Contains Nonbinding Recommendations

Guidance for Industry and FDA Staff

Exemption from Certain Reporting and Recordkeeping Requirements for Microwave Ovens

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Food and Drug Administration
Center for Devices and Radiological Health
Electronic Product Branch
Division of Mammography Quality and Radiation Programs
Office of Communication, Education, and Radiation Programs

Preface

Public Comment

Written comments and suggestions may be submitted at any time for Agency consideration to the Division of Dockets Management, Food and Drug Administration, 5630 Fishers Lane, Room 1061, (HFA-305), Rockville, MD, 20852. When submitting comments, please refer to the exact title of this guidance document. Comments may not be acted upon by the Agency until the document is next revised or updated.

Additional Copies

Additional copies are available from the Internet at: http://www.fda.gov/cdrh/comp/eprc.html. You may also send an e-mail request to dsmica@fda.hhs.gov to receive an electronic copy of the guidance or send a fax request to 301-847-8149 to receive a hard copy. Please use the document number (**1611**) to identify the guidance you are requesting.

Guidance for Industry and FDA Staff

Exemption from Reporting and Recordkeeping Requirements for Microwave Ovens

This guidance represents the Food and Drug Administration's (FDA's) current thinking on this topic. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. You can use an alternative approach if the approach satisfies the requirements of the applicable statutes and regulations. If you want to discuss an alternative approach, contact the FDA staff responsible for implementing this guidance. If you cannot identify the appropriate FDA staff, call the appropriate number listed on the title page of this guidance.

Introduction

Under Title 21 of the Code of Federal Regulations §1002.50 (21 CFR 1002.50), FDA may exempt manufacturers of electronic products from reporting and recordkeeping requirements subject to any conditions necessary to protect the public health. This guidance provides notification of FDA's exemption of microwave oven products from certain reporting requirements because of the low risk of exposure to microwave radiation and minimal risk to public health.

FDA's guidance documents, including this guidance, do not establish legally enforceable responsibilities. Instead, guidances describe the Agency's current thinking on a topic and should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited. The use of the word *should* in Agency guidances means that something is suggested or recommended, but not required.

The Least Burdensome Approach

We believe we should consider the least burdensome approach in all areas of medical device and electronic product regulation. This guidance reflects our careful review of the relevant scientific and legal requirements and what we believe is the least burdensome way for you to comply with those requirements. However, if you believe that an alternative approach would

be less burdensome, please contact us so we can consider your point of view. You may send your written comments to the contact person listed in the preface to this guidance or to the CDRH Ombudsman. Comprehensive information on CDRH's Ombudsman, including ways to contact him, can be found on the Internet at http://www.fda.gov/cdrh/ombudsman/.

Issue

All manufacturers of electronic products, which include all microwave oven products, must submit product and supplemental reports according to 21 CFR 1002.10 and 1002.11, and annual reports according to 21 CFR 1002.13. The FDA is now reducing the amount of required reporting information for microwave oven products, because of the low risk of exposure to microwave radiation and minimal risk to public health. Manufacturers should refer to the "Guide for Preparing Reports on Radiation Safety of Microwave Ovens" (http://www.fda.gov/cdrh/radhlth/pdf/mworptgd.pdf) which contains instructions and format for submitting hard copy reports to FDA.

Guidance

1. Why is FDA granting this exemption?

- This exemption reduces the regulatory burden on manufacturers of microwave oven products without compromising the public health.

2. What products does this exemption cover?

- This exemption covers all microwave oven products.

3. What requirements are reduced by this exemption?

- Manufacturers of microwave oven products are exempted from
    - All product reports except for the first product report as required by 21 CFR 1002.10
    - All supplemental reports as required by 21 CFR 1002.11
    - Quarterly updates to annual reports as required by 21 CFR 1002.13(c)
        - Part 11.0 of the "Guide for Preparing Reports on Radiation Safety of Microwave Ovens" (http://www.fda.gov/cdrh/radhlth/pdf/mworptgd.pdf) is no longer applicable.

provided the following conditions for use in question 4 are met.

4. What are the conditions for use of this exemption?

- The manufacturer must test and certify that the microwave oven products comply with the Federal performance standards contained in 21 CFR 1030.10.

- The manufacturer must file a ***single*** product report for a microwave oven product regardless of how many different model families are produced after the initial filing.
  (Manufacturers should refer to Parts 1-3 of the "Guide for Preparing Reports on Radiation Safety of Microwave Ovens," (http://www.fda.gov/cdrh/radhlth/pdf/mworptgd.pdf.)

- The manufacturer must file a ***single*** quality control report regardless of how many different model families are produced after the initial filing.
  (Manufacturers should refer to Parts 4-9 of the "Guide for Preparing Reports on Radiation Safety of Microwave Ovens," (http://www.fda.gov/cdrh/radhlth/pdf/mworptgd.pdf.)

5. What requirements are not included in this exemption?

- The manufacturer must continue to submit annual reports required by 21 CFR 1002.13, which contain listings of all products tested and certified during the reporting year. The listing must include all microwave oven products that were distributed into United States commerce during the reporting period, including information that previously would have been reported in a quarterly update to the annual report.

- Manufacturers must continue to meet all other applicable requirements, including

  - 21 CFR 1002.20 (Reporting of Accidental Radiation Occurrences)
  - 21 CFR 1002.30(a) and 1002.31 (Manufacturer's Records)
  - 21 CFR 1003 (Notification of Defects or Failure to Comply)
  - 21 CFR 1004 (Repurchase, Repairs, or Replacement of Electronic Products).

6. Can the Center revoke this exemption?

- Yes. FDA reserves the right to request additional information from the manufacturer concerning these products or full reports and recordkeeping if FDA determines this to be necessary in keeping with the intent of the U.S. Federal Food, Drug and Cosmetic Act, Chapter V, Subchapter C – Electronic Product Radiation Control. This would be the case if FDA has reason to believe that the manufacturer is not abiding by the conditions of the exemption.

Getting More Information

You can get more information about our requirements for microwave oven products from our electronic product radiation control web page at http://www.fda.gov/cdrh/comp/eprc.html.

If you have questions about this guidance, contact George Kraus, Center for Devices and Radiological Health (HFZ-240), Food and Drug Administration, 10903 New Hampshire Avenue, Silver Spring, MD 20993 or George.Kraus@fda.hhs.gov.