U.S. FOOD & DRUG ADMINISTRATION
OFFICE OF REGULATORY AFFAIRS

FDA Affirmations of Compliance for the Automated Commercial Environment

FDA.GOV

This document outlines the valid Affirmation of Compliance (AofC) codes for entries made in the Automated Commercial Environment. To determine when Affirmations of Compliance must be provided, refer to FDA's 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
CCM	EPRC Certified Component Manufacturer	Y
CFR	FDA Consolidator Food Facility Registration Number	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 Abbreviated New Drug Application No., New Drug Application No., or Therapeutic Biologic Application No.)	Y
DDM	Device Domestic Manufacturer	Y
DEV	Device Foreign Manufacturer Registration Number	Y
DFE	Device Foreign Exporter Registration Number	Y
DI	Device Identifier (part of the Unique Device Identifier , UDI)	Y
DLS	Drug Listing Number (Human and Animal) or National Drug Code (Human and Animal)	Y
ERR	Entry Review Requested	N*
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
FSR	Canadian Foreign Seller Registration Number	Y
FSX	Foreign Supplier Verification Program (FSVP) Exemption	N
GFR	Growers Food Facility Registration Number	Y
HCT	Human Cells & Tissue	N
HPC	Harmful and Potentially Harmful Constituents (Tobacco HPHC)	N
HRN	Biologics Human Cells, Tissues/ Cellular and Tissue-Based Product Establishment Registration Number	Y
IBP	Indian Black Pepper Certificate	Y
IDE	Investigational Device Exemption	Y
IFE	Import for Export	N
IFR	Importers Food Facility Registration Number	Y
ILS	Ingredient Listings Submission-Confirmation (Tobacco)	N
IND	Investigational New Drug Application Number	Y
IRC	Device Impact Resistance Lens Certification	N
JIF	Juice HACCP Importer Firm	Y
KIT	Device Imported Kit of Finished Devices	N

Code	Affirmation	Qualifier Required?
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	National Drug code (Animal Drugs Only)	Y
ORN	Owner Food Facility Registration Number	Y
PFR	Manufacturers Food Facility Registration Number	Y
PKC	Package/Can Code	Y
PLR	Pre Launch Activities Importation Request (PLAIR) Import Shipment	N
PM#	Device Premarket Number	Y
PMT	Premarket Tobacco Application	N
PRN	Pre-Import Request Number	Y
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 (Human and Animal)	Y
RNE	Food for Research and Evaluation	N
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 HACCP 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	Abbreviated New Animal Drug Number (ANADA)	Y
VES	Ocean Vessel Name	Y
VFD	Veterinary Feed Directive	N
VFL	Medicated Feed License (MFL)	Y
VFT	Voyage, Flight, or Trip Number	Y
VIN	Investigational New Animal Drug Number (INAD) and JINDA	Y
VNA	New Animal Drug Application Number (NADA)	Y
VOL	LACF/AF Volume	Y
VQI	Voluntary Qualified Importer Program (VQIP) Number	Y

COMMON FDA ACRONYMS/ABBREVIATIONS:

- **CBER:** Center for Biologics Evaluation and Research
- **CDER:** Center for Drug Evaluation and Research
- **CDRH:** Center for Devices and Radiological Health
- **CFSAN:** Center for Food Safety and Applied Nutrition
- **CTP:** Center for Tobacco Products
- **CVM:** Center for Veterinary Medicine
- **FFD&C Act:** Federal Food, Drug, and Cosmetic Act

DEFINITIONS OF AFFRIMATIONS OF COMPLIANCE:

ACC

EPRC Accession Number

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

Example: ACC 1210000
ACC 12C4567-901

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 594799
AIN 10192713
AIN E1234567

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 FDA/CDRH for the product identified in the FDA line.

Example: ANC 123xxxx (no more than two years old)
ANC 12C4567-901

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/CBER 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

This affirmation and qualifier are used to identify the carrier name for freight shipped by air.

Example: CAN Air China Cargo
CAN Air Jamaica

CCC

Chinese Ceramicware Factory Code

This affirmation and qualifier should be used to indicate that shipments of ceramicware are produced by a manufacturer certified as part of an 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

CCM

EPRC Certified Component Manufacturer

This affirmation and qualifier may be used to provide the name of the Certified Component Manufacturer. In the diagnostic x-ray systems and their major components performance standard, manufacturers of major components are required to certify such components, which can be assembled by others into finished x-ray systems. In cases where the certifying component manufacturer is different from the manufacturer who is shipping the entire system to the U.S., this affirmation and qualifier may be used to provide additional identifying information about that component manufacturer.

Example: CCM ABC Electronics Company

CFR

FDA Consolidator Registration Number

This affirmation and qualifier may be transmitted for the consolidator of a food shipment.

Example: CFR 12345678901

CIN
Color Index Number
This affirmation and qualifier are 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/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: COS 1061499
COS 1234567890

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. There is no qualifier for this code.

Example: CMT (there is no qualifier)

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.

Example: CPT (there is no qualifier)

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 or FDA/CDER for the drug product identified in the FDA line. Once approved, an applicant may manufacture and market the generic drug product.

For eligible prescription drugs offered for import under section 804 of the Federal Food, Drug, and Cosmetic Act, the affirmation and qualifier should be the New Drug or Abbreviated New Drug Application Number for the corresponding FDA-approved drug.

The qualifier is 6N (numeric) for drugs, and 8AN (alphanumeric) for biologics. If less than six digits, preceding zeros may be used to make six digits.

Examples: 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. This affirmation and qualifier should be the device registration number or (owner operator number if registration number is not yet assigned) 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 domestic firm registration number 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 if registration number is not yet assigned) issued by FDA/CDRH for the foreign firm manufacturing the product identified in the FDA line.

(**Note**: Should always be the foreign firm registration 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 if registration number not yet assigned) 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 (part of the Unique Device Identifier, UDI)

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

Example: DI 123456

DLS

Drug Listing Number (used for DLS and NDC for human drugs)

This affirmation and qualifier should be the Drug Listing Number (DLS), for a bulk API, or National Drug Code (NDC), for finished drugs, issued by FDA for the drug product identified in the FDA line. All foreign drug establishments shall comply with the drug listing requirements.

For eligible prescription drugs offered for import under section 804 of the Federal Food, Drug, and Cosmetic Act, this affirmation and qualifier is the NDC that the Importer will use when relabeling the drug product.

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.

Example: DLS 4444333221

ERR
Entry Review Requested

This affirmation 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". When this code is used, the specific reason the code is being transmitted will be entered in PG24, Remarks. There is no qualifier for this code.

Example: ERR *(there is no qualifier) and explain reason in the Remarks Field (PG24) i.e. “damaged in shipment”

EXE
Exemption from Substantial Equivalence (tobacco)

If not commercially marketed in the U.S. as of Feb. 15, 2007, this affirmation should be transmitted to affirm FDA has granted the tobacco product in the entry line an exemption from demonstrating substantial equivalence. When this affirmation is transmitted, TST and its qualifier must also be transmitted. There is no qualifier for this code.

Example: EXE (there is no qualifier)

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 79 061 01
FCC 12 456 890

FCE

Food Canning Establishment Number

This affirmation and qualifier will be the Food Canning Establishment Number (FCE) that identifies a manufacturer of acidified and/or low-acid canned food products. The qualifier will 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. See the SID and VOL Affirmation Code definitions 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

FSR

Canadian Foreign Seller Registration Number

This affirmation's qualifier is the drug registration number for the Canadian Foreign Seller registrant of eligible prescription drugs offered for imported under section 804 of the Federal Food, Drug, and Cosmetic Act. The FFD&C Act requires most establishments that manufacturer, prepare, propagate, compound, or process a drug or drugs, to register with the FDA. Currently, the drug establishment registration number is the Dun & Bradstreet number (DUNS) issued by FDA/CDER.

Example: FSR 123456789

FSX

Foreign Supplier Verification Program (FSVP) Exemption

This affirmation should be transmitted if the human or animal food offered for import is exempt from the Foreign Supplier Verification Program (FSVP) regulation requirements or if a later FSVP compliance date applies to the importer, the food, or the foreign supplier. Exemptions from the FSVP requirements include juice and fish and fishery products and ingredients for such products subject to HACCP regulations, food imported for personal consumption, alcoholic beverages, alcoholic beverage ingredients and certain non-alcohol foods, food that is transshipped through the United States, food imported for processing and export, and U.S. food returned.

Example: FSX (there is no qualifier)

GFR

Grower Food Facility Registration Number

This affirmation and qualifier may be transmitted for the grower of a food shipment.

Example: GFR 12345678901

HCT

Human Cells & Tissue. Now HCT=HCT/P Compliant

This affirmation should be used to indicate the HCT/P being imported or offered for import is in compliance with all applicable requirements of 21 CFR 1271. There is no qualifier for this code.

Example: HCT (there is no qualifier)

HPC

Harmful and Potentially Harmful Constituents (HPHC) (Tobacco)

This affirmation should be transmitted to affirm the Harmful and Potentially Harmful Constituents (HPHC) Report for the tobacco product in the FDA entry line was previously submitted to FDA. There is no qualifier for this code.

Example: HPC (there is no qualifier)

HRN

Biologics Human Cells, Tissues/ Cellular and Tissue-Based Product Establishment Registration Number. Now HRN=HCT/P Registration Number

This affirmation and qualifier are used if the establishment is registered with the FDA. The required qualifier should be the HCT/P establishment registration number issued by FDA/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 list of every HCT/P manufactured (21 CFR1271.21), 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

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 Investigational Device Exemption (CBER)

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 FDA/CBER IDE's is from 0-79,999.

Examples: IDE 1234
IDE 79999

IDE

Investigational Device Exemption Number (CDRH)

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. The qualifier will start with the letter "G".

For devices destined for non-significant risk study (NSR), an Institutional Review Boards (IRB) letter affirming NSR must be provided to FDA. In such case, NSR is a qualifier to the AofC IDE.

Example: IDE G089911
Or IDE NSR

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 FFD&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 FDA/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 FFD&C Act or 351(h) of the PHS Act. This affirmation cannot 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.

Example: IFE (there is no qualifier)

IFR

Importers Food Facility Registration Number

This affirmation and qualifier may be transmitted for the importer of a food.

Example: IFR 12345678901

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. There is no qualifier for this code.

Example: ILS (there is no qualifier)

IND

Investigational New Drug Application Number

This affirmation and qualifier should be the Investigational New Drug Application Number issued by FDA/CBER or FDA/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 lenses. There is no qualifier for this code.

Note: FDA has the authority to ask for copies of the actual test results. Each batch within the shipment must have its own test results.

Example: IRC (there is no qualifier)

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 1234567
JIF 3888440551

KIT

Imported Kit of Finished Device

This affirmation should be used for all kits and individual devices within kits imported into the US. 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 FFD&C Act 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). Domestically manufactured devices that are a part of a medical device convenience kit will require AofC: DDM, DFE, KIT, and LST. Foreign manufactured devices that are part of a medical device convenience kit will require AofC: DEV, DFE, KIT, and LST.

Importers of medical device kits who transmit only the kit (510(k) cleared kits) as a single line should continue to use the Affirmations of Compliance codes DEV, DFE, LST, and PMN# applicable for the medical device kit.

There is no qualifier for this code.

Example: KIT (there is no qualifier)

LFR

Location of Goods Food Facility Registration Number

This affirmation and qualifier may be transmitted for the facility holding a food shipment (location of goods).

Example: TFR 12345678901

LST
Device Listing Number
This affirmation and the qualifier for this code should be the device listing number issued by FDA/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. There is no qualifier for this code.

Example: LWC (there is no qualifier)

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's qualifier is the National Drug Code (NDC) listed with FDA. Each listed animal drug associated with a registration must include an animal drug unique identifier. Currently FDA uses the NDC numbering system to assign a drug listing number to each drug or class of drugs listed. An NDC is a unique 10-digit, three segment identifier that identifies the labeler, product (drug formulation), and trade package. Declare without dashes.

Example: NDC 4444333222

ORN
Owners Food Facility Registration Number
This affirmation and qualifier may be transmitted for the owner of a food shipment.

Example: ORN 12345678901

PFR
Manufacturers Food Facility Registration Number
This affirmation's qualifier is the Manufacturers Food Facility Registration Number. It is required unless a consolidator or grower role code is submitted for food in its natural state *OR* FME and reason code are submitted.

Example: PFR 12345678901

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

The qualifier will start with: P, N, D, H, K, DEN, BD, BP, BK, BH, BM, BR, or DK.

Example:	PM#	BP123456	Premarket Approval
	PM#	BK123456	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. This is a text field. The format is manufacturer specific.

Example: DEC 2215M2 21:06

PLR
Pre Launch Activities Importation Request (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. There is no qualifier for this code.

Example: PLR (there is no qualifier)

PMT

Premarket Tobacco Application

If not commercially marketed in the U.S. as of Feb. 15 2007, this affirmation should be transmitted to affirm FDA issued an order permitting marketing of the new tobacco product. When this affirmation is transmitted, TST and the qualifier must also be transmitted. There is no qualifier for this code.

Example: PMT (there is no qualifier)

PRN

Pre-Import Request number

This affirmation and qualifier should be the Pre-Importation Request number assigned by FDA for eligible prescription drug products offered for import under section 804 of the Federal Food, Drug, and Cosmetic Act.

Example: PRN 123456

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:

Importing into the US:
https://www.fda.gov/medical-devices/importing-and-exporting-devices/importing-us

Importing and Exporting Electronic Products:
https://www.fda.gov/radiation-emitting-products/getting-radiation-emitting-product-market/importing-and-exporting-electronic-products

The Form FDA 2877 can downloaded from the following link:
https://www.fda.gov/media/72236/download

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 are 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 FDA/CDRH.

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 (https://www.fda.gov/radiation-emitting-products/getting-radiation-emitting-product-market/products-subject-performance-standards). 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 (there is no qualifier)

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 (there is no qualifier)

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 (there is no qualifier)

“Importation of Radiation-Emitting Electronic Products for and Evaluation During Design Development” https://www.fda.gov/radiation-emitting-products/importing-and-exporting-electronic-products/form-fda-2877-guidance-imports-prototypes-affirmation-a6-may-14-1997

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”

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 (no 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 (there is no qualifier) **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.

The following RC Codes are used when products *DO NOT COMPLY* with performance standards and are expected to be either destroyed or exported; 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 C1 (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). There is no qualifier for this code.

Example: RC1 (there is no qualifier) (attach form FDA766 and evidence of TIB)

RC2

EPRC Product Declaration C2 (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 product(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

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 FDA/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 FDA/CDRH. There is no qualifier for this code.

Example: RD1 (there is no qualifier)
(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 District Office and FDA/CDRH. The reconditioning cannot proceed without an approved Form FDA 766.

Example: RD2 (there is no qualifier)

(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 FDA/CDRH).

Example: RD3 03/30/2016 "Petition Form FDA 766 will be provided within 60 days; TIB is obtained for the entry."

REG

Drug (Firm) Registration Number (Human/Animal/Biologics)

This affirmation's qualifier is the Drug Registration Number of the firm manufacturing the product identified in the FDA line. The Drug Registration Number is a unique facility identifier (UFI) submitted by a registrant to FDA/CDER, FDA/CVM or FDA/CBER. The FFD&C Act requires most establishments that manufacturer, prepare, propagate, compound, or process a drug or drugs, to register with the FDA. Currently, the preferred UFI System for a drug registration number for FDA/CDER and FDA/CVM is the DUNS number assigned and managed by Dun & Bradstreet. The drug establishment registration number can be the FEI or DUNS for FDA/CBER.

Example: REG 999999999
REG 1234

RNE

Food for Research or Evaluation

This affirmation should be transmitted if the human or animal food offered for import is exempt from the Foreign Supplier Verification Program (FSVP) regulation requirements because the food is intended to be used for research or evaluation. This exemption applies if the food is not intended for retail sale and is not sold or distributed to the public; the food is labeled with the statement, "Food for research or evaluation use"; and the food is imported in a small quantity that is consistent with a research, analysis, or quality assurance purpose, the food is used only for this purpose, and any unused quantity is properly disposed of.

Example: RNE (there is no qualifier)

RNO

Rail Car Number

This affirmation and qualifier are used to identify the car number for freight shipped by rail. If the Rail Car Number is not available, enter "Does Not Exist".

Example: RNO CP388686
RNO Does Not Exist

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 its qualifier must also be transmitted. There is no qualifier for this code.

Example: SE (there is no qualifier)

SFR

Shippers Food Facility Registration Number

This affirmation and qualifier may be transmitted for a food shipper.

Example: SFR 12345678912

SID

Submission Identifier (SID) Number

This affirmation and qualifier will be the number identifying a specific process filing for a Low-Acid Canned Food (LACF) or Acidified Food (AF) product filed with FDA for the product identified in the FDA line. See the FCE and VOL Affirmation Code definitions.

Example: SID 20110623005

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.

Example: SIF 3888440551

SRN

Submitter Food Facility Registration Number

This affirmation and qualifier may be transmitted for the Prior Notice Submitter of a food shipment.

Example: SRN 12345678901

STN

Biologics Submission Tracking Number

This affirmation and the qualifier for this code should be the Submission Tracking Number issued by FDA/CBER 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

This affirmation and qualifier may be transmitted for the Prior Notice Transmitter of a food shipment.

Example: TFR 12345678901

TST
Tobacco Submission Tracking Number
This affirmation, with required qualifier, should be the submission tracking number issued by FDA/CTP 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
This affirmation and qualifier may be transmitted for the ultimate consignee of a food shipment.

Example: UFR 12345678901

VAN
Abbreviated New Animal Drug Number (ANADA)
This affirmation and qualifier should be the Abbreviated New Animal Drug Number (ANADA) issued by FDA/CVM, for the animal drug product identified in the FDA line. This number is the approval number for an abbreviated new animal drug application. This number is always a 6 digit number listed as “200XXX”. The 200 number series indicates the product is a generic new animal drug.

Example: VAN 200123

VES
Ocean Vessel Name
This affirmation and qualifier will be the name of the vessel when the mode of transportation is ocean.

Example: VES Evergreen Teresa

VFD

Veterinary Feed Directive

This affirmation should be transmitted as confirmation to FDA/CVM that a Veterinary Feed Directive (VFD) notification has been submitted by the distributor of the product identified in the FDA line. VFD drugs are new animal drugs intended for use in or on animal feed, which are limited by an approved new animal drug application (NADA), conditionally approved NADA, or index listing to use under the professional supervision of a licensed veterinarian. Feeding of an animal with feed bearing or containing a VFD drug (VFD) must be authorized by a lawful VFD issued by a licensed veterinarian (21 CFR 558.6(a)(a)).

Example: VFD (there is no qualifier)

VFL

Medicated Feed Mill License (MFL)

This affirmation's qualifier should be the Medicated Feed Mill License number assigned by FDA/CVM for the manufacturer of the product identified in the FDA line. An approved medicated feed mill license, Form FDA 3448, is required for facilities that manufacture feed using Category II, Type A medicated articles; liquid and free-choice medicated feed containing a Category II drug; or liquid and free-choice medicated feed containing a Category 1 drug that follow an approved proprietary formula and/or specifications. 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: https://www.fda.gov/about-fda/reports-manuals-forms/forms.

Example: VFL 1234567

VFT

Voyage, Trip, Flight Number

This affirmation and qualifier will be the voyage number, trip number or flight number when the mode of transportation is ocean, truck, rail or air. If the trip number is not available, enter "Does Not Exist".

Example: VFT 1419E
VFT Does Not Exist

VIN

Investigational New Animal Drug Number (INAD) and Generic Investigational New Animal Drug Number (JINAD)

This affirmation and qualifier should be the Investigational New Animal Drug Number or Generic Investigational New Animal Drug Number issued by FDA/CVM for the product identified in the FDA line. This qualifier is a six (6) digit number.

Example: VIN 123456

VNA

New Animal Drug Application Number (NADA)

This affirmation and qualifier should be the New Animal Drug Application (NADA) issued by FDA/CVM for the product identified in the FDA line. The NADA number is a 6-digit number. This also includes conditionally approved new animal drugs, type A medicated articles and Minor Species Index File Numbers. Note: for drugs originally approved roughly prior to 1990 the number may be represented as having less than 6 digits but never less than 4.

Example: VNA 123456
VNA 1234 (approval prior to 1990 may have four digits x-xxx)

VOL

LACF/ AF Volume (Low Acid Canned Food / Acidified Food)

This affirmation and qualifier may 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 importer whether the container size/dimensions or volume were supplied to FDA by the manufacturer. Use of the VOL code instead of the Container Size/Dimension, when Container Size/Dimension is part of the scheduled process, will result in a failure of the automated data base look-up.

Example: VOL 64

VQI

Voluntary Qualified Importer Program Number

This affirmation and qualifier may be used to provide the Program Number of the Voluntary Qualified Importer. The number is provided to the Voluntary Qualified Importer after acceptance into the program and successful payment of the VQIP User Fee. This affirmation and qualifier should only be used for those lines of an entry containing foods that are included in an approved VQIP application (VQIP foods). Additional information about the program including information on the use of this affirmation and qualifier is outlined in the Voluntary Qualified Importer Program Guidance for Industry.

Example: VQI 12345