DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

July 24, 2014

VIA UNITED PARCEL SERVICE

Ref: FDA Docket No. 2013-V-0903
Accession No. 13A0197

Mr. David Fleenor
Epic FX, Inc.
4339 N. 18th Street
PHOENIX, AZ 85016

Dear Mr. Fleenor:

This letter is to inform you that, due to a very significant public safety hazard associated with laser light shows performed by your firm, your variance, Variance No. 2013-V-0903, is withdrawn in accordance with 21 CFR 1010.4 (c)(2), effective on the date of this letter. This means that your firm may no longer produce laser light shows which exceed the limits specified in 21 CFR 1040.11(c) in the United States.

Your firm was granted a laser light show variance by CDRH on 10/30/2013. This document states in part:

"[…] 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:

[…] Projection systems designed or intended to produce audience scanning effects."

Your variance requires as stated in Variance Attachment A, Condition 5:

"5. Scanning, projection, or reflection of laser and collateral radiation (light show radiation) into audience or other accessible uncontrolled areas shall not be permitted except for diffuse reflections produced by the atmosphere, added atmospheric scattering media, and target screens."

Furthermore, the Variance Attachment A stipulates in Condition 6:

"6. Access to radiation levels in excess of the limits of Class I by any person other than operators, performers, or employees shall not be permitted at any point less than 3.0 meters above any surface upon which

> such persons are permitted to stand or 2.5 meters below or in lateral separation from any place where such persons are permitted to be. Operators, performers, and employees shall not be required or allowed to view radiation above the limits of Class I or be exposed to radiation above the limits of Class II."

Video posted currently on your web site at:

http://epicfx.com/portfolio/interactive-laser-installation-artelphx-2013

documents audience scanning with Class IIIb and/or Class IV lasers. Although much of the audience scanning was done with fanned beams, your projector is not designed nor reported for safe audience scanning. Your variance prohibits audience scanning. Any laser beams projected into the audience directly or indirectly is considered audience scanning. This is in violation of Condition 5 of your variance.

Furthermore, the fact that people on the floor could put their arms in the beam path is direct evidence that your show did not meet the 3 meter clearance requirement specified in Condition 6.

According to your website, the audience scanning took place during an ArtelPH X 2013 event in Phoenix, AZ. We have no reason to doubt the accuracy of the evidence posted on your website.

Moreover, a youtube channel of your firm includes a video clip at:

http://www.youtube.com/watch?v=DvrOTzctdjw

that depicts a laser light show performed by your firm at a Decibel 2013 event in September 2013 in Seattle, WA. There are many instances, for example at 0:23 min timestamp, where the audience is scanned with laser beams or safety distances are not maintained. This unsafe and noncompliant operation of the laser light show is in conflict with the following statement in your laser light show report submitted in July 2013, Accession Number: 1310556:

"Par. 11.3 No effects require levels of laser radiation above Class 1 to strike performers, audience or operators, under any circumstances. The only laser radiation present in the audience or performer areas is that which is diffusely reflected from screen and other termination surfaces overhead. MPE is maintained at all times by all audience, performers and operators".

Please note that your variance also states in part:

"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."

Such a determination has been made and now your variance, No. 2013-V-0903, is withdrawn as stated above.

Please be informed that under 21 C.F.R. 1003.11(a)(3), you may submit your views and evidence to establish that the alleged failures to comply did not take place. We request that you provide such a response no later than 15 days after receipt of this letter. You should send your correspondence to:

U.S. Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center – WO66-G609
Attn: Magnetic Resonance and Electronic Products Branch
10903 New Hampshire Ave.
Silver Spring, Maryland 20993-0002

Your firm is also permitted to re-apply for a laser light show variance. For your new variance application to be considered, you must provide a description of what actions your firm will take to assure that the non-compliances which were cited above will not reoccur. This description should accompany the new variance application.

The laser light show variance application form can be found at:

http://www.fda.gov/downloads/aboutfda/reportsmanualsforms/forms/ucm080788.pdf

A laser light show report guide can also be downloaded at:

http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM081634.pdf

More information about the laser light show application process can be found in CDRH Laser Notices 51 and 55 which may be found at:

http://www.fda.gov/Radiation-EmittingProducts/RadiationEmittingProductsandProcedures/HomeBusinessandEntertainment/LaserProductsandInstruments/ucm116422.htm

Please note, however, that some of the terms and conditions in these notices might not apply or may be revised in your new variance approval.

For your firm to perform audience scanning, a separate variance approval must be granted by CDRH. Such a variance will not be automatically renewable; it will incorporate a description of all the effects you might use from projectors not designed for audience scanning and it will add the audience scanning effects but only for projectors specifically designed, reported, and certified for audience scanning. The audience scanning variance application will also need to be accompanied by a new show report or a laser light show report supplement to the first show report that provides the design(s) you will be using for audience scanning effects. In addition, the

application must include the compliance testing procedures you will use at your facility and on-site to assure that the scanning safeguard system design meets the requirements of the variance conditions and is properly operating to prevent audience exposures from exceeding Class I emission levels.

If you have any questions regarding the content of this letter, you may contact Dale Smith by internet electronic mail at lds@cdrh.fda.gov or by phone at (301)796-5868 or Woody Strzelecki at (301) 796-6939 or by internet electronic mail at Woody.Strzelecki@fda.hhs.gov .

Sincerely yours,

Mary S. Pastel, ScD
Deputy Director for Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices
and Radiological Health, FDA, HHS

cc: FDA Division of Dockets Management, Docket No. 2013-V-0903
Arizona State Regulatory Agency