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

ADVISORY OPINION

SUBJECT: LASER ENERGY SOURCE: 21 CFR 1040.10(b)(17)

QUESTION: A company manufactures a multiple purpose electron beam accelerator. The beam is capable of providing the excitation energy for selected laser media as evidenced by several research reports of this application in the company's advertising literature for the accelerator. The company asks if this laser energy source meets the criteria for being a laser product within the meaning of 21 CFR 1040.10(b)(17) and as such, is subject to 21 CFR 1040.10 and 1040.11 for laser products and specific purpose laser products.

ADVISORY OPINION: This electron beam accelerator, as a laser energy source, does not meet the criteria for a laser product as defined in paragraph 1040.10(b)(17). Therefore, it would not be subject separately to 21 CFR 1040.10 and 1040.11.

The electron beam accelerator generates an electron beam which provides for energy transfer for many applications. One application is the coupling of this beam into an appropriate medium to provide the excitation energy for the production of laser radiation. Advertising the accelerator for use as a possible energy source for customer built laser systems does not make the accelerator a laser product.

DATED: NOV 21 1975

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