

QUALITY MANAGEMENT BRANCH
92 JAN 27 PM 1:39

CENTER FOR DEVICES AND RADIOLOGICAL HEALTH
ATT:JOY LAZAROFF
OFFICE OF COMPLIANCE (HFZ-312)
8757 GEORGIA AVENUE
SILVER SPRING, MARYLAND 20910

Dear Joy:

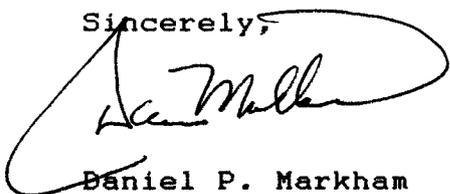
Can you believe it's already 1992!?! Having survived last year we are all left to deal with the realities of another new year. I hope you enjoyed the holidays and that you were able to get a few days to yourself. John and I spent all of a few days in town before running off again.

Anyway; with regards to the date, our variance expires on January 21, 1992 and we would like to proceed with certification for the next term. Enclosed you will find a copy of our current variance.

It is my understanding that this letter should serve as proper notification for variance certification. However; should you need any additional information, please do not hesitate to contact me at the Orlando office.

Thank you again for your assistance and we are looking forward to seeing you sometime in 1992. Happy New Year!

Sincerely,



Daniel P. Markham



87V-0401

EXP2



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
1390 Piccard Drive
Rockville, MD 20850

NOV 2 1989

Ref: FDA Docket No. 87V-0401
Accession No. 87A0266-01

Mr. John J. Markham
President
Chameleon Productions
6206 Forest City Road
Orlando, Florida 32810

Dear Mr. Markham:

In accordance with 21 CFR 1010.4(c)(1) notice is given that the petition of Chameleon Productions, dated September 27, 1989, for a an amendment of their variance, Number 87V-0401, 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

87V-0401

B. Effective Date

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

C. Termination Date

This variance shall be terminated on January 21, 1992.

D. Product for Which Variance is Granted

This variance is granted for the Chameleon Productions laser light shows, such as "Out of the Darkness," incorporating the Precision Projection Systems Model TL24D or the Laser Media Models LMS or LM Class IV ion laser projection systems. The laser light shows may be presented in any type of location for any contract duration. The laser effects to be used are front or rear screen projections, holographic displays, multiple reflection/diffraction effects, reflections from stationary mirrors, stationary or scanning irradiation of rotating mirror balls, 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 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, if included, 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 is in conformity with performance standards for laser products under 21 CFR Part 1040 except with respect to those characteristics authorized by Variance Number 87V-0401 effective January 21, 1988.

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,



Ann B. Holt, DVM
Acting Director
Office of Compliance
and Surveillance
Center for Devices and
Radiological Health

cc: FDA Dockets Management Branch, Docket No. 87V-0401

Attachments A and B

JAN 1992
RECEIVED
DMI/DMB
OCS

6206 FOREST CITY ROAD CORNERS, TN 37810



CENTER FOR DEVICES AND RADIOLOGICAL HEALTH
 ATT: JOY LAZAROFF
 OFFICE
 8757 G
 SILVER

FDA-757* 20101033 1991 01/21/92
 NOTIFY SENDER OF NEW ADDRESS
 : FOOD AND DRUG ADMINISTRATION
 1390 PICCARD DR
 ROCKVILLE MD 20850-4332

