



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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45-1-35 (purged)

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AUG 1 1997

Food and Drug Administration  
2098 Gaither Road  
Rockville MD 20850

WARNING LETTER

VIA FEDERAL EXPRESS

REF: OC:I1-1756

Mr. James Kingsley  
Senior Engineer, Product Safety  
Matsushita Microwave Oven  
Corporation of America  
9333 W. Grand Avenue  
Franklin Park, Illinois 60131

Dear Mr. Kingsley:

The Center for Devices and Radiological Health (CDRH), Food and Drug Administration (FDA), has completed its review of the FDA's Winchester Engineering and Analytical Center (WEAC) laboratory test of a Panasonic brand microwave oven Model NN-S546BA, serial number AW703100072, manufactured January 1997.

Our review of the test results reveals that microwave ovens manufactured by your firm are in violation of section 538 of the Federal Food, Drug, and Cosmetic Act (the Act), Chapter V, Subchapter C - Electronic Product Radiation Control, and Title 21 of the Code of Federal Regulations (CFR) 1030.10.

CDRH has determined that all products in this NN-S546BA model family and other similarly designed microwave ovens fail to comply with the Federal Performance Standard for Microwave Ovens, 21 CFR 1030.10, and associated regulations as follows:

21 CFR 1030.10(c)(2)(iv) - It was possible to insert a straight wire (0.035 inches in diameter) into the oven cavity while the door was closed which would be expected to cause the oven to leak microwave radiation greater than 5.0 mW/cm<sup>2</sup>. The wire could be inserted at the top right corner of the door.

A copy of the WEAC laboratory analysis is enclosed for your information.

Further distribution of ovens in this model family into United States (U.S.) commerce must be discontinued until these deviations are resolved, since section 538(a)(1) and (a)(5) prohibits any manufacturer (including importers) from certifying or introducing into commerce electronic products that do not comply with an applicable standard. This section also prohibits any manufacturer from failure to establish and maintain required records or to submit required reports.

You must respond in writing within 15 days of receipt of this letter to one of the options listed below. In your response, you must also provide the number of the referenced products which have been produced and the number of such products that have left the place of manufacture. In addition, if the product distribution was confined to specific geographical areas of the U.S., please specify those areas.

1. Refutation - You may submit your views and evidence in accordance with 21 CFR 1003.11 to establish that the alleged noncompliances do not exist, or do not relate to the safety of the product.
2. Exemption Request - You may request an exemption from user and dealer/distributor notification and from obligation to correct the violative products. Your request must include the grounds upon which such exemption is requested (see 21 CFR 1003.30 and 1003.31). Also, indicate all models and brands that are to be covered by the exemption along with the number produced and the dates of production.
3. Purchaser Notification and Corrective Action - If you neither refute the noncompliances nor request an exemption, then you must (a) notify purchasers and dealers/distributors of the violative products as specified in 21 CFR 1003.10(b), and (b) submit a written corrective action plan (CAP) to fulfill your obligation under 21 CFR 1004.1 to repair, replace, or refund the cost of the violative products at no charge to the user.
  - a. Notification Letter - Requirements for preparation of notification letters are prescribed in 21 CFR 1003.21 and 1003.22. A copy of the notification letter(s) sent to purchasers and dealers must also be sent to the CDRH. It is recommended that you submit a draft of this letter to us for review.
  - b. Corrective Action Plan (CAP) - Instructions for preparation of a CAP may be found in 21 CFR 1004.2, 1004.3, and 1004.4.

Failure to respond to this letter or to correct these products in a timely manner can result in regulatory action being initiated by the FDA without further notice. These actions may include an injunction and/or imposition of civil penalties as provided for in section 539 of the Act. Persons failing to correct violations are subject to civil penalties of up to \$1,000 per violation and up to a maximum of \$300,000 without further notification by the FDA.

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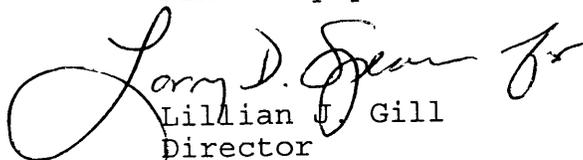
If you request additional time to prepare your refutation, notification, CAP, or evidence to support a requested exemption, you must provide the reasons for any delays and a reasonable target date for the full submission of your response. Be aware that if an acceptable CAP cannot be prepared promptly, you may be required by 21 CFR 1003.11(c) and 1003.21 to proceed with interim notification to affected persons. Therefore, you are encouraged to immediately begin your preparation of accurate user location lists.

When Matsushita has submitted sufficient information on the changes to the current testing program and product design which enables the CDRH to determine whether or not the testing program is adequate to ensure compliance and the modified product complies, Matsushita may resume the certification of the subject products. The CDRH will advise you whether the information you submit is satisfactory and when you may resume introduction into U.S. commerce of certified products, in this model family.

Your response should reference the case number assigned, 11-1756, and should be sent to: Director, Office of Compliance (HFZ-300), Center for Devices and Radiological Health, 2098 Gaither Road, Rockville, Maryland 20850. You are also requested to send a copy of your response to this letter to: Food and Drug Administration, Director, Compliance Branch (HFR-MW140), Chicago District Office, 300 S. Riverside Plaza, 5<sup>th</sup> Floor, Suite 550 South, Chicago, Illinois 60606.

If you have any questions about this letter or the regulations, please contact Mr. George W. Kraus of the Electronic Products Branch 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

Enclosure