



DEC 6 2007

Ref: FDA Docket No. 87V-0401

Mr. John J. Markham
President
Chameleon Productions
7101 Presidents Drive, Suite 205
Orlando, Florida 32809

Dear Mr. John J. Markham:

I am amending, in accordance with 21 CFR 1010.4(c)(1) and Laser Notice 55, your laser light show variance from 21 CFR 1040.10(c) of the performance standard for laser products 21 CFR 1040.10 and 1040.11.

The amendments are specified in the attached Attachment 1, which is made part of your variance by this notification.

Also attached is a copy of Laser Notice 55, "Procedures for Renewal and Amendment of Certain Laser Light Show Variances."

You are required by your variance (as amended) to keep copies of Laser Notice 55 and this notice of amendment with your variance records required to be available at your laser light shows.

As stated in the amendments specified in Attachment 1, your variance will be renewed on December 31st each year provided the annual report required by 21 CFR 1002.13 for that year has been submitted.

A review of our records shows that of the 132 variances subject to this amendment, only 23 manufacturers have submitted their annual report for 2006-2007. If you have not submitted your annual report for this year, you should do so immediately and remember to do so in each following year so that your variance may continue to be renewed for another year.

Sincerely yours,

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

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Attachment 1
General Variance Amendments
per Laser Notice 55

In accordance with 21 CFR 1010.4(c)(1) and Laser Notice 55 (copy attached) notice is given that the following paragraphs of your current variance are amended as follows:

B. Effective Date

Paragraph B is amended by replacing it with the following:
In accordance with 21 CFR 1010.4(c)(1), this variance amendment shall be considered effective on September 25, 2007. This variance shall be considered extended for one year effective December 31st following the due date of an annual report if and only if the annual report has been submitted as required by 21 CFR 1002.13.

C. Termination Date

Paragraph C is amended by replacing it with the following:
This variance shall be terminated after December 31, 2007, unless extended as provided under B above. In subsequent years the variance shall be terminated, in accordance with Attachment A, Condition 2.b of this variance, after December 31st following the due date of an annual report which was not submitted as required by 21 CFR 1002.13.

D. Product for Which Variance is Granted

The section of Paragraph D which specifies the products covered by this variance is amended by inserting the following sentences after the specification of products:

The firm also may manufacture, report, and certify Class IIIb or IV laser light show projectors under this variance. Further, the firm may incorporate into their laser light shows any laser projection systems, which have been certified and reported by the firm or by another manufacturer under an approved laser light show variance, except:

- 1) projection systems designed or intended to produce visible effects by means of invisible laser emissions, or
- 2) projection systems designed or intended to produce audience scanning effects.

Variance Attachment A, Condition 2 is amended by replacing Condition 2 with the following:

2.
 - a. All laser products, systems, shows, and projectors shall be certified to comply with applicable requirements of 21 CFR 1040.10 and the conditions of this variance and be reported as required by 21 CFR 1002.10 and 1002.11 using the reporting guides provided for such purpose. These actions shall be accomplished prior to any introduction into commerce.
 - b. The annual report required by 21 CFR 1002.13 shall be submitted by September 1st of the current year as a condition for renewal of this variance effective December 31st following the due date of the annual report.

c. The annual report shall also include a list identifying all laser light show projectors used in shows by your firm during the reported year. The list shall include manufacturer, model designation, and accession number under which each projector was reported.

Variance Attachment A, Condition 12 (or, if renumbered, the condition dealing with setup, alignment, testing procedures and records to be available with a show) is amended by modifying the third paragraph of Condition 12 as follows:

12. [...]

The variance holder shall retain the records of these procedures and the results of all tests as required by 21 CFR 1002.31. A copy of the variance application, the approval letter, Laser Notice 55, the most recent annual report, the CDRH acknowledgment of receipt for the annual report, current procedures, and records relating to each particular show shall be with the operator or other responsible individual and shall be made available for inspection by FDA and other responsible authorities.