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

MAR 20 2001

WARNING LETTER
WITH AUTOMATIC DETENTION

VIA FEDERAL EXPRESS

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

Ref: OC: 11-1893

Mr. James McCusker
President
DeLonghi America
Park 80 West, Plaza One
Saddle Brook, NJ 07633

Dear Mr. De'Longhi and Mr. McCusker:

This letter is to notify you that the Center for Devices and Radiological Health (CDRH), Food and Drug Administration (FDA), hereby disapproves the quality control and testing program for the microwave oven manufacturing facility in Treviso, Italy, effective immediately as of the date of this letter. This action is taken under the authority of the United States (U.S.) Federal Food, Drug, and Cosmetic Act (the Act), Chapter V, Subchapter C – Electronic Product Radiation Control.

The CDRH has taken the action of declaring the program disapproval because of the hazardous electrical condition found on a DeLonghi microwave oven while it was being tested by the FDA's Winchester Engineering and Analytical Center (WEAC). In addition, CDRH has found serious deficiencies in DeLonghi's retrofit program for the certification of compliance of microwave ovens with the Federal Performance Standard for Microwave Ovens, 21 Code of Federal Regulation (CFR) 1030.10.

Based on the findings listed below, CDRH has concluded that DeLonghi S.p.A. of Treviso, Italy has failed to conduct a testing program which assures compliance of its microwave oven products with the applicable performance standard. Under the authority of 534(h) of the Act and Title 21 of the Code of Federal Regulations (21 CFR) 1010.2(c), CDRH hereby disapproves the testing program for all microwave ovens subject to the standard, 21 CFR 1030.10, at DeLonghi S.p.A., Treviso, Italy, effective immediately. In accordance with 21 CFR 1010.2(c), “such certification is based upon a test, in accordance with the standard, of the individual article to which it is attached or upon a testing program which is in accordance with good manufacturing practices. The Director, CDRH (or his/her designee), may disapprove such a testing program on the grounds that it does not assure the adequacy of safeguards against hazardous electronic product radiation or that it does not assure that electronic products comply with the standards prescribed under this subchapter.”

Hazardous Electrical Condition

As part of the corrective action plan submitted in response to CDRH’s warning letter of September 1, 2000, (copy enclosed), DeLonghi S.p.A. redesigned the plastic interlock bracket so that their ovens would meet the secondary interlock microwave emission limit. DeLonghi S.p.A. provided three microwave oven samples with the retrofitted interlock bracket to WEAC for compliance testing and evaluation. These three ovens were supposedly tested in accordance with the procedures written in the radiation safety product report, and then shipped in December 2000 from their plant in Italy to DeLonghi USA New Jersey office and then eventually to WEAC.

On February 2, 2001, while testing one of the three DeLonghi microwave ovens, one of the WEAC laboratory analysts was almost electrocuted during the initial startup of the oven before the compliance testing began. The analyst plugged the oven in, as it was received, set the controls and pushed the start button for the initial evaluation. Sparks flew everywhere with the scary noise of electrical arcing. When the analyst unplugged the oven and took off its cover, the analyst found that the wires to the transformer were not connected and were tucked into the corners of the chassis. Thus the line voltage was running across the cover. Fortunately the analyst was trained to use one handed techniques for all of her analyses. CDRH immediately contacted Mr. James McCusker, both by phone and electronic mail and requested a full investigation of how this oven could have been shipped to WEAC without the required electrical and radiation safety tests conducted, which would have detected this problem.

Subsequently, Mr. McCusker responded by electronic mail on February 5 and explained that all DeLonghi microwave ovens are fully tested as part of the production process, and the electrical tests are done twice on the production line before final packaging. Mr. McCusker claimed that this package was not opened again while being shipped directly to DeLonghi America’s New Jersey office for shipment to WEAC. In addition,

Mr. McCusker provided a summary sheet showing final electrical input results and the final microwave emission test results for the three ovens. CDRH is completely dissatisfied with the answers because according to DeLonghi's Quality Control Aspect report (which describes all electrical and microwave test procedures at the Treviso factory), each oven tested on the production line would have had its own test record. Each oven's test record would have shown the results of specific electrical tests such as current input and the final microwave emission test, and any record of repair done to the oven (see sample document enclosed). Instead of receiving three test records for the three ovens, CDRH received from Mr. McCusker a summary sheet describing the final emission and electrical input results of all three ovens (see document enclosed).

CDRH is still concerned that DeLonghi has not conducted a full investigation of the hazardous oven, including tracking the shipment of the ovens, finding out who was handling the ovens, and obtaining any documentation of shipping records.

DeLonghi's Retrofit Program for 11,000 Microwave Ovens

The CDRH's other concern is with the serious deficiencies with the quality control and testing procedures performed during the retrofit program at DeLonghi's New Jersey warehouse. Two engineers from DeLonghi S.p.A.'s Italy facility failed to adequately train and supervise repair and final test personnel properly at the DeLonghi New Jersey warehouse. On February 9, 2001, Mr. George Kraus from CDRH, observed the initial set up of the retrofit program for the replacement of the interlock bracket on the DeLonghi microwave ovens, final electrical tests and final microwave emission tests. Prior to the beginning of the retrofit program, the two DeLonghi S.p.A. engineers supposedly trained the final test personnel in the warehouse in accordance with the final test procedures, which have been approved by CDRH. However, when the retrofit program started that Wednesday morning, February 9, the final emission test procedures were completely inadequate such that Mr. Kraus had to stop the retrofit operation temporarily and explain to the two engineers why those procedures were incorrect. For example, Mr. Kraus explained that:

1. Final test operator was scanning too fast (in excess of 3 inches per second).
2. Final test operator was using an incorrect beaker for the water load. He was using an Erlenmeyer flask (250 ml) instead of the required 600 ml beaker.
3. Final test operator was holding onto the probe barrel instead of the red portion of the handle of the [REDACTED] microwave survey meter.
4. Final test operator failed to reset the [REDACTED] survey meter after each test.

5. Some repair workers were forgetting to put extra screws in the back cover of the cabinet to prevent a wire from entering the oven's cavity.

All of the problems were corrected immediately after Mr. Kraus demonstrated to the DeLonghi engineers and the final test person how to perform the emission test properly. Mr. Kraus also told the two engineers that they were required to supervise the final test operator as much as possible to ensure that he was performing the test correctly. Mr. Kraus observed the retrofit operation for another 2 days and no further problems were encountered.

In conclusion, based on what occurred during the DeLonghi's retrofit operation, CDRH believes that DeLonghi's engineers from Italy had little or no understanding of the overall radiation safety testing procedures and their purposes, and did not train the retrofit personnel properly. In addition, CDRH is still dissatisfied with the unfinished DeLonghi investigation of the hazardous microwave oven with a serious electrical fault condition which could have seriously injured or killed anyone using this oven.

Results of WEAC Testing

Two samples of the retrofitted microwave ovens were selected from warehouse stock on February 9, and were shipped to WEAC for compliance testing. This office will notify you of the results as soon as the tests are completed.

Program Disapproval

This disapproval of the testing program means that DeLonghi S.p.A.'s microwave oven factory in Treviso, Italy, is prohibited by Sections 534(h) and 538 of the Act from:

1. certifying the electronic products manufactured under the disapproved testing program,
2. introducing or importing products into the United States commerce which bear false and misleading certification, that is, products certified under the testing program which has been disapproved, and
3. introducing or importing into the United States any product which does not have the certification label permanently affixed to the product, as required by 21 CFR 1010.2.

Under Section 536(a) of the Act, FDA may refuse entry or importation into U.S. commerce of any electronic product if it appears that the product fails to comply with the applicable standards, or the manufacturer's testing program has been disapproved.

Therefore, DeLonghi S.p.A. is being placed on the import detention list and its products will be automatically detained at port of entry until the quality control and testing program disapproval is rescinded.

The FDA may initiate regulatory action against any person who violates Section 538, including 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. This Act also prohibits anyone, including the importer, from failing to make any report required pursuant to Section 537(b) or to furnish or preserve any information required pursuant to Section 537(f).

Under 21 CFR 1005.21 and Section 536 of the Act, the manufacturer shall have an opportunity to present views and evidence that the products comply with the Federal Performance Standard for Microwave Ovens, 21 CFR 1030.10.

Resolution

Before the microwave ovens in New Jersey and the boxed stock in Italy can be released for distribution into U.S. commerce, CDRH is requesting the following:

1. An investigation of the loose wires, including test results of the microwave oven, handling of the oven before and after testing, packaging, shipping, storing, and timeframes of the three ovens shipped to the U.S., how long it was held in New Jersey, when it was shipped to WEAC, and all individuals who have handled the three microwave ovens, and
2. An evaluation or audit of your quality control and testing program, including knowledge and understanding of the Federal Performance Standard, 21 CFR 1030.10 and other applicable regulations, 1010.2 and 1010.3, and staff training in proper final microwave emission testing.

The CDRH will advise you whether your submittal is satisfactory and when introduction of certified products into U.S. commerce may resume from the DeLongi S.p.A. factory in Treviso, Italy. A copy of this letter will be posted on the FDA’s world wide web home page under Monthly Import Detention List and Warning Letters:
<http://www.fda.gov>.

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Within 15 days, please submit your response to: Food and Drug Administration, Center for Devices and Radiological Health, Office of Compliance, HFZ-342, Division of Enforcement III, 2098 Gaither Road, Rockville, Maryland 20850. In your response, please reference case I1-1893. If you have any questions, you may contact Mr. George W. Kraus of my staff at (301) 594-4654, or by facsimile at (301) 594-4672, or by electronic mail at gwk@cdrh.fda.gov.

Sincerely yours,

A handwritten signature in black ink that reads "Larry Spears". The signature is written in a cursive style with a prominent "L" and "S".

Larry Spears
Acting Director
Office of Compliance
Center for Devices and
Radiological Health

Enclosures:

Copy of test record taken from DeLonghi's radiation safety quality control report
Copy of summary record sent by Mr. James McCusker on February 2, 2001
Copy of September 1, 2000 Warning Letter