Form Approved: OMB No. 0910-0025
Expiration Date: May 31, 2010

FORM FDA 3645 (7/07)

Guide for Preparing Annual Reports for Ultrasonic Therapy Products

GUIDE FOR PREPARING ANNUAL REPORTS FOR

ULTRASONIC THERAPY PRODUCTS

September 1996

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES
Public Health Service
Food and Drug Administration
Center for Devices and Radiological Health
Rockville, Maryland 20850

Foreword

The Office of Compliance, Center for Devices and Radiological Health (CDRH) developed this guide. This guide will assist manufacturers[1] of electronic products which emit radiation in providing adequate reporting of radiation safety testing and compliance with federal performance standards. Title 21 of the Code of Federal Regulations (CFR), Parts 1002 and 1003 specify Reporting and Notification requirements[2, 3].

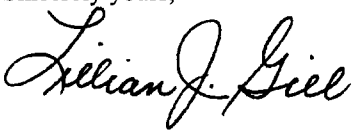
Reports submitted on radiation safety of electronic products must follow the appropriate guide (21 CFR 1002.7). If the report does not follow an applicable guide it must contain a sufficient justification for any deviations. The submitter of the report will receive an acknowledgment letter with the accession number we assign to the report. Please reference this accession number in the future when providing additional information about this model family in either a supplement or the annual report. If a report is incomplete or inadequate CDRH may reject it and return it for completion. CDRH will not enter a rejected report into our database. Also, a rejected report will not receive an accession number.

WE DO NOT APPROVE THESE REPORTS OR THE PRODUCTS BEING REPORTED. It is the manufacturer's responsibility to certify that their products comply with all applicable standards (21 CFR 1010 - 1050), based on a testing program in accordance with good manufacturing practices. Prior to the shipment of products in interstate commerce 21 CFR 1002 requires the manufacturer to submit the report and to comply with all applicable importation requirements (21 CFR 1005). If there are deficiencies, we may disapprove the firm's quality control and testing program, determine that the product contains a radiation defect, or determine that the product fails to comply with a standard. We will notify the manufacturer if we make such a determination. CDRH may require the manufacturer to cease introduction into U.S. commerce until deficiencies are corrected, and to initiate a corrective action program (21 CFR 1003 - 1004) for products already introduced into commerce.

Please mail your reports to the address below (FDA can not process electronic submissions at this time). Provide the original report with appropriate signature(s) (no facsimiles, please). Provide extra copies only if this guide specifically requires them. Submit the report written in the English language. Translate any text that appears in a language other than English into English in a complete and accurate manner. Keep a copy of the completed report in your records.

We are making our reporting guides and other regulatory information available on the Internet under http://www.fda.gov/cdrh. No copyright exists for these guides. Reproduce these guides as needed. If you would like to comment on the reporting guides, web site, or future electronic submissions, you may direct the comments to the address below. If you need additional regulations for electronic products or medical devices, you should contact the Division of Small Manufacturers Assistance by telephone at 1-800-638-2041 or 301-443-6597, or by facsimile at 301-443-8818.

Sincerely yours,



Lillian J. Gill
Director
Office of Compliance

MAILING ADDRESS (see 21 CFR 1002.7 for further information):

CENTER FOR DEVICES AND RADIOLOGICAL HEALTH
OFFICE OF COMPLIANCE (HFZ-307)
ATTN: ELECTRONIC PRODUCT REPORTS
2098 GAITHER ROAD
ROCKVILLE MD 20850

[1] **Manufacturer** (see 21 CFR § 1000.3(n)) means any person engaged in the business of manufacturing, assembling, or importing electronic products.

[2] **Accidental Radiation Occurrences**: 21 CFR 1002.20 requires manufacturers to immediately report accidental radiation occurrences (see 21 CFR 1000.3(a) for the definition).

[3] **Notification**: Title 21 CFR Part 1003 requires manufacturers to provide Notification of Defects or Failure to Comply. Send these notifications to the Director of the Office of Compliance (HFZ-300).

INSTRUCTIONS

General

You need to submit only the completed forms and any information you have provided on separate sheets. If you use separate sheets or additional copies of the forms, label each page with sequential lettering (example: Page 3a, Page 3b, Page 3c).

The forms provide blanks to be filled in, boxes [ ] to be checked, and tables or graphs to be completed. They may be prepared with a typewriter or hand-printed in black ink.

1. Identification of Manufacturer

Fill in the requested information and sign where indicated. Fill in the years in the reporting period (example: The report due on September 1, 1983, should cover the reporting year July 1, 1982, through June 30, 1983)

2. Production Status

Check the statement that applies to your firm and take the indicated action.

3. Current Production Tabulation

Provide production data, using the form or a comparable tabulation. If additional space is needed, use another copy of the form or attach a separate sheet and label it Part 3.

Accession No.:	For previously reported models, CDRH will have assigned this number and reported it to you.
Brand:	Provide the brand name of the product, if different than manufacturer's name. On a separate sheet, provide the complete address for each importer or distributor of each brand. Label the sheet Part 3.
Discontinued (mo/yr):	Provide discontinuation date for any model that is no longer in production, but was produced at some time during the reporting period.

4. Procedures for Quality Control and Testing

You are required by 21 CFR 1002.30(a)(1) and (2) to maintain written procedures for quality control and testing. The procedures in use and those submitted in previous product reports should be reviewed and updated. Compare your current procedures with those submitted in your previous product reports. Check the appropriate answers and take any indicated action.

5. Summary of Test Results

You are required by 21 CFR 1002.30(a)(2) to maintain results of quality control tests. For each product introduced into commerce, you should evaluate test results to be certain that the total program is adequate to assure radiation safety and compliance with the standard (21 CFR 1050.10).

5.1 Results of Production Tests

Check the appropriate answers and fill in the requested data.

5.2 Results of Audit Tests

Fill in the requested data.

6. Correspondence Concerning Radiation Safety

You are required by 21 CFR 1002.30(a)(4) to maintain copies of communications to or from dealers, distributors, and purchasers concerning radiation safety. Correspondence should be reviewed if it involves any of the following: complaints or concerns about radiation exposure; difficulties with safety components in use or servicing of the product; investigations made or instructions issued,concerning use, adjustment, and repair.

Fill in the number of documents sent or received and attach the copies, summaries, or samples as indicated.

NOTE: This summary does not replace the notification requirements for potential defects or noncompliances under 21 CFR 1003.10, or for suspected accidental radiation occurrences under 21 CFR 1002.20.

7. Distribution Records

You are required by 21 CFR 1002.30(b)(1) and (2) to maintain distribution records. Such records must allow tracing of products to the dealer and, if possible, to the user.

Fill in the information on the location of records storage and check the means of tracing products.

ULTRASOUND THERAPY ANNUAL REPORT (24)

1. Identification of Manufacturer

Report Date:

Company Name:

Address:

This Annual Report is submitted in accordance with 21 CFR 1002.11 for the period July 1, 19 through June 30,

Corresponding Official:

Name:

Title:

Telephone number:

Signature:

2. Production Status

[ ] Products were manufactured during this period and the firm is still in business. If you check this, submit 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, submit Part 6 of this report.

[ ] No products were manufactured during this period and the firm is now out of business. If you check this, submit Part 6 of this report.

[ ] Products were manufactured during this period but the firm is now out of business. If you check this, submit this entire report.

3. Current Production Tabulation

Accession Number	Generator Model Number	Brand Designator	Number of units produced	Introduced into commerce (mo/yr)	Discontinued (mo/yr)

4. Procedures for Quality Control and Testing

When, and by whom, were the written procedures for assessing and controlling radiation safety last reviewed? (These include prototype testing, incoming materials testing, assembly testing, retesting after repair, and service testing.)

For each model family currently in production, are reports provided to CDRH, and are the procedures contained in them up-to-date, complete, and accurate?

If you answered NO, provide the current procedures in a supplement to the appropriate product report.

5. Summary of Test Results

5.1 Results of Production Tests

What percentage of production units were tested for accuracy of indicated power?

Tests were performed at the following indicated power settings with the maximum measured error as indicated at each setting:

watts % error

watts % error

watts % error

watts % error

How many generators were outside the test specifications and required corrective action(s)?

Are all records of power calibrations reviewed by management prior to product release?

Have the measuring instruments used in the testing been modified, repaired or recalibrated within the last year?

If yes, explain the circumstances surrounding the modification, repair or recalibration:

5.2 Results of Audit Tests

Beam Nonuniformity Ratio (BNR)

How many BNR measurements were made?

What percentage of applicator model production had BNR measurements made?

What was the mean BNR?

What was the standard deviation?

What is the claimed maximum BNR?

Effective Radiating Area (ERA)

How many ERA measurements were made?

What percentage of applicator model production had ERA measurements made?

What was the mean ERA?

What was the standard deviation?

What is the claimed ERA?

What are maximum and minimum ERA values allowable?

Maximum	Minimum

6. Correspondence Concerning Radiation Safety

How many letters were received from users, dealers, or others about possible radiation exposure during use of the product?

Attach a copy of each letter.

How many letters were received from dealers, distributors, or others concerning the need for repair, adjustment, or replacement of a part to maintain radiation safety of the product?

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

How many notices or brochures were sent to users, dealers, or service personnel on precautions or actions to be taken to maintain the radiation safety of the product?

Attach a sample of any correspondence.

7. Distribution Records

Where are production facility shipping records and dealer records (when returned) maintained?

Products can be traced from these records by:

[ ] Model [ ] Serial Number
[ ] Date of manufacture [ ] Other (specify)