



MAR 23 1998

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

WARNING LETTER

REF:OC:I1-1779

VIA FEDERAL EXPRESS

Mr. Chen Pao Ling
Sales Manager
Hi-Vast International Co., Ltd.

and

Mr. Pao Chuan Chen
Manager
Hi-Vast International Co., Ltd.
No. 18, Lane 56, Hsi Kuen 2 St.
Pan Chiao City, Taipei Hsien
Taiwan

Dear Mr. Ling and Mr. Chen:

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 Hi-Vast International Co., Ltd., of Taiwan. 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 findings listed below, the CDRH declares that Hi-Vast International Co., Ltd. has failed to conduct a testing program which assures compliance with the Federal Performance Standard for Television Receivers 21 CFR 1020.10. Under the authority of 21 CFR 1010.2(c), the CDRH hereby disapproves the testing program for all television products manufactured at Hi-Vast International Co., Ltd., effective immediately.

This disapproval of the testing program means that your firm is prohibited by Section 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.

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 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.

This regulatory action is based on two product reports submitted to CDRH, chassis family GM710, dated January 24, 1998, and chassis family ED660XX, dated January 21, 1998. Our office reviewed both reports for accuracy and conformity to the reporting requirements of Title 21 of the Code of Federal Regulations (21 CFR) 1002.20. We discovered noticeable differences in the information in both reports concerning the quality control and testing program at Hi-Vast International Co., Ltd. When certain parts and attachments were examined side by side, the details were distinctly different. The major discrepancies and differences in the reports are as follows:

1. Part 1.2 U.S. Agent - Hi-Vast International Co., Ltd. submitted fraudulent information concerning the identification of the U.S. agent in one of the product reports. The product report for chassis family GM710 list the U.S. agent as Mr. [REDACTED]. Mr. [REDACTED] was contacted to verify the information because the product report was not signed by him. Mr. [REDACTED] informed the CDRH that he was NOT the U.S. agent for Hi-Vast International Co., Ltd.

The product report for chassis family ED660XX list the U.S. agent as Mr. [REDACTED]. Mr. [REDACTED] was contacted for the same reason listed above. Mr. [REDACTED] stated that the company was planning on importing products from Hi-Vast International Co., Ltd.

2. Part 6A Critical Component Incoming Inspection Program - Both product reports contain distinctly different procedures on how incoming critical components are inspected and what corrective action is taken upon rejection.
3. Part 6C Production Inspection and Testing - Both product reports contained distinctly different information on the sampling size, unit rejection limit, and lot rejection limit.
4. Part 6E X-Radiation Testing Instruments and Attachment M - The information on where the [REDACTED] (serial no. [REDACTED]) will be calibrated is misleading. One report states that a calibration lab here in the U.S., [REDACTED], will calibrate the [REDACTED] and the other report states that [REDACTED] will calibrate the instrument. The calibration data on the calibration certificates do not agree. How can this be possible when the certificates are for the same instrument calibrated on the same day?

The AC/DC voltmeters, beam current ammeters, and high voltage meters are distinctly different in each product report.

5. Attachment F CRT Isoexposure Curve and Corresponding Chassis Power Curve - The format used to graph the data from Attachment J is distinctly different in both reports.

Attachment F for chassis family ED660XX did not provide the worst case fault, whereas, the other report did give that information. The 0.5 mR/hr isoexposure curve states [REDACTED] but, the data provided by the cathode ray tube manufacturer states [REDACTED].

Attachment F for chassis family GM710 is missing the manufacturer's data for the Mitsubishi and the NEC cathode ray tubes used in the monitors.

6. Attachment I Hold-Down or Safety Circuit Information - For chassis family GM710 in Attachment J, you list component failed as [REDACTED] and [REDACTED] in the hold-down/safety circuits area. Attachment I does not show any of these components as being in the hold-down or safety circuit area.
7. Attachment K - The product report for chassis family GM710 provided an actual photocopy of the required labels, whereas, the other report just described what the labels look like. For chassis family ED660XX, there is a typographical error in the name of the manufacturer. The report states "Vi Vast International Co., Ltd."
8. Attachment O Production Quality Control and Testing of Shielding/Circuits That May Affect Radiation - In chassis family GM710 report, component [REDACTED] (short) was described as the fault used to activate the hold-down safety circuit. There is no such component in Attachment I.
9. Attachment P Detailed (Step-by-Step) Procedures for Production X-Radiation Testing - There is a discrepancy between both reports in the section "Radiation Detection with the [REDACTED]". This section should be the same since the instruments are exactly the same and are being used for the same purpose.

The check source used for the operational check on the [REDACTED] differs in the reports. Chassis family GM710 report states that the [REDACTED] is checked with a "[REDACTED]" source. Chassis family ED660XX report states that the [REDACTED] is checked with a "[REDACTED]" source. The report says to adjust the position of the "[REDACTED]" calibrator to predetermined position. The "[REDACTED]" is not an adjustable instrument.

For chassis family ED660XX, Attachment P refers to Attachment J4 for abnormal worst component. The actual component should be listed in Attachment P, not a reference to Attachment J4. In Part 6.12 of the product report, the unit reject limit is stated as "[REDACTED] mR/hr" but in Attachment P, "[REDACTED] mR/hr" is used.

Based on the information given in the two reports, particularly since they were written 3 days apart, we have serious doubts about the validity of any of the information because we are not certain which testing procedures from

either report are being carried out. Since the two product reports contain major discrepancies in the description of the manufacturer's quality control and testing program, our office cannot be assured of the proper certification of the products. The CDRH has concluded that Hi-Vast International Co., Ltd.'s quality control and testing program is not adequate to assure compliance with the Federal performance standard for television products.

To resolve this matter, all the information required under 21 CFR 1002.10 must be submitted such that the CDRH can determine that the manufacturer is in compliance with the Act, that the subject products comply with the performance standard, and that the testing program is in accord with good manufacturing practices. The CDRH will advise you whether your submittal is satisfactory and when introduction of certified products into U.S. commerce may begin. In the meantime, Hi-Vast International Co., Ltd., is being placed on the import detention list and will not be allowed to import television products into the U.S. until the quality control and testing program disapproval is rescinded.

You may 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 this letter and case I1-1779.

If you have any questions regarding this warning letter, you may contact Ms. Debra Clingan of my staff at (301) 594-4654.

Sincerely yours,



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

Enclosures: Report dated January 21, 1998, Chassis family
ED660XX

Report dated January 24, 1998, Chassis family
GM710