U.S. FOOD & DRUG ADMINISTRATION

U.S. Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center - WO66-G609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

February 15, 2024

Sean Populorum
Compliance Officer
LASER LIGHT COMPANY
P.O. BOX 7938
SEMINOLE, FL 33775

Reference: 15A0097-002

This is to acknowledge receipt of your February 15, 2024, document, which was filed pursuant to the regulations for the administration and enforcement of the Radiation Control for Health and Safety Act of 1968 (title 21, code of Federal Regulations, Subchapter J) as they pertain to Variance Request requirements.

Your document has been assigned an Accession Number of 15A0097-002, and has been classified as a(n) Variance Request (pursuant to Part 1002, Subpart B of the Regulation referenced above).

Further, the submittal has been assigned an informal subject title of "This submission is a(n) Variance Request supplement. These Laser Light Show/Display Products: Requesting renewal of Variance Docket No. 2015-V-1018. (Formerly known as BAP AGENCY, INC./DBA FULLCOLORLASERS.COM)."

This acknowledgement does not constitute approval of the document. You will be contacted if any questions or comments arise concerning your document.

WARNING:

THE ACCESSION NUMBER ASSIGNED TO YOUR SUBMISSION DOES NOT IMPLY, CONVEY OR CONSTITUTE FDA APPROVAL OF ANY REPORT, APPLICATION FOR VARIANCE OR EXEMPTION, NOTIFICATION, OR ANY OTHER SUBMISSION OR ITS CONTENTS. THE ACCESSION NUMBER IS ONLY AN ACKNOWLEDGMENT THAT FDA HAS RECEIVED YOUR SUBMISSION. IT MAY BE REVOKED BY FDA. ITS DISCLOSURE IS YOUR RESPONSIBILITY. IT IDENTIFIES YOUR SUBMISSION FOR PRODUCTS OR PRODUCT FAMILIES IDENTIFIED IN THIS MESSAGE.

Be advised that failure to comply with FDA regulations may result in notification of affected persons and corrective actions at no cost to the purchaser, pursuant to 21 CFR Part 1003 -- Discovery of Defect or Failure to Comply and 21 CFR Part 1004 -- Repurchase, Repairs, or Replacement of Electronic Products.

Please be aware that the following CDRH Product Code(s) have been assigned to the product(s) described in this report:

REB defined as High-Power Laser Light Show

If these products will be shipped to the United States, the shipping broker will need to provide the full FDA Product Code at the time of entry, structured as follows:

95R- -EB

If your current laser light show variance provides for an automatic one year extension of the variance on December 31st, remember that submission of your annual report for the current year is also required as the condition that permits the automatic renewal for next year to occur.

Please note that your firm is required to submit an Annual Report to CDRH every year by September 1.

CDRH recommends (but does not require) labeling on your product that cautions the purchaser with following or similar language: "CAUTION**- LASER LIGHT IS BRIGHT AND BLINDING - DO NOT SHINE AT AIRCRAFT OR VEHICLES AT ANY DISTANCE**".

All Radiological Reports may be prepared using FDA's Electronic Submissions software which can be downloaded at http://www.fda.gov/ForIndustry/FDAeSubmitter/ucm108165.htm. For more information on the FDA's eSubmitter program please see the following websites:

Radiological Health - http://www.fda.gov/Radiation-EmittingProducts/default.htm

Electronic Submissions (instead of paper reports) - http://www.fda.gov/ForIndustry/FDAeSubmitter/default.htm

FDA Electronic Submissions Gateway - http://www.fda.gov/ForIndustry/ElectronicSubmissionsGateway/default.htm

If you have any questions, please contact the Director of the Division of Radiological Health, or the branch chief of your respective product area, as listed on the CDRH Management Directory, under the Office of In Vitro Diagnostics and Radiological Health, Division of Radiological Health. http://www.fda.gov/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDRH/CDRHOffices/ucm127854.htm

Please include a primary (and optional secondary) contact email address in all submissions (and/or cover letters) to facilitate electronic correspondence.

Sincerely yours,

Division of Radiological Health
Office of In Vitro Diagnostics and Radiological Health
Center for Devices and Radiological Health