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DEPARTMENT OF HEALTH & HUMAN SERVICES

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Public Health Service

APR 30 1997

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

WARNING LETTER

VIA FEDERAL EXPRESS

Ref: OC: I1-1751

Mr. B. J. Kim
General Manager
Daesun Industrial Co., Ltd.
58-1, Gunji-Ri, Daeduk-Myun
Ansung-Gun, Kyunggi-Do
KOREA 456-830

Dear Mr. Kim:

On April 9, 1997, Mr. Mark Tseng and Mr. Emir Galevi of the United States (U.S.) Food and Drug Administration (FDA) conducted a pre-announced inspection of the computer monitor manufacturing facility, Daesun Industrial Co., Ltd., in Kyunggi-Do, South Korea. The FDA inspectors reported several serious deficiencies found in Daesun Industrial Co., Ltd.'s quality control and testing program for the certification of compliance of computer monitors with the United States (U.S.) Federal Performance Standard for Television Receivers, 21 CFR 1020.10. Based on their findings, the Center for Devices and Radiological Health (CDRH) believes that the current quality control and testing program at the Kyunggi-Do monitor factory is not fully adequate to assure that television products and monitors will comply with Federal performance standards and other applicable regulations.

Therefore, under the authority of Section 534(h) of 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 Daesun Industrial Co., Ltd., effective immediately. This program disapproval is designated for all monitors 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 the Daesun Industrial Co., Ltd.'s quality control and testing personnel as follows:

X-radiation Survey Instrumentation, Daily Check and Calibration Records

1. The company had only one x-radiation survey meter, Victoreen 440 RF/D, serial number 861, and it was missing the hexagonal knob that activates the internal radioactive check source. Therefore, no daily check was possible to ensure that the instrument was working properly each time before compliance testing. In addition, since the internal source was non-operational, it was not certain that this meter was working properly for previous production since the last calibration date. This instrument is used primarily for compliance x-radiation measurements as required by 21 CFR 1020.10.
2. The company had no back-up x-radiation survey meter in the event the Victoreen 440 RF/D was out for repair or annual calibration.

3. Daesun Industrial Co., Ltd., could not provide any calibration certificate for the Victoreen 440 RF/D for any periods before 1996. It was not possible to trace calibration history and the true ownership of this instrument for the years 1994 and 1995. According to the annual report records, Daesun Industrial Co., Ltd. has been manufacturing monitors for the U.S. since 1994.
4. Daesun Industrial Co., Ltd's quality control and testing personnel did not have a complete copy of the operating manual for the Victoreen 440 RF/D.
5. Daesun Industrial Co., Ltd., had no qualitative x-radiation search meter, such as the Wm. B. Johnson TVX-1B, for rapidly scanning the monitor for x-radiation. Their current meter, Victoreen 440 RF/D cannot be used as a search instrument because of its slow response time, small collecting area, and low sensitivity.

Engineering Analysis and Phase III Radiation Testing for Selected Computer Monitors

The investigators reviewed the engineering analysis information in the product reports for several chassis families and observed the demonstration of the Phase III x-radiation testing in the quality control testing laboratory.

1. In the engineering analysis and subsequently Phase III x-radiation testing, the user and service controls were not adjusted properly to produce maximum high voltage at each beam current settings (minimum, intermediate and maximum) at which the monitor continues to operate and provides a usable picture. The investigators reported that in one model tested in the laboratory the high voltage could be further increased by 3 kilovolts simply by adjusting the high voltage control.
2. Only one technician in the laboratory had any training or experience in Phase III x-radiation testing and the proper use of x-radiation instrument (other than the manager). The investigators recommended that more technicians be trained in proper Phase III x-radiation testing and the use of x-radiation survey instruments. Several technicians (at least three) should be able to do the tests so there will always be someone at the laboratory who is able to do the tests properly even if some technicians are out sick, in

training, or detailed to other areas of the factory. Their duties should also be rotated on a periodic basis to ensure uniformity of experience.

3. Daesun Industrial Co, Ltd., had no written reaction plan in case the x-radiation rejection limit was exceeded.
4. It was not clear from the inspection who actually performed the required engineering analysis. The FDA investigators could not determine if the consulting agent, [REDACTED] performed the engineering analysis or the manufacturer, Daesun Industrial Co., Ltd. The responsible individual who signed the Daesun Industrial Co., Ltd.'s product reports was not available for questioning and no one else could answer their questions. For that reason, the investigators could not assess or make any reasonable evaluation of the engineering analysis.

False Certification of Monitors

1. The investigators observed Daesun personnel placing certification labels on all monitors produced, even for sets that were made for countries other than the U.S., and had not been tested for x-radiation. This labeling practice is prohibited under Section 538(a)(5)(B) of the Act, in that it is unlawful to issue a 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."

Although these monitors were not intended for U.S. commerce, other countries may rely on U.S. certification labels to ensure that the monitors are in compliance with radiation safety performance standards and they are safe.

Labeling

1. The identification labels that were placed on these monitors did not meet the requirements of 21 CFR 1010.3 because they lacked the complete address of the manufacturer (or importer) and the manufacturing date was abbreviated.

To resolve this matter, you must submit a written response to each item such that CDRH can determine that Daesun Industrial Co., Ltd., is in compliance with the Act, that the subject

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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. The CDRH will advise you whether or not your submittal is satisfactory and when you may resume introduction of certified products into commerce.

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 I1-1751 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

CC:

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President and United States Agent
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