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

DEC 11 1979

TO: MANUFACTURERS AND POTENTIAL MANUFACTURERS OF LASER PRODUCTS

SUBJECT: Enforcement Policy for Certain Laser Light Shows, Displays, and/or Devices. (21 CFR 1040.10 and 1040.11)

BACKGROUND:

On February 21, 1978, the Bureau of Radiological Health issued an interim enforcement policy for certain laser light shows and displays. That document established the policy that the Bureau would not object to the assembly and continued operation of any laser light show, display, and/or device in the absence of a variance, if a specified set of conditions including operational safety criteria were satisfied.

At that time, processing an application for a variance from one or more requirements of a performance standard involved a lengthy process. On August 17, 1979, an amendment to the administrative procedures for ruling on variance applications was published in the Federal Register and became effective on September 17, 1979. This amendment permits the Director of the Bureau of Radiological Health to approve or deny in whole or in part a requested variance, or amendment or extension of a variance. BRH must inform the applicant in a written notice that specifies, among other things, the conditions of the variance, as well as its effective date. The amended procedures no longer include formal publication of variance approvals in the Federal Register, with a 30-day objection period, thus expediting the process considerably. However, a notice of availability of an approved variance will be published in the Federal Register.

In addition the Bureau has developed a variance application form to assist laser light show manufacturers in providing all of the information needed by the Bureau to rule on their variance request. The use of this form will also speed up the variance evaluation process within the Bureau, and is available upon request.

Since these actions will result in reducing the time required to obtain a variance, there is no longer any reason to permit laser light shows, displays, or devices that do not comply with the requirements of the standard for demonstration laser products (i.e., they are Class III or IV laser products) to be introduced into commerce unless a variance (specific authorization to vary from the standard) has been obtained.

POLICY:

Effective May 1, 1980, all manufacturers or assemblers of Class III or IV laser light shows, displays, and devices manufactured or assembled after August 1, 1976, must have an approved variance before introducing them into commerce or continuing their operation. The Food and Drug Administration will take appropriate enforcement action to prevent the manufacture, assembly, introduction into commerce, and continued operation of Class III or IV laser light shows, displays, and devices which fail to comply with the laser product performance standard and with the conditions of the applicable variance. This effective date has been chosen to provide adequate time for all known manufacturers to apply for and obtain a variance and for the laser light show industry to implement policies and procedures necessary to assure compliance.

Please note that Part 1010.4(c)(3) of the Regulations requires the Director, Bureau of Radiological Health, to amend or withdraw a variance whenever the Director determines that such action is necessary to protect the public health or is otherwise justified by 21 CFR, Chapter I, Subchapter J. Therefore, introduction into commerce of any laser light show, display, or device which fails to comply with the applicable requirements of the performance standard or the conditions of its approved variance may be considered grounds for withdrawal of the variance. Also, if the Bureau subsequently determines that the conditions of an approved variance are insufficient to protect the public health, the Director must amend or withdraw the variance.

Although the variance approval process is substantially shortened, it will still require some time to rule on the application. It is recognized by the Bureau that quite often a very short lead time may be given to the manufacturer to produce a show. Even in such a situation, it will be necessary for the manufacturer to obtain an approved variance before producing the show. Therefore, we urge manufacturers to apply for a variance(s) for all of the types of laser light shows, displays, and devices that they would consider producing so that an approved variance can be obtained thus enabling the manufacturer to accept such projects on short notice. Manufacturers may apply for a single general variance or for several different variances to cover distinct types of projects such as indoor shows versus outdoor shows or permanent installations versus touring shows.

Manufacturers are reminded that each laser light show, display or device, regardless of its class, must be reported (by model family) as required by 21 CFR Part 1002; the purpose of the report is to demonstrate compliance with the performance standard and must follow the reporting guide issued by the Bureau. For those laser light shows, displays, and/or devices produced under a variance, the report must also provide the details showing how they comply with the conditions of the variance. A new reporting guide is being prepared specifically for laser light

shows, displays and devices. Copies of this new guide will be available upon request in the near future.

In addition to the reports, we request that the Director, Division of Compliance, BRH be notified in writing of any planned installations or tours (and any changes to such) at least 30 days in advance so that inspections can be arranged and local authorities can be notified. If the Bureau cannot be notified in this manner, we request that you telephone the Light Products Section with the information at the earliest possible date.

If there are any questions regarding this policy, please contact the Light Products Section, Division of Compliance, Bureau of Radiological Health, HFX-430, 5600 Fishers Lane, Rockville, MD 20857, telephone (301) 443-4874.

John C. Villforth
Director
Bureau of Radiological Health