



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

FEB 7 1996

Food and Drug Administration  
2098 Gaither Road  
Rockville MD 20850

Ref:

Dear Submitter:

We appreciate your effort to notify us about new models being introduced into United States commerce that are subject to reporting under the Electronic Product Radiation Control provisions of the Federal Food, Drug, and Cosmetic Act. However, we no longer require submission of certain types of reports. Several years ago, the U.S. Office of Management and Budget directed the Food and Drug Administration to reduce the reporting and recordkeeping burden on the electronic products industry. In keeping with that directive, we amended the regulations in 21 CFR 1002, effective October 19, 1995, to eliminate some requirements, consolidate others, and simplify still others.

Sporadic reports that add new model numbers when there is no change in radiation emissions or compliance with a performance standard will no longer be accepted by our agency. These models should only be reported in annual reports (or quarterly updates to annual reports) as specified in the amended regulations and in the revised reporting guides. Therefore, your document(s) is (are) being returned to you with this letter.

If you are concerned about documentation for import clearance refer to the latest annual report (see enclosed notice dated November 15, 1993). Thank you for your cooperation.

Sincerely yours,

A handwritten signature in cursive script that reads "Joanne Barron".

Joanne Barron  
Regulatory Operations  
Office of Compliance  
Center for Devices  
Radiological Health

Enclosures



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

NOV 15 1993

Food and Drug Administration  
1390 Piccard Drive  
Rockville MD 20850

To: Manufacturers and importers of electronic products  
subject to FDA radiation control performance standards

Subject: Guidance on Importation of Certain Electronic Products

When electronic products subject to performance standards are imported, Form FD 2877 "Declaration For Products Subject To Radiation Control Standards" must be completed and submitted with the import entry papers. One of the requirements for such products is that they be reported to the Center for Devices and Radiological Health (CDRH) unless they are exempted from the standards or the reporting requirements. In the past, guidance to import officers in the FDA district offices has been to deny entry to products for which reports had not been submitted. Therefore, imports officers in the ports of entry have been requesting the importer to provide the accession number of the report on the product being imported. The accession number is then used by the imports officers to query the CDRH computer data base to verify that the product being imported has been certified and reported.

However, it is necessary for information on model numbers to have been entered in the CDRH computer data base to be available to the imports officers. Although model numbers have usually been entered for initial, model change and supplemental reports, the size of the entry field in the CDRH data base and the resources available for data entry have always limited the number of model designations that could be entered under a given accession number. In particular, long lists of model numbers, such as appear in some annual reports, cannot be entered. In some cases, manufacturers have not received the acknowledgement letters notifying them of the assignment of the accession number at the time of actual importation. With extremely competitive industries producing more and more models plus more demands on CDRH resources this problem has gotten worse. For these reasons, a search of the data entered for a particular accession number may not yield the model designation of a particular model that has been reported.

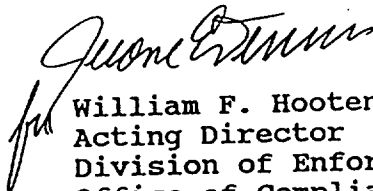
It is important to note that the accession number assigned to a report is merely a file point. There is no necessary correlation between an accession number and the model numbers contained within the report. Further, if the model is exempted, a report may not exist for it so that a properly certified product may not be identified by a unique accession number. All current models should be reported in the manufacturers' annual reports but that

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Accession numbers are merely administrative reference numbers used to facilitate document control at the CDRH. It is not always possible to correlate an accession number with certain models of electronic products for which radiation control performance standards are in effect. The district offices have been requested to use accession numbers only to verify that the CDRH did, in fact, assign that number to a report on a similar regulated electronic product submitted by the manufacturer in question. The existence of an initial report or a current annual report should also be sufficient for the release of products covered by an exemption from continued reporting.

Any questions about this letter should be directed to the NonMedical Radiological Devices Branch of the CDRH at (301) 594-4654.

Sincerely yours,

A handwritten signature in cursive script, appearing to read "William F. Hooten".

William F. Hooten  
Acting Director  
Division of Enforcement III  
Office of Compliance  
Center for Devices  
and Radiological Health