

This guidance was written prior to the February 27, 1997 implementation of FDA's Good Guidance Practices, GGP's. It does not create or confer rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statute, regulations, or both. This guidance will be updated in the next revision to include the standard elements of GGP's.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

JUN 14 1983

Food and Drug Administration
Rockville MD 20857

TO: All Microwave Oven Manufacturers and/or Importers

SUBJECT: Reporting of New Model Numbers to Existing Model Families

The regulations enforcing the Radiation Control for Health and Safety Act of 1968 require manufacturers to submit a report on each new or modified model prior to introduction of that model into commerce. Until now, the Division of Compliance has requested that new model numbers be reported in supplements to the Initial or Model Change Report in which the model family was reported.

The above procedure has resulted in the submission of numerous report supplements. In order to reduce the administrative and financial burden on both the manufacturer and the Division, a new reporting procedure will be implemented. Effective July 1, 1983, we are asking manufacturers to submit a single quarterly report covering all new models of previously reported model families which are to be introduced into commerce during the next three month reporting period. (See item 4 below for reporting periods). In order to consolidate this information on new models, we request that these periodic submissions be submitted as supplements to the most recent Annual Report. (See item 4 below for further instructions).

The reporting procedure is as follows:

1. The Initial or Model Change Report submitted for a new model family must contain a list of model numbers for the new family. (This has not changed from the previous procedures).
2. Additional models intended for introduction into commerce are to be submitted in a supplement (see item 4 below) to the last Annual Report using the forms of Attachment 1.

It is important to note that this new report procedure applies ONLY to new models of previously reported model families. Changes in models that will allow the use of this new procedure include:

- (a) cosmetic changes
- (b) new brand names
- (c) control panel changes
- (d) addition of a temperature probe feature
- (e) changes in areas of the circuitry that could not affect the RF leakage characteristics of the oven and/or safety interlock(s) and monitor function.

Any of these changes listed above may be explained by a note on the Attachment 1 form.

2 - Reporting of New Model Numbers to Existing Model Families

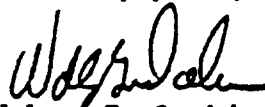
3. If a change is made in an area that could affect the RF leakage characteristics or the function of the safety interlock(s) and monitor, the model number and the details of the change must be submitted as a supplement to the appropriate Initial or Model Change Report (see the definition of model family in the Initial Reporting Guide).
4. The reporting period shown below is intended to minimize the number of submissions required while still maintaining a realistic forecasting period. Please note that it is quite acceptable to submit reports earlier than the due date.

<u>Quarterly Reporting Period</u>	<u>Due Date</u>
January, February, March	January 1
April, May, June	April 1
July, August, September	July 1
October, November, December	October 1

5. If a model is to be introduced into commerce during a reporting period but was not reported at the beginning of the reporting period, it must be reported as a supplement to the last annual report separately. This must be submitted (using the forms enclosed as Attachment 1.) prior to its introduction into commerce.
6. If no new models are intended to be introduced during the forthcoming reporting period, you are not required to submit a quarterly report.

The Division of Compliance believes that changing to this reporting method will reduce the number of reports submitted by the manufacturer and still permit the manufacturer to meet his obligations as required by law. If there are any questions concerning our reporting requirements, please contact the Microwave/Acoustics Products Section of the Consumer-Industrial Products Branch at (301) 443-6540. Letter inquiries should be directed to the undersigned.

Sincerely yours,



Walter E. Gundaker
Director, (HFX-400)
Division of Compliance
National Center for Devices
and Radiological Health
5600 Fishers Lane
Rockville, Maryland 20857

Attachments 1

General

For ease of photocopying, all instructions are on the left-hand pages while the corresponding forms are on the right-hand pages. 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.

Part 1. Identification of Manufacturer/Importer

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

Check the statement and fill in the report identification if you are submitting a supplement to an annual report.

If you are providing only new model numbers, complete Parts 1 and 8 only and submit pages 1 and 6 as a supplement to the last annual report you submitted to NCDRH.

Part 2. Production Status

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

Part 8. New Model Report Supplement

New model numbers added to previously reported model families may be reported in a supplement to the current Annual Report if the information in the Initial or Model Change Report is still applicable. It is recommended that these new models be reported on a quarterly basis. Changes that may be reported in a new model report supplement include:

- (a) cosmetic changes
- (b) new brand names
- (c) control panel changes
- (d) addition of a temperature probe feature
- (e) changes in areas of the circuitry that could not affect the RF leakage characteristics or the function of the safety interlock(s).

Use 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 8.

Check the appropriate answer to the question and check the reporting period for which the report supplement is being filed.

"Brand": You may use a code for each brand in the chart. On a separate sheet, provide the complete address for each importer or distributor of each brand and identify any codes. Label the sheet Part 8.

"Oven Type": Indicate whether the model is common cavity (COM), countertop commercial (CTC), countertop domestic/household (CTD), high/low or over/under (HLO), module (MOD), wall hanging oven (WHO), built-in single oven (BSO), or built-in double oven (BDO).

"Plant Location": Codes may be used. On a separate sheet provide the complete address for each manufacturing location and identify any codes. Label the sheet Part 8.

"Changes": State the model number of the old model that is most similar to the new model. Using codes a-e for the changes listed above, indicate the changes made in the new model.

If the new models contain any changes that could affect the RF leakage characteristics or the function of the safety interlock(s), the new model number(s) and the details of the change(s) must be submitted as a supplement to the appropriate Initial or Model Change Report.

MICROWAVE OVEN ANNUAL REPORT: Page 1

Part 1. Identification of Manufacturer

Report Date: _____

Corporate Name: _____

Address: _____

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

() This is a supplement to Annual Report NCDRH Accession No. _____
submitted on _____.

(date)

Corresponding Official: _____

(Signature)

(Name)_____
(Title)() _____
(Telephone)

Importer: (Complete if applicable)

Company Name: _____

Address: _____

Corresponding Official: _____

(Signature)

(Name)_____
(Title)() _____
(Telephone)Part 2. Production Status

() 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 5.

() 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 5.

() Products were manufactured during this period but the firm is now out of business. If you check this, complete and mail this entire report.

