



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Center for Devices and
Radiological Health
2098 Gaither Road
Rockville, MD 20850

AUG 16 2004

Ref: FDA Docket No. 2004V-0317
Accession No. 04A0647

Mr. William E. Baldwin
President
Caliente Resort LLC
21240 Gran Via Boulevard
Land O Lakes, Florida 34637

Dear Mr. Baldwin:

In accordance with 21 CFR 1010.4(c)(1) notice is given that the petition of Caliente Resort LLC, dated February 20, 2004, for a variance from 21 CFR 1040.11(c) of the performance standard for laser products is approved. This variance will allow the introduction into commerce of the laser light show products described in paragraph D below.

A. Variance Number

2004V-0317

B. Effective Date

In accordance with 21 CFR 1010.4(c)(1), this variance shall become effective on the date of this letter.

C. Termination Date

This variance shall be terminated two (2) years from the date of this letter.

D. Product for Which Variance is Granted

This variance is granted for the Class IIIb laser light shows assembled and produced by Caliente Resort LLC. The shows will be produced with a certified LUMALASER BeamBurst Amber 50 projector containing a GaAlAs Diode/GaN laser emitting at 630-680 and 410 nm and a DPSS Nd:YVO4 laser emitting at 532 nm.

The shows will be presented from a fixed installation in a discotheque or night club for more than 15 days. The effects employed may be front or rear screen projections, multiple reflection/diffraction effects, reflections from stationary mirrors, and enhanced scattering effects.

E. Provision from Which Variance is Granted

This variance is granted from 21 CFR 1040.11(c) of the performance standard for laser products requiring that each demonstration laser product shall comply with all of the applicable requirements of 21 CFR 1040.10 for a Class I, IIa, II, or IIIa laser product and shall

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not permit human access to laser radiation in excess of the accessible emission limits of Class I and, if applicable, Class IIa, Class II, or Class IIIa.

F. Conditions under Which Variance is Granted

In lieu of the requirements referred to in Item E above, the conditions as specified below in Variance Attachment A and Variance Attachment B shall apply to the products and devices manufactured under this variance and to the shows assembled and produced under this variance.

G. Basis for Approval of Variance

In accordance with 21 CFR 1010.4(a)(2), it has been determined that the product is required to perform a necessary function or is intended for a special purpose which cannot be performed or accomplished with equipment meeting the requirements referred to in Item E. Suitable means of radiation safety and protection will be provided by constraints on the physical and optical design, and by warnings in the user/purchaser information.

H. Certification Label

The certification label required by 21 CFR 1010.2 shall be modified in accordance with 21 CFR 1010.4(d) to state: This product complies with performance standards for laser products under 21 CFR Part 1040 except with respect to those characteristics authorized by Variance Number 2004V-0317 effective **AUG 16 2004**.

This variance action is available for public disclosure in the Food and Drug Administration (FDA) Dockets Management Branch and a notice of availability will be published in the Federal Register. The variance will remain in effect until the termination date unless a determination is made that the variance should be amended or withdrawn to protect the public health and safety.

Sincerely yours,



Timothy A. Ulatowski
Director
Office of Compliance
Center for Devices and
Radiological Health

cc: FDA Division of Dockets Management, Docket No. 2004V-0317

Attachments A and B