



Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

FEB 21 2002

WARNING LETTER
PROGRAM DISAPPROVAL

VIA Federal Express

Mr. John Chan
Engineering Manager
Bay Area Compliance Laboratory Corporation
230 Commercial Street, # 2
Sunnyvale, California 94086

Ref: OC: II-1903

Mr. Wu Xiaodong
Technology Support Engineer
Shunde MD Microwave Oven Manufacturing Co., Ltd.
Penglai Road, Beijiao
Shunde Guangdong, CHINA

Dear Mr. Chan and Mr. Xiaodong:

This letter notifies you that the Center for Devices and Radiological Health (CDRH), Food and Drug Administration (FDA), disapproves the quality control and testing program for Shunde MD Microwave Oven Manufacturing Co., Ltd. of Guangdong, China. 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.

Based on the inspection findings listed below, CDRH has concluded that Shunde MD Microwave Oven Manufacturing Co., Ltd. (hereafter referred to as Shunde MD) failed to conduct an adequate testing program to assure compliance of its microwave ovens 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 disapproves the testing program for all microwave ovens subject to the standard, 21 CFR 1030.10, at Shunde MD manufacturing facility 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, 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."

On July 25-26, 2001, Mr. Seth Mailhot and Mr. Sean Boyd from the FDA conducted a pre-announced inspection of your microwave oven company, Shunde MD, located in Guangdong, China. The purpose of this inspection was to review Shunde MD's quality control and testing program for certifying compliance of microwave ovens with the U.S. Federal Performance Standard for Microwave Ovens, 21 CFR 1030.10.

This inspection covered:

- Inventory control and warehouse
- Incoming testing for critical components (including metal and welding fabrication, weld testing, inspection of doors and cavities)
- Production line assembly, testing (including safety interlock and monitor testing, and door open start test), and repair of microwave ovens
- Final microwave radiation emission testing
- Quality audit procedures and reaction plans
- Door cycle endurance testing
- Instrumentation, including the intercomparison system
- Instrument calibration and checks (daily and monthly)
- Microwave oven labeling
- Recordkeeping

During the inspection, the FDA inspectors reported the following deficiencies:

1. Incoming component control was inadequate. For example,
 - a. Incoming parts acceptance was not clearly identified for each carton of parts status (e.g., waiting for testing, tested OK, tested rejected).
 - b. Incoming parts of different acceptance status were not physically segregated from one another.
 - c. Incoming cartons of components are not individually labeled after testing has been completed.
 - d. Old forms and handwritten forms are used in place of the current labels.
2. Production component control was inadequate. For example,
 - a. Test procedures were not available in all areas where the testing was performed.
 - b. Inspection forms identifying the acceptance status of production components were not placed in their proper location.
3. Production line procedures were inadequate. For example,
 - a. Door installation adjustment and checks were not performed.
 - b. Door travel before secondary interlock actuation test was not performed.
 - c. RF emission tests were not performed for door pull, all interlocks functioning.
 - d. Door open operation testing is not repeated after ovens are repaired.

- e. Final RF testing is not repeated after ovens are repaired.
4. Final RF emission tests were inadequate. For example,
 - a. All measurements were made at a high scan rate (greater than 2.5 centimeters per second).
 - b. Measurements were not made for door pull with all interlocks functioning at final emission test.
 - c. Measurements were not made in front of the control panel.
 - d. Measurements were not made on the left side vent of outer casing.
 - e. Water was not frequently replaced during testing.
 - f. RF measurements were not set to appropriate filter (2) and scale ($2\text{mW}/\text{cm}^2$).
 5. RF measurement meter intercomparison system was inadequate. For example,
 - a. RF measurement instruments were not set to appropriate filter (2) and scale ($2\text{mW}/\text{cm}^2$).
 - b. Initial reference field was not properly established for the LCR ellipticity check.
 - c. Records were not available for each microwave survey meter including calibration data, daily check records, and repair records.
 - d. Intercomparison system and meter were not stabilized for 10 minutes with the RF switch in the “on” position.
 6. Quality audit testing was inadequate. For example,
 - a. All measurements were made at a high scan rate (greater than 2.5 centimeters per second).
 - b. RF measurement was not made for door pull with all interlocks functioning.
 - c. RF measurements were not made in front of the control panel.
 - d. RF measurements were not made on the left side vent of outer casing.
 - e. Door travel before secondary interlock actuation test was not performed.
 - f. Open door operation test was not separately recorded on the test results.
 - g. Check of the concealed safety interlock was not performed.
 - h. Check for caution statements in user manual was not performed.

A copy of the establishment inspection report is enclosed for your information.

Conclusion

This disapproval of the testing program means that your firm’s factory is prohibited by Sections 534(h) and 538 of the Act from:

1. certifying the electronic products manufactured under the disapproved testing program (you may not certify that any microwave ovens comply with the U.S. standard, Title 21 CFR Chapter I, Subchapter J, Part 1030.10),

2. introducing or importing products into U.S. commerce certified under a disapproved testing program and bearing false and misleading certification (you may not ship any falsely certified products to the U.S.), and
3. introducing or importing products bearing no certification (you may not ship products to the U.S. without certification labels).

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, Shunde MD 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.

To resolve this matter, you must submit a written response to each deficiency noted during the inspection. Shunde MD must therefore, under 21 CFR 1002.10, submit to CDRH an updated quality control report for all active model families. This report must contain all of the corrective actions in response to the deficiencies cited in this Warning Letter.

In addition, Shunde MD must demonstrate that its products comply with the U.S. Federal Performance Standard for Microwave Ovens, 21 CFR 1030.10, and that its testing program is in accord with good manufacturing practices. Under 21 CFR 1002.10(k), CDRH requests the following additional information:

1. Shunde MD's quality control and testing program must be inspected by an independent consultant or a firm who will compare the actual quality control and testing procedures used at the factory with those reported in the up-dated quality control product report. The inspection should include the following:
 - Inventory control and warehouse
 - Incoming testing for critical components (including metal and welding fabrication, weld testing, inspection of doors and cavities)
 - Production line assembly, testing (including safety interlock and monitor testing, and door open start test), and repair of microwave ovens

- Final microwave radiation emission testing
- Quality audit procedures and reaction plan
- Door cycle endurance testing
- Instrumentation, including the intercomparison system
- Instrument calibration and checks (daily and monthly)
- Microwave oven labeling
- Recordkeeping

This independent inspection report should be furnished along with any response concerning this program disapproval. Please note that our office cannot recommend or endorse any consultant or firm for this independent inspection.

2. Shunde MD must provide CDRH with a videotape of the final microwave oven emission testing procedures, audit testing procedures and microwave survey calibration procedures. The audio portion of the tape must be in English.
3. Shunde MD must provide CDRH with a training report. From the deficiencies reported at Shunde MD, it is clearly evident that there is a need for a periodic training program. The training program must ensure that all personnel including supervisors, managers, quality control and testing personnel adequately perform their assigned responsibilities and learn how particular job functions relate to the overall quality system. This training program should cover the consequences of improper performance so that personnel can identify problems and be aware of the effect their actions can have on the radiation safety of the product. A copy of the final training report should be translated to English for our review. We recommend the same consultant hired to perform the independent inspection review the training report for completeness and accuracy before submitting it to CDRH.
4. Also, there appears to be lack of supervision in critical areas of the quality control and testing program areas. Your up-dated quality control and testing program should require supervisors to periodically observe quality control and test personnel to ensure that they are doing their tasks correctly. Supervisor responsibilities may include double checking testing records, checking that microwave measurement technicians are performing the test properly (for example, scanning at the correct scan speed of no more than 2.5 centimeters per second), and so on.
5. We recommend that an annual internal audit program be set up to assure that the quality system requirements are being met and to monitor the effectiveness of the quality system. We recommend that the quality audit be conducted by a qualified individual who does not have direct responsibility for the matters being audited. Please describe how this annual audit will be conducted, who will do it and when. CDRH recommends that after the rescission of the program disapproval the company be audited twice during the first 12 months and then annually afterwards if no major problems are found.

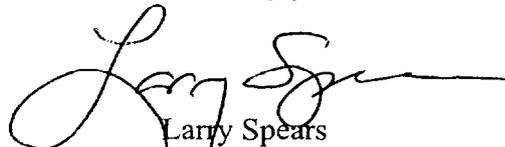
6. Pursuant to 21 CFR 1003.11(b), you are requested to provide CDRH with the total number of microwave ovens that have been produced and the approximate number of such products which have left the place of manufacture since the inspection in July 2001. We understand that the FDA investigators inspected Shunde MD on its first day of production, July 25, 2001.

The CDRH will advise you whether your submittal is satisfactory and when introduction of certified products into U.S. commerce may resume from the Shunde MD factory in Guangdong China. 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/foi/warning.htm>.

Additionally, three letters have been written by FDA since the inspection requesting additional information on product reports submitted by Shunde MD. These letters were addressed to Mr. John Chan of Bay Area Compliance Laboratory and Mr. Wu Xiao Dong of Shunde MD and dated October 11, 2001, October 29, 2001, and November 16, 2001. Written response to each of these letters is also requested.

Within 15 days, please submit your response for each of the above items 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 I1-1903. If you have any questions, you may contact Mr. Sean Boyd of my staff at (301) 594-4654, or by facsimile at (301) 594-4672, or by electronic mail at sbb@cdrh.fda.gov.

Sincerely yours,



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

Enclosure: FDA establishment inspection report