ACE Affirmations of Compliance

This document outlines the valid Affirmation of Compliance codes for entries made in the Automated Commercial Environment). To determine when Affirmations of Compliance must be provided, refer to FDA' Supplemental Guide.

Note: Declaration of any code not listed below will result in an entry rejection.

Code	Affirmation	Qualifier Required
ACC	EPRC (Electronic Product Radiation Control) Accession Number	Y
AIN	Food Additive Identification Number	Y
ANC	EPRC Radiation-emitting Products Annual Report Accession Number	Y
BLN	Biologics License Number	Y
CAN	Carrier Name	Y
CCC	Chinese Ceramicware Factory Code	Y
CIN	Color Index Number	Y
CMT	Commercially Marketed Tobacco	N
COS	Cosmetic Registration Number	Y
CPT	Component Identifier	N
DA	Drug Application Number (Use for Biologics New Drug, Abbreviated New Drug Application Number, New Drug Application Number, or Therapeutic Biologic Application Number)	Y
DDM	Device Domestic Manufacturer	Y
DEV	Device Foreign Manufacturer Registration Number	Y
DFE	Device Foreign Exporter Registration Number	Y
DI	Device Identifier	Y
DLS	Drug Listing Number	Y
ERR	Entry Review Recommended	Y
EXE	Tobacco Exemption from Substantial Equivalence	N
FAP	Food Additive Petition Approval Number	Y
FCC	French Cheese Facility Certification Number	Y
FCE	LACF/AF Food Canning Establishment Number	Y
FME	Food Processing Facility Registration Exemption	Y
HPC	Harmful of Potentially Harmful Constituents (Tobacco HPHC)	N
HRN	Biologics Human Cells, Tissues/ Cellular and Tissue-Based Product Establishment Registration Number	Y
HTS	Harmonized Tariff Schedule Number	Y
IBP	Indian Black Pepper Certificate	Y
IDE	Investigational Device Exemption	Y
IFE	Import for Export	N
ILS	Ingredient Listings Submission-Confirmation (Tobacco)	N
IND	Investigational New Drug Application Number	Y
IRC	Device Impact Resistance Lens Certification	N
JIF	Juice HAACP Importer Firm	Y
KIT	Device Imported Kit of Finished Devices	N
LFR	Location of Goods (Holding Facility) Food Facility Registration Number	Y
LST	Device Listing Number	Y
LWC	Device Electrode Lead Wire or Patient Cable	N
MDL	EPRC Radiation-emitting Products Model Number	Y
NDC	Drug National Drug code (Animal Drugs Only)	Y
ORN	Owner Food Facility Registration Number	Y
PKC	Package/Can Code	Y
PM#	Premarket Approval Number or Notification	Y
PMT	Premarket Tobacco Application	N
RA1,RA2, RA5,RA7	EPRC Radiation-emitting Products–use if FDA compliance is non-applicable, see Form FDA 2877	Y
RA3,RA4, RA6	EPRC Radiation-emitting Products–use if FDA compliance is non-applicable, see Form FDA 2877	N

RB1	EPRC Radiation-emitting Products-use if product is FDA compliant, see Form FDA 2877 (no qualifier but must transmit with ANC or ACC)	N
RB2	EPRC Radiation products-use if product is FDA compliant, see Form FDA 2877	Y
RC1	EPRC Radiation products-use if product is FDA non-compliant, see Form FDA 2877	N
RC2	EPRC Product Declaration C2 (FDA 2877)	Y
RD1, RD2	EPRC Radiation products-use if product is non-compliant but will be re-conditioned under bond and Form FDA766, see Form FDA 2877	N
RD3	EPRC Radiation products-use if product is non-compliant but will be re-conditioned under bond and Form FDA766, see Form FDA 2877	Y
REG	Drug Registration Number	Y
RNO	Rail Car Number	Y
SE	Substantially Equivalent (Tobacco)	N
SFR	Shipper Food Facility Registration Number	Y
SID	LACF/AF Submission Identifier Number	Y
SIF	Seafood HAACP Importer Firm	Y
SRN	Submitter Food Facility Registration Number	Y
STN	Biologics Submission Tracking Number	Y
TFR	Transmitter Food Facility Registration Number	Y
TST	Tobacco Submission Tracking Number	Y
UFR	Ultimate Consignee Food Facility Registration Number	Y
VAN	Veterinary Abbreviated New Animal Drug Number (ANADA)	Y
VES	Ocean Vessel Name	Y
VFL	Veterinary Feed Mill License (FML)	Y
VFT	Voyage, Flight, or Trip Number	Y
VIN	Veterinary Investigational New Animal Drug Number (INAD)	Y
VNA	Veterinary New Animal Drug Application Number (NADA)	Y
VOL	LACF/AF Volume	Y

Definitions:

ACC
EPRC Accession Number
This code and qualifier should be the Electronic Product Radiation Control (EPRC) product or abbreviated report accession number issued by CDRH for the product identified in the FDA line.

Example: ACC 1210000

AIN
Food Additive Identification Number
This affirmation is used only when importing the pure food additive intended for use in a food manufacturing process and the qualifier should be the CAS (Chemical Abstract System) number. The European Economic Community has also identified food additives by "E" numbers (identification numbers/letters beginning with E). Any of these identifying numbers can be used for the product identified in the FDA line.

Example: AIN 59479
AIN 10192713

ANC
EPRC Annual Report Accession Number

This code and qualifier should be the EPRC current annual report (due annually by September 1) accession number issued by CDRH for the product identified in the FDA line.

Example: ANC 123xxxx (no more than two years old)

BLN
Biologics License Number
This affirmation and the qualifier for this code should be the four digits of the U.S. Biologics License Number issued by FDA, Center for Biologics Evaluation and Research to the manufacturer of the biological product identified in the FDA line. The Biologics License Number is the U.S. license number (not the Submission Tracking Number (STN)). The BLN at a maximum would be a four digit number.

Example: BLN 1234

CAN
Carrier Name

CCC
Chinese Ceramicware Factory Code
This affirmation and qualifier should be used to indicate shipments of ceramic ware are produced by a manufacturer certified as part of a FDA/Peoples Republic of China (PROC) Memorandum of Understanding (MOU). The code requires a qualifier consisting of the factory code assigned to the individual manufacturer. This code will have to be
obtained from the manufacturer by the filer or their client. Paper certificates (CCIB) will no longer be used in FDA's evaluation of these entries.
The qualifier is the factory code assigned to the individual manufacturer.

Example: CCC 13X005

Example: CN

CFR
FDA Consolidator Registration Number

CIN
Color Index Number
This affirmation and qualifier is only used when importing the pure color additive to be used in FDA regulated items. The affirmation and qualifier should be the Color Identification Number recognized as the international color identification number for the product identified in the FDA line.

Example: CIN RED 40 /BLUE 1

COS
Cosmetic Registration Number
This affirmation and qualifier should be the Cosmetic Registration Number issued by FDA/CFSANfo
FDA/CFSAN for the firm manufacturing the product identified in the FDA line. Form FDA

2511 should be used for registration. This is a voluntary registration. The assignment of a registration number by FDA does not denote approval of a firm, raw material, or product by FDA.

Example: COS1061499

CMT
Commercially Marketed Tobacco
This affirmation should be transmitted if the tobacco in the entry line was commercially marketed (other than exclusively in test markets) in the U.S. as of February 15, 2007. These products are considered "grandfathered" and not considered new.

CPT
Device Component
This affirmation and qualifier should be used when importing a component of a device that requires further processing or inclusion into the finished device. Component means any raw material, substance, piece, part, software, firmware, labeling, or assembly which is intended to be included as part of the finished, packaged, and labeled device.

Finished device means any device *or accessory* to any device that is suitable for use or capable of functioning, whether or not it is packaged, labeled, or sterilized.

This code is not to be used if the device component is classified by FDA as a finished device.

There is no qualifier for this code.

DA
Drug Application Number (New Drug, Abbreviated New Drug or Therapeutic Biologic Application Number)
This affirmation and qualifier should be the New Drug, Abbreviated New Drug or Therapeutic Biologic Application Number issued by FDA/CBER of CDER for drug product identified in the FDA line. Once approved, an applicant may manufacture and market the generic drug product. The qualifier is six digits, and for biologics has a leading BA or BN. If less than six digits, preceding zeros may be used to make six digits.

Example: DA BA004444 (CBER)
DA 123456 (CDER)

DDM
Device Domestic Manufacturer
This affirmation and qualifier should be the device registration number issued by FDA/CDRH for the US firm manufacturing the product identified in the FDA line.

DDM is only to be used for those U.S. manufactured devices declared as part of a kit. This affirmation and qualifier should be the device registration number or owner operator number issued by FDA/CDRH for the U.S. firm that is manufacturing the product identified in the FDA line**.**

Example: DDM 3003999999
(Note: Should always be the DDM associated with the U.S. manufacturer and **not** the Foreign Manufacturer)

DEV
Device Foreign Manufacturer Registration Number
This affirmation and the qualifier for this code should be the device registration number or owner operator number issued by FDA/CDRH for the firm manufacturing the product identified in the FDA line.

(Note: Should always be the DEV associated with the foreign manufacturer and not the US specifications developer)

Examples: DEV 3003999999
DEV 9699123

DFE
Device Foreign Exporter Registration Number
This affirmation and the qualifier for this code should be the device registration number or owner operator number issued by FDA/CDRH for the exporter who exports or offers for export to the United States (U.S.), a device manufactured or processed by another individual, partnership, corporation or association in a foreign country, as well as devices originally manufactured in the United States.

Examples: DFE 3003999999
DFE 9710083

DI
Device Identifier
This affirmation and qualifier should be the Device Identifier portion of the Unique Device Identifier (UDI)

Example: 123456

DLS
Drug Listing Number
This affirmation and qualifier should be the Drug Listing Number issued by FDA/CDER for the BULK drug product identified in the FDA line. The drug listing number is provided on the application for drug listing, Form FDA 2657. All foreign drug establishments shall comply with the drug listing requirements. Bulk drug substances are identified and reported using a unique number. The first segment of numbers is the labeler code. This number identifies the manufacturer of the product. Declare without dashes.

Note – for human drugs, declare “DLS” rather than NDC.

Examples: DLS 444433322

ERR
Entry Review Recommended
This affirmation, with a required qualifier, can be used when a filer becomes aware, prior to transmitting entry data, there is a legitimate need for FDA to examine the commodities in an entry e.g., the filer has been notified that refrigeration failure in a truck or ship has caused damage to a partial or total shipment. Transmission of this code will generate a "FDA Hold" on screening and eliminate the need to return a shipment for FDA sampling. This code can also be used, at FDA's request, if a filer is asked to withdraw and retransmit an entry to correct an erroneous "May Proceed". The qualifier (up to 20 characters) should indicate the reason the code is being transmitted.

Example: ERR damaged in shipment

EXE
Exemption from Substantial Equivalence (tobacco)
If not commercially marketed in the U.S. as of Feb. 15, 2007, FDA has granted the tobacco product in the entry line an exemption from demonstrating substantial equivalence. When this affirmation is transmitted, TST and the qualifier must also be transmitted. (See TST for example.)

FAP
Food Additive Petition Approval Number
This affirmation is used only when importing the pure food additive which will be used in a food manufacturing process. This affirmation and qualifier should be the Food Additive Petition Approval Number issued by FDA/CFSAN for the product identified in the FDA line.

Example: FAP 123456

FCC
French Cheese Facility Certification Number
This affirmation and qualifier should be the French Cheese Facility Certification Number issued by the French government for the product/plant identified in the FDA line.

Example: FCC 7906101

FCE
Food Canning Establishment Number
This affirmation and qualifier should be the Food Canning Establishment Number (FCE) that identifies a manufacturer of acidified and/or low-acid canned food products. The qualifier should be the Food Canning Establishment Number issued by FDA where the site specific manufacturer of Low Acid and/or Acidified Food is registered. Form FDA 2541 is used for the manufacturing firm registration. When possible, the Affirmation of Compliance Codes for the SID (Submission Identifier), VOL (Volume) and/or specific container size/dimensions should also be used when the FCE affirmation code is provided. See the SID and VOL Affirmation Code definitions below and refer to the Container Dimension guidance in the “Transmission of Data Guidance” section below.

Example: FCE 12345

FME
Food Processing Facility Registration Exemption
This affirmation is used when food or feed is no longer in its natural state or when the PFR is not provided. Either FME or PFR is required in the case of manufacturer, or when consolidator or grower is entered in lieu of manufacturer for food in natural state. FME must be submitted with one of the following exemption codes:

A – Facility is out of business
B – Facility is a private residence
C – Facility is a restaurant
D – Facility is a retail food establishment
E – Facility is a non-processing fishing vessel
F – Facility is a non-bottled drinking water collection and distribution establishment
K – Unable to determine the registration number of the manufacturer

Example: FME K

FTZ
FTZ Admission Number

GFR
Grower Food Facility Registration Number

HPC
Harmful of Potentially Harmful Constituents (HPHC) (Tobacco)
This affirmation should be transmitted to affirm the Harmful or Potentially Harmful Constituents (HPHC) Report for the tobacco product in the FDA entry line was previously submitted to FDA.

HRN
Human Cells, Tissues and Cellular and Tissue-Based Product Establishment Registration Number. Now HRN=HCT/P Registration Number
This affirmation and qualifier is used if the establishment is registered with the FDA. The required qualifier should be the HCT/P establishment registration number issued by FDA's Center for Biologics Evaluation and Research (CBER) for the product's manufacturing firm identified in the FDA entry line. Most foreign manufacturers of biologic products are required to register and submit a lit of every HCT/P manufactured (21 CFR 1271.21), except those exempt from registration under 21 CFR 1271.15.
For Example; individuals (such as physicians) are not required to register or list if they are under contract, agreement, or other arrangements with a registered establishment and engaged solely in recovering tissue.
Preceding zeros are used to assure the qualifier is always 10 characters.

Examples: HRN 0001234567
HRN 1234567890

HTS
Harmonized Tariff Number

IBP
Indian Black Pepper Certificate
This affirmation and qualifier should be used when the manufacturer has provided an Inspection Certificate for Export of Black Pepper from the Export Inspection Agency, Ministry of Commerce Government of India, which includes results of filth and salmonella analyses. The qualifier should be the Certificate number.

Examples: IBP A19508
IBP BP/C- 09924

IDE
Biologics (CBER) Investigational Device Exemption
This affirmation and qualifier should be the Investigational Device Exemption Number issued by FDA/CBER for the product identified in the FDA line. Devices that qualified experts use on human subjects, to conduct investigations of their safety and effectiveness, are considered investigational devices. The range for CBER IDE's is from
0-79,999.

Examples: IDE 1234
IDE 79999

IDE
Investigational Device Exemption Number
This affirmation and qualifier should be the Investigational Device Exemption Number issued by FDA/CDRH for the product identified in the FDA line. Devices that qualified experts use on human subjects, to conduct investigations of their safety and effectiveness, are considered investigational devices. The qualifier for this code should be the investigational device exemption number issued by FDA/CDRH for the product identified in the FDA line. Note that the qualifier will start with the letter "G".

Example: IDE G089911

IFE
Import for Export
This affirmation allows for importation of violative or non-compliant articles (including drug and device components, food and color additives, and dietary supplements) under the import for export provisions of the FD&C Act [801(d)(3)(a)].

The "import for export" requirements for blood, blood components, plasma, and source leukocytes differ from those for drugs and other biological products. The Act allows for the importation of these blood products and components provided they comply with section 351(a) of the PHSA or FDA permits such imports "under appropriate circumstances and conditions" as determined by the Center for Biologics Evaluation and Research (CBER) (section 801(d)(4) of the Act).

The imported article must be incorporated into a product for export by the initial owner or consignee. Note: This can be someone other than the importer of record. The product must be exported from the United States by the initial owner or consignee in accordance with the provisions of Sections 801(e) and 802 of the FD&C Act or 351(h) of the PHS Act. This affirmation <u>cannot</u> be used for transshipment of devices through the United States.

It cannot be used to store, in U.S. warehouses, finished devices intended solely for import. Refer to the FDA Regulatory Procedures Manual (RPM) Chapter 9 for additional guidance and information.

There is no qualifier for this code.

ILS
Ingredient Listings Submission-Confirmation (Tobacco)
This affirmation should be transmitted to affirm the product ingredient listing for the tobacco product in the entry line has been submitted to FDA.

IND
Investigational New Drug Application Number
This affirmation and qualifier should be the Investigational New Drug Application Number issued by FDA/CBER or CDER for the product identified in the FDA line. Investigational drugs are new drugs intended solely for investigational use by experts qualified by scientific training and experience to investigate the safety and effectiveness of drugs.

The FFD&C Act requires that a drug be the subject of an approved marketing application before it is transported or distributed across state lines (including import). A sponsor who wants to ship the investigational drug to clinical investigators, must seek an exemption from that legal requirement. The IND is the means through which the sponsor obtains its exemption from the FDA. An active IND allows for the shipment of an investigational new drug.

Example: IND 999000
IND 055555

IRC
Device Impact Resistance Lens Certification
This affirmation is used to certify that the filer has, on hand, the test results or a certificate that shows that the product on the FDA line has met the standards for impact resistance lens.

Note: FDA has the authority to ask for copies of the actual test results. Each shipment must have its own test results unless it is part of a larger lot that was shipped to the U.S. over time.

Example: IRC There is no qualifier for this code.

JIF
Juice HACCP Importer Firm
This affirmation and required qualifier should be used to identify the responsible U.S. firm as defined by 21 CFR 120.14. The HACCP Importer is defined as either the U.S. owner or the U.S. consignee at the time of entry, responsible for insuring the goods are in compliance with the requirements of the HACCP regulation. The term HACCP "Importer" is not the same as the "Importer of Record" as defined by U.S. Customs regulations. However, an Importer of Record may also be the U.S. owner or U.S. consignee. The qualifier required is the FDA Establishment Identifier (FEI) for the HACCP Importer.

Example: JIF 3888440551

KIT
Imported Kit of Finished Device
This affirmation should be used for all individual devices within kits imported in the US. There is no qualifier. Some kits contain drug products which must comply with applicable labeling

and approval requirements including but not limited to application number, registration, and listing. For example, the foreign firm's drug registration per FFDCA 510(i) must include the known US importers. If the registration does not include the importer or consignee, then detention may be indicated.

Kit importers should consider obtaining the Affirmation of Compliance information from their vendors to minimize the need for manual review of applicable lines by the FDA.

NOTE: This information only applies to medical device kit importers who have been specifically informed by CBP that they must transmit every device contained in a kit on a separate line (also referred to as 'X' and 'V' lines). Importers of medical device kits who transmit only the kit as a single line should continue to use the Affirmations of Compliance codes DEV (foreign manufacturer medical device registration #) and LST (medical device listing #) applicable for the medical device kit.

Example: KIT There is no qualifier for this affirmation.

LFR
Location of Goods Food Facility Registration Number

LST
Device Listing Number
This affirmation and the qualifier for this code should be the device listing number issued by CDRH for the product identified in the FDA Line.

Example: LST E199100

LWC
Device (Electrode) Lead Wire or Patient Cable
This affirmation should be used when importing electrode lead wires, patient cables, or devices that use them. The affirmation indicates either (1) the device shipment does not contain any pre-wired electrodes, electrode lead wires, or patient (transducer) cables, or (2) any pre-wired electrodes, electrode lead wires or patient cables comply with 21 CFR
898, Performance Standard for Electrode Lead Wires and Patient Cables

Example: LWC There is no qualifier for this code.

MDL
Model Number (Device and EPRC (Radiation Products))
This affirmation and qualifier should be the manufacturer's model number for the product identified in the FDA line.

There is no specific format for this qualifier. The model data may be whatever the manufacturer uses as a model number.

Examples: MDL AAA-1234
MDL X98-0345673
MDL 65-125

NDC
National Drug Code (for Animal Drugs only)

This affirmation and qualifier is the National Drug Code listed with FDA.

PM#
Premarket Approval Number or Notification
This affirmation and the qualifier for this code should be the Device Premarket Approval Number or the Device Premarket Notification (510(K)) number issued by CDRH or CBER for the product identified in the FDA line. Premarket number should always be the number that is on the listing record.

Example:	PM#	BP123456	Premarket Approval
	PM#	BK1234	Premarket Notification
	PM#	P979999	Premarket Approval
	PM#	D970000	Product Development Protocols

PKC
Package/Can Code (for foods only)
This affirmation and qualifier should be used to indicate the package/can code assigned by the manufacturer at time of production.

Example: DEC2215M2 21:06

PLR
PLAIR Import Shipment
This affirmation should be used to indicate the entry is subject to a PLAIR (Pre-Launch Activities Importation Request) based on anticipated approval of a pending new drug application or an abbreviated new drug application.

PMT
Premarket Tobacco Application
If not commercially marketed in the U.S. as of Feb. 15 2007, affirms FDA issued an order permitting marketing of the new tobacco product. When this affirmation is transmitted, TST and the qualifier must also be transmitted.

– Radiation Devices –

EPRC Declaration for Imported Electronic Products Subject to Radiation Control Standards

Entries of radiation emitting electronic products require the submission of the Declaration for Imported Electronic Products Subject to Radiation Control Standards, Form FDA 2877. Complete details about the import entry review for medical and non-medical radiation emitting electronic products can be found in the following links:

"Letter to Industry about Import Entry Review Process (March 24, 2011)"
http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/ucm248321.htm

"Letter to Industry about Import Entry Review Process (September 6, 2011)"
http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/ucm271180.htm

The Form FDA 2877 can downloaded from the following link:
http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM080778.pdf

FDA will permit the electronic filing of the Form FDA 2877 and waive submission and filing of the original paper Form FDA 2877 in the following four (4) conditions:

1. The appropriate AofC code and Qualifier data is transmitted for the FDA line. Only one Rad Health Product AofC code can be used per FDA line.

2. The filer maintains the appropriate documentation in their files for five years to support their electronic submission of the Form FDA 2877 AofC data. The documentation must be specific with regard to make and model numbers entered and include the name and address of the site specific manufacturer rather than the corporate name and address. This documentation may be either:

A) The signed original Form FDA 2877 for the entry in question.
B) A letter of authorization, from the importer, to electronically file the Form FDA 2877 information.

OR

C) An alternate documentation method which has been previously approved by the Center for Device and Radiological Health.

3. The filer has met and continues to meet the requirements to file "paperless" entries based on an evaluation for accurate data submission.

4. The entry containing the FDA line must receive an electronic MAY PROCEED notice through the FDA/USCS Interface.

Medical devices that emit electronic product radiation, subject to U.S. Federal Performance Standards, are also subject to medical device regulations, which include establishment registration, device listing and premarket notifications and approvals. Examples of radiation-emitting medical devices, subject to the U.S. Federal Performance Standard, include medical x-ray, fluoroscopy, Computed Tomography (CT), medical laser and sunlamp/tanning booth products.

Listed below are examples of AofC codes that should be transmitted at the time of entry for a medical device or a radiation emitting electronic product subject to a U.S. Federal performance standards (http://www.fda.gov/Radiation-EmittingProducts/ElectronicProductRadiationControlProgram/GettingaProducttoMarket/RegulatedProducts/default.htm). For products subject to both the medical device requirements and the radiation emitting electronic product requirements, each entry line should contain AofC codes applicable to both medical devices and radiation emitting electronic products.

RADIATION EMITTING PERFORMANCE STANDARD AofC Codes List

RA1 or RA2 or RA3 or RA4 or RA5 or RA6 or RA7
RB1 or RB2
RC1 or RC2
RD1 or RD2 or RD3
ACC or ANC
MDL (if applicable)

The following RA Codes are used when products are *NOT* subject to Radiation Performance Standards

RA1
EPRC Product Declaration A1 (FDA 2877)
This affirmation and qualifier should be transmitted for products that were manufactured prior to the effective date of an applicable performance standard.
The qualifier is the date of manufacture, which must be the date before the performance standard was effective.

Example: RA1 Feb 5, 2011

RA2
EPRC Product Declaration A2 (FDA 2877)
This affirmation and qualifier should be transmitted when the products are excluded from the applicability clause or definition in the standard or by FDA written guidance. Specific reason for exclusion is required, as the qualifier, with transmission of this code. For example, laser products which are purchased by Department of Defense (DOD) are allowed to be imported uncertified if they have met the DOD exemption requirements in
21 CFR 1010.50 and Laser Notice 52.

Example: RA2 Laser Notice 52- DOD Exemption

RA3
EPRC Product Declaration A3 (FDA 2877)
This affirmation should be transmitted when the products are personal household goods of an individual entering the U.S. or being returned to a U.S. resident.

No qualifier is required but the quantity is limited to 3 of each product and it must be transmitted at the FDA line level. Examples include microwave ovens, laser optical drives inside CDs, DVD players, etc. Confirm personal household goods (limit = 3). No introduction into U.S. commerce is permitted.

Example: RA3

RA4
EPRC Product Declaration A4 (FDA 2877)
This affirmation should be transmitted when the products are property of a party residing outside the U.S. and will be returned to the owner after repair or servicing. For example, a Canadian firm is sending a non-certified commercial laser machine to U.S. for repair and will be returned to Canada.
No qualifier is required, however firm must document import/export process. No introduction into U.S. commerce is permitted.

Example: RA4

RA5
EPRC Product Declaration A5 (FDA 2877)
This affirmation and qualifier should be transmitted when the products are components or subassemblies to be used in manufacturing or as replacement parts (NOT APPLICABLE TO DIAGNOSTIC X-RAY COMPONENTS.)

The qualifier required is the textual description of the end product.

Example: RA5 Laser diodes

RA6
EPRC Product Declaration A6 (FDA 2877)
This affirmation should be transmitted for specified radiation emitting electronic products (Class 1 optical drives, microwave ovens, and TV receiver (CRT only) and intended for ongoing product development by the importing firm. The products are labeled “FOR TEST/EVALUATION ONLY,” and will be exported, destroyed, or held for future testing (i.e., not distributed).

No qualifier is required but the quantity (number of units) must be transmitted at the FDA line level. Quantities are limited per instructions on back of Form 2877.

For example TVs, or Microwave Ovens = 50 units. Class 1 laser CD-ROM players or DVD players = 200 units.

Example: RA6

"Importation of Radiation-Emitting Electronic Products for and Evaluation During Design Development" http://www.fda.gov/Radiation-EmittingProducts/ElectronicProductRadiationControlProgram/GettingaProducttoMarket/ImportingandExportingElectronicProducts/ucm118732.htm

RA7
EPRC Product Declaration A7 (FDA 2877)
This affirmation and qualifier should be transmitted when the products are being reprocessed in accordance with The FDA Export Reform and Enhancement Act of 1996 (P.L. 104-134), or other FDA guidance, and are labeled "FOR EXPORT ONLY," after reprocessing. Products being reprocessed must be exported by the importer, without intermediate transfer of ownership. For example a U.S. firm is importing an uncertified laser product which is then installed inside medical equipment and then exported to a foreign buyer. The qualifier required is the textual description of the end product.

Example: RA7 Laser medical device for Europe market; outside containers are marked 'FOR EXPORT ONLY"

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The following RB Codes are used WHEN PRODUCTS COMPLY with Performance Standards. Select the code and qualifier, if appropriate, that best describes the product information being transmitted.

RB1
EPRC Product Declaration B1 (FDA 2877)
This affirmation and qualifier should be transmitted when compliance to the performance standard is documented in the most current annual report (code is ANC) or Product/ Initial/ Abbreviated report (code is ACC). If this code is transmitted, the ACC **or** ANC code and qualifier must also be transmitted.

The Manufacturer's name in either report must match the name on the Form FDA 2877.

Examples: RB1 **and** ACC 1114999 **OR** ANC 1135999

RB2
EPRC Product Declaration B2 (FDA 2877)
This affirmation and qualifier should be transmitted when the product complies with the standard but the manufacturer or report numbers are unknown. For example, the importer doesn't know the name of the manufacturer or the accession number for the product report or annual report; however, importer can provide evidence such as photos

of certification labels on the products that the products are in compliance with the US Federal performance standard.

For example, an importer purchased a large quantity of microwave ovens from a foreign distributor but was able to provide photographs of certification labels on the ovens (example, the certification label states " This oven complies with U.S. Federal Performance Standard, 21 CFR 1030.10.").
The qualifier required must state reason the product complies.

Example: RB2 Filer submitted digital photos of cert labels affixed to the products.

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The following <u>RC Codes</u> are used when products *DO NOT COMPLY* with performance standards and <u>are expected to be either destroyed or exported</u>; are being held under temporary import bond; will not be introduced into commerce; will be used under a radiation protection plan; and will be destroyed or exported under CBP supervision when the following mission is complete. Select the code and qualifier, if appropriate, that best describes the product information being transmitted

RC1
EPRC Product Declaration <u>C1</u> (FDA 2877)
This affirmation should be transmitted when the product does not comply and is for research, Investigations/Studies, or training. Form FDA 766 will be required and must provide a full description of the subject electronic product, the purpose for which the product is being imported, how the product will be used, where the product will be located, and the approximate length of time and dates the product will be in the country. Entry cannot be released until the Form FDA 766 has been approved by the local FDA District Director. Note: Non-compliant radiation-emitting electronic medical products subject to the EPRC standards (such as medical x-ray, medical laser, and therapy ultrasound) cannot be legally imported and/or distributed and used domestically for IDE or clinical studies because the performance standards already exist for these products. Importer must obtain Temporary Import Bond (TIB)

Example: RC1 (attach form FDA766 and evidence of TIB)

RC2
EPRC Product Declaration <u>C2</u> (FDA 2877)
This affirmation and qualifier should be transmitted when the product does not comply with the applicable performance standard and is being imported for trade shows or demonstrations. The qualifier must list the dates of trade shows. Use restrictions, such as a sign stating that "The product does not comply with FDA performance standards" must be displayed at all times during the display of the products(s). All medical products, cabinet x-ray or Class IIIb and IV lasers may NOT be powered on at trade shows. It is recommended that these devices be disabled in such a way as to not be accidently powered on. Non-compliant signs must be posted on products while at the

show. Form FDA766 is not required. Importer must obtain Temporary Import Bond (TIB).

Example: RC2 Trade show June 2-6, 2012; TIB is attached

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The following RD Codes are used when products *DO NOT COMPLY* with U.S. Federal performance standards but are in the process of being brought into compliance. The products are being held intact in a bonded warehouse and will remain under Temporary Import Bond (TIB); will not be introduced into commerce until notification is received from FDA that the products have been brought into compliance in accordance with an FDA approved petition (Form FDA 766).

A Form FDA 766, a Corrective Action Plan (CAP) and a new product report must be provided to bring these products into compliance. Select the code and qualifier, if appropriate, that best describes the product information being transmitted. A completed Form FDA 766 will be submitted to the FDA district office that has detained the importation. District offices typically confer with CDRH with the review of the Form FDA 766 petitions, the CAP and a new product report, to ensure necessary corrections to the product will be done correctly.

RD1

EPRC Product Declaration D1 (FDA 2877)

This affirmation should be transmitted when products do not comply with the applicable U.S. Federal Performance Standard and an approved petition (Form FDA 766) is provided. Entry must be held intact in bonded warehouse and an approved Form FDA 766 must be provided along with TIB, approved CAP, and a radiation safety product report accepted by CDRH. There is no qualifier.

Example: RD1 (and attach an approved form FDA 766 along with evidence of Temporary Import Bond (TIB))

RD2

EPRC Product Declaration D2 (FDA 2877)

This affirmation should be transmitted when products do not comply with the applicable U.S. Federal Performance Standard and a petition request (Form FDA 766) is provided for approval. Entry must be held intact in bonded warehouse; obtain Form FDA 766, and Temporary Import Bond (TIB). The firm's CAP and radiation safety product report are to be reviewed by Import Office and CDRH. The reconditioning cannot proceed without an approved Form FDA 766.

There is no qualifier.

Example: RD2

A completed Form FDA 766 along with evidence of Temporary Import Bond (TIB) should be submitted with applicable entry documentation at time of entry).

RD3
EPRC Product Declaration D3 (FDA 2877)
This affirmation should be transmitted when products do not comply with the applicable U.S. Federal Performance Standard and a detailed petition (Form FDA 766) will be provided within 60 days for FDA approval. Entry must be held intact in bonded warehouse, and the entry must be placed on Temporary Import Bond (TIB). The importer has 60 days to submit Form FDA 766 and provide the CAP and radiation safety product report (which will be jointly reviewed by the District Office and CDRH).

Example: RD3 "Petition Form FDA 766 will be provided within 60 days; TIB is obtained for the entry."

REG
Drug Registration Number
This affirmation and qualifier is the Drug Registration Number issued by FDA/CDER for the firm manufacturing the product identified in the FDA line. The Federal Food, Drug and Cosmetic Act (FFD&CA) Section 510[21 USC 360] requires most establishments that manufacturer, prepare, propagate, compound, or process a drug or drugs, to register with the FDA. Currently, the establishment registration number is the Dun & Bradstreet number (DUNS).

Example: REG 999999999

RNO
Rail Car Number

SE
Substantially Equivalent (Tobacco)
If not commercially marketed in the U.S. as of Feb. 15 2007, this affirmation should be transmitted to affirm the submission of a substantial equivalence reports to FDA for the tobacco product in the entry line. When this affirmation is transmitted, TST and the qualifier must also be transmitted.

SID
Submission Identifier (SID) Number
This affirmation and qualifier should be the number identifying a specific process filing for a Low Acid (LACF) or Acidified Food (AF) Product filed with FDA for the product identified in the FDA line.

If the product is a LACF, when using the SID code, the FCE code and qualifier, **OR** container dimensions must also be transmitted in the container dimensions field.

If the product is an AF, when using the SID code, the FCE code and qualifier **OR** container dimensions in PG28 (either height and diameter or height/length, width and thickness) **OR** the container volume.

See definitions below. Container size/dimensions must be entered as described in the Transmission of Data portion of this document, below. Please follow your software vendor's instruction for entering this data. The format of the SID data

may be dependent on your vendor's specific software implementation, but, would include the year, month, day and ID of the product.

Example: SID 2011-06-23/005

SIF
Seafood HACCP Importer Firm
This affirmation and required qualifier should be used to identify the responsible U.S. firm as defined by 21 CFR 123.3. The HACCP Importer is defined as either the U.S. owner or the U.S. consignee at the time of entry, responsible for insuring the goods are in compliance with the requirements of the HACCP regulation. The term HACCP "Importer" is not the same as the "Importer of Record" as defined by U.S. Customs regulations. However an Importer of Record may also be the U.S. owner or U.S. consignee. The qualifier required is the FDA Establishment Identifier (FEI) for the HACCP Importer. If not already known, filers can do an ABI query for the firm's FEI for use in transmission of this AofC code.

Example: SIF 003888440551

SFR
Shipper Food Facility Registration Number

SRN
Submitter Food Facility Registration Number

STN
Biologics Submission Tracking Number
This affirmation and the qualifier for this code should be the Submission Tracking Number issued by FDA's Center for Biologics Evaluation and Research for the licensed biological product identified in the FDA line. The Submission Tracking number is the biologics license application (BLA) number. The STN is associated with the manufacturer and a specific product. The first six digits represent the original submission tracking number.

Example: STN 123456

TFR
Transmitter Food Facility Registration Number

TST
Tobacco Submission Tracking Number
This affirmation, with required qualifier should be the submission tracking number issued by FDA's Center for Tobacco Products for the tobacco product identified in the FDA line. The submission tracking number is the Substantially Equivalent (SE), Premarket Tobacco Application (PMT), or Exemption from Substantial Equivalence (EX) number. This affirmation is mandatory if the tobacco product was not commercially marketed in the U.S. as of February 15, 2007.

Example: TST PM1234567
TST EX1234567
TST SE1234567

UFR
Ultimate Consignee Food Facility Registration Number

VAN
Veterinary Abbreviated New Animal Drug Number
This affirmation and qualifier should be the Veterinary Abbreviated New Animal Drug Number (VAN) issued by FDA, Center for Veterinary Medicine (CVM), for the animal drug product identified in the FDA line. This number is the approval number for an abbreviated new animal drug application. Animal drugs have to be shown to be generally safe and effective for each use in each animal species for which they are intended. In addition to the general requirements for efficacy and safety for animal use, animal drugs intended for use in food producing animals must not leave unsafe residues in edible tissues or other food products for human consumption.

This application is used when a sponsor is pursuing approval of a generic drug. It is "abbreviated" because certain requirements of 21 CFR 514 can be met by referencing an approved VNA (Veterinary New Animal Drug Application Number) for which the patent protection or a period of exclusivity has expired.

Example: VAN 299-1234 (six digit number) The qualifier begins with a "2."

VFL
Veterinary Feed Mill License
This affirmation and qualifier should be the Veterinary Medicated Fee Mill License number assigned by FDA/Center for Veterinarian Medicine (CVM) for animal feeds containing new animal drugs. The qualifier is the FDA license number assigned by FDA/CVM.
The FDA application Form FDA 3448 and instructions for filling out the form that can be used by a new licensee can be found at:
http://www.fda.gov/AboutFDA/ReportsManualsForms/Forms/default.htm

Example: VFL 500-000 (six digit number) the qualifier begins with a "5"

VIN
Veterinary Investigational New Animal Drug Number
This affirmation and qualifier should be the Veterinary Investigational New Animal Drug Number issued by FDA/CVM for the product identified in the FDA line. Investigational new animal drugs are animal drugs that may be distributed solely for investigational use by experts qualified by scientific training and experience to investigate the safety and effectiveness of animal drugs for a particular purpose. An unapproved new animal drug (distributed in accordance with 21 CFR Part 511) can be used for research
for the collection of data intended to be submitted in support of an VNA (Veterinary New Animal Drug Application Number) approval; or a generic VIN (Veterinary Investigational New Animal Drug Number).

Example: VIN 12-345

VNA
Veterinary New Animal Drug Application Number
When the sponsors believe that sufficient data have been collected to establish the safety and effectiveness of their drug product, they may apply for approval. A New Animal Drug Application (NADA) is submitted along with supporting data, including all adverse effects associated with the drug's use. The NADA must also include information on the drug's chemistry; composition and component ingredients; manufacturing methods, facilities,
and controls; proposed labeling; analytical methods for residue detection and analysis if applicable; an environmental assessment; and other information.

Example: VNA 123-456 (six digit number)
VNA 1-234 (approval prior to 1990 may have four digits x-xxx)

VOL
LACF/ AF Volume (Low Acid Canned Food / Acidified Food)
This affirmation and qualifier can be used to communicate the container volume and unit of measure of an Acidified Food (AF) or Low-Acid Food product that is packaged in a container that does not have a traditional size/dimension. The filer should verify with the manufacturer whether container size/dimensions or volume were supplied to FDA for the SID identified. The VOL code is acceptable for glass or ceramic containers and semi- rigid container, large steel or plastic drums, pails, fiberboard. (Large industrial sized containers.)

For example, when sending data for pickled peppers packaged in a glass bottle, an Affirmation of Compliance of VOL with a qualifier of 16 oz would be transmitted. Use of the VOL code instead of the Container Size/Dimension, when Container Size/Dimension is part of the schedule process, will result in a failure of the automated data base look-up.