



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 5 2004

Ref: FDA Docket No. 02V-0286  
Accession No. 01A1729-01

Mr. Robert L. Adams  
President  
Adams Audio Laboratories Laser Division  
2015 Lord Fairfax Road  
Vienna, Virginia 22182

Dear Mr. Adams:

In accordance with 21 CFR 1010.4(c)(1) notice is given that the petition of Adams Audio Laboratories Laser Division, dated June 5, 2004, for a renewal of their variance, Number 02V-0286, 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

02V-0286

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 July 1, 2007.

D. Product for Which Variance is Granted

This variance is granted for the Class IIIb or IV laser light shows assembled and produced by Adams Audio Laboratories Laser Division. The laser shows may incorporate any of the following certified laser projectors: LSDI models PM3500, LMB, or Excalibur; Laser Innovations models Pyramid, Oasis, Mirage controllers and optical heads; LaserMedia models LMS or Fiberay; or Precision Projection Systems models RCS-1C, RLS-1, or RGS-1. The projectors will incorporate certified argon, krypton, argon/krypton, or frequency-doubled DPSS Nd:YAG lasers.

The shows will be presented from permanent or temporary installations in any type of facility or outdoor, unenclosed area for any contracted duration. The effects employed may be front or rear screen projections, multiple reflection/diffraction effects, reflection from stationary mirrors, fiber optic projections, and enhanced scattering effects including water fountain illuminations.

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

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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 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**

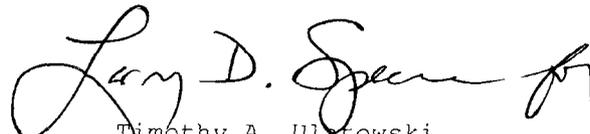
In accordance with 21 CFR 1010.4(a)(2), it has been determined that the product is required to perform a necessary function or is intended for a special purpose which cannot be performed or accomplished with equipment meeting the requirements referred to in Item E. Suitable means of radiation safety 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 02V-0286 effective July 1, 2002.

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 Dockets Management Branch, Docket No. 02V-0286

Attachments A and B