



SEP 1 2000

Food and Drug Administration  
2098 Gaither Road  
Rockville MD 20850

m4162v

## WARNING LETTER

VIA Federal Express

Ref:OC: I1-1864

Mr. Giuseppe De'Longhi  
President  
DeLonghi S.p.A.  
3100 Treviso ITALY

Dear Mr. De'Longhi:

This letter is written to advise you of violations of the Electronic Product Radiation Control provisions of the United States (U.S.) Federal Food, Drug, and Cosmetic Act (the Act). The Food and Drug Administration (FDA) Norfolk Resident Post, Baltimore District Office, detained three separate shipments of noncompliant DeLonghi microwave ovens intended for the U.S. importer, [REDACTED] [REDACTED] sets of DeLonghi microwave ovens were detained on July 21, 2000, (entry number [REDACTED]), [REDACTED] sets of DeLonghi microwave ovens were detained on July 21, 2000, (entry number [REDACTED]), and [REDACTED] [REDACTED] DeLonghi microwave ovens were detained on August 7, 2000, (entry number [REDACTED]). All of these shipments have been detained based on the lack of required certification of these microwave ovens with the U.S. Federal Performance Standard for Microwave Ovens, 21 Code of Federal Regulations (CFR) 1030.10.

One microwave oven was collected as a sample from the detained shipments and sent to the FDA's Winchester Engineering and Analytical Center (WEAC) for a comprehensive laboratory analysis of compliance with the U.S. Federal Performance Standard, 21 CFR 1030.10 and other applicable regulations. The WEAC laboratory completed the analysis on August 30, 2000, and a copy of their report is enclosed for your information.

We have determined that this microwave oven and other similarly designed ovens fail to comply with the Federal Performance Standard for Microwave Ovens, 21 CFR 1030.10, and other applicable regulations as follows:

1. 21 CFR 1030.10(c)(2)(v) - The oven failed to comply with the requirements that the secondary safety interlock prevent microwave emission in excess of 5 mW/cm<sup>2</sup>. WEAC reported that the oven emitted 49.5 mW/cm<sup>2</sup> with just the secondary interlock operating. A separate check by another analyst reported that the oven emitted approximately 73.6 mW/cm<sup>2</sup>. Furthermore, the oven also emitted 49 mW/cm<sup>2</sup> in the

original analysis and  $73.6 \text{ mW/cm}^2$  in the check analysis when only the tertiary interlock (logic switch) was operating. The purpose of testing the logic switch was to confirm that no other interlock could operate as the secondary interlock.

2. 21 CFR 1010.2 and 1030.10 - The DeLonghi microwave ovens are not certified and are not properly labeled to meet the U.S. Federal Performance Standard for Microwave Ovens. The WEAC analysis confirmed that no certification label exists on the sampled microwave oven.
3. 21 CFR 1030.10(c)(2)(iv) – It was possible to insert a straight wire into the oven cavity through a hole in the back, upper right corner of the oven. This would be expected to cause the oven to leak microwave radiation greater than  $5.0 \text{ mW/cm}^2$ , a violation of the Federal Performance Standard.
4. 21 CFR 1002.10 – A product report has not been filed with the FDA to indicate that the models have been tested for compliance with the requirements of the performance standard. In absence of such information FDA cannot determine the radiation safety of products that are intended for U.S. commerce.
5. 21 CFR 1010.3(a)(1) - The identification label on this oven lacked the full address of the manufacturer (or the name of the buyer or importer).
6. 21 CFR 1030.10(c)(4)(iii) - The user instructions contain wording discrepancies from that required by the Federal Performance Standard. The “PRECAUTIONS TO AVOID POSSIBLE EXPOSURE TO EXCESSIVE MICROWAVE ENERGY” in the user manual substituted “dirt, grease” for the required word “soil” and the warnings in the recipe book are similar to but not the same as those required for user instructions. The recipe book should contain the same “PRECAUTIONS TO AVOID POSSIBLE EXPOSURE TO EXCESSIVE MICROWAVE ENERGY” as other user manuals.
7. 21 CFR 1030.10(c)(5)(iv) – The service manual, which was received after the original analysis, was found to contain the following discrepancies:
  - a) It does not remind the service personnel to reconnect and check the continuity of the monitor switch.
  - b) It does not specify a distance for interlocks to actuate for non-zero motion door.
  - c) The microwave leakage test guidelines specify an improper water load and scan rate (We also note that the set time of 5 minutes is probably too long because the water will boil in that time and cause the leakage measurements to be inaccurate).

Section 538(a)(1) and (a)(5) of the Act, Chapter V, Subchapter C of the Act prohibit any manufacturer from certifying or introducing into U.S. commerce microwave ovens which do not comply with the standard, or from failing to issue certification when there is an applicable standard. Section 538(a)(4) also prohibits any manufacturer from failure to establish and maintain required records or to submit required reports. Failure to respond to this letter may be considered a violation of 538(a)(4) of the Act. Under the Act, an importer is also considered to be a manufacturer (Section 531(3)).

The FDA is prepared to invoke regulatory actions if you fail to comply with these requirements. These actions may include automatic detention of imported products, injunction, and/or imposition of civil penalties as provided for in Section 536 and 539 of the Act. Persons failing to correct violations and/or continued violations of the Act are subject to civil penalties of up to \$1,000 per violation and up to a maximum penalty of \$300,000 without further notification by the FDA. In cases where a foreign manufacturer fails to respond, penalties may be imposed upon importers.

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 manufacture and introduced into to U. S. commerce for the past 5 years. Provide copies of invoices and lists of applicable serial numbers with dates of shipments. 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 to establish that the alleged failures to comply do not exist.
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).
3. Purchaser Notification and Corrective Action – If you neither refute the noncompliance 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 corrective action plan (CAP) to fulfill your obligation under 21 CFR 1004.1 to repair, replace, or refund the cost of the violative products.
  - 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 FDA. It is recommended that you submit a draft of this letter to us for review.

- b. Corrective Action Plan – Instructions for preparation of a CAP may be found in 21 CFR 1004.2, 1004.3, or 1004.4.

If you request additional time to prepare your refutation, notification, CAP, or evidence to support 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 to proceed with interim notification to affected persons as required by 21 CFR 1003.11(c) and 1003.21. Therefore, you are encouraged to immediately begin your preparation of accurate user location lists.

If you believe that no violations have occurred, you may submit your views and evidence in a regulatory hearing before the FDA pursuant to Part 16 of this chapter (21 CFR 1003.11(a)(3)).

A copy of this letter will be posted on the FDA's world wide web home page under Monthly Import Detention Listing and Warning Letters: <http://www.fda.gov>.

In your reference, please reference this letter and our case number I1-1864. Mail it to:

Director  
Division of Enforcement III  
Office of Compliance (HFZ-342)  
Center for Devices and Radiological Health  
2098 Gaither Road  
Rockville, Maryland 20850.

You are also requested to send a copy of your response (letter only) to:

Director  
Compliance Branch  
Baltimore District Office  
900 Madison Avenue  
Baltimore, Maryland 21201

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If you have further questions on these requirements, please contact Mr. George W. Kraus, Jr. of the Electronic Products Branch at 301-594-4654, or by facsimile at 301-594-4672.

Sincerely yours,



Steven M. Niedelman  
Acting Director  
Office of Compliance  
Center for Devices and  
Radiological Health

Enclosure: WEAC Test Results – Sample No. 105998

CC:

  
Chairman, CEO

  
  
  
  
Mr. Jim McCusker  
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, Esquire

  
  
