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Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

WARNING LETTER

VIA Federal Express

Mr. James Yu
Supervisor
Quality Assurance Department
ADI Corporation
No. 1, Lane 162, Bu Teu Kung
Kuanghwa Li, Tai Pin City
Taichung Hsien, TAIWAN, R.O.C.

Ref: OC: I1-1861

Dear Mr. Yu:

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 ADI Systems Mexico, S.A. de C.V. 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, CDRH has concluded that ADI Systems Mexico, S.A. de C.V. has failed to conduct a testing program which assures compliance of its television products 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 hereby disapproves the testing program for all television and video display products subject to the standard, 21 CFR 1020.10, at ADI Systems Mexico, S.A. de C.V. 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 June 23, 2000, Mr. Joseph C. Teixeira and Ms. Lesley N. Kerr from the FDA conducted a pre-announced inspection of your computer monitor company, ADI Systems Mexico, S.A. de C.V., which is operated by ADI Corporation of Taiwan. The purpose of this inspection was to review ADI Corporation's quality control and testing program for the certification of compliance of computer monitors with the U.S. Federal Performance Standard for Television Receivers, 21 CFR 1020.10.

This inspection involved observing the production lines in operation and reviewing the quality control and testing programs, including Phase III x-radiation testing procedures, calibration checks of the x-radiation survey instruments, and engineering analysis procedures. During the inspection, the FDA inspectors reported the following deficiencies:

1. Phase III X-Radiation Testing of Monitors – Failure To Test For Compliance With 21 CFR 1020.10(c)(3)(iii)

The FDA investigators observed that the technician failed to introduce the worst case fault and failed to adjust the user and service controls during the required x-radiation testing of monitors (commonly referred to as “Phase III testing”). Instead the technician was measuring x-radiation of a normally operating set and high voltage and beam current measurements were not made. This practice is contrary to what was reported in many of the company’s product reports filed with the FDA (such as the product report for the model family CM502, accession number [REDACTED]).

Section 1020.10(c)(3)(iii) requires that the monitor be tested under Phase III test conditions. Phase III test conditions are performed with the worst component failure in place, and all user and service controls that affect the beam current and high voltage settings adjusted to where the chassis power curve comes closest to or most exceeds the 0.5 mR/hr isoexposure rate limit curve (IRLC) of the cathode ray tube. For a valid test there must be a useable picture (synchronized and transmitting some viewable intelligence) and the input voltage must be adjusted up to the maximum test voltage specified in 21 CFR 1020.10(b)(2).

In essence, the ADI Systems Mexico, S.A. de C.V. failed to test the monitors for compliance with the Federal Performance Standard, 21 CFR 1020.10. The failure to test those monitors for compliance with the Federal Performance Standard is a Prohibited Act as stated under Section 538(a)(5): “It shall be unlawful ... for any person (A) to fail to issue a certification as required by section 534(h), or (B) 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.”

2. Ineffectively Sealed Controls

The seals on the high voltage adjust and hold down adjust variable resistor (VR) components were not permanent. The FDA investigator, Mr. Teixeira, easily removed the seals using his fingernail. The company’s current policy calls for [REDACTED] percent visual inspection and this methodology appears to be ineffective.

Critical controls affecting the high voltage, or radiation safety were sometimes adjusted during the manufacturing process and then sealed by the manufacturer once their optimum position has been set (see item 5 below). The glue or sealant used for sealing high voltage or other critical controls should be investigated by the quality control and testing personnel for quick drying and permanency. If sealing the control is critical for compliance with the standard, the seal on the control should be tested for permanency by using a screwdriver or a knife to pry or cut it without damaging the control itself. Any critical controls that are not sealed effectively must be adjusted during Phase III x-radiation testing and the problem should be addressed to the attention of the quality control manager for corrective action.

3. Incomplete X-Radiation Test Records

The FDA investigators noted several deficiencies in the x-radiation test records as follows: (a) The technician failed to record the serial numbers of the radiation survey meters as well as the electrical meters, (b) the technician incorrectly recorded the source reading as background reading (e.g., "1.9 mR/hr"), (c) background and source readings are not always recorded for the [REDACTED] survey meter, (d) some of the test data had overwrites, (e) if the qualitative meter did not find any radiation the result was recorded as "0 cpm" instead of the correct recording of "None Detected."

4. Lack Of Back-Up Survey Instruments

The FDA investigators reported that the Mexico factory did not have back up survey instruments. They were able to borrow both survey meters ([REDACTED] and [REDACTED]) from ADI Corporation in Taiwan. Their quality control and testing program did not have a written reaction plan in the event one or both meters are sent out for repair or calibration. Furthermore, no calibration records could be found for the borrowed meters from Taiwan, therefore it was not possible to trace calibration history and true ownership of the meters.

5. Failure To Conduct Hold-Down Safety Circuit Check On The Production Line

The technician did not check the hold-down safety circuit on sets produced on the line. Instead the technician adjusted the variable resistor (VR) of the high voltage hold-down safety circuit to specified values and then sealed it with a soft white bonding material that did not appear permanent (see item 2 above).

Since proper operation of the hold-down safety circuit is essential to radiation safety, it must be checked on every set. According to Attachment O of a current ADI Corporation product report (detailing the production quality control and testing of shielding/circuits that may affect radiation), the technician is required to [REDACTED]

[REDACTED] will appear on the screen of the color monitor. Then the technician is required to [REDACTED]. In this case, the technician was not doing that.

6. Improper Use Of The [REDACTED] Survey Meter

The FDA investigators noted that the technician had the speaker turned down so it was not possible to listen for the increased sound of clicking in the event the meter detected any x-radiation. Also, by having the speaker turned down, the technician would not know if the meter was working, e.g., picking up background radiation.

Conclusion

This disapproval of the testing program means that your firm's factory in Mexico 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 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, 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, ADI Systems Mexico, S.A. de C.V. 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.

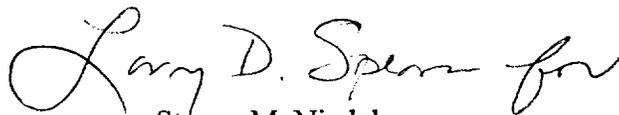
The FDA may initiate regulatory action against any person who violates Section 538, including an injunction and/or imposition of civil penalties as provided for in Section 539 of the Act. Persons failing to correct violations are subject to civil penalties of up to \$1,000 per violation and up to a maximum 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).

3. This office noted that similar quality control and testing program deficiencies were found in another ADI Corporation factory during the inspection on May 20, 1999, (see copy of letter enclosed, dated November 5, 1999). We are concerned that other factories may also have similar quality control problems. Therefore, we are recommending that your company conduct an immediate audit followed by annual audits of its quality control and testing program in all monitor and television factories to ensure that these procedures and documentation are effectively implemented. Please confirm that the audits of the quality control and testing program will be conducted for all of the factories and provide the name(s) of the individual(s) who will be responsible for conducting such audit.
4. Pursuant to 21 CFR 1003.11(b), you are requested to provide CDRH with the total number of television products that have been produced and the approximate number of such products which have left the place of manufacture. Our records show that ADI Systems Mexico, S.A. de C.V. has been in operation since June 1998.

The CDRH will advise you whether your submittal is satisfactory and when introduction of certified products into U.S. commerce may resume from the ADI factory in Mexico. 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>.

Within 15 days, please 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 case II-1861. If you have any questions, you may contact Mr. George W. Kraus of my staff at (301) 594-4654, or by facsimile at (301) 594-4672, or by electronic mail at gwk@cdrh.fda.gov.

Sincerely yours,



Steven M. Niedelman
Acting Director
Office of Compliance
Center for Devices and
Radiological Health

Enclosures: July 7, 2000 Inspection Report of ADI Systems Mexico, S.A. de C.V.
November 5, 1999 letter regarding inspection of ADI (Thailand) Co., Ltd.