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

DEC 8 1976

REF:DOC:9090-MA

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