboratory, Environmental Research Laboratories, Boulder, Colorado 80303; the office phone number is (303) 499-1000 X6359.



Robert G. Britain
Director
Division of Compliance
Bureau of Radiological Health

Attachment 8

Federal Food, Drug, and Cosmetic Act
Chapter V: Drugs and Devices; Sections 534(a)(5) and 538(b)

SEC 534 [21 USC §360kk] Performance Standards for Electronic Products

(a)(5) The Secretary may exempt from the provisions of this section any electronic product intended for use by departments or agencies of the United States provided such department or agency has prescribed procurement specifications governing emissions of electronic product radiation and provided further that such product is of a type used solely or predominantly by departments or agencies of the United States.

SEC. 538. [21 USC §360oo] Prohibited Acts

(a) It shall be unlawful—

> (1) for any manufacturer to introduce, or to deliver for introduction, into commerce, or to import into the United States, any electronic product which does not comply with an applicable standard prescribed pursuant to section 534;
>
> (2) for any person to fail to furnish any notification or other material or information required by section 535 or 537; or to fail to comply with the requirements of section 535(f);
>
> (3) for any person to fail or to refuse to establish or maintain records required by this subchapter or to permit access by the Secretary or any of his duly authorized representatives to, or the copying of, such records, or to permit entry or inspection, as required by or pursuant to section 537;
>
> (4) for any person to fail or to refuse to make any report required pursuant to section 537(b) or to furnish or preserve any information required pursuant to section 537(f); or
>
> (5) for any person (A) to fail to issue a certification as required by section 534(h), or (B) to issue such a certification when such certification is not based upon a test or testing program meeting the requirements of section 534(h) or when the issuer, in the exercise of due care, would have reason to know that such certification is false or misleading in a material respect.

(b) The Secretary may exempt any electronic product, or class thereof, from all or part of subsection (a), upon such conditions as he may find necessary to protect the public health or welfare, for the purpose of research, investigations, studies, demonstrations, or training, or for reasons of national security.