

INSTRUCTIONS TO IMPORTERS/BROKERS OF ELECTRONIC PRODUCTS

PURPOSE: The Form FDA 2877 must be completed for electronic products subject to Radiation Control Standards (21 CFR 1010 and 1020-1050) prior to entry into the United States. The local Food and Drug Administration (FDA) district office will review the declaration and notify the importer/agent if the products may be released into U.S. commerce or if they must be held under bond until exported, destroyed, or reconditioned. Until the shipment is released, it may be subject to redelivery for FDA examination.

PAPER OR ELECTRONIC SUBMISSION: Paper entries may be made by submitting the signed original FDA 2877 along with U.S. Customs forms to the local FDA district office; if electronic products are given a MAY PROCEED, a signed copy of CF 3461 will be returned, or if not given a MAY PROCEED, a FDA Notice of Action will be issued. For electronic entries, follow U.S. Customs Service ACS/ABI format and procedures, supported by a signed copy of this form or similar letter. Multiple entries of the same product and model families that are filed electronically may be supported by one form dated not more than 12 months previously.

DECLARATION: Select A, B, C, or D and then select the appropriate number; fill in requested information and sign. For electronic entries, AofC (affirmation of compliance) = RA#, RB#, RC# or RD# (e.g., Radiation Declaration A5 = RA5). **Transmit model number using AofC code MDL and transmit brand name using FDA line level brand name field. If RA3 or RA6 is selected, you must transmit quantity (number of units) using the Quantity and Unit of Measure Pairs at the FDA line level.**

DECLARATION A: Importers should be prepared to demonstrate compliance to or non-applicability of FDA standards, regulations, or guidance. Components or sub-assemblies must be non-functioning. Products being reprocessed must be exported by the importer, without intermediate transfer of ownership. For RA3 the quantity limit is 3 and for RA6 the limit = 50 units TV products, microwave ovens, and Class 1 laser products limit = 200 units CD-ROM and DVD (digital versatile disc) laser products; see May 14, 1997, notice to industry issued by the Center for Devices and Radiological Health (CDRH).

DECLARATION B: If declaration RB1 is selected, provide the FDA Establishment Identifier (FEI) of the manufacturer who filed the radiation product/abbreviated report to FDA, CDRH, Rockville, Maryland. To transmit the accession number of that report use AofC code ACC. If the manufacturer cannot be determined or located, the importer must be able to provide evidence showing a certification (certifi.) label on each product and state reason: returned to orig exporter or certifi. label evidence. The new AofC codes (RB1, RB2) for this declaration will not be activated until a process is made available to determine the FEI of the responsible firm. Continue to use RAB in electronic transmission until the FEI query is available and industry is notified of its availability.

DECLARATION C: Noncompliant products may be imported only for research, investigations/studies, demonstration or training. They should be used only by trained personnel and under controlled conditions to avoid unnecessary radiation exposure. Product(s) will be detained by the local FDA district office. Since product(s) for which "C" Declarations are made will be under Temporary Import Bond (TIB) or equivalent, ultimate disposition is limited to export or destruction under U.S. Customs supervision when the purpose has been achieved or the length of time stated has expired. For purposes other than demonstration, the Form FDA 766, outlining protections, must be approved by FDA prior to use. The importer/broker must include with the FDA 766:

1. A full description of the subject electronic product(s).
2. The purpose for which the product(s) is being imported.
3. How the product(s) will be used.
4. Where the product(s) will be located.
5. The approximate length of time and dates the product(s) will be in this country.

For product(s) being used for trade shows/demonstrations, list the dates and use restrictions (Form FDA 766 is not required). A sign stating that the product does not comply with FDA performance standards must be displayed and viewable at all times during the use of product(s). All medical products, cabinet x-ray, or Class IIIb and IV lasers may NOT operate (turn on product(s)) at trade shows.

DECLARATION D: Noncompliant products must be brought into compliance with standards under FDA supervision and following a plan approved by FDA. The plan, documented on the Form FDA 766, must address technical requirements, labeling, and reporting. Some plans may need approval by both the CDRH and the local FDA district office. Use of this declaration is limited to occasional shipments; ongoing reconditioning is considered manufacturing that is handled through other means. Product(s) will be detained by the local FDA district office. An FDA 766 must be filed indicating the procedure intended to bring the product into compliance. This procedure will include a satisfactory corrective action plan and/or a product report. The FDA 766 must include all of the information requested under Declaration C. The approximate length of time will be for the amount of time needed to bring product(s) into compliance. Declaration D is also made for failure to provide reports, failure to certify, etc.

If an importer/broker intends to import equipment into the United States for purposes of research, investigation, studies, demonstrations, or training but also wishes to retain the option of bringing the product into compliance with the performance standard, check Declarations C and D on the FDA 2877 and insert the word "or" between the Affirmations. Note: The U.S. Customs Service will treat this entry as a "D" Declaration for purposes of duty. Such requests must be made on the FDA 766; include Items 1, 2, and 3 under Declaration C, a statement of the need to use the option "C" or "D" Declaration, a statement of how the product(s) will be brought into compliance and the approximate length of time necessary to evaluate or demonstrate the product(s) and the time necessary to bring the product(s) into compliance (both actions must be accomplished within the period of time granted by FDA). For electronic entries select Declaration RD3.

Ultimately, product(s) must be brought into compliance with the applicable standard in accordance with a corrective action plan which has been approved by the FDA. If the product(s) are not brought into compliance within the allotted time frame of the approved application and an extension is not requested of, or granted by, the FDA, the local FDA district office shall refuse entry on the shipment and require the product(s) to be either exported or destroyed under U.S. Customs supervision.

If additional guidance is needed, please contact your local FDA district office or consult the following FDA web pages: www.fda.gov/cdrh, www.fda.gov/ora/hier/ora_field_names.txt, and www.fda.gov/ora/compliance_ref/rpm_new2/contens.html