

FDA - ACS INTERFACE

AFFIRMATION OF COMPLIANCE CODES

Background

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 product identified in a FDA line meets requirements specific to each code. While submission of this information is voluntary, transmission of the data can greatly 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 a random exam or may fall under other screening criteria resulting in a directed exam or a detention without physical examination.

Three new AofC codes have been added since the last issuance (7/98) of this document. They are IBP, CCC and DHC. IBP - Indian Black Pepper is used to affirm there is an inspection certificate covering the shipment. CCC – Chinese Ceramicware Factory Code is used to affirm shipments of ceramicware are produced by a manufacturer certified as part of a FDA/PROC Memorandum of Understanding (MOU). DHC – Dioxin Health Certificate Code is used to certify that shipments subject to FDA Import Alert 99-24 (Detention Without Physical Exam of Human Food Products and Animal Feeds Contaminated with Dioxin and/or PCB) are accompanied by a Health Certificate from Belgium. See additional information about these new codes in the description portion of this document.

Following is an index of all AofC Codes with their title and a code to indicate of whether a qualifier is required. After the index are descriptions of each AofC arranged by code. Following the codes is information on the transmission of the data to use with these codes.

Current Changes/Additions

New Codes:

IBP – Indian Black Pepper Certificate

CCC – Chinese Ceramicware Factory Code

DHC – Dioxin Health Certificate

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Code	Affirmation of Compliance Title (Arranged by Title)	Qualifier Required?
ANA	Abbreviated New Animal Drug Number	Y
AND	Abbreviated New Drug Application Number	Y
BFL	Biologic Establishment License Number	Y
BPL	Biologic Product Number	Y
CCC	Chinese Ceramicware Factory Code	Y
CFR	Code of Federal Regulations Section	Y
CIN	Color Index Number	Y
COS	Cosmetic Registration Number	Y
LST	Device Listing Number	Y
PMA	Device Premarket Approval Number	Y
PMN	Device Premarket Notification Num (510K)	Y
DEV	Device Registration Number	Y
DHC	Dioxin Health Certificate	N
DLS	Drug Listing Number	Y
REG	Drug Registration Number	Y
LWC	Electrode Lead Wire Patient Cable	N
ERR	Entry Review Recommended	Y
AIN	Food Additive Identification Number	Y
FAP	Food Additive Petition Approval Number	Y
FCE	Food Canning Establishment Number	Y
FCC	French Cheese Facility Certification No	Y
IBP	Indian Black Pepper Certificate	Y
IDE	Investigational Device Exemption Number	Y
IRC	Impact Resistance Lens Certification	N
IFE	Import for Export	N
INA	Investigational New Animal Drug Number	Y
IND	Investigational New Drug Number	Y
LF1	Low Value-Food/Food Related Products <=\$200	N
LF2	Low Value-Food/Food Related Products >\$200 - <=\$500	N
LF3	Low Value-Food/Food Related Products >\$500 - <=\$10000	N
LR1	Low Value-Non Rx Rad. Emitting Products <=\$200	N
LR2	Low Value-Non Rx Rad. Emitting Products >\$200 - <=\$1000	N
LWC	Electrode Lead Wire Patient Cable	N
MFA	Medicated Feed Application Number	Y
MDL	Model Number	Y
NAD	New Animal Drug Application Number	Y
NDA	New Drug Application Number	Y
PAC	Private Analytical Certificate Date	Y
ACC	RCHSA Accession Number	Y
REG	Drug Registration Number	Y
SID	Schedule Identifier Number	Y
SIF	Seafood HACCP Importer Firm	Y
UFC	Unacceptable to Foreign Country	Y

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ACC RCHSA Accession Number

This affirmation and qualifier should be the Radiological Health Accession Number issued by FDA for the product identified in the FDA line.

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.

ANA Abbreviated New Animal Drug Number

This affirmation and qualifier should be the Abbreviated New Animal Drug Number (ANADA) 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 their food products for human consumption.

AND Abbreviated New Drug Application Number

This affirmation and qualifier should be the Abbreviated New Drug Application Number (ANDA) issued by FDA, Center for Drug Evaluation and Research (CDER), for the human drug product identified in the FDA line. This number is the approval number in response to an abbreviated new drug application.

BFL Biologic Establishment License Number (formerly Biologic Firm License Number)

This affirmation and qualifier should be the Biologic Establishment License Number issued by FDA, Center for Biologic Evaluation and Research (CBER) for the manufacturer of the biological product identified in the FDA line.

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Biological products are legally defined also as "drugs" or "devices" and are therefore subject to all of the adulteration, misbranding, and registration provisions of the Food Drug & Cosmetic Act. See CFR 601.30 for exemptions to licensing requirements. The Public Health Service Act defines a biological product as any virus, therapeutic serum, toxin, antitoxin, vaccine, blood, blood component or derivative, allergenic product or analogous product applicable to the prevention, treatment or cure of diseases or injuries of man. Biologic drugs for animals are regulated by the U.S. Department of Agriculture. Under the Public Health Service Act, a foreign manufacturer wishing to ship a biological product for sale for importation to the US must obtain a license for both the site specific manufacturing establishment and the product intended for shipment.

BPL Biologic Product License Number

See biologic product definition above. The qualifier for this affirmation will be the same as the Biologic Establishment License Number issued by FDA, Center for Biologic Evaluation and Research (CBER) for a specific manufacturing site. Each manufacturing site for an individual manufacturer will have a unique license number. This license number is issued for both the manufacturing site and the first product licensed for that site at the time of original licensing. The manufacturer is required to label the original product licensed and those products subsequently licensed for that site with this number. To verify a specific product has been licensed for the specific site, contact should be made with CBER, Division of Establishment Licensing.

CCC Chinese Ceramicware Factory Code

The affirmation and qualifier should be used to indicate shipments of ceramicware 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 it's client. Paper certificates (CCIB) will no longer be used in FDA's evaluation of these entries.

CFR Code of Federal Regulations Section

The affirmation and qualifier should be the Code of Federal Regulations Section reference which is pertinent to the product identified in the FDA line. Most of FDA's regulations are in Title 21.

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CIN Color Index Number

This affirmation 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 is recognized as the international color identification number for the product identified in the FDA line.

COS Cosmetic Registration Number

The affirmation and qualifier should be the Cosmetic Registration Number issued by FDA/CFSSAN 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.

DEV Device Registration Number

This affirmation and qualifier should be the Device Registration Number issued by FDA/CDRH for the firm manufacturing the product identified in the FDA line. Owners or operators of all device establishments that engage in the manufacture, preparation, propagation, compounding, assembly, or processing of a device intended for human use are required to register. The term device includes all in-vitro diagnostic products and in-vitro diagnostic biological products not subject to licensing under the Public Health Service Act. The registration requirements shall pertain to any person who initially distributes devices imported into the United States. Foreign establishments are encouraged, but not required to register. Registration is done on Form FDA 2891.

DHC Dioxin Health Certificate

This affirmation should be used for shipments of products potentially subject to FDA Import Alert 99-24 (Detention Without Physical Exam of Human Food Products and Animal Feeds Contaminated with Dioxin and/or PCB) are accompanied by a Health Certificate from Belgium. No qualifier is required for this code.

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DLS Drug Listing Number

This affirmation and qualifier should be the Drug Listing Number issued by FDA/CDER for the 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.

ERR Entry Review Recommended

This affirmation, with a required qualifier, can be used when a filer becomes aware, prior to transmitting entry data, there is a legitimate need for FDA to examine the commodities in an entry e.g., the filer has been notified that refrigeration failure in a truck or ship has caused damage to a partial or total shipment. Transmission of this code will generate a "FDA Review" 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 in an OASIS district 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, e.g., "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.

FCE Food Canning Establishment Number

This qualifier should be the Food Canning Establishment Number issued by FDA when the site specific manufacturer of Low Acid and Acidified Canned Foods is registered. Do not use the FCE number issued for the firm's corporate name and address. Form FDA 2541 is used for this firm registration. When possible, the AofC Code SID and specific container dimensions should also be used when the FCE AofC code is provided. See SID AofC Code definition.

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.

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IBP Indian Black Pepper Certificate

This affirmation and qualifier should be used when the manufacturer has provided a 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.

IDE Investigational Device Exemption Number

This affirmation and qualifier should be the Investigational Device Exemption Number issued by FDA/CDRH for the product identified in the FDA line. Devices that qualified experts use on human subjects, to conduct investigations of their safety and effectiveness, are considered investigational devices.

IFE Import for Export

This affirmation allows for importation of violative articles (including drug and device components, food and color additives, and dietary supplements) under the new import for export provisions of the FD&C Act [801(d)(3)(a)]. The article must be incorporated, by the initial owner or consignee, (which can be someone other than the importer of record) into a product for export. The product must be exported from the United States by this initial owner or consignee in accordance with the provisions of Section 801(e) and 802 of the FD&C Act or 351(h) of the PHS Act. No qualifier is required but QUANTITY AND VALUE MUST BE TRANSMITTED when using this AofC.

INA Investigational New Animal Drug Number

This affirmation and qualifier should be the 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.

IND Investigational New Drug Number

This affirmation and qualifier should be the Investigational New Drug Number issued by 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.

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IRC Impact Resistance Lens Certification

This Affirmation of Compliance 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. No qualifier is necessary.

LF1/LF2/LF3

Low Value-Food/Food Related Products

LR1/LR2

Low Value-Non RX Radiation Emitting Products

These affirmations may be used with entries containing only foods, cosmetics, and dinnerware or entries containing only non-medical, radiation emitting devices. The Low Value AofC is applied on an Entry basis and all lines in an entry must be subject to the same group of Low Value AofC codes (either "LF_" or "LR_"). The total value of the entry is used to determine which AofC code is applicable. At this time there are no Low Value AofC available for use with Drug and Medical Device products. No Affirmation of Compliance Qualifier is required.

Food, Cosmetics and Dinnerware AofC Codes:

Entry Value

Less than or equal to \$200

Greater than \$200 and less than or equal to \$500

Greater than \$500 and less than or equal to \$1000

AofC Code

LF1

LF2

LF3

Non-Medical, Radiation Emitting Devices AofC Codes:

Entry Value

Less than or equal to \$200

Greater than \$200 and less than or equal to \$1000

AofC Code

LR1

LR2

The data transmitted for each FDA line of the entry must contain the appropriate AofC code for the entry.

The use of these Affirmation of Compliance codes is voluntary. However, if a filer chooses to use them, the filer must also transmit quantity and value data with all FDA lines in the entry.

LST Device Listing Number

This affirmation and qualifier should be the Device Listing Number issued by FDA, Center for Devices and Radiological Health (CDRH) for the product identified in the FDA line. Listing is accomplished by Form FDA 2892. The foreign manufacturer must list. The sole initial distributor may submit listing on behalf of the manufacturer only if he submits to FDA a letter from the foreign owner/operator authorizing the initial distributor to list and maintain the required historical listing file.

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LWC (Electrode) Lead Wire or Patient Cable

This affirmation of compliance is used when importing electrode lead wires, patient cables, or devices that use them. The affirmation means that (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.

MFA Medicated Feed Application Number

This affirmation and qualifier should be the Medicated Feed Application Number issued by FDA/CVM for the product identified in the FDA line. Animal feeds containing new animal drugs must be the subject of Medicated Feed Application. Medicated feed application Form FDA 1900, must be submitted to FDA/CVM.

MDL Model Number

This affirmation and qualifier should be the manufacturer's Model Number for the product identified in the FDA line.

NAD New Animal Drug Number

This affirmation and qualifier should be the New Animal Drug Number issued by FDA/CVM for the product identified in the FDA line. New animal drugs are drugs which are not generally recognized as safe and effective for use in each of the animal species for which they are intended. In addition, animal drugs intended for use in food producing animals must not leave unsafe residues in edible tissues or other food products for human consumption.

NDA 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 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.

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PAC Private Analytical Certificate Date

This affirmation and qualifier should be the Private Analytical Certificate Date for the product identified in the FDA line.

PMA Device Premarket Approval Number

This affirmation and qualifier should be the Device Pre-market Approval Number issued by FDA/CDRH for the product identified in the FDA line. Pre-market 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.

PMN Device Premarket Notification Number (510k)

This affirmation and qualifier should be the Device Pre-market Notification Number of 510k number issued by FDA/CDRH 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 old device with a major change in intended use.

REG Drug Registration Number

This affirmation and qualifier should be the Drug Registration Number issued by FDA/CDER for the firm manufacturing the product identified in the FDA line. Foreign manufacturers and importers are not required to drug register, but may do so voluntarily.

RAA/RAB/RAC/RAD

Rad Health Product Affirmations

Entries of electronic radiation emitting products require the submission of the Declaration for Products Subject to Radiation Control Standards form FDA 2877¹.

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

¹Definitions of the four types of declarations and instructions for filing may be found on the FDA 2877 form.

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- 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. For example, a RAB (complies with performance standards) must not be transmitted with a RAD (does not comply with performance standards).
- 2 The filer maintains the appropriate documentation in their files for five years to support their electronic submission of the 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 FDA 2877 for the entry in question.
 - B) a letter of authorization, from the importer, to electronically file the 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.

The following Affirmations and Qualifiers should be used with the appropriate declaration.

<u>Declaration</u>	<u>Code</u>	<u>Qualifier</u>
A	RAA	Date of Manufacture and Model Number
B	RAB	Model Number
C	RAC	Model Number
D	RAD	Model Number

SID Schedule Identifier Number

The FCE AofC code and qualifier must be used with this affirmation. The SID AofC code qualifier should be the number identifying a specific process filing for a Low Acid or Acidified Canned Food Product accepted by FDA for the product identified in the FDA line. When using the SID code, container dimensions must be entered as described in the Transmission of Data portion of this document.

SIF Seafood HACCP Importer Firm

This AofC code 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 ensuring 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. OASIS will not currently screen for the presence of this code and qualifier but transmission of the code will expedite on-screen-review of an entry and provide filers experience transmitting the necessary data to be utilized once the screening criteria is activated in OASIS. 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.

UFC Unacceptable to Foreign Country

This affirmation, with a required qualifier, can be used when a filer becomes aware, prior to transmitting entry data, a shipment or portion of a shipment 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 "FDA

Review" 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 in an OASIS district is asked to withdraw and retransmit an entry due to FDA receipt of such a reject report. The qualifier required should include the identification of the foreign country's reject report (up to 20 characters).

Transmission of Data

Affirmation of Compliance

In addition to the usual entry data, the following information must be transmitted for each FDA line in an entry 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 furnished using the FD05 Record. The Affirmation of Compliance Code is a three-character field. If an Affirmation of Compliance Qualifier is required, this field is a 25-character field and must be used. 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 insure 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 are used for Low Acid and Acidified Canned Food Products. There are three fields for the dimensions in the FD03 Record. Each field can handle four numeric digits. If the container is rectangular, the dimensions are in width, height, and length order. 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.