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DEPARTMENT OF HEALTH & HUMAN SERVICES M905 N Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

MAY 9 1997

WARNING LETTER

VIA FEDERAL EXPRESS Ref: OC I1-1752

Mr. Richard V. Long
Senior Product Safety Engineer
Product Safety Department
Sharp Electronics Corporation
Sharp Plaza
Mahwah, New Jersey 07430-2135

Dear Mr. Long:

On March 3, 1997, Mr. William S. Boivin and Mr. Joseph C. Teixeira, from the United States (U.S.) Food and Drug Administration (FDA) conducted a pre-announced inspection of the Sharp Appliances (Thailand), Ltd. microwave oven manufacturing facility in Bangpakong, Thailand, (the Bangpakong, Thailand factory will be referred to as "Sharp" factory in the rest of this letter). The FDA inspectors reported several serious deficiencies found in Sharp's quality control and testing program for the certification of compliance of microwave ovens with the U.S. Federal Performance Standard for Microwave and Radiofrequency Emitting Products, 21 Code of Federal Regulations (CFR) 1030.10. Based on their findings, the Center for Devices and Radiological Health (CDRH) believes that the current quality control and testing program at the Thailand microwave factory is not fully adequate to assure that microwave oven products will comply with the Federal performance standards and other applicable regulations.

Therefore, under the authority of Section 534(h) of the U.S. Federal Food, Drug, and Cosmetic Act (the Act), Chapter V, Subchapter C - Electronic Product Radiation Control (21 CFR 1010.2(c)), the CDRH hereby disapproves the quality control and testing program for Sharp Appliances (Thailand), Ltd., effective immediately. This program disapproval is designated for all microwave ovens being produced for U.S. commerce.

This disapproval of the testing program means that your firm 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 U.S. 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 U.S. commerce 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, entry or importation into U.S. commerce must be refused for 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.

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).

The following deficiencies have been brought to the attention of Sharp's quality control and testing personnel:

<u>Final Microwave Emission Testing and Record-keeping</u>

1. On "A" line, one final emission test operator measured "[redacted] mW/cm^2" for the ventilation grill area behind the oven and recorded this information on the "sub record sheet" (see enclosure under tab A). The rejection limit for microwave leakage was [redacted] mW/cm^2. Even though the recorded value exceeded the reject limit, the oven was not pulled off the assembly line at this point.

   There are 7 more microwave scanning personnel on the assembly line who each measured a portion of the oven and recorded their results on the "sub record sheet." The final or the 8th scanner recorded the no-load value and also the highest values from the "sub record sheet" onto another record called the "microwave oven data sheet."

The "sub record sheet" was removed from the oven at that station while the "microwave oven data sheet" traveled with the oven until the very end of the assembly line.

Mr. Boivin retrieved the "sub record sheet" where the 8th operator worked and asked the supervisors to see the "microwave oven data sheet" for this oven and also asked why this oven had not been pulled off the assembly line. Mr. Boivin was told that what should have happened was that the first operator who measured [redacted] mW/cm^2 should have flipped up the marker on the pallet which would have automatically removed the oven prior to the last of the 8 emission test operators. One of the Sharp supervisors went down the line and came back with a microwave oven data sheet which had been clearly altered to change a "[redacted]" to a "[redacted]" mW/cm^2 (see enclosure under tab B). An oven was pulled off onto a repair cart further down the line as well.

Mr. Boivin, Mr. Teixeira and the Sharp supervisors examined the "microwave oven data sheet" and then Mr. Boivin asked to see the oven itself in order to verify that this was the one which leaked [redacted] mW/cm^2. The oven was apparently gone and had been removed to a repair station. Mr. Boivin asked to go there to see the oven itself. Upon arrival at the repair station (not even one minute later), the FDA investigators were told that the oven "had already been repaired." The repair sheet already said "dirt under the magnetron" (written in Thai). The FDA investigators were told that this oven would be re-inserted into the assembly line for retesting. The FDA investigators asked for and received copies of the "microwave oven data sheet," the "sub record sheet" as well as the copy of the "microwave oven data sheet" after the oven had been through the final emission testing the second time.

In conclusion, CDRH has determined, based on the observations and records obtained by the FDA investigators, as well as the review of your quality control report filed with CDRH, that:

a. The first operator, who measured [redacted] mW/cm^2, failed to reject the oven;

b. The 8th operator, who supposedly reviewed the "sub record sheet" and found the two maximum emission values (front and back), also failed to reject the leaking oven;

c. A "microwave oven data sheet" was clearly altered from "[redacted]" to "[redacted]" mW/cm^2;

d. Sharp's personnel clearly had no way of knowing that this is the right record for the oven being investigated as leaking [redacted] mW/cm^2 since the "sub record sheet" had no serial number or any means of identifying it with the oven itself or the "microwave oven data record."

e. This incident is further complicated by the fact that this "sub record sheet" is not in Sharp's quality control report filed with CDRH (up-dated report dated February 6, 1997, accession number 85C0925). The quality control report does not mention any such record and does not mention transferring microwave emission results from one record to another. By not notifying CDRH of this "sub record sheet," the company failed to furnish such information as required by the Act.

2. In some records, microwave leakage readings were not recorded. Even at zero levels, leakage readings such as "0 mW/cm^2" must be written to show that measurements were taken. Under Sections 537(b) and (c) of the Act, manufacturers are required to maintain and provide performance data and other technical data related to radiation safety.

3. Defect and repair information on the test records were either poorly written or not written at all. Sharp production line personnel must clearly record the reason for failure and repair personnel must clearly record what actions were taken to repair the ovens. Vague or unclear statements like "no good," to describe the defect or "test is OK," to describe the repair are not acceptable.

If Sharp's personnel had any doubt as to the validity of their quality control and testing process and their record-keeping, they should have stopped the line and re-tested at least one lot to confirm, by separate auditors or final test operators, that microwave emission levels were being recorded as measured and leaking ovens were being rejected and repaired in accordance to their procedures.

We are distressed that two Sharp final test operators failed to perform their duties. Since the FDA investigators clearly documented that two operators did not reject this leaking oven, our office has no assurance that either of them or anyone else in other production lines would have caught leaking ovens.

We have reasons to believe that this problem may have been going on undetected for sometime under the purview of Sharp's management. We are also concerned that there did not appear to be any management review of the sub-records prior to release of the lot.

Since the oven with the [redacted] mW/cm^2 emission leakage was not found and Sharp personnel could not have possibly tracked it down under their current production line process and record-keeping practice, we cite Sharp company with the following violations of the Act, subject to possible fines of $1,000 each as noted above:

Section 538(a)(2) - Failure to furnish any notification or other material or information required by section 535 or 537. Sharp failed to notify CDRH regarding the "sub record sheet" as part of the final test record in the quality control report (1 violation).

Section 538(a)(3) - Failure to establish or maintain records as required by the Act. The [redacted] mW/cm^2 "sub record sheet" leakage data was not properly transferred to the final test record, and the "sub record sheet" was not attached or linked to the final test record. The final "microwave oven data sheet" record was clearly altered from "[redacted]" to "[redacted]" mW/cm^2 (2 violations).

Section 538(a)(5)(B) - Failure for any person to issue such certification when such certification is not based upon a test or testing program meeting the requirements of section 534(h) or when the issuer, in the exercise of due care, would have reason to know that such certification is false or misleading in a material respect. This suspected oven has left the factory with a certification label that is based on an inadequate final emission test, therefore this certification label is false and misleading (1 violation).

This program disapproval warning letter for the Thailand microwave factory also affects your corporate company as a whole because previous inspections of other Sharp microwave factories here in the U.S. as well as Japan revealed numerous similar deficiencies in their quality control and testing program for the certification of compliance with Federal performance standard for microwave ovens (June 12, 1996, Sharp Manufacturing Corporation of America, Memphis, Tennessee and September 8, 1992, Sharp Yao Plant, Osaka, Japan). From the deficiencies reported in those

factories, it appears that there is a need for a periodic training program to 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 an overall quality system. This training program should cover the consequences of improper performance so that personnel know what defects to look for, as well as be aware of the effect their actions can have on the safety of the product. In addition, we believe that a corporate-wide internal audit for all microwave oven factories is necessary to assure that the quality system is in compliance with established quality system requirements and to determine 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.

To resolve this program disapproval warning letter, you must submit all of the information requested above such that CDRH can determine that Sharp Appliances (Thailand) is in compliance with the Act, that the subject products comply with the Federal Performance Standard for Microwave and Radiofrequency Emitting Products, 21 CFR 1030.10, and that the testing program is in accord with good manufacturing practices.

Please submit your response within 15 days of receipt of this letter regarding the deficiencies cited above. It should be sent 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 II-1752 and this letter. If you have any questions, you may contact Mr. George W. Kraus at (301) 594-4654, or by facsimile at (301) 594-4672.

Sincerely yours,

Gladys Rodriguez for

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