|  |  |
| --- | --- |
|

|  |
| --- |
| TITLE 21--FOOD AND DRUGS |

 |
|

|  |
| --- |
| CHAPTER I--FOOD AND DRUG ADMINISTRATIONDEPARTMENT OF HEALTH AND HUMAN SERVICES |

 |
|

|  |
| --- |
| SUBCHAPTER J--RADIOLOGICAL HEALTH |

 |

[PART 1010 -- PERFORMANCE STANDARDS FOR ELECTRONIC PRODUCTS: GENERAL](http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?CFRPart=1010)

Subpart A--General Provisions

|  |
| --- |
| Sec. 1010.2 Certification.  |

|  |
| --- |
| (a) Every manufacturer of an electronic product for which an applicable standard is in effect under this subchapter shall furnish to the dealer or distributor, at the time of delivery of such product, the certification that such product conforms to all applicable standards under this subchapter. (b) The certification shall be in the form of a label or tag permanently affixed to or inscribed on such product so as to be legible and readily accessible to view when the product is fully assembled for use, unless the applicable standard prescribes some other manner of certification. All such labels or tags shall be in the English language. (c) Such certification 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. The Director, Center for Devices and Radiological Health 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. (d) In the case of products for which it is not feasible to certify in accordance with paragraph (b) of this section, upon application by the manufacturer, the Director, Center for Devices and Radiological Health may approve an alternate means by which such certification may be provided.  |

|  |  |
| --- | --- |
|

|  |
| --- |
| TITLE 21--FOOD AND DRUGS |

 |
|

|  |
| --- |
| CHAPTER I--FOOD AND DRUG ADMINISTRATIONDEPARTMENT OF HEALTH AND HUMAN SERVICES |

 |
|

|  |
| --- |
| SUBCHAPTER J--RADIOLOGICAL HEALTH |

 |

[PART 1000 -- GENERAL](http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?CFRPart=1000)

Subpart A--General Provisions

|  |
| --- |
| Sec. 1000.3 Definitions.  |

|  |
| --- |
| As used in this subchapter J: |

(j) *Electronic product* means:

(1) Any manufactured or assembled product which, when in operation:

(i) Contains or acts as part of an electronic circuit and

(ii) Emits (or in the absence of effective shielding or other controls would emit) electronic product radiation, or

(2) Any manufactured or assembled article that is intended for use as a component, part, or accessory of a product described in paragraph (j)(1) of this section and which, when in operation, emits (or in the absence of effective shielding or other controls would emit) such radiation.

Useful Links

**FDA form 2877** - this is the required Imports Form for radiation-emitting electronic products subject to a performance standard, see the form and further information here [Importing and Exporting Electronic Products](http://www.fda.gov/Radiation-EmittingProducts/ElectronicProductRadiationControlProgram/GettingaProducttoMarket/ImportingandExportingElectronicProducts/default.htm)

* [Importation of Radiation-Emitting Products: Product Code Status Update](http://www.fda.gov/Radiation-EmittingProducts/ElectronicProductRadiationControlProgram/GettingaProducttoMarket/ImportingandExportingElectronicProducts/ucm118397.htm)
* [Procedures for Importing Electronic Products which Emit Radiation (PDF - 632KB)](http://www.fda.gov/downloads/Radiation-EmittingProducts/ElectronicProductRadiationControlProgram/GettingaProducttoMarket/ImportingandExportingElectronicProducts/UCM118719.pdf)
* [Declaration for Imported Electronic Products Subject to Radiation Control Standards - Form #2877 (PDF - 670KB)](http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM080778.pdf)
* [Use of FDA-assigned Manufacturer Report's Accession Numbers (PDF - 133KB)](http://www.fda.gov/downloads/Radiation-EmittingProducts/ElectronicProductRadiationControlProgram/GettingaProducttoMarket/ImportingandExportingElectronicProducts/UCM118720.pdf)
* [Imports of Radiation-Emitting Consumer Electronics for Investigation](http://www.fda.gov/Radiation-EmittingProducts/ElectronicProductRadiationControlProgram/GettingaProducttoMarket/ImportingandExportingElectronicProducts/ucm118732.htm)

Bottom of Form



Part, SKU, or other identifying Number:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Commercial Description:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Intended Use Code (see attached): \_\_\_\_\_\_\_\_\_

FDA Product Code, (if known):\_CD/DVD or Other:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

*(If you do not know the product code, one will be assigned for you to approve before filing.)*

Source Country: \_\_\_\_\_\_\_\_\_\_\_\_\_

(Country where the item was produced.)

Trade Name or Brand Name:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Unique Product Characteristics (if any):\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Manufacturer: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ (or DUNS#)\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Address (1):\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Address (2):\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

City/State/Province:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Country:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Postal Code:\_\_\_\_\_\_\_\_\_\_\_

Contact Name:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Email address:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ -OR-

FAX #:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Point of Contact In US:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

(Contact name of someone in US that FDA could contact, if needed)

Phone#:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Email or FAX#:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Model #:\_\_\_\_\_\_\_\_\_\_\_ Accession#:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

|  |
| --- |
| ***Intended Use Code*** |
| 085000 | For Veterinary Medical Use as a Non-Food Product under controlled Distribution |
| 090.000 | For Military Use as a Non-Food Product |
| 100.000 | For Personal Use as a Non-Food Product |
| 110.000 | For Public Exhibition or Display as a Non-Food Product |
| 120.000 | For Public Safety use as a Non-Food Product |
| 130.000 | For Consumer use as a Non-Food Product |
| 140.000 | For Charitable Organization use as a Non-Food Product |
| 150.000 | For Commercial Processing as a Non-Food Product |
| **155.000** | **For Commercial Assembly as a Non-Food Product** |
| 170.000 | For Repaid of a Non-Food Product |
| 180.000 | For Research and Development as a Non-Food Product |
| 970.000 | For Import for Export |
| 980.000 | For Other Use |

If your product is not actively regulated by FDA due to low RF Fields then acceptable terminology for A2. “Specify reason for Exclusion:” may be similar to the following.

***No Mandated FDA performance Standards for this product***



FDA 2877 – DISCLAIM NOTICE

Products that are disclaimed from FDA filing, must be documented by the Importer of record, as to reason and must be signed by a competent party to the transaction. (Please Print)

Date:

Name:

Address:

City/State, Zip:

Contact Name:

Contact Phone:

Contact email:

Part #:

|  |
| --- |
|  **DECLARATION: I / WE DECLARE THAT THE PRODUCTS IDENTIFIED ABOVE: *(Circle* *applicable statements, fill in blanks, & sign)***  |
|

|  |
| --- |
|  |
| 1. ARE NOT SUBJECT TO RADIATION PERFORMANCE STANDARDS BECAUSE THEY:

 1. Were manufactured prior to the effective date of any applicable standard;

Please provide date of manufacture:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_1. **Are excluded by the applicability clause or definition in the standard** or by FDA written

 Guidance.Specify reason for exclusion: No mandated FDA Performance Standards for this product. \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_Signature and Title of party noted above:  |

 |