



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

M 223617

SEP 8 1998

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

WARNING LETTER

Ref: OC: I1-1801

Mr. Fu Long Seng
Assistant QA Manager
Shenzhen Ksai Electronics Co., Ltd.
Number 8, Section C, 73rd District
Bo An, Shenzhen, Guangdong, CHINA

Mr. [REDACTED]
Manager
[REDACTED]
[REDACTED]
[REDACTED]

Dear Mr. Seng and Mr. [REDACTED]:

On June 18-19, 1998, Mr. Mark Tseng and Mr. Seth A. Mailhot, from the United States (U.S.) Food and Drug Administration (FDA), conducted a pre-announced inspection of the Shenzhen Ksai Electronics Co., Ltd. and [REDACTED] ([REDACTED]). Both facilities are located in Shenzhen, Guangdong, China. Shenzhen Ksai Electronics Co., Ltd. will be referred to as "Ksai," and [REDACTED], will be referred to as [REDACTED] in the rest of this letter.

Ksai is a manufacturer of computer monitors for U.S. commerce. [REDACTED] is an independent laboratory and consulting firm in the business of performing product safety testing including x-radiation testing. Ksai contracted [REDACTED] to prepare and submit the product reports for FDA, perform engineering analysis and Phase III x-radiation testing.

The purpose of visiting Ksai and its contracted laboratory, [REDACTED], was to conduct compliance inspection of a television receiver (or monitor) manufacturer and observe their quality control and testing program for compliance with the U. S. Federal Performance Standard for Ionizing Radiation Emitting Products - Television Receivers (or Monitors); 21 Code of Federal Regulations (CFR), 1020.10, and other applicable regulations.

The FDA inspectors reported several serious deficiencies found in Ksai's quality control and testing program for the certification of compliance of television products with 21 CFR 1020.10 and other applicable regulations including labeling (21 CFR Parts 1010 and 1020) and recordkeeping (21 CFR 1002.30). Based on their findings, the Center for Devices and Radiological Health (CDRH) believes that the current quality control and testing program at Ksai's manufacturing facility and its contract testing laboratory [REDACTED], is not fully adequate to assure that television 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 Shenzhen Ksai Electronics Co., Ltd., effective immediately. This program disapproval is designated for all television (or monitor) products being produced for U.S. commerce.

Since Federal regulations do not apply to contract testing laboratories, Ksai is ultimately responsible for assuring that quality control and testing procedures and equipment used by a contract laboratory are exactly as reported in the product report submitted to the CDRH.

This disapproval of the testing program means that Ksai 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 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 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.

The Act also prohibits anyone, including the importer, from failing to make any report required pursuant to Section 537(b) and from failing to furnish or preserve any information required pursuant to Section 537(f).

The following deficiencies have been brought to the attention of Ksai's quality control and testing personnel (Shenzhen Ksai Electronics Co., Ltd. - June 18, 1998, inspection conducted by FDA investigators Mr. Mark Tseng and Mr. Seth A. Mailhot):

Failure to Test Monitors for Compliance with 21 CFR 1020.10(c)(3)(iii) and False Certification

1. Currently, Ksai arranges for [REDACTED] laboratory to test samples of monitors for Phase III x-radiation on the 5th of each month. This allows for up to a month delay before testing is performed. The FDA investigators learned that Ksai could not provide any documentation that x-radiation testing had been performed on a recent lot of model M-1438, manufactured on May 27, 1998, (serial numbers K480516121 through K480516936). Ksai's records clearly showed that computer monitors were manufactured on or around May 27, 1998, (see exhibit-A) and then shipped on June 3, 1998, (see exhibit B), without any sample tested by Audix by the 5th of June. This was further substantiated by the inspection of [REDACTED] on the next day (June 19) and the lab had not received any monitors from Ksai for the previous month of production.

Since this lot, representing approximately 810 boxes of models M-1438, had not been tested for Phase III x-radiation, Ksai has the option of finding a sample from the lot of serial numbers K480516121 through K480516936 and testing it. Otherwise, CDRH will cite Ksai for violation of the Act, subject to possible fines of \$1,000 each as noted below:

Section 538(a)(5)(B) - It shall be unlawful 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 lot of monitors left the factory without Phase III testing performed, therefore this certification label is false and misleading (1 violation).

Section 538(a)(3) - It shall be unlawful for any person to fail or refuse to establish or maintain records as required by this subchapter.

Since a sample of the lot is yet to be tested, a final x-radiation test record is unavailable (1 violation).

No Engineering Analysis Was Performed on Last Model in Production

2. No worst tolerance chassis (W.T.C.) was ever built for the last model in production. For every new chassis family, the manufacturer (or contracted laboratory) must construct and analyze a W.T.C. or conduct an equivalent analysis to demonstrate that the product is designed conservatively with respect to its potential for emitting x-radiation. The W.T.C. engineering analysis provides information critical to the product report, the Phase III x-radiation testing (Attachment P), the Critical Component Warning labeling and most importantly, the overall safety of any new design. It tells us the performance of the worst case monitor that might be assembled on the manufacturer's production line. The FDA investigators also learned that the W.T.C. has not been constructed for their next model, tentatively called "CT-558."
3. Certain critical controls in the chassis were not sealed. Without a proper design engineering analysis with the W.T.C., it is not known if this is necessary. If it is determined that the monitor needs certain controls sealed, a sealing method will need to be developed and tested for durability.

Inadequate Labeling

4. There was no Critical Component Warning label for the last monitor produced. Part 21 CFR 1020.10(c)(4) of the regulations require that a warning label be affixed on all

monitors. The Critical Component Warning label must warn against improper adjustment or replacement of components that could affect the radiation safety of the receiver (monitor) and include high voltage specifications and adjustment instructions. It is uncertain if the monitor was eligible for labeling exemption, because the W.T.C. was never constructed for the design engineering analysis.

5. The identification label does not have a full name and address, as required by 21 CFR 1010.3 (see exhibit C).

Inadequate Recordkeeping

6. Ksai has only been retaining x-radiation test data for one year. These records must be kept for 5 years (21 CFR 1002.31).
7. The Phase III x-radiation test record needs additional information. It needs to include the name of the test technician, test date, the survey instruments used, the serial numbers of the survey instruments used, the survey results for all sides of the monitor and the background x-radiation reading. There should also be an entry for the supervisor after checking the record for completeness and accuracy. A copy of this record should be submitted as part of Attachment P in the product report.

The following deficiencies have been brought to the attention of [REDACTED]'s engineering staff and managers ([REDACTED] - June 19, 1998, inspection conducted by Mr. Mark Tseng and Mr. Seth A. Mailhot):

Failure to Maintain Adequate Instrumentation, Maintenance and Calibration Program

1. [REDACTED]'s laboratory failed to maintain an adequate instrumentation, calibration, maintenance and training program for their x-radiation survey and electronic test instruments. For example:
 - (a) Calibration intervals for the William B. Johnson TVX-1A x-radiation survey meter were inconsistent in spite of the reports requiring that it should be performed every six months. The actual calibration intervals ranged from 2 months to one year and five months.

(b) Reasons for inconsistent calibration cycles had never been recorded or documented. Audix could not explain the discrepancies in the calibration intervals.

(c) Thirty (30) day checks on the William B. Johnson TVX-1A were not performed.

(d) The user's manual for the Victoreen 440 RF/D x-radiation survey meter could not be located.

(e) The individuals responsible for using the Victoreen 440 RF/D x-radiation survey meter were not familiar with the operation of the instrument. This was observed when the test engineer did not use the Victoreen 400 RF/D internal check source for its daily check during the Engineering Analysis/Phase III test demonstrations.

(f) There appears to be an inadequate training program for new technicians who have been recently hired. Likewise, there appears to be no training file for each new employee documenting their training on instrumentation.

(g) The beam current meter (Sun Wa, YX-360TRN) needs to be repaired or replaced. During the Engineering Analysis/ Phase III demonstration, it was observed that it was not operating properly.

(h) There are no alternative x-radiation and electronic instruments available should the instruments in use require repair or calibration.

(i) Well written product reports (and Attachment P) conflicted with actual testing being performed on the day of inspection. Personnel changes and lack of training of new employees may have contributed to inadequate demonstration of testing and of engineering analysis/phase III.

Inadequate Engineering Analysis of New Models

2. According to Ksai's product reports, [REDACTED] laboratory was responsible for the engineering analysis of the worst tolerance chassis (W.T.C.) and design center chassis. According to the FDA investigators, [REDACTED] personnel did not fully understand how to construct and test a W.T.C. and a design center chassis.

3. [REDACTED] laboratory did not retain a W.T.C. for their client. The W.T.C. should be kept at least two years from the date of filing the product report in case the test results are determined to be inaccurate.

Inadequate Phase III X-radiation Compliance Testing

4. [REDACTED] personnel were not thoroughly familiar with Phase III x-radiation testing requirements. During the demonstration of Phase III x-radiation testing on a sample monitor, [REDACTED] test personnel did not adjust the service controls on the monitor being tested. The user and service controls must be adjusted to maximize x-radiation emissions, that is, so the power point setting for the x-radiation survey is in the region of the chassis power curve that most closely approaches the isoexposure rate limit curve for the cathode ray tube, or most exceeds it.

Inadequate Recordkeeping

5. The Phase III x-radiation test record was found to be inadequate and it needs to include the same information listed in item 7, above.

To resolve this program disapproval warning letter, Shenzhen Ksai Electronics Co., Ltd. must submit all of the information requested above so that CDRH can determine that Ksai is in compliance with the Act, that the subject products comply with the Federal Performance Standard for Television Receivers, 21 CFR 1020.10, and that the testing program is in accord with good manufacturing practices.

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>.

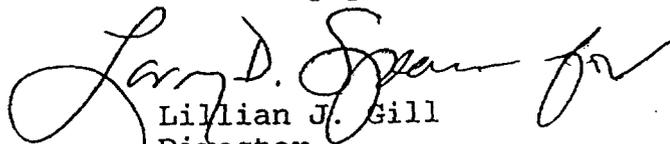
Please submit your response regarding the deficiencies cited above within 15 days of receipt of this letter. It should be sent to:

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.
U.S.A.

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In your response, please reference case I1-1801 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,



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

Enclosures:

- Exhibit A - Ksai Final Product Inspection Report, dated 5/27/98
- Exhibit B - Shenzhen Ksai Electronic shipping record, dated 6/3/98
- Exhibit C - Copy of inadequate identification label for model M-1438