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

Ref: FDA Docket No. 03V-0124  
Accession No. 03A0375

Mr. Jon G. Fuller  
Senior Manager  
Environmental Health and Safety  
Universal Studios Florida  
1000 Universal Studios Plaza  
Orlando, Florida 32819

Dear Mr. Fuller:

In accordance with 21 CFR 1010.4(c)(1) notice is given that the petition of Universal Studios Florida, dated April 30, 2005, for a renewal of their variance, Number 03V-0124, 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

03V-0124

B. Effective Date

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

C. Termination Date

This variance shall be terminated after April 14, 2008.

D. Product for Which Variance is Granted

This variance is granted for the Class IV laser display assembled and produced by Universal Studios Florida. The display will incorporate a certified Precision Projection Systems model TL-8 laser projection system which may contain certified argon, krypton, helium-neon, visible diode, or frequency-doubled Nd: YAG laser systems.

The laser special effects display will be produced from a permanent indoor installation in the Einstein II Theater in Building 42 of the Universal Studios Florida theme park. The effects employed may be front or rear screen projections, holographic displays, multiple reflection/diffraction effects, reflections from stationary mirrors, fiber optic projections, 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

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21 CFR 1040.10 for a Class I, IIa, II, or IIIa laser product and shall 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**

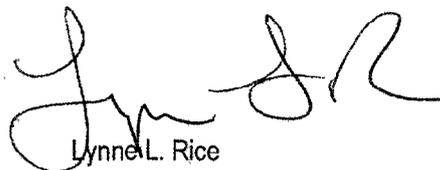
In accordance with 21 CFR 1010.4(a)(2), it has been determined that the product is required to perform a necessary function or is intended for a special purpose which cannot be performed or accomplished with equipment meeting the requirements referred to in Item E. Suitable means of radiation safety 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 03V-0124 effective April 14, 2003.

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,



Lynne L. Rice  
Director  
Office of Communication, Education,  
and Radiation Programs  
Center for Devices and Radiological Health

cc: FDA Division of Dockets Management, Docket No. 03V-0124

Attachments A and B