



DEPARTMENT OF HEALTH & HUMAN SERVICES

FDA/DDM HFA-305

Public Health Service

AUG 5 2004

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

Ref: FDA Docket No. 01V-0138
Accession No. 01A0541-01

Mr. Tony Kotwicki
Owner
DJ Tony
1860 Kristina Drive
White Lake, Michigan 48386

Dear Mr. Kotwicki:

In accordance with 21 CFR 1010.4(c)(1) notice is given that the petition of DJ Tony, dated July 21, 2004, for a renewal of their variance, Number 01V-0138, 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

01V-0138

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 May 15, 2007.

D. Product for Which Variance is Granted

This variance is granted for Class IIIB and IV laser light shows assembled and produced by DJ Tony, 1860 Kristina Drive, White Lake, Michigan 48386. The shows may incorporate any of the following certified laser projection systems: Lowell Products Development, Inc. Q series Models Q-40RG, Q-40MC, Q-100G, Q-150G, and Q-500G or the OmniSistem Stinger-GR 300mW containing certified DPSS frequency-doubled Nd:YAG or 635- or 680-nanometer solid state diode laser systems.

The shows may be presented from permanent or temporary locations in any type of facility or outdoor, unenclosed area for any contracted duration. The shows may employ 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

01V-0138

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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 01V-0138 effective May 15, 2001.

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. 01V-0138

Attachments A and B