DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

0406 '02 MAY 28 P1:19

MAY 17 2002

Mr. Michael Petricone
Vice President
Technology Policy
Consumer Electronics Association
2500 Wilson Boulevard
Arlington, Virginia 22201

Ref: FDA Docket No. 01P-0518

Dear Mr. Petricone:

This is in response to your petition dated November 6, 2001, requesting changes in the record and reporting requirements for manufacturers of television products, as required by 21 CFR Part 1002, and in the agency's policy for sampling and testing of those products to certify that they meet federal performance standards, as required by 21 CFR Part 1020.

You request the following changes in record and reporting requirements for television product manufacturers through amendments to 21 CFR 1002:

- Remove all requirements for test records and distribution records for manufacturers of television products.

- Simplify the reporting requirements by eliminating the Product Report and Supplemental Report requirements and replacing them with an Abbreviated Report requirement for all television products.
- In lieu of filing the Abbreviated Reports with FDA/CDRH, manufacturers of television products would be required to retain each Abbreviated Report on file until two years after the manufacture of products covered by the report has ceased.

- Annual Reports would be reduced to include only the manufacturer's name; the importer's name; a declaration of compliance with the part of the performance standard in 21 CFR 1020.10(c); and name(s), signature(s) and contact information for person(s) responsible for compliance. Manufacturers of television products would be required to establish and maintain a record of the information in the Annual Report.

You request changes in the sampling of television products from factory production lines for the purpose of testing to support manufacturers' certification of compliance. You propose to change the minimum acceptable sampling rate for the Phase III x-radiation emission test from one product from each separate chassis/CRT-size combination produced on each

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production line during each production shift each day to one unit from each chassis family/CRT size combination per production line per shift per week.

You also stated that you surveyed several of your members and none could "...recall any cases of Accidental Radiation Occurrences or factory x-radiation measurements that exceeded 0.1 mR/hr within the last twenty years." They also expressed the belief that televisions with diagonal screen sizes no larger than 20 inches generally have high voltages less than 25 kV and that "...all current televisions include a safety circuit that shuts off the high voltage at a safe threshold."

Although we have carefully considered all the proposals, we are denying your requests. We would like to work with you on ways to ensure the radiation safety of television products and still find ways to reduce the regulatory burden for all manufacturers. However, we are obliged to balance the goal to reduce the regulatory burden with our role as a public health agency whose primary concern necessarily focuses on the need to protect all U.S. residents, especially children, from the hazards of electronic product radiation.

Your proposals for the reduction in reporting and filing lack sufficient information so that FDA can identify products for the purpose of testing or for scheduling inspections of television product factories, including sub-contracted factories. For example, the agency would not know model numbers, production figures, schematics, test data, factory addresses, or factory names, all of which are necessary for conducting our testing and inspectional programs. Given the extremely competitive nature of the television product business and the fact that not all manufacturers throughout the world are members of CEA, we must ensure that all manufacturers are familiar with and meet FDA requirements. In the past, our inspection of television product factories and review of manufacturers' Product Reports have found serious deficiencies leading to the agency's disapproval of the quality control and testing programs of manufacturers that fail to meet FDA's performance standard requirements. Deficiencies have included the lack of operational and calibrated x-radiation survey meters; falsified instrumentation and test records; and inadequate or ineffective test procedures to certify compliance with federal performance standards.

The records and procedures required by FDA of manufacturers of television products establish a basis for a strong quality system. Establishing and maintaining such records and procedures is a fundamental element of any adequate quality control program. The information requested is necessary for us to know where to look for possible problems.

Regarding your proposals for changing the reporting requirements, the proposals for reduction in reporting and filing, as written in the petition, would not provide FDA sufficient information to select products for testing or to schedule inspections of television product factories and the sub-contract factories. As proposed in the petition, we would not know model numbers, production figures, schematics, test data, factory addresses, or factory names, all of which are used to select products for testing and scheduling inspections. As you know, the television product business is an extremely competitive worldwide business that encompasses manufacturers of many different products. Consequently, we try to make reporting as easy as possible for this industry. We ask only for summaries or copies of

records and procedures whenever possible. However, the information is necessary in order to conduct the agency's electronic product safety program.

The agency's program staff reviews test data and procedures for a number of items, each of which help to ensure compliance with federal requirements. For example, the agency's staff looks at test data and procedures to see whether the tests are being done correctly; they check copies of instrumentation calibration certificates to verify that each manufacturer has the correct instruments at each factory and that the calibrations are up to date. Our staff is trained to look for the possible falsification of test data, test procedures and calibration certificates. They also reconcile the number of units produced and the number tested to see if they are consistent with the manufacturer's reported sampling plan. Finally, the staff checks to see whether manufacturers are reporting any radiation problems either in test data or correspondence concerning radiation safety. All of this information is necessary in order to prioritize and select products and factories for the product testing and factory inspections by FDA.

In an effort to reduce the burden of record keeping and reporting, we plan to develop an electronic reporting program that should make reporting easier for manufacturers. This project will require the development of suitable reporting guides for each product line. We will soon implement a pilot program for the electronic reporting of required information for laser products. If electronic reporting works well for laser products, we then will develop the reporting guides for other products subject to reporting requirements. Expanding this electronic reporting format to television products will receive careful consideration due to the large number of television product reports submitted to the agency.

Regarding your proposal for a reduction in sampling of television products for testing and certification of compliance with the federal standard to one product from each chassis family production line per shift per week, we noted that the same proposal was already submitted by CEA in May 2001. The August 14, 2001, written response from the Office of Compliance addressed your proposal. A copy of that letter is enclosed. We stated that such reduced testing could be acceptable but only under restrictive conditions. Those conditions required a conservative design and the manufacturer would be expected to hold each production lot until test results, indicating the lot had passed, were received. As stated in the August 14, 2001, letter, however, we try to evaluate each manufacturer's design and quality control program (including the sampling plan) on a case-by-case basis.

While we fully appreciate the industry's good safety record, we note that in this November 6, 2001, petition you did not reference or mention our August 14, 2001, letter. You also failed to discuss or mention the five cases of non-compliance due to excessive x-radiation emissions that CDRH cited in the meeting on July 24, 2001, with CEA representatives, Messrs. David Wilson and Ralph Justice. Four of those five cases were found through routine FDA laboratory testing under the Phase III test conditions specified in the federal performance standard. The other case of non-compliance was found through Phase III testing by the manufacturer. Further review of the agency's files of test reports from the FDA's Winchester Engineering and Analytical Center (WEAC) found five more cases showing detectable x-radiation from television products when they were tested under Phase

III conditions. Also, examination of the test reports from WEAC did not support CEA's claim that television products with screens less than 20 inches do not exceed 25 kV. To the contrary, sets with screens as small as 13 inches, and in 1 case 10 inches, exceeded 25 kV when tested under Phase III test conditions. Furthermore, while most sets may have high voltage hold down circuits, manufacturers' reports show that this is not uniformly the case. Since the Phase III testing specified by the standard requires introducing the worst case fault in the set, a fault in the hold down circuit must be considered in testing television products for compliance with the standard. This important information does not support CEA's petition and needs to be considered before changes in regulations for television products are proposed.

We understand your position that changes in technology have made television products less likely to emit harmful x-radiation. However, the use of similar products has changed with the introduction of personal computers and video games because children and adults sit much closer to the product for much longer periods of time. Some jobs require people to sit in front of banks of television monitors or surrounded by video monitors. For the reasons stated above, we believe we need to be very cautious about relaxing the regulations on all television products for all manufacturers.

We will continue to consider reasonable ways to reduce the regulatory burden associated with the record keeping and reporting requirements for television products as we balance that goal with our obligation to ensure the safety of all television products under FDA's jurisdiction. If you have any questions concerning these matters, please contact Dr. Edward Dawson in the Electronic Products Branch by telephone at 301-594-4654 or facsimile at 301-594-4672.

Sincerely yours,

Linda S. Kahan

Linda S. Kahan
Deputy Director
Center for Devices
and Radiological Health

Enclosure
Copy of letter dated August 14, 2001, from the CDRH Office of Compliance

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

AUG 14 2001

Mr. David E. Wilson
Director, Technology & Standards
Consumer Electronics Association
2500 Wilson Boulevard
Arlington, Virginia 22201-3834

Dear Mr. Wilson:

As discussed in our recent meeting with you and Mr. Ralph Justice, the following is our response to CEA's request for a reduction in the minimum sampling for final x-radiation testing of television receivers as contained in your letter of May 10, 2001, to Dr. Orhan Suleiman. Under certain conditions we would not object to your proposed sampling plan calling for testing of just "one product on a weekly basis from each separate chassis/CRT-size combination produced on each production line during each shift." Those conditions are a matter of policy and guidance. The design would have to be considered very conservative, with all manufacturer engineering test data below the 0.1 mR/hr isoexposure rate limit curve, including data from Phase III testing of a worst-tolerance chassis. The manufacturer's overall quality control program would have to be considered adequate to prevent possibly non-compliant products from being produced. Should any possibly non-compliant products be detected, the manufacturer's program must prevent those products from being shipped.

Manufacturers must remember, the regulations require that their certification of television products "shall be 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" as stated in 21 CFR 1010.2(c). In practice almost all television products are certified based upon a testing program rather than a test of each individual product. The regulations go on to say that the Center for Devices and Radiological Health may disapprove a testing program on the grounds that it does not assure the electronic products comply with the standard. Policy and guidance to enforce those regulations has been developed over many years. As you noted in your letter, our current written guidance says the minimum rate consists of "one product from each separate chassis/CRT-size combination produced on each production line during each shift." As we discussed, that is an over simplification because television products range from ones that require much more frequent sampling to ones that do not need to be sampled that frequently. We still believe the guidance is a good rule of thumb for most manufacturers but we try to evaluate each manufacturer's design and quality control program on a case by case basis. If a manufacturer chooses to sample at a lower rate they should explain why. They should also hold each production lot of products until the results of the tests on the sample are known. If the results should indicate a possible failure to comply, the production lot must not be shipped.

We understand that today it is rare to find a television product that emits measurable x-radiation, even under the Phase III test conditions in the Federal Performance Standard. Nevertheless, CDRH has found, in 5 cases since 1989, television products that emitted x-radiation in excess of the limit (0.5 mR/h) of the standard under Phase III test conditions. We have found other cases of manufacturers not doing the tests correctly. Technology has greatly reduced the chances of a television product emitting measurable x-radiation but the use of television products has greatly increased our exposure to them. We believe the regulations, the policies and guidance developed with respect to television products are in accordance with good manufacturing practices and are still good for public health and safety after many years. We are willing to consider manufacturer's alternative sampling plans but their overall quality control programs must still provide assurance that all television products introduced into United States' commerce will comply with the Federal Performance Standard.

If you have any questions or comments concerning this letter please direct them to Mr. Collin Figueroa, Chief of the Electronic Products Branch, in our Division of Enforcement III. He may be reached by telephone at 301-594-4654 or by facsimile at 301-594-4672.

Sincerely yours,

Gladys Rodriguez

for Larry D. Spears
Acting Director
Office of Compliance
Center for Devices
and Radiological Health

cc: Dr. Orhan Suleiman