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

MAY 26 1978

ENED-11

JAN 11 1997
RECEIVED

Mr. James Liverman
Acting Assistant Secretary
for Environment
Department of Energy
Washington, D. C. 20545

Dear Mr. Liverman:

This letter is in response to yours of December 29, 1977, to the Director, Bureau of Radiological Health, Food and Drug Administration, requesting an exemption from the FDA radiation safety performance standard for laser products (21 CFR 1040.10 and 1040.11).

Under the authority delegated to the Commissioner of Food and Drugs by the Assistant Secretary for Health, Department of Health, Education, and Welfare (21 CFR 5.1), pursuant to Sections 358 and 360B(b) 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) and redelegated to the Director and Deputy Director, Bureau of Radiological Health (21 CFR 5.87), I hereby exempt from the provisions of 21 CFR 1040.10 and 1040.11, and from the provisions of 21 CFR Part 1002 (except § 1002.20), laser products of a type that meet the following conditions: (1) products used exclusively by the Department of Energy or by their contractors at DOE designated, government-owned contractor-operated (GOCO) facilities, and that are used in unique research applications or as components in larger research and development systems, and (2) products not of a model usually manufactured as certified laser products.

The Bureau of Radiological Health has considered the enclosure : submitted by the Department of Energy including the standard health and safety clause integral to all contracts and sub-contracts; the September 22, 1977, list of contractor facilities; the list of health and safety program standards applicable to these contractor operations, dated March 26, 1973, and the representative sampling of laser safety procedures of various GOCO facilities.

The exemption is granted upon the following conditions:

1. The Department of Energy shall provide and enforce to the extent practicable, consistent with the research objectives within each DOE or GOCO facility using exempted laser products, the American National Standard for Safe Use of Lasers (ANSI Z-136.1-1976) and the Federal Standard as set forth in 21 CFR 1040.10, 1040.11 and 1002.

2. The Department of Energy shall establish monitoring procedures to assure that laser products procured or used by the DOE or its contractors pursuant to the requested exemption shall be designed expressly for use as components in larger research and development systems or in unique research applications. The DOE shall provide written authorization to manufacturers to sell or transfer to DOE or its contractors each exempt laser product. Such authorization shall include a reference to the authority provided by this letter and, for each exempted product, (a) an identification by make and model; (b) an overall description of the product and (c) a description of the incorporated laser.

3. The Department of Energy shall maintain a permanent record of identity by make and model of all exempted laser products.

4. Exempted products shall not be disposed of through excess or surplus property channels without advance authorization by the FDA.

5. The Department of Energy shall provide an annual report to FDA summarizing the internal records specified in paragraph (3) above, on the exempted products, identifying types of laser products and manufacturers.

6. The Department of Energy procurement specifications for such exempted products shall include, to the extent practicable, the radiation safety provisions of the applicable Federal Standard (21 CFR 1040.10 and 1040.11). Adequate alternative safety controls are to be provided by the DOE where it is not practicable, consistent with the research objectives, to adhere to the Federal standard. Any substantive amendments to the radiation safety procedures enclosed with your letter of December 29, 1977, shall be submitted to the FDA.

7. All exempted laser products are to be clearly identified by a label permanently affixed to or inscribed on such product so as to be legible and readily accessible to view when the product is fully assembled for operation. The label shall contain the wording set forth below:

CAUTION

This electronic product has been exempted from FDA laser radiation safety performance standards prescribed in the Code of Federal Regulations, Title 21, Chapter I, Subchapter J, pursuant to Exemption No. 78SL-0100S 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.

This exemption is granted upon the understanding that all of the above commitments, and those additional conditions set forth in your letter of December 29, 1977, are fulfilled by the Department of Energy and its contractors. 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 caused by products exempted pursuant to this authorization.

This exemption shall be referred to as Exemption No. 78EL-0100K issued on May 26, 1978, and any correspondence concerning its implementation should be directed to the Director, Division of Compliance, Bureau of Radiological Health. A copy of your December 29, 1977, letter requesting the exemption (with attachments) and this notice of approval will be filed in the FDA Public Records and Documents Center, Room 4C-04, 5600 Fishers Lane, Rockville, Maryland.

We appreciate your cooperation in this matter.

Sincerely yours,

John C. Villforth
Director
Bureau of Radiological Health