

SONY

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Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Rm 1061,
Rockville, MD 20852

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August 2, 2000

Subject: Comments on FDA Information Collection Activities, Docket No. 00N-1283

Sony Electronics Inc. hereby respectfully submits its comments on FDA information collection activities, docket 00N-1283.

1. Elimination of Reporting Requirements and Enforcement of Field Surveillance

Product report (1002.10), Supplemental report (1002.11), Abbreviated report (1002.12), Annual report (1002.13) and FDA Form 2877

The current reporting requirements are excessive and unnecessary and not in line with the present international trend. The EU and Japan, for example, have no reporting requirements. In the EU, only conformity to the essential requirements contained in the Low Voltage Directive and General Product Safety Directive is required. Neither certification from third parties nor reports to the government are required. With regard to lasers, Sweden has its own regulations but it only requires conformity to the standard.

The FDA will be better able to insure radiation safety by using its resources for field surveillance (marketplace sampling) rather than adhering to the current practice. Instead of the current report filing requirements, a "Supplier's Declaration of Conformity" to the emission standards would be sufficient.

Elimination of the reporting requirements will result in savings of both time and money in connection with (1) reporting and filing, (2) FDA's detention of imports pending FDA release and (3) government review of filings.

As a manufacturer and importer, we can provide FDA with the information required in the current reporting requirements upon request.

2. Elimination of Requirements of Class I Laser Products

In case FDA does not eliminate reporting requirements of annual report and FDA Form 2877, we would like to point out some issues regarding class I laser products containing class I laser.

Since the laser radiation from class I laser products containing class I laser is not considered to be hazardous as defined in 1040.10, we believe such products can be excluded from the scope of annual report without any impact to the public.

Since such products are not reported to FDA, it is not efficient to provide Customs with accession number of the last annual report when such products are imported.

FDA Form 2877 may be modified to add one check box for such product as a declaration of B3 (compliant products) of Form 2877.

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3. FDA Form 2877

In case FDA does not eliminate reporting requirements including Form 2877, we would like to point out some issues regarding importation process and Form 2877.

A. General

In general, the FDA's import requirements are out of date because they are based on pre-automation processes. Much of the information required to be filed for each and every transaction is redundant. For example, manufacturer name, address and country of origin are repeatedly filed for the same merchandise subject to the same accession number. Similarly, product description is a data element already on file for each model number previously reported to the FDA under Part 1002 of its regulations.

To simplify the import clearance process, it would make sense to limit data fields to importer, model code and accession number. With this information, FDA can cross-reference to other data already on file. In the event of a regulatory action by the FDA, all necessary information about the product can be accessed through FDA's database or provided by the manufacturer of record.

Another general problem with the form is that it does not take into account that multiple regulated products can be included in each entry. Each product may be subject to a distinct description, manufacturer and country of origin. Therefore, a separate form would have to be prepared for each product, a wholly inefficient procedure. FDA should revise its template to take into account multiple product shipments.

B. Specific Fields

1. Name and Address of Manufacturing Site, Country of Origin

As previously stated, this information is already on file with the FDA. Therefore, transaction-by-transaction filing of the data is inefficient.

The requirement that the Address of Manufacturing Site be provided transaction-by-transaction is not only redundant, but it also creates confidentiality concerns for the manufacturer of record. When a manufacturer of record contracts with an OEM plant to produce a certain product, this is proprietary information not ordinarily available to the public. If the manufacturer of record must provide this information at time of import, numerous Customs brokers will have access to this confidential information. Further, if the manufacturer of record sells the goods overseas to a U.S. buyer, the buyer will be required to obtain the actual manufacturer identification in order to file the 2877. Thus, in situations in which the manufacturer of record utilizes an OEM to produce the goods, this otherwise confidential fact will become known to the buyer. This unnecessary and unintended result can be eliminated by deleting this data field whenever the actual manufacturer has been previously identified in an earlier FDA filing associated with an accession number.

2. Declaration C – Non-Compliant Products

According to the declaration, all non-compliant products must be held under bond for exportation or destruction. In fact, bonding is not required for importation of limited quantities for investigation and evaluation during the design and development stage. This import exemption for non-compliant products was set out in a May 14, 1997 notice from Lillian Gill, Director of the Office of Compliance, Center for Devices and Radiological Health. Accordingly, there should be a declaration option to effectuate the 1997 notice. This will avoid unnecessary and burdensome bonding and record keeping requirements.

4. Electronic Report Submission

In case FDA does not eliminate reporting requirements, we would like FDA to accept electronic filing for reports in addition to the current paper format. This will reduce unnecessary time and cost to print and mail reports to FDA and FDA will be able to reduce filing space.

If you have any questions on this matter, please contact the undersigned at (201) 930-6974 or FAX No. (201) 358-4055.

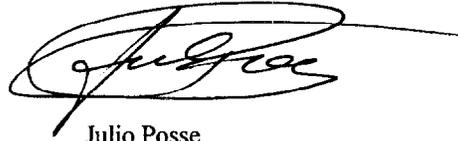
Thank you very much for your continued cooperation.

Very truly yours,

Approved by:



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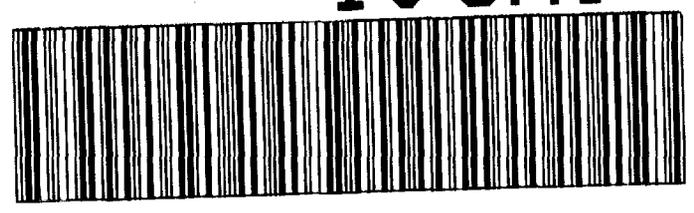
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