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

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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.

The exemption may be withdrawn or amended if any of the terms of the agreement between the Food and Drug Administration and Department of Defense are not adhered to, or if other information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.

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