JAN 20 1975

REF:DOC:3215-MA

TO: All Microwave Oven Manufacturers

SUBJECT: Incident of Open Door Microwave Oven Operation Caused by a Loose Connector

An incident of excessive microwave exposure resulting from the use of a microwave oven capable of operation with its door open was recently reported to the Bureau of Radiological Health. Examination of the oven revealed that a bare snap-on connector became loose from its designated terminal, touched an adjacent terminal and became welded to it; an occurrence which caused all safety interlocks to be by-passed and the oven to be operable with its door open. The snap-on connector was attached to a wire leading to the primary side of the high voltage transformer while the adjacent terminal received its power through the timer directly from the input voltage line of the oven.

After the manufacturer examined more than 2,500 unsold ovens, the Bureau determined that the occurrence was an isolated incident. However, in view of the highly significant risk of injury manifested by this incident, we urge you to examine your present and future microwave oven designs and production processes to determine if there are adequate safeguards to prevent similar occurrences. Please consider the following or similar methods and procedures:

1. Use of plastic covers on all snap-on connectors so that if a connector became loose and touched another energized terminal, no transfer of electrical energy could be made.

2. Securely anchor any wire near its snap-on connector so that if the connector becomes loose, no contact to another energized terminal within the radius of free movement of the wire could be made.

3. Provide sufficient separation between one group of terminals that feed energy to points prior to the safety interlocks and those that receive energy through the safety interlocks so that any (snap-on) connector of one group within the free movement of its wire could not reach any terminal of the other group.

4. Initiate quality control procedures to assure that snap-on connectors are securely mated to their designated terminals.

The Bureau of Radiological Health will evaluate future oven designs to determine if a potential exists for a repetition of the subject incident.

Sincerely yours,

Robert G. Britain

Robert G. Britain
Director
Division of Compliance
Bureau of Radiological Health

DEPARTMENT OF HEALTH. EDUCATION. AND WELFARE
PUBLIC HEALTH SERVICE
FOOD AND DRUG ADMINISTRATION
ROCKVILLE. MARYLAND 20857

MAR 2 8 1980

To: All Manufacturers and Importers of Microwave Ovens

Subject: Open Door Operation of Microwave Ovens as a Result of Oven Miswiring

Recently there have been three incidents in consumer locations in which the microwave oven operated with the door open due to oven miswiring. These incidents have resulted in expensive oven retesting and recall programs. It has also been learned that several workers at one manufacturing location had accidently been exposed to microwave radiation in several instances during oven testing, due to oven miswiring that resulted in the continued operation of the oven after the door was opened.

The Bureau is greatly concerned that future incidents such as these could occur and result in the exposure of individuals to high levels of microwave energy. To reduce the potential for such open door operation, due to miswiring of the oven circuitry, the Bureau strongly recommends that all manufacturers consider instituting design features that will, (1) preclude analagous accidental miswiring of microwave ovens, or (2) if miswiring occurred, prevent the unit from operating with the door open.

It is recommended that all manufacturers consider:

1. Locating one safety interlock on the neutral side of the line and another on the high side of the line.

2. Locating the monitor circuit as the last circuit branch in parallel with the high voltage transformer, or making the "hot" A.C. line connection to the monitor circuit the last connection prior to connection with the primary of the power transformer.

3. Performing a failure mode effects analysis on each unique design to identify critical connections and wires where the accidental interchange would result in electrically by-passing all safety interlocks and the monitor.

4. Designing critical wire terminal connect points so as to mechanically preclude accidental interchange of these wires to any unsafe configuration.

5. Covering the terminals of critical wires with insulation to prevent any loose wire from being able to contact another point that might result in by-passing the safety interlock or monitor circuit.

6. Using wire ties to limit the degree of movement of any wire that could become disconnected.

7. Instituting other design features that would prevent the miswiring of units or prevent units that are miswired from operating with the door open.

Manufacturers must be careful not to introduce design changes that could result in noncompliance with the Federal performance standard. It is requested that proposed changes be submitted to the Bureau for review prior to incorporating the changes on production models. It may also be appropriate to submit prototype units to the Bureau for evaluation.

It is equally important that certain good quality control practices be observed to help prevent these undesirable conditions. The Bureau is hereby requesting that all manufacturers now institute, if not already a part of their quality control and testing program, a specific test of each unit to determine that the unit will cease operating when the door is opened, and that it cannot be restarted, when the door is open. Any test that provides positive indication of magnetron shutdown upon latch release or door opening will be acceptable.

The test must also include an attempt to restart the unit while the door is unlatched. This should be attempted both with the unit programed and not programed (for operation)for digital units, and with and without time on the timer for nondigital units, if the status of these controls could alter the possibility of starting with the door open.

We recognize that these tests require care in order to prevent the exposure of the operator to high levels of 'microwave energy. In each case the door should be unlatched slowly and the operator instructed to terminate the test immediately if a problem is noted. Also a mechanical stop is recomecded that would allow the door to be unlatched and opened slightly but which would prevent the door from opening to a position that would allow hazardous levels of microwave energy to leak from the oven.

Regardless of the type of test performed the test must be conducted at a point on the production that is subsequent to any assembly, adjustment or repair of the unit that could alter the oven wiring. All operators must be instructed to immediately report any findings of open door operation to the proper quality control person so that the defective unit can be analyzed to deternine the cause of the failure. Manufacturers should take corrective action to prevent future incidents.

Since the failure could be the result of a defective wiring component that is assembled in-house or purchased from a vendor, it is recommended that the assemblers of such components receive additional training and assembly aids that will help prevent defective wiring components. Units of the components should be inspected on a sampling or 100%basis prior

to being sent to the production line. If a defective component is found in a lot, then that lot should be rejected or 100 per cent tested prior to allowing the components to be sent to the assembly line. Where sampling is used, lots received after a rejected lot should be tested under a tightened sampling schedule until the results allow for return to a normal sampling schedule.

Please institute any design and testing program changes necessary to prevent open door operation. The Bureau would welcome other suggestions which could help prevent such incidents.

Robert G. Britain
Director
Division of Compliance
Bureau of Radiological Health

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE
PUBLIC HEALTH SERVICE
FOOD AND DRUG ADMINISTRATION
ROCKVILLE, MARYLAND 20852

JAN 28 1975

REF:DOC:3217MA

To: All Manufacturers and Importers of Microwave Ovens

subject: Safety Interlock Monitor Requirement (21 CFR 1030.10 (c)(2)(vi))

The Performance Standard for microwave ovens requires that "A means of monitoring one or both of the required safety interlocks shall be provided which shall cause the oven to become inoperable and remain so until repaired if the required safety interlock(s) should fail to perform required functions as specified in this section."

There have been some misunderstandings with regard to the meaning of the phrase "monitoring one or both required safety interlocks." This provision requires that a microwave oven be rendered inoperable following the failure of either the primary or secondary interlock or the failure of both the primary and secondary interlocks. A microwave oven which is not rendered inoperable unless an additional interlock (other than the primary and/or secondary) also fails, does not comply with the performance standard. You are being notified of this to avoid such misunderstandings in the future.

Please address any inquiries or questions concerning this matter to the attention of the consumer-Industrial Products Branch, Division of Compliance (301-443-6540).

Sincerely yours,

Robert G. Britain

Robert G. Britain
Director
Division of Compliance
Bureau of Radiological Health

DEPARTMENT OF HEALTH. EDUCATION. AND WELFARE
PUBLIC HEALTH SERVICE
FOOD AND DRUG ADMINISTRATION
ROCKVILLE. MARYLAND 20857

MAR 22 1978

TO: All Manufacturers of Microwave Ovens

SUBJECT: Potential Misadjustment of Safety Interlock and Monitor Switches

The Federal Performance Standard for Microwave Ovens, 21 CFR 1030-10, requires that each microwave oven have a minimum of two operative safety interlocks which are intended to prevent generation of microwave energy when access to the cavity is possible, In addition, the performance standard requires that each oven be provided with a means of monitoring one or both of the required safety interlocks which shall cause the oven to become inoperable if the monitored interlock(s) should fail in an unsafe condition.

The most common method of meeting these safety interlock and monitor requirements is through the use of snap action switches, On a few models tested at the FDA laboratory in Winchester, Massachusetts it has been possible to mechanically adjust one or more of these safety switches to an unsafe failed condition, i.e., so that interlock contacts are always closed or monitor contacts are always opened.

Service literature prwided by the manufacturers cautions service personnel to make sure that these switches are properly adjusted and provides adjustment procedures as required by the Standard, However, the Bureau is concerned that the procedures contained in service manuals. may not be adequate to prevent these safety switches from being improperly installed or improperly adjusted during servicing so that one or more of these switches may be set to an unsafe failed condition, This concern is heightened by recent findings of noncompliance on individual ovens that were the result of improper servicing of ovens for which proper service instructions had been published and made available in accordance with the provisions of the Standard.

To eliminate the possibility of these safety switches being improperly adjusted to an unsafe condition the Bureau requests each manufacturer of microwave ovens to take the following actions;

(1) Examine all model family designs in current production to determine if any of the interlock or monitor switches can be adjusted so that the interlocks are always closed or the monitors are always opened,

(2) For those models or model families where such misadjustment is possible, manufacturers are requested to take whatever measures may be necessary to limit interlock or monitor switch adjustment range so that the switches cannot be adjusted to an unsafe failed condition,

(3) Report any design or manufacturing changes made concerning these switches in a supplement to the appropriate initial or model change report already submitted to the Bureau,

(4) Examine all future model family designs to make sure *that* this problem does not exist in future models.

The Bureau will closely monitor conformance with these requests and believes that any necessary design or manufacturing changes can be implemented within six months. If for any reason any specific models cannot be modified and the changes put into production in a six month period, please report *to* the Bureau, *the* proposed changes, the reason for the delay and time needed to *implement the* change.

Authority for this policy is found *in* 21 CFR, Subchapter J, 1030.10(c)(2)(iii).

Your cooperation in investigating this matter and reporting on any changes made is appreciated. If you have any questions concerning *this* matter please contact the Microwave/Acoustic Products Section at (301) 443-6540.

Sincerely *yours*,

Robert G. Britain

Robert G. Britain
Director
Division of Compliance
Bureau of Radiological Health.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
8757 Georgia Avenue
Silver Spring MD 20910

JAN 25 1988

TO: ALL MANUFACTURERS AND IMPORTERS OF MICROWAVE OVENS AND MICROWAVE BEATING EQUIPMENT

SUBJECT: POTENTIAL CHEMICAL INTERACTION ON SAFETY INTERLOCK SWITCHES

The Center for Devices and Radiological Health, Food and Drug Administration has documented a serious accidential radiation occurrence in which a laboratory worker was exposed to high levels of microwave radiation while using a household microwave oven to heat corrosive chemicals. Both the required safety interlock switches and the monitor system failed to prevent the oven from operating with the door open. The corrosive chemicals and vapors inside the oven cavity interacted with the contacts and springs of the safety interlock switches thereby rendering them inoperable. These chemicals, including reactive sulfides and chlorides, interacted with the switches in one or two ways: (a) corrosion of critical metal parts such as springs and contacts occurred causing the springs to become brittle and the silver contacts to separate; and (b) the current-carrying switches became overheated due to high contact resistance caused by deposit of the chemicals on the metal parts.

In this particular case the movable' spring inside the primary safety switch was fractured, one of the silver contacts inside the secondary safety switch was separated, and the movable spring inside the monitor switch was brittle. The oven was able to operate with the door open because there was permanent electrical continuity through the primary and secondary safety switches and permanent noncontinuity through the monitor switch. According to an analysis by an independent laboratory, it is believed that the corrosion and high contact resistance caused by the deposit of reactive chemicals were the primary initiators of severe overheating and spring failure of the switches.

Manufacturers of household/commercial microwave ovens are encouraged to warn their users in the user instruction manuals to avoid using corrosive chemicals and vapors in the ovens, This type of oven is specifically designed to heat, cook or dry food and for use in homes, restaurants, food vending, or service establishments, on interstate carriers, and in similar facilities. They are not designed for industrial or laboratory use,

Manufacturers of industrial microwave heating equi'pment such as those designed for laboratory use, should be aware of all potential environmental contamination of electronics and critical safety interlock switches, If a microwave oven or an industrial microwave heating unit is to be used or modified for heating substances containing or producing corrosive chemicals, then it is essential that the equipment be designed to prevent harmful effects to the safety systems, i.e., adequate shielding of the electronics and venting of the corrosive fumes away from the oven as well as the user. Periodic checks of the continuity of the safety interlock switches is also recommended if the equipment is subjected to a severely corrosive chemical environment.

If you have any further questions or concerns please contact the Microwave/ Acoustics Products Section at (301) 427-7187.

Edwin A. Miller

Edwin A. Miller
Director, Division of
Radiological Products
Office of Compliance
Center for Devices
and Radiological Health

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
8757 Georgia Avenue
Silver Spring MD 20910

OCT 31 1988

TO: ALL MANUFACTURERS AND IMPORTERS OF MICROWAVE OWNS

.SUBJECT: INFORMATIONAL REQUIREMENTS FOR COOKBOOKS AND USER AND SERVICE MANUALS

This notice is issued by the Center for Devices and Radiological Health (CDRH) to serve as guidance to manufacturers, importers, and assemblers of microwave oven products in the preparation of cookbooks and user and service manuals for their products. The outline below summarizes the specific requirements developed by CDRH for use in reviewing submissions. All microwave oven cookbooks and user and service manuals must meet these requirements to be considered acceptable.

USER MANUALS AND COOKBOOKS

1. The user manual must contain the required wording of the user precaution statements specified in 21 CFR 1030.10(c)(4)(iii). The required wording is specified by the regulations and cannot be changed. The Director of CDRH may also decide, if additional radiation safety precautions or instructions are necessary.

2. The PRECAUTIONS title must be emphasized to elicit the attention of the reader. This can be accomplished by the use of bold print, contrasting color, or a heavy-lined border. The print size of the title should be at least as large as that of any other title that appears on the same page as the user instructions. The print size of the precaution statements should be at least as large as that of any other statements (excluding titles) that appear on the same page.

3. The user precaution statements must be printed near the front of the user manual and before the operating instructions.

4. Additional precaution statements are permitted so long as they do not detract from the required warnings.

5. If the user precaution statements do not appear on the inside front cover of the manual or on a page prior to the table of contents, then the precaution statements should be referenced by page number in the table of contents. The table of contents should contain the wording "PRECAUTIONS TO AVOID POSSIBLE EXPOSURE TO EXCESSIVE MICROWAVE ENERGY" and the page number on which the user precaution statements appear.

6. Supplements'to the user manual or cookbook, such as recipe booklets or quick reference cards or guides, may or may not require user precaution statements. In general, any supplements which include operational information for the oven should include the precaution statements or reference the location of the caution statements in the user manual or cookbook.

SERVICE MANUALS

REQUIRED STATEMENTS

1. The service manual must contain the required wording of the service precaution statements as specified in 21 CFR 1030.10(c)(5). The required wording is specified by the regulations and cannot be changed. The Director of CDRH may decide that additional radiation safety precautions or instructions are necessary for particular oven designs.

2. The PRECAUTIONS title must be emphasized to elicit the attention of the reader. This can be accomplished by the use of bold print, contrasting color, or a heavy-lined border. The print size of the title should be at least as large as that of any other title that appears on the same page as the user instructions. The print size of the precaution statements should be at least as large as that of any other statements (excluding titles) that appear on the same page.

3. The service precaution statements must be printed near the front of the service manual and before the servicing instructions.

4. Additional precaution statements are permitted so long as they do not detract from the required warnings.

5. If the service precaution statements do not appear on the inside front cover of the manual or on a page prior to the table of contents then these statements should be referenced by page number in the table of contents. The table of contents should contain the wording: "PRECAUTIONS TO BE OBSERVED BEFORE AND DURING SERVICING TO AVOID POSSIBLE EXPOSURE TO EXCESSIVE MICROWAVE ENERGY," and the page number on which the service precaution statements appear.

SCHEMATICS

1. 21 CFR 1030.10(c)(2)(v) states that the two required safety interlocks shall be designated as "PRIMARY" or "SECONDARY" in the manual for the oven. This designation should be shown on the schematic or wiring diagram or it may appear in the body of the service manual.

2. Although not required by the regulations, we recommend that the monitor be identified on the schematic or in the manual as "MONITOR" or "SHORT SWITCH" or other similar wording.

3. There should be no discrepancies between oven wiring diagrams and the schematic diagrams.

4. The monitor circuit(system) may contain a maximum of two safety interlocks. One interlock system may be made up of a switch and a relay.

5. Additional timers, fuses, and thermal protectors in the monitor circuit (system) are acceptable. Other components such as relays, triac, etc. may not be acceptable.

6. If a relay or other unusual component is present in the monitor circuit (system), it must not be able to disrupt the monitoring function if any electrical or mechanical failure occurred. If it is able to, then the circuit is noncompliant and cannot be used. We recommend active testing of the monitor circuit (system) by simulating a failure and then checking to see that the oven will not operate with the door open.

SERVICING PROCEDURES

21 CFR 1030.10(c)(2)(iii) states that:

> "Service adjustments or service procedures on the microwave oven shall not cause the safety interlocks to become inoperative or the microwave radiation emission to exceed the power density limits of this section as a result of such service adjustments or procedures."

Manufacturers, importers, and assemblers should incorporate review procedures for the following requirements in their quality control and testing programs to ensure that user and service instructions will not violate this standard.

A. General:

1. Adherence to the servicing instructions listed in the service manual, including adjustment and replacement procedures, should result in proper operation of the oven.

2. The service manual should advise the reader that if the oven is operative prior to servicing, a microwave emission check should be performed prior to servicing the oven.

3. The service manual should direct the reader to inform the manufacturer, importer, or assembler of any certified oven unit found to have a microwave emission level in excess of 5 mW/cm^2. The manufacturer, importer, or assembler should instruct the service person to repair any unit found to have excessive emission levels at no cost to the owner (see 21 CFR 1004.2) and should attempt to ascertain the cause of the excessive leakage. The owner of the unit should be instructed not to use the unit until the oven has been brought into compliance.

4. If the oven operates with the door open, the manual should instruct the service person to: 1) tell the user not to operate tile oven and 2) contact the manufacturer and CDRH immediately.

B. Electrical Continuity Test:

1. Review the continuity test procedures for accuracy and completeness. Check that the test should correlate with the wiring diagram and schematic in the manual.

2. All page references in trouble-shooting sections should refer to the correct test procedures.

C. Safety Interlocks/Monitor Replacement and Adjustment:

1. The procedures listed in the service manual should be adequate to ensure that replacement and adjustment of the safety interlocks, monitor, mounting bracket, and/or latch mechanism will not result in excessive microwave emission.

2. If the oven has been rendered inoperative due to the failure of the monitored safety interlock(s) then the manual should instruct the service person to replace all of the monitored safety interlock switches and the monitor switch.

3. The procedures listed for changing the safety interlocks and monitor should correlate with the wiring diagram.

4. The procedures listed should remind the serviceman to connect the monitor switch after replacement and to check interlock/monitor continuity.

5. For non-zero motion door model designs, the procedures listed should include a check to ensure that the safety interlocks and monitor switches will actuate within a specified distance recommended by the manufacturer.

D. Magnetron, Door and Hinge Replacement and Microwave Emissions Test:

1. There should be adequate instructions provided in the service manual to allow the correct replacement of the magnetron, including a check for the presence of the wire mesh gasket.

2. There should be adequate instructions provided to allow the correct replacement of the door, including a check for correct alignment with the hinge and cavity front face.

3. Microwave emission testing procedures provided in the manual should be adequate. Instructions for testing should include: the correct water load (275 ml.), the correct emission limit (no greater than 4 mW/cm^2 to allow for measurement uncertainty), the correct scan speed (no faster than one inch per second), instructions to check all surface and vent openings, etc.

Questions regarding this guidance should be directed to the Microwave/Acoustics Products Section of CDRH at (301) 427-7187.

Ann B. Holt

Ann B. Holt, DVM
Acting Director
Office of Compliance
Center for Devices and
Radiological Health

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE
PUBLIC HEALTH SERVICE
FOOD AND DRUG ADMINISTRATION
ROCKVILLE, MARYLAND 20852

REF:DOC:3198-MA

TO: All Microwave Oven Manufacturers

SUBJECT: Microwave Emission in Excess of the Standard as a Result of Improper Repair Procedure

Two recent instances of excessive leakage from microwave ovens have been traced to inadequate servicing procedures in which a magnetron was replaced and the metal mesh gasket used to provide an RF shield was omitted. In both instances emission levels in excess of 70 mW/cm^2 were found.

As a result of these occurrences, the Bureau of Radiological Health wishes to remind all microwave oven manufacturers that 21 CFR 1030.10(c)(4)(i) requires that adequate instructions for service adjustments and procedures be provided. This includes adequate instructions (including precautions) for installation of RF seals and other devices to prevent microwave leakage.

The Bureau requests that all manufacturers review their service instructions and replacement parts handling procedures to assure that they have provided adequate safeguards to prevent similar occurrences.

Specifically we suggest that the following areas be checked:

1. Packaging of magnetrons and fit of RF gaskets to the magnetron to prevent accidental loss.

2. Insertion of warning sheet with replacement magnetrons emphasizing importance of correct installation including any shielding device and of making an emission check after installation whenever possible.

3. Review of service instructions for adequacy of warnings in this regard.

4. Training programs for repair personnel for adequate emphasis on the need for proper installation of all R.F. shielding devices and of the importance of emission checks whenever repair work is carried out on components or assemblies which must contain the microwave energy.

5, Quality control procedures to assure proper packaging of magnetrons and inclusion of all necessary shielding devices and instructions,

Sincerely yours,

Robert G. Britain

Robert G. Britain
Director
Division of Compliance
Bureau of Radiological Health

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE
PUBLIC HEALTH SERVICE
FOOD AND DRUG ADMINISTRATION
ROCKVILLE, MARYLAND 20852

SEP 29 1975

REF:DOC:3556-MA

TO: Microwave Oven Manufacturers, Industry Association, State Radiation Control Agencies and Other Interested Parties

SUBJECT: FDA Interpretation Pursuant to 21 CFR 1030.10(c)(6)(ii), Location of Warning Labels to Service Personnel

It is apparent from the analysis of reports submitted by manufacturers that certain types of residential cooking ranges and built-in wen combinations which include a microwave oven are designed to have service performed without moving the range or built-in unit. Location of the warning label for service personnel, required by 21 CFR 1030.10(c)(6)(ii), on the back of such a unit is inappropriate, but the regulation as now worded requires that the label be on the external surface of the oven. Location of such a label on the front or side of such a product may be undesirable to both the user and the manufacturer.

It is essential that the label "be legible and readily viewable during servicing," and "be so located as to elicit the attention of service personnel" as required by the regulation, These requirements are of overriding consideration in determining an acceptable location for the label- In the case of ranges or other microwave ovens not intended for portable or countertop nse and in which the rear surface is not normally accessible for servicing, the intent of the regulation would be met if the label is located on any surface of the oven which meets the following conditions:

1. The label must be legible and readily viewable before the microwave oven is accessible for any servicing which could expose servicing personnel to microwave radiation levels which exceed the limits of the standard or which could affect compliance of the product with the standard.

2. The location and design of the label must elicit the attention of service personnel.

Examples of such locations include interior surfaces of control panels which must be opened to perform maintenance service, or surfaces exposed by removal of trim which must be removed for servicing.

Samples of labels and details of their location must be submitted in a report supplement for all affected models, An appropriate amendment to the regulations to reflect the interpretation set forth above will be promulgated in the near future.

Sincerely yours,

John C. Villforth
Director
Bureau of Radiological Health

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Center for Devices and
Radiological Health
2098 Gaither Road
Rockville MD 20850

JAN 13 1994

To: All Importers and Manufacturers of Microwave Ovens

Subject: Excessive Rusting Inside Microwave Ovens

In the last several years, the Center for Devices and Radiological Health (Center) has received several reports of radiation leakage incidents as the result of excessive rusting in microwave ovens. The reports were on ovens built more than 7 years ago. This is not surprising because many microwave ovens purchased in the late 1970s and early 1980s are still operating in consumers' homes and commercial establishments. This issue is of serious concern to the Center because of the potential health hazard to consumers and food service employees.

In several incidents, the Center has found excessive rusting which resulted in penetration of the cavity wall or deterioration of the door, thereby allowing harmful microwave radiation to escape. In some cases the user could not see the rust because it was hidden under the glass tray, along the rim or above the stirrer fan cover in the ceiling of the cavity. Contributing factors for the excessive rusting include design problems such as poor ventilation of moisture, entrapment of moisture in confined spaces, poor sealing of shelves, doors, etc., inadequate painting of the cavity at the factory, and of course, use of a steel that will rust.

Any manufacturer or importer who becomes aware of any excessive rusting or deterioration should pay special attention to this problem and determine the cause and extent of the rust. An attempt should be made to ascertain whether the rust is surface rust or if there is excessive rusting that will likely result in penetration through the cavity wall in the future under continued operation.

If the rusting is advanced beyond what is considered a slight cosmetic problem, or there is penetration through the cavity wall, the oven should be examined by qualified service personnel, usually connected with the oven manufacturer. The service person should examine the rust area for size and depth and determine if the rust patches are near the rim of the glass tray, site of welds or near corners or cavity seams where sides are joined together.

Sometimes poor ventilation of moisture is the cause of rusting, especially if the oven fan is not working properly or the oven is installed so that condensed water vapor cannot be properly vented.

Significant rust problems, of course, should be reported to the oven manufacturers for tracking, analysis and possible field testing of similarly designed ovens. If an oven manufacturer determines that particular oven models are prone to rusting, then further action, such as field testing and possible recall, may be necessary.

Records concerning microwave oven rust problems should be kept by manufacturers in the same manner as files on consumer inquiries on radiation safety of microwave ovens. If an oven violates the Federal performance standard radiation limit of 5 mW/cm^2, the manufacturer must notify the Center immediately as required by 21 CFR 1003.

The Center hereby requests all microwave oven manufacturers and importers to search their service record and customer complaint files for occurrences of similar rust problems. If such occurrences are found that may result in excessive leakage of microwave radiation, this should be reported to the Center immediately.

Of course, minor rust affecting only cosmetics is not a concern. Service personnel should not be allowed to take advantage of worried consumers or food service employees.

The Center and FDA offices throughout the United States will monitor microwave oven rust problems through reports and communications from manufacturers, service personnel, consumers, field surveys and inspection of manufacturers' records.

Reports of rust problems should be sent to attention of the Non-Medical Radiological Devices Branch (NMRDB) at the Office of Compliance (HFZ-312), Center for Devices and Radiological Health, 2098 Gaither Road Rockville, Maryland 20850. If there are any questions you may contact the NMRDB by telephone at 301-594-4654 or by facsimile at 301-594-4672.

Sincerely yours,

William Hewitt

Ronald M. Johnson
Director
Office of Compliance
Center for Devices and
Radiological Health

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE
PUBLIC HEALTH SERVICE
FOOD AND ORUG ADMINISTRATION
ROCKVILLE, MARYLAND 20857

MAR 21 1980

To: All Manufacturers and Importers of Microwave Ovens

Subject: Field Modifications of Microwave Ovens

The Bureau has learned of a field modification program that involved replacement of the main wire harness and which was performed by service organizations at the direction of an oven manufacturer. In order to. complete the modification it was necessary to essentially rewire the oven. The modification instructions required that, at the completion of the modification, the service organization check only for proper operation of the oven in the cooking mode.

Since the replacement of the wire harness involved reconnecting the safety interlock and monitor *wiring* it is possible that an improperly performed modification could have resulted in the failure of the safety interlocks or monitor to perform their intended function. There is also concern that other miswirings could have been introduced that would have resulted in hazardous situations or additional noncompliances.

In order to prevent field modifications from resulting in noncompliance of the modified wens it is requested that all manufacturers follow the procedures below prior to *starting* a field modification program:

1. Perform an analysis of the proposed modification to determine if the modification could affect the function of the safety interlock or monitor circuits, the RF leakage characteristics of the oven, or if improperly performed, could result in a hazardous situation or *any* other noncompliance with the microwave oven st

2. If the proposed modifications can in any way affect radiation safety of the oven, or compliance with the standard, submit to the Bureau, a copy of the proposed modification instructions, the reason for performing the modification and the affected model numbers. This information shculd include, as applicable: a) a copy of the revised wen schematic diagram, b) a list of components to be replaced, c) a complete description of the electrical or mechanical modifications that will be performed, and d) complete instructions to be provided to personnel performing the mcdification including instructions for performing any checks, or *tests* to assure that the modifications were properly performed.

3. Include as a part of the program instructions that the service organizations perform an RF leakage check and a complete check of the functioning of the interlock and monitor circuits prior to releasing the oven to the owner.

The Bureau will review the proposed instructions and may suggest other specific tests, precautions, or steps that should be included in the instructions. Manufacturers may be requested to submit a unit to the Bureau along with the modification kit and final instructions for our evaluation.

Robert G. Britain
Director
Division of Compliance
Bureau of Radiological Health-

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
8757 Georgia Avenue
Silver Spring MD 20910

FEB 8 1988

TO: ALL PERSONS WHO MODIFY MICROWAVE OVENS OR MICROWAVE HEATING EQUIPMENT

SUBJECT: FDA REGULATIONS CONCERNING MODIFICATION OF HOUSEHOLD OR COMMERCIAL MICROWAVE OVENS AND/OR MICROWAVE HEATING EQUIPMENT

The Center for Devices and Radiological Health (CDRH), of the Food and Drug Administration (FDA), is issuing this guidance to assist persons or manufacturers who modify household (consumer) and commercial microwave ovens or microwave heating equipment in understanding the Federal regulations which cover such products. The products of concern are commercially available but then modified for special industrial, laboratory and/or medical uses, such as laboratory heating equipment, blood-plasma warmers, pathological and biological analyzers, etc.

The CDRH is concerned that any modification of original radiation safety components, such as the door sealing systems, door latching mechanism, safety interlocks and monitor actuation system, etc., could increase the level of microwave energy emitted by the modified product. This could be hazardous to the user. CDRH is mandated by Federal law, the Radiation Control for Health and Safety Act of 1968, to protect the public or user from unneccessary exposure to electronic product radiation. Therefore, it is essential that CDRH review any changes to these products to ensure that they will not be hazardous.

Any individual or manufacturer who is engaged in the business of modifying and offering any of these products for sale to purchasers is subject to the regulations set forth in the Act. The regulations also affect those individuals or manufacturers who offer a conversion kit with all of the components necessary to assemble a complete modified product for special uses. The regulations do not apply to those individuals who are modifying products solely for their own laboratory or research uses and are not offering the product for sale or transfer to another individual. In addition, this guidance is not to be confused with the present Federal Performance Standard for Microwave Ovens which applies to those products used in homes, restaurants, food vending or service establishments, on interstate carriers and in similar locations (21 CFR 1030.10).

Manufacturers or individuals who are offering modified microwave ovens or microwave heating equipment for sale are required to submit an initial report on radiation safety and design modifications prior to introducing any products into commerce. The initial report requirements are detailed in 21 CFR 1002.10 of the regulations. Reports of model changes are also required as specified in Section 1002.12 of the regulations. In addition, Sections 1003 and 1004 of the regulations concerning product defects, and Section 1002.20 concerning reporting of accidental radiation occurrences must be met.

It is unlawful for manufacturers or importers to fail to submit reports required by 21 CFR 1002. If a company fails to comply with the reporting requirements, it may be restrained by a U.S. District Court from further violation and be subject to a penalty of up to $1,000 per violation and a maximum penalty of $300,000.

If a microwave oven or microwave heating equipment is modified for medical or clinical uses, manufacturers or individuals should be aware of the medical device requirements of the Food, Drug and Cosmetic Act (FD&C Act). Assistance in understanding these medical device regulations can be obtained from the Division of Small Manufacturers Assistance, Office of Training and Assistance, CDRH (HFZ-220), Rockville, Maryland 20857, telephone 800-638-2041 or 301-443-6597. Briefly, the main requirements of the FD&C Act include:

1. filing of a 510(k) notice (Premarket Notification, 21 CFR Sections 807.81 - 807.97),

2. registering as a medical device manufacturer and listing the device to be manufactured (21 CFR Sections 807.20 - 807.40),

3. complying with the labeling provisions of the FD&C Act (21 CFR Section 801), and

4. complying with Good Manufacturing Practices for medical devices (21 CFR Section 820).

If you have any questions concerning this guidance or need additional assistance in filing the required reports, please contact the Microwave/ Acoustic Products Section at (301) 427-7187. Our address is: Office of Compliance, Center for Devices and Radiological Health, HFZ-312, 8757 Georgia Avenue, Silver Spring, Maryland 20910.

Edwin A. Miller

Edwin A. Miller, Director
Division of Radiological Products
Office of Compliance
Center for Devices
and Radiological Health

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MO 20850

MAY 14 1997

TO: Manufacturers and Importers of Consumer Electronic .Products

SUBJECT: Importation of Radiation-Emitting Electronic Products for Investigation and Evaluation During Design Development

ISSUE

The Consumer Electronics Manufacturers Association has requested that the Food and Drug Administration (FDA), Center for Devices and Radiological Health (CDRH), expand the exemption for consumer products imported for the purpose of test and evaluation during design and production development.

BACKGROUND

Section 536(a) of the Electronic Product Radiation Control provisions of the Federal Food, Drug, and Cosmetic Act (the Radiation Control for Health and Safety Act of 1968) requires that all imported electronic products, for which applicable radiation performance standards exist, shall comply with the standards and shall bear certification of such compliance. Before the products can be permitted to enter the U.S., importers are required to submit with each shipment certain import entry papers through the District Director, U.S. Customs Service, to the appropriate FDA district office.

Exemption from certification of electronic products for the purpose of research, investigations, studies, demonstrations, or training is permitted by Section 538(b) of the Act. Current policy permits FDA district offices to grant such exemptions for individual entries, usually for 180 days, while the products remain in import detention status. Importers must make a written declaration to FDA (Form FDA 2877, "Affirmation C") and execute a bond with the U.S. Customs Service. Liquidation of the Customs bond is attained only through exportation or destruction of the products.

By letters dated May 17, 1982; August 25, 1983; and May 22, 1987, CDRH exempted up to 10 units of the following products from the applicable performance standard when they are intended for investigations: television products, microwave ovens, and laser products that do not exceed the limits of Class I during any conditions of operation, maintenance, or service (hereafter referred to as inherent Class I laser products). The products are not subject to certification requirements or the Customs bonding process under certain conditions. These products are generally used for acceptance testing (FCC, UL, etc.), establishment of production line procedures, and applications evaluation. While they may be fully operational, they may not be the final design and have not received final acceptance testing.

On March 7, 1996, the Consumer Electronics Manufacturers Association (CEMA), a sector of the Electronic Industries Association, requested a change to the industry-wide investigations and evaluation exemption. CEMA asks that the number of units to which the exemption applies be increased to 50 units for TV products and Class I laser products and to 200 units for CD-ROM and new DVD (digital versatile disc) laser products, to reduce unnecessary costs to manufacturers in both time and money. Increase to 50 units will accommodate the industry need for establishing production processes. Increase to 200 units for CD-ROMs and DVDs will accommodate the need for software evaluation and development. Because there will be no commercial distribution of the products. the change is expected to reduce the tracking and paperwork burden on industry, FDA, and U.S. Customs, without impact on public health.

EXEMPTION

Under the authority of Section 538(b) of the Act, exemption from-certification to the applicable radiation performance standards and the execution of a customs bond is granted for consumer electronic products imported into the U.S. for investigations and evaluation during the design and production development phase with the following conditions:

1. The quantity of products in any single import entry of television products, microwave ovens, and inherent Class I laser products can not exceed 50 units; except other laser products requiring software to operate, such as CD-ROMs and DVDs, are limited to 200 units.

2. Each product and its shipping carton must bear a label stating: "TESTING/EVALUATION ELECTRONIC PRODUCT - NOT TO BE SOLD IN THE UNITED STATES. THIS PRODUCT HAS NOT BEEN TESTED FOR COMPLIANCE WITH THE APPLICABLE U.S. RADIATION PERFORMANCE STANDARD."

3. The importer or consignee must establish written procedures for maintaining control and final disposition of the products,

4. Form FDA 2877 (Declaration For Electronic Products Subject to Radiation Performance Standards), or the equivalent electronic filing, must be submitted to the FDA district office before the shipment arrives. Until the Form 2877 is revised to provide an affirmation for this exemption, mark Affirmation A and write: "These products meet the CDRH Exemption For Product Development and will not be commercially distributed at any time."

5. Shipments in excess of the quantities specified in item 1, or otherwise not meeting the conditions above, shall be placed in import detention status.

Movement of uncertified products in U.S. commerce is a violation of Section 538(a)(1) of the Act. Violations will result in voiding this exemption for the responsible parties and are subject to civil penalties not to exceed $1000 per violation and $300,000 maximum. Providing false information to the U.S. government is a violation of the U.S. Code, Title 18, and subject to criminal prosecution.

This exemption supersedes the previous exemptions dated May 17, 1982; August 25, 1983; and May 22, 1987.

Any questions regarding this exemption or any imports procedure should be directed to the imports officer at the FDA district office nearest the port of entry.

Sincerely yours,

Lillian J. Gill

Director
Office of Compliance
Center for Devices and
Radiological Health

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
8757 Georgia Avenue
Silver Spring MD 20910

JUN 28 1988

TO: All Manufacturers and Importers of Microwave Ovens

'SUBJECT: Importation of Noncompliant Microwave Ovens Which Are Intended for Use in Countries Other Than the United States

Importers have been allowed to import certain noncertified television receivers for exportation purposes provided that certain specific criteria for exemption from the television performance standard were met. These products were sold to United States (U.S.) distributors who, in turn, sold them to consumers who were either traveling or relocating overseas. The receivers were not designed to operate in the U.S. from 60Hz, 110-120 VAC power sources or U.S. television signals. Those distributors now would like to sell noncertified microwave ovens the same way. If properly labeled for export only as explained below such importation and sale of noncertified microwave ovens will be permitted.

Some manufacturers already test and certify their microwave ovens in accordance with the U.S. standard. These products may be imported into the U.S. claiming Affirmation B on Form PD 2877. They should not be labeled for export only. Other manufacturers have chosen not to certify these products for U.S. use. These manufacturers should notify their customers that these products may not be imported into the U.S., and they should not ship such products to U.S. addressees unless they meet the exemption criteria below.

Food and Drug Administration (FDA) District personnel and the U.S. Customs Service have been notified that all microwave ovens which are capable of operation in the U.S. may not be imported and are to be detained unless they are certified by the manufacturer to comply with the Performance Standard for Microwave Ovens.

Exemption Criteria

Importers are permitted to import for exportation purposes only noncertified microwave ovens which are designed to operate on 50Hz 220 VAC and which are sold without U.S. power plugs or adaptors and when specific criteria for exemption from the appropriate performance standard have been met. Such products are excluded from the performance standard as prescribed in Section 358(a)(3) of the Radiation Control for Health and Safety Act if:

- The foreign manufacturer affixes a label or tag to each shipping container which states

  "WARNING - MICROWAVE OVEN FOR EXPORT ONLY/NOT INTENDED FOR USE IN THE UNITED STATES. THIS PRODUCT HAS NOT BEEN TESTED FOR COMPLIANCE WITH THE U.S. FEDERAL PERFORMANCE STANDARD FOR MICROWAVE OVENS."

- The warning statement shall be in all boldface capitals, no smaller than 5 mm, on a contrasting background.

- The microwave oven also has one label permanently affixed to the product's exterior(excluding the bottom) and another "stick on" temporary label affixed to the center of the oven door. These labels shall contain the wording shown above.

- The importer(on or prior to date of entry) provides FDA with a statement that all imported products bear the required labeling for exemption.

Edwin A. Miller

Director, Division of
Radiological Products
Office of Compliance
Center for Devices
and Radiological Health

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

MAY 14 1997

TO: Manufacturers and Importers of Consumer Electronic Products

SUBJECT: Date of Manufacture Label for Electronic Products Subject to Radiation Standards

ISSUE

The Consumer Electronics Manufacturers Association has requested that the Food and Drug Administration (FDA), Center for Devices and Radiological Health (CDRH), exempt manufacturers of electronic products from the required label providing the date of manufacture or to permit date coding.

BACKGROUND

Manufacturers of electronic products are required to comply with radiation performance standards promulgated under Section 534(a)(1) of the Electronic Product Radiation Control provisions of the Federal Food, Drug, and Cosmetic Act (the Radiation Control for Health and Safety Act of 1968). The regulations, 21 CFR 1010.3, specify that an identification label or tag must be affixed to each product with the date of manufacture.

On March 7, 1996, the Consumer Electronics Manufacturers Association (CEMA), a sector of the Electronic Industries Association, requested a change in the date format specified in the regulations and then subsequently questioned the need for providing a date on the label at all. ,The original intent of the label was to identify which products are subject to a standard (as opposed to ones manufactured prior to the effective date) and to identify products subject to differing requirements when the performance standards are amended. Since the television and microwave oven standards have not been amended since 1983 and the laser standard is seldom amended in any manner that affects the consumer product industries, CEMA asks that the requirement for the label be exempted until any future amendments to these standards are promulgated. The change is expected to reduce the tracking resources and paperwork burden on industry, with negligible impact on FDA or public health.

GUIDANCE

The CDRH concurs that there is little need for the date of manufacture on the identification label at this time and failing to provide the information does not impact public health. As permitted by Section 539(d) of the Act, the CDRH

will not object to manufacturers omitting the date of manufacture from the identification label required by 21 CFR 1010.3 from consumer (non-medical) electronic products under the following conditions:

1. Each product is marked with a serial number or other identification by which the manufacturer may identify the date of manufacture in case of any regulatory action or investigation.

2. The date of manufacture is included on the label within 30 days after a final rule to amend an applicable standard is published in the Federal Register, if the amendment adds or amends (not reduces or eliminates) any aspect of performance to which that electronic product must comply.

Failure to comply with an applicable standard is a violation of Section 538(a)(1) of the Act. Violations will result in disallowing this guidance by the responsible parties and are subject to civil penalties not to exceed $1000 per violation and $300,000 maximum. Providing false information to the U.S. government is a violation of the U.S. Code, Title 18, and subject to criminal prosecution.

In accordance with FDA's Good Guidance Practices, comments are invited. This guidance document represents the agency's current thinking on date of manufacture labeling on consumer electronic products. It does not create or confer any right 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 and/or regulations.

Any comments or questions should be directed to the Electronic Products Branch at the address above, by telephone at 301-594-4654 or by facsimile at 301-594-4672.

Sincerely yours,

Lillian J. Gill
Director
Office of Compliance
Center for Devices and,
Radiological Health