



Memorandum

Date May 9, 2013
From CAPT Domenic Veneziano, Director, Division of Import Operations
Subject Updated: FDA Affirmation of Compliance (AofC) Codes
To U.S. Import Trade Community

One of the functions of the FDA - ACS Interface is the automated screening of FDA regulated import entries to determine which entries to "MAY PROCEED" without FDA examination and which entries require further "FDA REVIEW." Affirmation of Compliance (AofC) codes, transmitted at the FDA line level, is one data element used in this screening process.

By using an AofC code, the filer affirms the firm or product identified in a FDA line meets requirements specific to each code. While submission of this information is voluntary, transmission of the data may expedite initial screening and further review of an entry. The manufacturer or shipper should be able to indicate when these affirmations should be used and supply the qualifier information when required.

Use of these codes does not guarantee a May Proceed, as the FDA line, or other FDA lines in the entry, may be subject to routine surveillance or may fall under other screening criteria resulting in a directed exam or a detention without physical examination.

Several new AofC codes have been added since the last issuance (3/2000) of this document. There have also been changes to existing codes and some codes have been end-dated. These changes and additions are noted below.

See additional information about these new codes in the description portion of this document.

The following is an index of all current AofC Codes with their title and a Yes/No column to indicate whether a qualifier is required.

After the index table you will find descriptions of each AofC arranged by code. An example of the code and qualifier (if applicable) is included in the description.

Following the codes is information on the transmission of the data to use with these codes. Additional FDA resources and guidance can be found in the last section of this document.

Please send questions/comments to: FDASImportsInquiry@fda.hhs.gov

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**Current Changes/Additions since Last Publication
of this Document (March 28, 2000)**

| New Code | Description | Qualifier Required? | Reference CSMS ABI message |
|------------------|--|---------------------|-------------------------------------|
| HCT | Biologics Human Cells, Tissues/ Cellular and Tissue-Based Products | N | 06-000042 06-000088 |
| HRN | Biologics Human Cells, Tissues/ Cellular and Tissue-Based Product Establishment Registration Number | Y | 06-000042 06-000088 |
| BLN | Biologics License Number | Y | 08-000019 11-000258 |
| STN | Biologics Submission Tracking Number | Y | 08-000019 11-000258 |
| CPT | Device Component | N | 09-000324 |
| DDM | Device Domestic Manufacturer | Y | 11-000315 |
| DFE | Device Foreign Exporter Registration Number | Y | 09-000324 |
| KIT | Device Imported Kit of Finished Device | N | 11-000315 |
| DII | Device Initial Importer Registration | Y | 09-000324 |
| ANC | EPRC Radiation Products Annual Report Accession Number | Y | 09-000324 |
| RA1,RA2, RA5,RA7 | EPRC Radiation products–use if FDA compliance is non-applicable, see Form FDA 2877 | Y | 09-000324 |
| RA3,RA4, RA6 | EPRC Radiation products–use if FDA compliance is non-applicable, see Form FDA 2877 | N | 09-000324 |
| RB1 | EPRC Radiation products-use if product is FDA compliant, see Form FDA 2877 (no qualifier but must transmit with ANC or ACC) | N | 13-000171 |
| RB2 | EPRC Radiation products-use if product is FDA compliant, see Form FDA 2877 | Y | 09-000324 |
| RC1 | EPRC Radiation products-use if product is FDA non-compliant, see Form FDA 2877 | N | 09-000324 |
| RC2 | EPRC Radiation products-use if product is FDA non-compliant, see Form FDA 2877 | Y | 09-000324 |
| 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 | 09-000324 |
| 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 | 09-000324 |
| RF1 thru RF5 | Food that was Refused Entry by Another Country (FSMA Requirement) | Y | 11-000182 |
| VOL | LACF/AF Volume | Y | 11-000259 |
| PND | Prior Notice Disclaim | N | 04-001240 04-001779 04-002171 |
| VAN | Veterinary Abbreviated New Animal Drug Number (ANADA) | Y | 13-000207 |
| VFL | Veterinary Medicated Feed License (MFL) | Y | 13-000207 |
| VIN | Veterinary Investigational New Animal Drug Number (INAD) | Y | 13-000207 |
| VMS | Veterinary Minor Species Index File (MSIF) | Y | 13-000207 |
| VNA | Veterinary New Animal Drug Application Number (NADA) | Y | 13-000207 |

Changes:

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- Titles of some of the AofCs have been changed to reflect the commodity where the AofC should be used. This should make it easier for the import trade community to see which AofC should be used with which commodity.
- In some cases, the same AofC code may be used with multiple commodities but have qualifiers with different prefixes or lengths. These have been noted in the description of the AofC.

Certain AofCs have been End-Dated/Deleted and should no longer be used:

| Code | Description | End Date | Reference CSMS ABI message |
|-------------|---|-----------------|-----------------------------------|
| BFL | Biologic Establishment License Number | 2/27/2008 | 08-000019 11-000258 |
| BPL | Biologic Product Number | 2/27/2008 | 08-000019 11-000258 |
| ANA | Abbreviated New Animal Drug Number (ANADA) | 6/1/2013 | 13-000207 |
| CFR | Code of Federal Regulations Section | 6/1/2013 | 13-000207 |
| DHC | Dioxin Health Certificate | 6/1/2013 | 13-000207 |
| INA | Investigational New Animal Drug Number (INAD) | 6/1/2013 | 13-000207 |
| LF1 | Low Value-Food/Food Related Products <= \$200 | 6/1/2013 | 13-000207 |
| LF2 | Low Value-Food/Food Related Products >\$200 but <=\$500 | 6/1/2013 | 13-000207 |
| LF3 | Low Value-Food/Food Related Products >\$500 but <=\$1000 | 6/1/2013 | 13-000207 |
| LR1 | Low Value-Non Rx Rad. Emitting Products <= \$200 | 6/1/2013 | 13-000207 |
| LR2 | Low Value-Non Rx Rad. Emitting Products >\$200 but <=\$1000 | 6/1/2013 | 13-000207 |
| MFA | Medicated Feed Application Number | 6/1/2013 | 13-000207 |
| NAD | New Animal Drug Application Number (NADA) | 6/1/2013 | 13-000207 |
| PAC | Private Analytical Certificate Date | 6/1/2013 | 13-000207 |

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Following is an index of all current AofC Codes with their title and a Yes or No (Y or N) code to indicate whether a qualifier is required.

| Code | Affirmation of Compliance Complete List (Arranged by Title) | Qualifier Required? |
|----------------------|---|------------------------|
| AND | Biologics Abbreviated New Drug Application Number | Y |
| PMA | Biologics Device Premarket Approval Number | Y |
| HCT | Biologics Human Cells, Tissues/ Cellular and Tissue-Based Products | N |
| HRN | Biologics Human Cells, Tissues/ Cellular and Tissue-Based Product Establishment Registration Number | Y |
| IND | Biologics Investigation New Drug Application Number | Y |
| IDE | Biologics Investigational Device Exemption | Y |
| BLN | Biologics License Number | Y |
| NDA | Biologics New Drug Application | Y |
| PMN | Biologics Pre-Market Notification Number (510(k)) | Y |
| STN | Biologics Submission Tracking Number | Y |
| CCC | Chinese Ceramic Ware Factory Code | Y |
| CIN | Color Index Number | Y |
| COS | Cosmetic Registration Number | Y |
| CPT | Device Component | N |
| DDM | Device Domestic Manufacturer | Y |
| LWC | Device Electrode Lead Wire or Patient Cable | N |
| DFE | Device Foreign Exporter Registration Number | Y |
| DEV | Device Foreign Manufacturer Registration Number | Y |
| IRC | Device Impact Resistance Lens Certification | N |
| KIT | Device Imported Kit of Finished Device | N |
| DII | Device Initial Importer Registration | Y |
| IDE | Device Investigational Exemption Number | Y |
| LST | Device Listing Number | Y |
| MDL | Device Model Number | Y |
| PMA | Device Premarket Approval Number | Y |
| PMN | Device Premarket Notification Number (510K) | Y |
| AND | Drug Abbreviated New Drug Application Number | Y |
| IND | Drug Investigational New Application Number | Y |
| DLS | Drug Listing Number | Y |
| NDA | Drug New Drug Application Number | Y |
| NDC | Drug National Drug code | Y |
| REG | Drug Registration Number | Y |
| ERR | Entry Review Recommended | Y |
| ACC | EPRC (Electronic Product Radiation Control) Accession Number | Y |
| ANC | EPRC Radiation Products Annual Report Accession Number | Y |
| MDL | EPRC Radiation Products Model Number | Y |
| *RA1,RA2, RA5,RA7 | EPRC Radiation products–use if FDA compliance is non-applicable, see Form FDA 2877 | Y |
| *RA3,RA4, RA6 | EPRC Radiation products–use if FDA compliance is non-applicable, see Form FDA 2877 | N |
| RB1 | EPRC Radiation 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 Radiation products-use if product is FDA non-compliant, see Form FDA 2877 | Y |

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| | | |
|-----------|---|---|
| *RD1,RD2 | EPRC Radiation products-use if product is non-compliant but will be re-conditioned under bond and Form FDA 766, see Form FDA 2877 | N |
| *RD3 | EPRC Radiation products-use if product is non-compliant but will be re-conditioned under bond and Form FDA 766, see Form FDA 2877 | Y |
| AIN | Food Additive Identification Number | Y |
| FAP | Food Additive Petition Approval Number | Y |
| FCC | French Cheese Facility Certification No | Y |
| IFE | Import for Export | N |
| IBP | Indian Black Pepper Certificate | N |
| FCE | LACF/AF Food Canning Establishment Number | Y |
| SID | LACF/AF Schedule Identifier Number | Y |
| VOL | LACF/AF Volume | Y |
| | LACF/AF Container Dimensions (see "Transmission of Data Guidance" section) | |
| PND | Prior Notice Disclaim | N |
| RF1 – RF5 | Foods that were Refused Entry by Another Country (FSMA Requirement) | Y |
| SIF | Seafood HACCP Importer Firm | Y |
| UFC | Unacceptable to Foreign Country (Products Other than Food) | Y |
| VAN | Veterinary Abbreviated New Animal Drug Number (ANADA) | Y |
| VFL | Veterinary Feed Mill License (FML) | Y |
| VIN | Veterinary Investigational New Animal Drug Number (INAD) | Y |
| VMS | Veterinary Minor Species Index File (MSIF) | Y |
| VNA | Veterinary New Animal Drug Application Number (NADA) | Y |

*Version 2. Date: 5/30/2013 - RAD Health Codes "Qualifier Required" notation corrected

AFFIRMATION OF COMPLIANCE CODES
Definitions and Examples of Qualifiers

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 CAS number is issued by Chemical Abstract Services. Another possible qualifier could be the FEMA (Food Extract Manufacturing Association) number used to identify flavor extracts used as food additives. 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 59-47-9
AIN 10192-71-3

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)

AND

Biologics (CBER) Abbreviated New Drug Application Number

This affirmation and qualifier should be the Abbreviated New Drug Application Number (AND) issued by FDA/CBER for the generic human drug product identified in the FDA line. This number is the approval number in response to an abbreviated new drug application by FDA/CBER and it begins with 'BA' followed by numbers.

Example: AND BA1234
AND BA12345

AND

Drugs (CDER) Abbreviated New Drug Application Number

This affirmation and qualifier is the Abbreviated New Drug Application Number (ANDA) issued by FDA, Center for Drug Evaluation and Research (CDER), for the generic human

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drug product identified in the FDA line. This number is the approval number in response to an abbreviated new drug application. The ANDA contains data that, when submitted to FDA's CDER, provides for the review and ultimate approval of a generic drug product. Generic drug applications are called "abbreviated" because they are generally not required to include preclinical (animal) and clinical (human) data to establish safety and effectiveness. Instead, a generic applicant must scientifically demonstrate that its product is bioequivalent (i.e., performs in the same manner as the innovator drug). Once approved, an applicant may manufacture and market the generic drug product. The qualifier is six digits. If less than six digits, preceding zeros may be used to make six digits.

Example: AND 004444

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

CCC

Chinese Ceramic Ware 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

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

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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: F1061499

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.

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)

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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

DII

Device Initial Importer Registration Number

This affirmation and the qualifier for this code should be the device registration number issued by FDA/CDRH for the importer who takes first title to devices imported into the U.S.

Examples: DII 3003999999
DII 1022365

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, three-segment number. The first segment of numbers is the labeler code. This number identifies the manufacturer of the product. The second segment of numbers identifies the specific ingredient/strength/formulation manufactured by the firm. The last segment of numbers identifies a specific package code. The DLS affirmation is *not* used for finished drug products.

Examples: DLS 4444-333-22
DLS 4444-4444-22
DLS 55555-333-22
DLS 55555-4444-1

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 "Hold Line" on screening and eliminate the need to return a shipment for FDA sampling.

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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

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

HCT

Human Cells, Tissues and Cellular and Tissue-based Products. 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. No qualifier is required.

Example: HCT (No qualifier)

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 list 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

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

Device (CDRH) 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".

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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 PHS Act 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 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. However, **QUANTITY AND VALUE MUST BE TRANSMITTED** when using this AofC.

IND

Biologics (CBER) Investigational New Drug Application Number

This affirmation and qualifier should be the Investigational New Drug Application Number issued by FDA/CBER 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. With a few exceptions, the range for CBER IND's is from 0-79,999.

Example: IND 000123
IND 079999

IND

Drugs (CDER) Investigational New Drug Number

This affirmation and qualifier is the Investigational New Drug Number (IND) issued by FDA/CDER for the product identified in the FDA entry 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 FD&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

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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.

KIT

Device -Imported Kit of Finished Device

This affirmation should be used for all individual devices within kits imported in the US. There is no qualifier.

Additionally, 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.

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

NDA

Biologics (CBER) New Drug Application

This affirmation and qualifier is the New Drug Application Number issued by FDA, CBER for the product identified in the FDA line. A drug may be "new" if (1) it contains a newly developed chemical; (2) it contains a chemical or substance not previously used in medicine; (3) the drug has previously been used in medicine but not in the dosages or conditions for which the sponsor now recommends its use; or (4) the drug has become recognized by qualified experts as safe and effective for its intended uses as a result of investigational studies but has not otherwise been used to a material extent or for a material time. A new drug cannot be commercially marketed in the U.S. unless it has been approved as safe and effective by the FDA based on a New Drug Application. The qualifier required is the NDA number assigned to the product by FDA, CBER, and it begins with 'BN' followed by numbers.

Examples: NDA BN001234
NDA BN12345

NDA

Drugs (CDER) New Drug Application Number

This affirmation and qualifier is the New Drug Application Number issued by FDA/CDER for the product identified in the FDA line. A drug may be "new" if (1) it contains a newly developed chemical; (2) it contains a chemical or substance not previously used in medicine; (3) the drug has previously been used in medicine but not in the dosages or conditions for which the sponsor now recommends its use; or (4) the drug has become recognized by qualified experts as safe and effective for its intended uses as

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a result of investigational studies but has not otherwise been used to a material extent or for a material time. A new drug can not be commercially marketed in the U.S. unless it has been approved as safe and effective by the FDA based on a New Drug Application. The qualifier required is the NDA number assigned to the product by FDA. If less than six (6) digits are given, then zeros precede the number to make 6 digits in total.

Example: NDA 055555

NDC

National Drug Code

This affirmation and qualifier is the National Drug Code listed with FDA/CDER for the finished dosage form drug product identified in the FDA line. The NDC Directory contains ONLY information on final marketed drugs submitted to FDA in electronic listing files by labelers. (A labeler may be either a manufacturer, including a firm that is performing repackaging or relabeling, or, for drugs subject to private labeling arrangements, the entity under whose own label or trade name the product will be distributed). Inclusion of information in the NDC Directory does not indicate that FDA has verified the information provided. Assignment of an NDC number does not denote FDA approval of the product. Any representation that creates an impression of official approval because of possession of an NDC number is misleading and constitutes misbranding (21 CFR 207.39). The qualifier required is the NDC number assigned to the product by FDA/CDER.

Example: NDC 4444-333-22
NDC 4444-4444-22
NDC 55555-333-22
NDC 55555-4444-1

PMA

Biologics (CBER) Device Premarket Approval Number

The affirmation and qualifier should be the Biologics Device Pre-Market Approval Number issued by FDA/ CBER for the product identified in the FDA line. Premarket approval can be required of devices if general controls are not sufficient to ensure safety and effectiveness and there is not enough information to establish a performance standard. The prefix for the required qualifier is always "BP".

Example: PMA BP123456

PMA

Device (CDRH) Premarket Approval Number

This affirmation and the qualifier for this code should be the device Premarket Approval (PMA) number, Product Development Protocols (PDP) number or Humanitarian Device Exemption (HDE) number issued by CDRH for the product identified in the FDA line. A PMA number begins with the letter 'P', a PDP number begins with the letter 'D', and a HDE begins with the letter 'H'. A PMA number beginning with the letter 'N' is a grandfathered number; no new PMAs are assigned with this prefix.

Example: PMA P979999 Premarket Approval

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| | | |
|-----|---------|-------------------------------|
| PMA | D970000 | Product Development Protocols |
| PMA | H970000 | Humanitarian Device Exemption |
| PMA | N000000 | Valid Grandfathered Prefix |

(**Note:** The PMA number should always be the number that is on the listing record)

(**Note:** PDP and HDP are *not* separate Affirmations of Compliance codes. The prefix of the qualifier (P, D, H, and N) identifies the approval type.)

PMN

Biologics (CBER) Pre-Market Notification Number (510(k))

This affirmation and qualifier should be the Device Pre-Market Notification Number or 510(k) number issued by FDA/CBER for the product identified in the FDA Line. The foreign manufacturer has the primary responsibility, but can delegate to an initial distributor. A manufacturer must submit a pre-market notification when introducing a new device to the market, a device new to a particular manufacturer even though a similar device may already be marketed by another manufacturer, a device which is a modification of an existing product if the modification has significant impact on the safety and effectiveness of the device, or an existing device with a major change in intended use. The required qualifier is a FDA/CBER number that begins with 'BK' followed by numbers.

Examples: PMN BK1234
PMN BK12345

PMN

Device (CDRH) Premarket Notification Number (510k)

The qualifier for this code should be the device premarket notification (510(k)) number issued by CDRH for the product identified in the FDA line.

Example: PMN K979009
(PMN number should always be the number that is on the listing record)

PND

Prior Notice Disclaim

This affirmation is used when the tariff code is flagged as FD3 but the product is not subject to Prior Notice. The PND code is used to indicate that the product is not subject to Prior Notice, otherwise the system would expect to see PN data. Use of PND doesn't preclude the use of other AofC codes like IND.

Example: PND (there is no qualifier)

– 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 be 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.

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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.

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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.

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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”

=====

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.

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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)

Example: RC1 (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 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 accidentally 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).

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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).

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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. A firm Registration Number is presented to the establishment upon registering with FDA/CDER. Currently, the establishment registration number is the Dunn and Bradstreet number (DUNS).

Example: REG 999999999

RF1 – RF5

Imported Foods Refused Entry by Another Country (FSMA Section 304 Requirement)

These affirmation codes and qualifiers should be used to report the name(s) of up to five (5) countries or areas where the article of food, including food for animals, has been refused entry. This information is required by Section 304 of the Food Safety Modernization Act (FSMF) of January, 2011.

Commodities other than food that have been refused entry by another country should be transmitted with the **UFC** (Unacceptable to Foreign Country) affirmation.

Example RF1 France
RF2 Japan

SID

Submission Identifier (SID) Number

This affirmation and qualifier should be the number identifying a specific process filing for a Low Acid or Acidified Food Product filed with FDA for the product identified in the FDA line. When using the SID code, the FCE code and qualifier, along with the container size/dimensions and/or VOL with qualifier must also be transmitted. The filer should verify with the manufacturer whether container size/dimensions or volume were supplied to FDA for the SID identified. 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

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

Example: 2011-06-23/005
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. 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

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

UFC

Unacceptable to Foreign Country

This affirmation, with a required qualifier, can be used when a filer becomes aware, prior to transmitting entry data, that a shipment or portion of a shipment of **NON-FOOD** products has been rejected by another country's government agency. FDA may be notified of this reject for appropriate action. Transmission of this code will generate a "Hold Line" 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 due to FDA receipt of such a reject report. The required qualifier should include the identification of the foreign country's reject report (up to 25 characters). **Imported food products (including animal foods) that have been refused by other countries should be reported using the Food Safety Moderation Act 2011 (FSMA) Affirmation of Compliance code RF1 through RF5. The RFx codes allow for the names of up to 5 different countries that have refused the food product identified in the transmitted entry line.**

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Example: UFC "unacceptable steel standards"

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 Feed 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

VMS

Veterinary Minor Species Index File

This affirmation and qualifier should be used for the product identified in the entry line when the intended use of the drug in a minor species, for an indication that occurs infrequently and in only a small number of animals or in limited geographical areas and in only a small number of animals annually.

The index of Legally Marketed Unapproved New Animal Drugs can be found at:
<http://www.fda.gov/AnimalVeterinary/DevelopmentApprovalProcess/MinorUseMinorSpecies/ucm125452.htm>

Example: VMS 123-456 (six digit number)

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.

Example: VOL 16 oz
Container Size/Dimension is a fielded data elements described below in the "Transmission of Data Guidance" section below.

Transmission of Data Guidance

Affirmation of Compliance

In addition to the usual entry data, the following information must be transmitted for each FDA line in an entry when a filer desires to use an Affirmation of Compliance.

A single Affirmation of Compliance with or without qualifier is input on the FD01 Record. Any additional Affirmations of Compliance (2nd up to 999), with or without qualifiers, can be supplied using the FD05 Record.

The **Affirmation of Compliance Code** is a three-character field.

If an **Affirmation of Compliance Qualifier** is required, then data must be entered for this field. There is a limit of 25-characters. Be sure to follow your software vendor's instructions.

Quantity

Quantity and Units of Measure Pairs (FD02 & FD04 RECORDS).

Multiple positions are used as needed to describe the quantity. Two decimal places are implied. If the value is a whole number, the two low-order positions contain zeros. Consult the FDA-ACS Interface Quantity Data Instructions for further information. Be sure to follow your software vendor's instructions.

Value

Value in US \$ (FD03 RECORD)

Two decimal places are implied. If the value is a whole number, the two low-order positions contain zeros. Be sure to follow your software vendor's instructions. The value of the FDA line(s) cannot exceed the total value of the Customs line or entry. To ensure the Customs line/entry value is not exceeded, it is permissible to decrease the FDA line value to make required adjustment. Such line value adjustments should be recorded on the invoice. These annotations will expedite review and comparison of the entry documents to the electronic data.

Brand Name

Brand Name (FD03 RECORD)

Multiple positions are used as needed to identify the make of the article from the label or invoice. The brand name is required when a Radiological Health Product Declarations AofC code is transmitted.

Container Dimensions

Container Dimensions (FD03 RECORD)

Container dimensions are used for Low Acid and Acidified Canned Food Products. There are **three fields for the dimensions in the FD03 Record**.

Each field can accept **four numeric digits**.

1. If the container is rectangular, pouch, or irregularly shaped, the dimensions are in width, height, and length order.
2. If the container is cylindrical, the dimensions are in diameter and height order.

Measurements are in inches and sixteenths inches. For example, a can which is 2 1/2 inches in diameter and 3 3/16 inches in height would be listed as 208 303. Two and 1/2 inches would translate to 2 inches and 8/16ths of an inch or 208. The dimensions should be for the product as shipped and be in the same format as used when submitting the manufacturing process for acceptance.

ADDITIONAL GUIDANCE and RESOURCES:

| |
|--|
| CBER – Center for Vaccines, Blood & Biologics |
|--|

Imported Biologics Products:

<http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/ComplianceActivities/BiologicsImportingExporting/default.htm>

Biological Specimen for Research and Testing:

Generally, biological specimens used only for testing in a clinical laboratory or for basic scientific research and not intended for the prevention, treatment, diagnosis, or cure of disease, injuries, or conditions in humans, are not subject to FDA jurisdiction.

Short Supply Products:

21 CFR 601.22 allows an unlicensed establishment to conduct the initial and partial manufacturing of a biological product at places other than the establishment approved in the BLA provided that:

- 1) The products are for further manufacture only and not for final distribution
- 2) The manufacturers are registered with FDA
- 3) A short supply agreement between the collection facility and the manufacturer of the final, licensed product is in effect prior to or at the time of shipment

Currently, the products that may be supplied under 21 CFR 601.22 are:

- Recovered plasma
- Red blood cells
- Snake venoms,
- Hymenopteran (bee) venoms

Q&A for Importing CBER regulated Products:

<http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/ComplianceActivities/BiologicsImportingExporting/ucm143371.htm>

Link to the 7342.007 Compliance Program Guidance manual for Imported CBER-Regulated Products:

<http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/ComplianceActivities/Enforcement/CompliancePrograms/ucm095245.htm#ANALYTICAL>

Link to the 7342.007 Addendum for the HCT/Ps:

<http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/ComplianceActivities/Enforcement/CompliancePrograms/ucm095250.htm>

INDs Transferring from CBER to CDER (Biologics to Drugs)

<http://www.fda.gov/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CBER/ucm123940.htm>

CDER – Center for Drug Evaluation and Research

CDER Office of Drug Security Integrity and Recalls: Imports Exports Compliance Branch:

<http://www.fda.gov/drugs/drugsafety/drugintegrityandsupplychainsecurity/default.htm>

Importation of Personal Shipments of Drugs: RPM, Section 9-2:

<http://www.fda.gov/downloads/ICECI/ComplianceManuals/RegulatoryProceduresManual/UCM074300.pdf>

Drug Shortages List:

<http://www.fda.gov/Drugs/DrugSafety/DrugShortages/default.htm>

Electronic Drug Registration and Listing Instructions:

<http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/DrugRegistrationandListing/ucm078801.htm>

Note: New Drug Application (NDA):

When the sponsor of a new drug believes that enough evidence on a new drug's safety and effectiveness has been obtained to meet FDA's requirements for marketing approval, the sponsor submits, to FDA, a new drug application (NDA). The application must contain data from specific technical viewpoints for review, including chemistry, pharmacology, medical, biopharmaceutics, and statistics. If the NDA is approved, the product may be marketed in the United States. For FDA internal tracking purposes: all NDA's are assigned an NDA number. When there is a relevant supplement which applies to the shipping of the new drug or its ingredients, the shipper may add "/S" to the qualifying application number and add the relevant supplement number. Supplement numbers are three digits long. Supplement numbers also apply to Abbreviated New Drug Applications.

CDRH – Center for Medical Devices and Radiation Emitting Products

Importing Medical Devices and Radiation-Emitting Products:

<http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/ImportingandExportingDevices/ucm050126.htm#>

Medical Devices :

Letter to Industry about Import Entry Review Process (March 24, 2011):

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/ucm248321.htm>

Radiation-Emitting Products:

Letter to Industry about Import Entry Review Process (September 6, 2011):

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/ucm271180.htm>

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Medical Device Registration and Listing:

<http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/RegistrationandListing/default.htm>

Medical Device Establishment Registration and Listing - Notice of Changes for FY 2013:

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/ucm314844.htm>

CFSAN – Center for Foods, Dietary Supplements and Cosmetics

Prior Notice of Imported Foods:

<http://www.fda.gov/Food/GuidanceComplianceRegulatoryInformation/PriorNoticeofImportedFoods/default.htm>

Registration of Food Facilities:

<http://www.fda.gov/Food/GuidanceComplianceRegulatoryInformation/RegistrationofFoodFacilities/default.htm>

Reportable Food Registry for Industry:

<http://www.fda.gov/Food/FoodSafety/FoodSafetyPrograms/RFR/default.htm>

Acidified & Low-Acid Canned Foods (LACF):

<http://www.fda.gov/Food/FoodSafety/Product-SpecificInformation/AcidifiedLow-AcidCannedFoods/default.htm>

FDA Guidance – By Product Area and By Topic:

<http://www.fda.gov/ForIndustry/FDABasicsforIndustry/ucm234622.htm>

CVM – Center for Veterinary Medicine

Importing – Animal Feed:

<http://www.fda.gov/AnimalVeterinary/Products/ImportExports/ucm050072.htm>

Importing – Veterinary Drugs:

<http://www.fda.gov/AnimalVeterinary/Products/ImportExports/ucm050077.htm>

FDA Imports Other Information

Import Basic Information

<http://www.fda.gov/ForIndustry/FDABasicsforIndustry/ucm273038.htm>

Import for Export

FDA Investigations Operations Manual

<http://www.fda.gov/ICECI/Inspections/IOM/ucm122539.htm#6.2.3.4.1>

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FDA Regulatory Procedures Manual – Chapter 9-15

<http://www.fda.gov/ICECI/ComplianceManuals/RegulatoryProceduresManual/ucm179481.htm>

IND – Investigational New Drug/Biologic Application Number

Transferring from CBER to CDER (Biologics to Drugs)

<http://www.fda.gov/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CBER/ucm123940.htm>