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