

SIGHT & SOUND

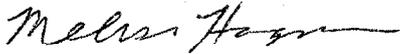
Date: January 14, 2000

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

To whom it may concern,

Please find attached two annual reports. Please excuse our tardiness in filing, as we are making efforts to alleviate this error. I ask that you also consider this letter a request for a renewal of our variance. If you have any questions or concerns, please don't hesitate to contact me - 717-687-4220 ext. 6219. We will also be filing a show report corresponding with this equipment in the next few months.

Sincerely,



Melissa Hagman
Technical Services
Sight & Sound Ministries, Inc.

Attachments: Laser Light Show Annual Report

cc: Manuel Karos, CDRH

97V-0238

EXP 1

2660 '00 JAN 24 P2:06

LASER PRODUCT/LASER LIGHT SHOW ANNUAL REPORT: Page 1

Part 1. Identification of Manufacturer

Report Date: 01/14/00

Company Name: Sight and Sound Ministries, Inc.

Address: 300 Hartman Bridge Rd
Strasburg, PA 17579

Corresponding Official signature: *Thomas J Heninger*

Name & title: Thomas J Heninger

Telephone: (717) 687-4220 ext 6220

Firm name & address, if different from above: _____

This Annual Report is submitted in accordance with 21 CFR 1002.13 for the period July 1, 1998 through June 30, 1999.

Part 2. Production Status

- (X) Products were manufactured during this period and the firm is still in business. If you check this, complete and mail this entire report.
- () No products were manufactured during this period but the firm is still in business and expects to manufacture in the future. If you check this, complete Part 6 and mail pages 1 and 4.
- () No products were manufactured during this period and the firm is now out of business. If you check this, complete Part 6 and mail pages 1 and 4.
- () Products were manufactured during this period but the firm is now out of business. If you check this, complete and mail this entire report.

Part 3. Current Production Tabulation

3.1. All Laser Products

| Accession Number | Family Designation | Selling Model Numbers | Product Function | Class | Production Status | | |
|------------------|--------------------|-----------------------|------------------|-------|-------------------|------------------|-------|
| | | | | | Active | Discont. (mo/yr) | Plant |
| <u>NOT</u> | <u>APPLICABLE</u> | | | | | | |

3.2. Laser Light Shows

| Accession Number | Projector or Show Family Designation | Permanent or Touring | Class | Lasing Media | Production status | |
|------------------|--------------------------------------|----------------------|-------|--------------|---------------------|------------------|
| | | | | | No. Shows Performed | Discont. (mo/yr) |
| 97A0640 | RAINBOW I PROJECTOR | PERMANENT | IV | Ar Kr | 362 | N/A |

Part 4. Procedures for Quality Control and Testing

The written procedures for assessing and controlling radiation safety have been reviewed. (These include prototype testing, incoming materials testing, assembly testing, retesting after repair, and service testing.) The procedures for maintaining quality control testing equipment have also been reviewed. All procedures are up-to-date, complete, and accurate.

(X) YES () NO

The reports provided to CDRH for each model family currently in production have been reviewed and the procedures contained in them are up-to-date, complete, and accurate.

(X) YES () NO

If you answered "no" to either question, provide the current procedures in a supplement to the appropriate model family report.

Part 5. Summary of Test Results

| Model Number or Name of Show | Number Produced | Number Tested | | |
|------------------------------|-----------------|---------------------------------|--------|---------------------------------|
| | | Performance Requirements | Labels | Light Show Variance Conditions |
| LIVING WATERS | 362 | ALL SHOWS MET CDRH REQUIREMENTS | YES | ALL SHOWS MET CDRH REQUIREMENTS |

Part 6. Correspondence Concerning Radiation Safety

The number of letters received from users, dealers, or others about possible radiation exposure or safety-related failures during use of the product was 0.

Attach a copy of each letter.

The number of letters received from dealers, distributors, or others concerning the need for repair, adjustment, or replacement of a part to maintain radiation safety of the product was 0.

Attach a summary of correspondence or a sample. Identify any trends in failed components or adjustments needed during servicing.

The number of notices or brochures sent to users, dealers, or service personnel on precautions or actions to be taken to maintain radiation safety of the product was 0.

Attach a summary of correspondence or a sample.

Part 7. Distribution Records

Production facility shipping records and dealer records (when returned) are maintained at Sight and Sound Ministries, Inc.

Products can be traced from these records by:

- (✓) Model
- (✓) Serial Number
- (✓) Date of Manufacture
- (✓) Other, specify: Invoice of Purchase on file

LASER PRODUCT/LASER LIGHT SHOW ANNUAL REPORT: Page 1

Part 1. Identification of Manufacturer

Report Date: 01/14/00

Company Name: Sight and Sound Ministries, Inc

Address: 300 Hartman Bridge Rd
Strasburg, PA 17579

Corresponding Official signature: *Thomas J. Henninger*

Name & title: Thomas J. Henninger

Telephone: (717) 687-4220 ext 6220

Firm name & address, if different from above: _____

This Annual Report is submitted in accordance with 21 CFR 1002.13 for the period July 1, 1997 through June 30, 1998.

Part 2. Production Status

- (X) Products were manufactured during this period and the firm is still in business. If you check this, complete and mail this entire report.
- () No products were manufactured during this period but the firm is still in business and expects to manufacture in the future. If you check this, complete Part 6 and mail pages 1 and 4.
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Part 3. Current Production Tabulation

3.1. All Laser Products

| Accession Number | Family Designation | Selling Model Numbers | Product Function | Class | Production Status | | |
|-----------------------|--------------------|-----------------------|------------------|-------|-------------------|------------------|-------|
| | | | | | Active | Discont. (mo/yr) | Plant |
| <u>NOT APPLICABLE</u> | | | | | | | |

3.2. Laser Light Shows

| Accession Number | Projector or Show Family Designation | Permanent or Touring | Class | Lasing Media | Production status | |
|------------------|--------------------------------------|----------------------|-------|--------------|---------------------|------------------|
| | | | | | No. Shows Performed | Discont. (mo/yr) |
| 97A0640 | RAINBOW I PROJECTOR | PERMANENT | IV | Ar Kr | 625 | N/A |

Part 4. Procedures for Quality Control and Testing

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(X) YES () NO

The reports provided to CDRH for each model family currently in production have been reviewed and the procedures contained in them are up-to-date, complete, and accurate.

(X) YES () NO

If you answered "no" to either question, provide the current procedures in a supplement to the appropriate model family report.

Part 5. Summary of Test Results

| Model Number or Name of Show | Number Produced | Number Tested | | |
|------------------------------|-----------------|--------------------------------|--------|--------------------------------|
| | | Performance Requirements | Labels | Light Show Variance Conditions |
| LIVING WATERS | 625 | ALL SHOWS MET CDRH REQUIREMENT | YES | ALL SHOWS MET CDRH REQUIREMENT |

Part 6. Correspondence Concerning Radiation Safety

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ROUTE 896 P.O. BOX 310
STRASBURG, PA 17579-0310

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FIRST CLASS MAIL