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LFI
international

April 19, 2005

FDA Dockets Management Branch
HFA-305, Room 1065
5630 Fishers Lane
Rockville, MD 20852

RE: EIR 2-20-05, GLZ

To Whom It May Concern:

We acknowledge receipt of the copy of the establishment inspection report (EIR) for the inspection that was conducted at our facility located in Bellevue, WA on February 10, 2005 by U. S Food and Drug Administration (FDA) Regional Electro-optics Specialist Gary L. Zaharek.

Attached is the CAP response to the EIR prepared by our Director Production/Laser Safety Officer, Ms. Roberta McHatton. Ms. McHatton has implemented a CAP to correct the deficiency in records within the agreed period of 90 days. Included in the response to the EIR are copies of all test records for 2003 and 2004 and a copy of our manufacturing procedures.

Per Mr. Zahareks recommendation our manufacturing department will relocate emission indicators on remote projector heads higher up on the front panel so that they can be more clearly seen. In addition we have relocated the laser aperture warning labels higher upon the top of the heads and projectors instead of right next to the aperture on the front panel.

LFI International has taken corrective action and is now current and up to date with regards to all our manufacturing records. In addition LFI International has implemented Mr. Zaharek's recommendations. Therefore, LFI International is now in compliance with CDRH 21 CFR 1040.10.

Please don't hesitate to contact us with any questions or concerns.

Best regards

Robert Baldridge
CEO
LFI International

Cc: FDA/OC/DOE3/EPB:Manuel Karos – Washington D.C., and Gary Zaharek – San Jose, CA

80P-0100

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LFI INTERNATIONAL

April 19, 2005

Response to:
EIR: Conducted by Regional Electro-optics Specialist Gary L. Zaharek
Greenco LLC dba LFI International
Bellevue, WA
EI 2-10-05, GLZ

CAP prepared by:
Roberta McHatton
Director/LSO
Production and Technical Services
LFI International

RE: FDA Docket No.: 80P-0100, Accession No.: 80A0286-16

RESPONSE SUMMARY TO FINDINGS:

LFI International understands that objectionable conditions were limited due to lack of manufacturing records for equipment manufactured during 2003 (i.e. that records were not on file at time of inspection.) LFI International acknowledges and agrees that products on hand were found to be in compliance with the laser performance standards. Management promised corrections and is filing this CAP within the agreed period of 90 days. Attached are copies of all records for 2003 and 2004. (See Exhibit 1: Manufacturing Records 2003 and Exhibit 2 Manufacturing Records 2004)

RESPONSE TO HISTORY OF BUSINESS:

The information reported by Mr. Zaharek is true and accurate.

RESPONSE TO PERSONS INTERVIEWED INDIVIDULA RESPONSIBILITY:

The information reported by Mr. Zaharek is true and accurate.

RESPONSE TO LASER PRODUCTS:

The information reported by Mr. Zaharek is true and accurate. In addition to the equipment laser products Mr. Zaharek refers to in this section LFI International also manufactures laser shows, which are considered to be laser products. LFI International holds a variance: FDA Docket No.: 80P-0100 (see section D Product for Which Variance is Granted of Exhibit 3: Variance).

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RESPONSE TO OPERATIONS:

The information reported by Mr. Zaharek is true and accurate. It is understood that our firm must complete "Final Check out Sheet" that details the inspections and tests done to each unit. While we have had standard operating procedure in place for our staff to follow we have recently revised and reviewed these procedures with our staff to insure accurate records will be kept in the proper place in the future. (See Exhibit 4: Standard Operating Procedure for the Manufacturing Process)

OBJECTIONAL CONDITIONS:

LFI International agrees that the objectionable conditions found during the inspection were limited to items reported by Mr. Zaharek.

We are pleased to inform you that most of the records had been filled out at the time of manufacture. The problem lay in that the original records had been imbedded in the User/Operator manuals and no copies had been made and/or kept by our manufacturing department. We were able to contact our customers who currently own the units and obtain copies of the records they possessed or we had the final checkout sheets on hand in our copies of the User/Operator manuals. There were a few units sent to us for certification and service as well as a couple units we did have to send a technician to the venue location in order to certify and service. All records are now accounted for and filed properly in yearly binders. Copies of all the manufacturing records for 2003 and 2004 are attached in Exhibit 1: Manufacturing Records 2003 and Exhibit 2 Manufacturing Records 2004).

It is important to note that some of the units specifically noted in the OBJECTIONAL CONDITIONS item 1 were electronics units and therefore not subject to laser product certification requirements. NOTE: All units that are subject to CDRH laser product certification requirements are marked with a check mark on the log sheets which are located in front of all copies of the 'Final Checkout Sheet's' for 2003 and 2004 (Exhibits 1 & 2). Those items marked N/A (non applicable) are those that do not need to meet CDRH certification requirements because they are either an electronics type unit or are a proto type unit under research and development thus are not used for public display or to be sold.

DISCUSSION WITH MANAGEMENT:

Our manufacturing department will be following the recommendations Mr. Zaharek reported in this section.

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CAP prepared by:
Roberta McHatton
Director/LSO
Production and Technical Services
LFI International

ATTACHEMENTS:

1. EXHIBITS:
    1. Manufacturing Records 2003
    2. Manufacturing Records 2004
    3. Variance
    4. Standard Operating Procedures for the Manufacturing Process
    5. LFI International Business Structure