U.S. FOOD & DRUG ADMINISTRATION

Making ACE Work for You: Importing FDA Regulated Products

Office of Enforcement and Import Operations and
Office of Information Systems Management

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US Food and Drug Administration

October 2019

Agenda

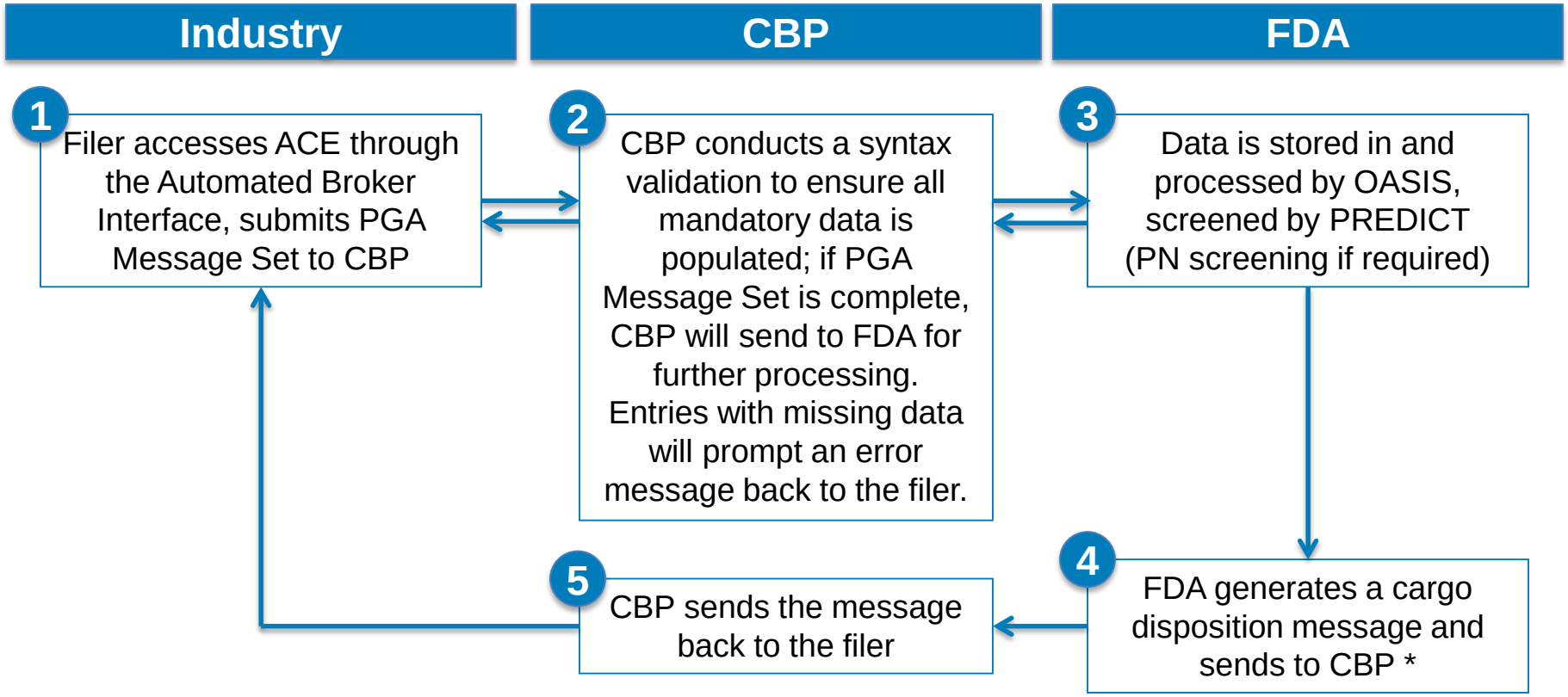
Overview: ACE and FDA	Commodity Specific Information	Information and Resources for All FDA Regulated Products
• What is ACE? • How ACE Works for FDA • FDA Current Status • Most Common CBP and FDA Rejections • Common Data Errors • FDA Flags • FDA ACE Final Rule Changes	• Know the Product Being Imported • Information Needed for Submission • Common Reasons for Commodity Specific Entry Processing Delays • Commodity Specific Resources	• Avoiding Delays with FDA • Use the Supplemental Guide • Summary • Frequently Asked Questions • Resources • FDA Points of Contact for Imports

OVERVIEW: ACE AND FDA

What is ACE?

The Automated Commercial Environment is a centralized system for all transactions related to imports and exports. Filers electronically submit all information related to an inbound shipment and the government processes the transaction systematically and sends status updates.

How ACE & PREDICT Work for FDA



* Data that is electronically validated may be automatically "May Proceeded"

FDA Current Status

- ACE became mandatory in June 2016
- Final Rule issued in November 2016
- FDA Supplemental Guide version 2.5.1 released April 2018
- FDA continues to work closely with importers, brokers, and software developers to ensure understanding and compliance of the ACE process
- FDA also continues to collaborate with CBP to troubleshoot issues and make system enhancements

FDA Current Status

- Automated May Proceeds have increased in ACE, and the percentage of lines requiring manual review have decreased.
  - In 2014, only **26%** of (ACS) lines were Automated May Proceeds.
  - In 2018, **70%** of lines were Automated May Proceeds.

FDA Current Status

- In ACE, FDA requests less documents.
  - In 2014, approximately **3%** of (ACS) lines needed additional information to make an admissibility decision (Documents Required).
  - In 2018, approximately **2%** of (ACE) lines needed additional information to make an admissibility decision (Documents Required).

Most Common CBP & FDA Rejects

CBP Rejects Jan – Sep 2019	FDA Rejects Jan – Sep 2019
• Missing or Invalid Affirmations of Compliance	• Invalid Product Code
• Missing or Invalid Entities	• Cancelled Food Facility Registration
• Missing or Invalid PG21 Record or Individual Qualifier Code	• Invalid State/Zip Combination
• Missing or Invalid Entity ID Code for FEI or DUNS	• Food Facility Registration Not on File
• Missing or Invalid FEI or DUNS Number	• Food Facility Registration Invalidated by PGA
• Only Mandatory Entities Allowed	• Mismatch Between Food Facility Registration and Manufacturer

Common Data Errors

Areas for Improvement

- Must know the Intended Use Code of the product prior to transmitting entry data (foods do not require an IUC)
- Know required Entities and Affirmation of Compliance (AoC) Codes for commodity type
- Other than the few repeatable AoC codes listed in the SG, do not submit the same AoC code more than once per line
- Submit correct entity addresses and DUNS or FEI number

Common Data Errors

Consumer Use is different than Personal Use

- Base Code 130 For Consumer Use as a Non-Food Product
- Base Code 100 For Personal Use as a Non-Food Product
- Base Code 210 For Personal Use as Human Food

FD Flags

- **FD1** – Indicates that the article may be subject to FDA jurisdiction, including FDA review under 801(a) of the FD&C Act. For products not subject to FDA jurisdiction, a filer can "Disclaim" product from FDA notification requirements.

- **FD2** – Indicates that the article is under FDA jurisdiction and review of entry information by FDA under section 801(a) will take place. However, the article is not "food" for which prior notice information is required.

- **FD3** – Indicates that the article may be subject to prior notice under section 801(m) of the FD&C Act and 21 CFR Part1, subpart I. , e.g., the article has both food and non-food uses.

- **FD4** – Indicates that the article is "food" for which prior notice is required under section 801(m) of the FD&C Act and 21 CFR Part1, subpart I.

Final Rule

The Final Rule for submission of information to the Automated Commercial Environment (ACE) was published in the Federal Register on November 29, 2016.

Reminders

- **Optional** – Line Value
- **Optional** – Quantity and Unit of Measure
  - Except for Radiation Emitting Products subject to a Form FDA 2877, Declaration for Imported Electronic Products Subject to Radiation Control Standards
  - Prior Notice datasets
- **Mandatory** – Importer of Record contact information is required for all non-food lines

• Although data elements may be optional, transmitting them may expedite processing •

Making ACE Work for You: Importing FDA Regulated Products

BIOLOGICS

BIO

FDA

Submitting Biologic Entries in ACE

- Know the Product Being Imported
- Information Needed for Submission
- Common Reasons for Biologic Entry Processing Delays
- Additional Resources

Know the Product Being Imported

A Biologic Product is defined in Section 351 of the Public Health Service Act as, “a virus, therapeutic serum, toxin, antitoxin, vaccine, blood, blood component or derivative, allergenic product, protein (except any chemically synthesized polypeptide), or analogous product, or arsphenamine or derivative of arsphenamine (or any other trivalent organic arsenic compound), applicable to the prevention, treatment, or cure of a disease or condition of human beings.”

Human cells, tissues, or cellular or tissue-based products (HCT/Ps) are defined in Section 361 of the PHS Act as “Human cells, tissues, or cellular or tissue-based products (HCT/Ps) means articles containing or consisting of human cells or tissues that are intended for implantation, transplantation, infusion, or transfer into a human recipient.”

Know the Product Being Imported

Examples of biologic products

- Blood and blood products for transfusion and/or manufacturing into other products
- Allergenic extracts, which are used for both diagnosis and treatment (for example, allergy shots)
- Vaccines
- Gene therapies
- Cellular therapies
- Tests to screen potential blood donors for infectious agents such as HIV
- HCT/Ps - for example, bone, ligaments, skin, dura mater, heart valve, cornea, hematopoietic stem/progenitor cells derived from peripheral and cord blood, and semen or other reproductive tissue.

BIO

FDA

Information Needed for Submission

Program & Processing Codes

Program Code for biologic commodities is **BIO**.

The **Processing Code** will be determined by the commodity sub-type:

PG01 - Government Agency Code	Commodity Type	PG01 - Government Agency Program Code	Commodity Sub-Type	PG01 - Government Agency Processing Code
FDA	Biologics	BIO	Allergens	ALG
FDA	Biologics	BIO	Vaccines	VAC
FDA	Biologics	BIO	Human Cells & Tissue	HCT
FDA	Biologics	BIO	Xenotransplant	XEN
FDA	Biologics	BIO	Cell & Gene Therapy	CGT
FDA	Biologics	BIO	Blood and Blood Products	BLO
FDA	Biologics	BIO	Licensed Devices	BLD
FDA	Biologics	BIO	Blood Derivatives	BDP
FDA	Biologics	BIO	Blood Bag with Anti-coagulant	BBA
FDA	Biologics	BIO	Plasma Volume Expanders	PVE

Information Needed for Submission

Product Code Overview

Structure of the FDA Product Code					
Position	1-2	3	4	5	6-7
Name	Industry Code (N)	Class Code (A)	Sub Class Code (A or "-")	Process Identification Code – PIC (A or "-")	Product (AN)
Legend: N – Numeric; A – Alphabetic; AN - Alphanumeric					

- FDA Product Code errors are among the most common reasons for FDA Entry Rejections.
- Use a valid FDA Product Code per the FDA Product Code Builder.

BIO

FDA

Information Needed for Submission

Product Codes

- Product code is mandatory.

PG01: Program Code & Commodity	PG01: Processing Code & Commodity Subtype	PG02: Industry Code
BIO - Biologic	ALG - Allergens	57
	BLO - Blood & Blood Products	
	CGT - Cell and Gene Therapy	
	HCT - Human Cells & Tissue	
	VAC – Vaccines	
	XEN – Xenotransplants	
	BDP - Blood Derivatives	
	BBA - Blood Bag with anti-coagulant	
	BLD - Licensed Devices	
	PVE - Plasma Volume Expanders	

Information Needed for Submission

Product Descriptions, Packaging and Condition

Data Requirement	Biologics
Commodity Characteristic Description	Mandatory
Trade Name/Brand Name	Mandatory *only* if one of the following government agency processing codes applies: ALG, BDP, BLD, BLO, CGT, VAC, XEN, BBA or PVE
Quantity and Packaging*	Optional but encouraged (if entered, the rules from the SG must be followed)
PGA Line Value	Optional but highly encouraged

Information Needed for Submission

Intended Use Codes and Affirmations of Compliance

- Intended Use Code is mandatory for biologics.
- Affirmation of Compliance requirements depend on the Intended Use Code.

Intended Use Codes	Import Scenario	Affirmations of Compliance
180.009	Biological or chemical for research and development into a pharmaceutical product – Investigational New Drugs (IND); clinical trials or other human/animal use	Mandatory: IND Conditional: REG
080.000	CBER-regulated Final product; ready for use. Importation of a licensed biological product. The Biologics License number (BLN) is the U.S. License Number. The Submission Tracking Number (STN) is associated with the manufacturer and a specific product and the first six digits represent the original submission tracking number.	Mandatory: BLN or STN or both Conditional: REG, DLS
080.000	CBER-regulated Final product; ready for use. Importation of drug regulated by CBER.	Mandatory: DA, REG, (DA includes NDA and ANDAs only) Conditional: DLS
082.000	Human Cells, tissues, and cellular and tissue based products (HCT/Ps) for implant, transplant, infusion, or transfer into a human recipient. The HCT affirmation should be used to indicate the HCT/Ps being importer or offered for import are in compliance with all applicable requirements of 21 CFR 1271.	Mandatory: HCT (No Qualifier Needed for HCT)

Information Needed for Submission

Intended Use Codes and Affirmations of Compliance

- Intended Use Code is mandatory for biologics.
- Affirmation of Compliance requirements depend on the Intended Use Code.

Intended Use Codes	Import Scenario	Affirmations of Compliance
082.000	Human Cells, tissues, and cellular and tissue based products (HCT/Ps) for implant, transplant, infusion, or transfer into a human recipient. The HRN Affirmation should be used for Importation of human cells, tissues and cellular and tissue-based product where the establishment is registered with the FDA.	Mandatory: HRN Conditional: HCT
180.016	CBER Product sample for testing or lot release	Mandatory: BLN or STN or both Conditional: REG, DLS
155.000	CBER product For further manufacture of a licensed biological product under a short supply agreement (21 CFR 601.22)*	Mandatory: BLN or STN or both Conditional: REG, DLS
100.000	Importation for personal use	
150.007	Bulk biological drug substance for processing into a pharmaceutical product	Mandatory: BLN or STN or both Conditional: IND, REG, DLS
150.007	Bulk drug substance for processing into a pharmaceutical product	Mandatory: DA Conditional: IND, REG, DLS
140.000*	Standard import of a biological drug or device for non-commercial distribution in government and non-government support program.	Conditional: BLN, STN, DA, IND

Information Needed for Submission

Intended Use Codes and Affirmations of Compliance

- Intended Use Code is mandatory for biologics.
- Affirmation of Compliance requirements depend on the Intended Use Code.

Intended Use Codes	Import Scenario	Affirmations of Compliance
110.000*	Import of a biological drug or device for trade show	Conditional: BLN, STN, DA, IND
170.000*	For reconditioning or repair of a non-food product	Conditional: BLN, STN, DA, IND, HCT, HRN
970.000*	Importation of non-compliant articles (including blood, blood components, Source plasma and source leukocytes) under the import for export provisions 801(d) (3), & 801(d) (4) of the FD&C Act.	Mandatory: IFE (No qualifier required)
180.000	Import of a biologic for non-clinical research use only, bench testing, etc. These entries could be disclaimed if the HTS code allows it.	
940.000*	Importation of a drug (including a biological product) or device for compassionate use/emergency use	Conditional: BLN, STN, DA, IND, HCT, HRN
920.000	Import of US Goods Returned	

- Optional product affirmation of compliance data:
  - Entry Review Requested (ERR)

Information Needed for Submission

Entities

Entity Role (Code)	Entity Name	Entity Address	Individual Name, Tel# and eMail
Manufacturer (MF)	Mandatory	Mandatory	
Shipper (DEQ)	Mandatory	Mandatory	
FDA Importer (FD1)	Mandatory	Mandatory	Mandatory
Delivered to Party (DP)	Mandatory	Mandatory	
Filer's/Broker's Point of Contact (PK)	Optional but encouraged	Optional but encouraged	Optional but encouraged

- DUNS and FEI are optional, but encouraged.

Information Needed for Submission

Origin and Arrival

Data Requirement	Biologics
Country of Production or Country of Source	Mandatory
Country of Refusal	Mandatory if refused by other country(-ies)

Anticipated Arrival Date	Mandatory
Anticipated Arrival Time	Mandatory
Anticipated Port of Entry	Optional

Summary

- Know the product being imported and associated requirements
- Understand the data elements
- Provided correct and accurate information
- Give Entry Filers the information they need
- Obtain all necessary information from the Importer

NOTE: FDA will not be able to process an entry without this information. You can help expedite FDA's review of your imported product(s) by initially providing accurate and complete information and by responding quickly to requests from FDA for additional documents or information.

Common Reasons for Biologic Entry Processing Delays

Entry review processing delays occur when the requirements for submission are not understood.

- FDA PREDICT lookup failures: 5.27% have insufficient Affirmation of Compliance Code transmitted for biologic products.

Additional Resources

- For more information about vaccines, blood & biologics, visit http://www.fda.gov/BiologicsBloodVaccines/default.htm

- For more information about human cells & tissues, visit http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/EstablishmentRegistration/TissueEstablishmentRegistration/FindaTissueEstablishment/default.htm

- CBER approved and cleared devices can be found under the CDRH registration and listing system, visit http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfRL/rl.cfm

- Drug products regulated by CBER – Establishments Current Registration Site, visit http://www.accessdata.fda.gov/scripts/cder/drls/default.cfm

COSMETICS

COS

FDA

Submitting Cosmetic Entries in ACE

- Know the Product Being Imported
- Information Needed for Submission
- Additional Resources

COS

FDA

Know the Product Being Imported

A Cosmetic is defined in the Federal Food & Cosmetic Act as “(1) articles intended to be rubbed, poured, sprinkled, or sprayed on, introduced into, or otherwise applied to the human body or any part thereof for cleansing, beautifying, promoting attractiveness, or altering the appearance, and (2) articles intended for use as a component of any such articles; except that such term shall not include soap.”

COS

FDA

Know the Product Being Imported

Examples of cosmetic products

- Eye makeup (eye shadow, eyeliner, mascara)
- Bath products (shower gel, shampoo, bubble bath)
- Manicure and shaving products
- Oral hygiene
- Hair coloring
- Perfume/cologne/toilet water
- Hand, face and body cream/lotions
- Ingredients to be used to manufacture cosmetics
- Hair brushes and cosmetic brushes and sponges

COS

Information Needed for Submission

Program & Processing Codes

Program Code for all cosmetic commodities is **COS**.

There is no **Processing Code** for cosmetics.

COS

Information Needed for Submission

Product Code

Structure of the FDA Product Code					
Position	1-2	3	4	5	6-7
Name	Industry Code (N)	Class Code (A)	Sub Class Code (A or “-”)	Process Identification Code – PIC (A or “-”)	Product (AN)
Legend: N – Numeric; A – Alphabetic; AN - Alphanumeric					

- FDA Product Code errors are among the most common reasons for FDA Entry Rejections.
- Use a valid FDA Product Code per the FDA Product Code Builder.
- Product code is mandatory.

PG01: Program Code & Commodity	PG01: Processing Code & Commodity Subtype	PG02: Industry Code
COS - Cosmetic	N/A	50 or 53

COS

FDA

Information Needed for Submission

Product Descriptions, Packaging and Condition

Data Requirement	Cosmetics
Commodity Characteristic Description	Mandatory
Quantity and Packaging*	Optional but encouraged (if entered, the rules from the SG must be followed)
PGA Line Value	Optional but highly encouraged

COS

Information Needed for Submission

Intended Use Codes and Affirmations of Compliance

- Intended Use Codes are not applicable to cosmetics.
- Affirmations of Compliance are optional for cosmetics.
  - Cosmetic Registration Number (COS)
  - Entry Review Requested (ERR)
  - Import for Export (IFE)

COS

FDA

Information Needed for Submission

Entities

Entity Role (Code)	Entity Name	Entity Address	Individual Name, Tel# and eMail
Manufacturer (MF) Required	Mandatory	Mandatory	
Shipper (DEQ) Required	Mandatory	Mandatory	
FDA Importer (FD1) Required	Mandatory	Mandatory	Mandatory
Delivered to Party (DP) Required	Mandatory	Mandatory	
Filer's/Broker's Point of Contact (PK) Optional but encouraged	Optional but encouraged	Optional but encouraged	Optional but encouraged

- DUNS and FEI are optional, but encouraged.

COS

Information Needed for Submission

Origin and Arrival

Data Requirement	Biologics
Country of Production	Mandatory
Country of Refusal	Mandatory if refused by other country(-ies)

Anticipated Arrival Date	Mandatory
Anticipated Arrival Time	Mandatory
Anticipated Port of Entry	Optional

Summary

- Know the product being imported and associated requirements
- Understand the data elements
- Provided correct and accurate information
- Give Entry Filers the information they need
- Obtain all necessary information from the Importer

NOTE: FDA will not be able to process an entry without this information. You can help expedite FDA's review of your imported product(s) by initially providing accurate and complete information and by responding quickly to requests from FDA for additional documents or information.

Additional Resources

- For more information about cosmetics, visit http://www.fda.gov/Cosmetics/default.htm
- Is It a Cosmetic, a Drug, or Both? (Or Is It Soap?), visit https://www.fda.gov/Cosmetics/GuidanceRegulation/LawsRegulations/ucm074201.htm
- For additional information about FDA Authority Over Cosmetics, visit https://www.fda.gov/Cosmetics/GuidanceRegulation/LawsRegulations/ucm074162.htm

DRUGS

Submitting Drug Entries in ACE

- Know the Product Being Imported
- Information Needed for Submission
- Common Reasons for Drug Entry Processing Delays
- Additional Resources

Know the Product Being Imported

“Drug” is defined in the Food, Drug, and Cosmetic Act as, "articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease" and "articles (other than food) intended to affect the structure or any function of the body of man or other animals" **[FD&C Act, sec. 201(g)(1)].**

This includes:

- Articles that are not active ingredients, but are labeled with a claim to “diagnose, cure, mitigate, treat, or prevent disease”

Know the Product Being Imported

Examples of drug products

- Active pharmaceutical ingredients (API)
  - boric acid powder used to manufacture antiseptic
- Over-The-Counter (OTC)
  - acetaminophen pain killer (analgesic)
- Prescription Drugs (RX)
  - Dexamisole (anti-depressant)
- Pharmaceutical Necessities
  - inactive ingredients, excipients, intermediates
- For Research Use Only
  - not to be used with humans and may be used in animals
- Investigational Use Only
  - will be used with humans or animals

DRU

Information Needed for Submission

Program & Processing Codes

Program Code for drug commodities is **DRU**.

The **Processing Code** will be determined by the commodity sub-type:

PG01 - Government Agency Code	Commodity Type	PG01 - Government Agency Program Code	Commodity Sub-Type	PG01 - Government Agency Processing Code
FDA	Drugs	DRU	Prescription	PRE
FDA	Drugs	DRU	Over the Counter	OTC
FDA	Drugs	DRU	Pharmaceutical Necessities, Containers, Inactive Pharmaceutical Ingredients and Excipients	PHN
FDA	Drugs	DRU	Research and Development	RND
FDA	Drugs	DRU	Investigational	INV

Information Needed for Submission

Product Code Overview

Structure of the FDA Product Code					
Position	1-2	3	4	5	6-7
Name	Industry Code (N)	Class Code (A)	Sub Class Code (A or “-”)	Process Identification Code – PIC (A or “-”)	Product (AN)
Legend: N – Numeric; A – Alphabetic; AN - Alphanumeric					

- FDA Product Code errors are among the most common reasons for FDA Entry Rejections.
- Use a valid FDA Product Code per the FDA Product Code Builder.

DRU

Information Needed for Submission

Product Codes

- Product code is mandatory.

PG01: Program Code & Commodity	PG01: Processing Code & Commodity Subtype	PG02: Industry Code
DRU – Drug*	PRE - Prescription	54, 56, 60, 61, 62, 63, 64, 65, or 66
	OTC - Over the Counter	
	RND - Research & Development	
	INV - Investigational	
	PHN - Pharmaceutical Necessities	55, various codes could apply

*Subject to additional rules based on FDA Program/Processing/Product codes. See PG02 in individual chapters of the Supplemental guide.

Information Needed for Submission

Product Descriptions, Packaging and Condition

Data Requirement	Drugs
Commodity Characteristic Description	Mandatory
Quantity and Packaging*	Optional but encouraged (if entered, the rules from the SG must be followed)
PGA Line Value	Optional but highly encouraged

* See Appendix D of the FDA Supplemental Guide for ACE for valid units of measure for Drugs Packaging Containers.

Information Needed for Submission

Intended Use Codes (IUC) and Affirmations of Compliance (AoC)

- IUC is mandatory for drugs. Only IUCs listed in the chart can be used for drugs.
- AoC requirements depend on the IUC.

Intended Use Codes	Import Scenario	Affirmations of Compliance
080.012	Prescription health or medical product for human use that is the subject of an approved new drug application, abbreviated new drug application, or biologics license application	Mandatory: REG, DLS, DA Optional: PLR
100.000	Importation for Personal Use	
130.000	For Consumer Use as a Non-Food Product – Over the Counter (OTC)	Mandatory: REG, DLS Optional: DA
150.007	Active Pharmaceutical Ingredient / Bulk Drug Substance for processing into a pharmaceutical product	Mandatory: REG, DLS Conditional: DA
150.013	Active Pharmaceutical Ingredient / Bulk Drug Substance to be used for Pharmacy Compounding	Mandatory: REG, DLS
150.017	Importation of a drug component (API) for use in a medical product regulated under a device (CDRH) application type (e.g., for use in a PMA/510(k) drug-device combination product)	Mandatory: REG, DLS Optional: DA, LST, PM#, IDE

Information Needed for Submission

Intended Use Codes (IUC) and Affirmations of Compliance (AoC)

- IUC is mandatory for drugs. Only IUCs listed in the chart can be used for drugs.
- AoC requirements depend on the IUC.

Intended Use Codes	Import Scenario	Affirmations of Compliance
155.009	Importation of a drug constituent part (drug product) for use in a medical product regulated under a device (CDRH) application type (e.g., for use in a PMA/510(k) drug-device combination product).	Mandatory: REG, DLS Optional: DA, LST, PM#, IDE
180.009	Chemical for research and development of a pharmaceutical product – subject of an Investigational New Drug application (IND), including Placebos	Mandatory: IND
180.017	Chemical for research and development of a pharmaceutical product – laboratory testing only , no human/animal use	
180.018	Chemical for research and development; investigational use in animals	

Information Needed for Submission

Intended Use Codes (IUC) and Affirmations of Compliance (AoC)

- IUC is mandatory for drugs. Only IUCs listed in the chart can be used for drugs.
- AoC requirements depend on the IUC.

Intended Use Codes	Import Scenario	Affirmations of Compliance
180.026	Finished drug or API intended for use in an in vivo bioequivalence or bioavailability study in humans that qualifies under 21 CFR 320.31 for an exemption from the Part 312 requirements; or finished drug intended for use in clinical investigation in humans that qualifies for an exemption from Part 312 requirements.	
920.000	US Goods Returned	Optional: REG, DLS, DA, IND
970.000	Import for Export	
980.000	For Other Use: (APIs or Finished Drugs not elsewhere classified)	Mandatory: REG, DLS

Information Needed for Submission

Entities

Entity Role (Code)	Entity Name	Entity Address	Individual Name, Tel# and eMail
Manufacturer (**MF**)	Mandatory	Mandatory	
Shipper (**DEQ**)	Mandatory	Mandatory	
FDA Importer (**FD1**)	Mandatory	Mandatory	Mandatory
Delivered to Party (**DP**)	Mandatory	Mandatory	
Filer's/Broker's Point of Contact (**PK**)	Optional but encouraged	Optional but encouraged	Optional but encouraged
Sponsor (New) – if different than MF or FD1 (**SPO**)	Optional	Optional	
Producer (Producer of API) (**GD**)	Optional	Optional	

- DUNS and FEI are optional, but encouraged.

Information Needed for Submission

Origin and Arrival

Data Requirement	Drugs
Country of Production or Country of Source	Mandatory
Country of Refusal	Mandatory if refused by other country(-ies)

Anticipated Arrival Date	Mandatory
Anticipated Arrival Time	Mandatory
Anticipated Port of Entry	Optional

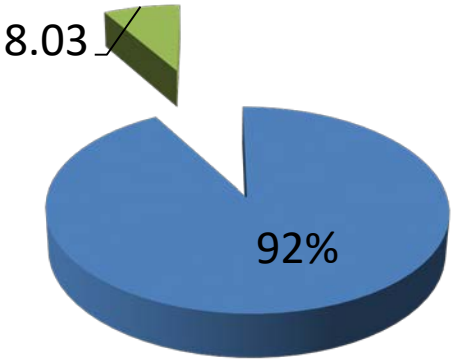
Summary

- Know the product being imported and associated requirements
- Understand the data elements
- Provided correct and accurate information
- Give Entry Filers the information they need
- Obtain all necessary information from the Importer

NOTE: FDA will not be able to process an entry without this information. You can help expedite FDA's review of your imported product(s) by initially providing accurate and complete information and by responding quickly to requests from FDA for additional documents or information.

Common Reasons for Drug Entry Processing Delays

Entry review processing delays occur when the requirements for submission are not understood.



- FDA PREDICT lookup failures: 8.03% of Affirmation of Compliance Codes are incorrectly transmitted for drug products.

Additional Resources

- **Drug Approvals and Databases:** http://www.fda.gov/Drugs/InformationOnDrugs/default.htm
- **Guidance, Compliance, & Regulatory Information:** http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/default.htm
- **Drug Firm Registration Lookup:** http://www.accessdata.fda.gov/scripts/cder/drls/default.cfm
- **DUNS Number Lookup:** http://www.dnb.com/duns-number/lookup.html
- **NDC Number Lookup:** http://www.fda.gov/Drugs/InformationOnDrugs/ucm142438.htm
- **NDA/ANDA Lookup:** http://www.accessdata.fda.gov/scripts/cder/daf/index.cfm
- **Inactive Ingredient Lookup:** http://www.accessdata.fda.gov/scripts/cder/iig/index.cfm
- **Drug Approval Process:** http://www.fda.gov/Drugs/DevelopmentApprovalProcess/HowDrugsareDevelopedandApproved/default.htm
- **Research Use Only Labeling:** http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfCFR/CFRSearch.cfm?fr=312.160

Additional Resources continued

- **Investigational New Drugs (IND):** http://www.fda.gov/Drugs/DevelopmentApprovalProcess/HowDrugsareDevelopedandApproved/ApprovalApplications/InvestigationalNewDrugINDApplication/default.htm
- **Investigational Use Only Labeling:** http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfCFR/CFRSearch.cfm?fr=312.6
- **OTC (Nonprescription) Drugs:** http://www.fda.gov/Drugs/DevelopmentApprovalProcess/HowDrugsareDevelopedandApproved/ucm209647.htm
- **OTC Drug Labeling:** http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfCFR/CFRSearch.cfm?CFRPart=201
- **New Drug Applications (NDA):** http://www.fda.gov/Drugs/DevelopmentApprovalProcess/HowDrugsareDevelopedandApproved/ApprovalApplications/NewDrugApplicationNDA/default.htm
- **Abbreviated New Drug Applications (ANDA):** http://www.fda.gov/Drugs/DevelopmentApprovalProcess/HowDrugsareDevelopedandApproved/ApprovalApplications/AbbreviatedNewDrugApplicationANDAGenerics/default.htm
- **Prescription Drug Labeling:** http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfCFR/CFRSearch.cfm?CFRPart=201

HUMAN AND ANIMAL FOOD

Submitting Human and Animal Food Entries in ACE

- Know the Product Being Imported
- Information Needed for Submission
- Common Reasons for Food Entry Processing Delays
- Additional Resources

Know the Product Being Imported

The term "**food**" means

- Articles used for food or drink for man or other animals
- Chewing gum
- Articles used for components of any such article

FOO

Know the Product Being Imported

Examples of food products

- Fruits and vegetables
- Seafood
- Bottle water
- Dietary supplements
- Pet food
- Animal feed

Overview: Products Requiring Prior Notice

- Human and animal food products requiring Prior Notice include:
  - Food imported for use, storage, or distribution in the United States
  - Food transshipped through the United States to another country
  - Food imported for future export
  - Food for use in a Foreign Trade Zone (FTZ)
  - Food for Trade Shows
  - Food to be sold in Duty Free Shops

Options for Submitting Human and Animal Food Entries in ACE

- Stand Alone Prior Notice Submission [PN Standalone]
- Food Commodity Combined Entry Submission [PN + 801(a)]
- Non-PN Food Commodity or PN Requirements Previously Met [Non-PN and PN Previously Met]

FOO

Information Needed for Submission

Program & Processing Codes

Program Code for all food commodities is **FOO**.

The **Processing Code** will be determined by the commodity sub-type:

PG01 - Government Agency Code	Commodity Type	PG01 - Government Agency Program Code	Commodity Sub-Type	PG01 - Government Agency Processing Code
FDA	Food	FOO	Natural State Food	NSF
FDA	Food	FOO	Processed Food	PRO
FDA	Food	FOO	Animal Food (includes pet food, medicated feed and feeds)	FEE
FDA	Food	FOO	Additives and Colors	ADD
FDA	Food	FOO	Dietary Supplements	DSU
FDA	Food	FOO	Ceramicware or Food Contact Substance	CCW

Information Needed for Submission

Product Code Overview

Structure of the FDA Product Code					
Position	1-2	3	4	5	6-7
Name	Industry Code (N)	Class Code (A)	Sub Class Code (A or “-”)	Process Identification Code – PIC (A or “-”)	Product (AN)
Legend: N – Numeric; A – Alphabetic; AN - Alphanumeric					

- FDA Product Code errors are among the most common reasons for FDA Entry Rejections.
- Use a valid FDA Product Code per the FDA Product Code Builder.

FOO

Information Needed for Submission

Product Codes

- Product code is mandatory.

PG01: Program Code & Commodity	PG01: Processing Code & Commodity Subtype	PG02: Industry Code
FOO – Food*	NSF - Natural State Food	01-46, 48, 49, 50, 52, 54, 69, 70, 71 or 72
	PRO - Processed Food	
	FEE - Animal Feed	
	DSU - Dietary Supplement	
	ADD - Additives and Colors	
	CCW - Ceramicware or Food Contact Substance	52

LACF and Acidified

- **LACF** Industry Codes: 02-39, 41, 71, & 72 with PIC: **F** (Aseptic) and **E** (Commercially Sterile)
- **AF** Industry Codes: 02-39, 41, 71, & 72 with PIC: **I** (Acidified)

Information Needed for Submission

Packaging and Condition

Data Element	PN Standalone	PN+801(a)	Non-PN and PN Previously Met
Quantity	Mandatory	Mandatory	Optional but highly encouraged
Unit of Measure	Mandatory	Mandatory	Mandatory if Quantity is entered
Lot Number Information	Mandatory for Infant formula, Acidified Foods, and LACF products	Mandatory for Infant formula, Acidified Foods, and LACF products	
PGA Line Value	Optional but highly encouraged	Optional but highly encouraged	Optional but highly encouraged

* See FDA Supplemental Guide for ACE for valid units of measure for Human and Animal Food Packaging Containers.

Information Needed for Submission

Intended Use Codes

- Intended Use Code is not required for foods, food contact surfaces, and prior notice.
- If providing an Intended Use code, the following are applicable options:

CFSAN Regulated Products Import Scenario	Intended Use Code	CBP Intended Use Name
For Research Use as Human Food	**260.000**	For Research Use as Human Food
For Research Use as an Animal Food	**015.000**	For Research Use as an Animal Food
Personal Importation	**210.000**	For Personal Use as Human Food

FOO

Information Needed for Submission

Entities

Entity Data Requirement	PN Standalone	PN+801(a)	Non-PN and PN Previously Met
Prior Notice Submitter (**PNS**)	Mandatory	Mandatory	
Prior Notice Transmitter (**PNT**)	Mandatory	Mandatory	
Manufacturer (**MF**) or FDA Consolidator (**FDC**) or Grower (**DFI**)	Mandatory	Mandatory	Mandatory (Only MF allowed)
Shipper (**DEQ**)	Mandatory	Mandatory	Mandatory
FDA Importer (**FD1**)	Mandatory (Except for T&E entries)	Mandatory	Mandatory
Ultimate Consignee (**UC**)	Mandatory (Except for T&E entries)	Mandatory	
Owner (**DFP**)	Mandatory (Except for T&E entries)	Mandatory	
Location of Goods (**LG**)	Mandatory when the article of food/feed was refused for inadequate PN and moved under CBP Supervision	Mandatory when the article of food/feed was refused for inadequate PN and moved under CBP Supervision	
Foreign Supplier Verification Program Importer (**FSV**)		Mandatory beginning May 30, 2017	Mandatory beginning May 30, 2017
Delivered to Party (**DP**)			Mandatory
Broker/Filer Point of Contact (**PK**)	Optional but highly encouraged	Optional but highly encouraged	Optional but highly encouraged

FSVP Reminders

- FSVP Data Elements:
  - Firm name
  - Firm address
  - Email Address
  - Duns #
  - Individual's name and phone # (optional)

- FSVP Exemptions:
  - Affirmations of Compliance
    - Research and Evaluation (RNE)
    - FSVP Exempt (FSX)

- CSMS message #17-000314 titled DA Foreign Supplier Verification Programs (FSVP) Initial Compliance Date: https://apps.cbp.gov/csms/viewmssg.asp?Recid=22717&page=&srch_argv=17-000314&srchtype=all&btype=&sortby=&sby
- Infographic depicting who is subject to FSVP Requirements: https://www.fda.gov/downloads/Food/GuidanceRegulation/FSMA/UCM472461.pdf
- For regulatory, technical, and policy questions that are not already addressed online or internally about FSVP (and Preventive controls), the Technical Assistance Network (TAN): https://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm459719.htm

FOO

Information Needed for Submission

Affirmations of Compliance

Required Affirmation of Compliance Codes	PN Standalone	PN+801(a)	Non-PN and PN Previously Met
PFR or **CFR** or **GFR** or **FME**	Mandatory	Mandatory	
RNO Required for Rail or Containerized Rail	Conditional	Conditional	
CAN Required if using PG13 or if SCAT or IATA not provided	Conditional	Conditional	
VFT Required for Air, Rail, Truck, or Ocean	Conditional	Conditional	
VES Required for Ocean	Conditional	Conditional	
FCE Required for LACF and AF products		Conditional	Conditional
SID Required for LACF and AF products		Conditional	Conditional
VOL Required for LACF and AF products if container dimensions not provided		Conditional	Conditional
FSX Required if applicable beginning May 30, 2017		Conditional	Conditional
RNE Required if applicable beginning May 30, 2017		Conditional	Conditional

	Optional Affirmation of Compliance Codes (O for Optional)																				
	SFR	UFR	IFR	TFR	ORN	SRN	CFR	GFR	LFR	CCC	CIN	ERR	FAP	FCC	IBP	IFE	PKC	AIN	JIF	SIF	VQI
PN Standalone	O	O	O	O	O	O	O	O	O												
PN+801(a)	O	O	O	O	O	O	O	O	O		O	O	O	O	O	O	O	O	O	O	O
Non PN & PN Prev. Met										O	O	O	O	O	O	O	O	O	O	O	O

FOO

Information Needed for Submission

Origin, Shipment, and Arrival

Data Element	PN Standalone	PN+801(a)	Non-PN and PN Previously Met
Country of Production or Place of Growth	Mandatory	Mandatory	Mandatory
Country of Shipment	Mandatory	Mandatory	
Country of Refusal	Mandatory if refused by other country(-ies)	Mandatory if refused by other country(-ies)	Mandatory if refused by other country(-ies)
Container Number	Mandatory if containerized cargo by water, air, rail, or land	Mandatory if containerized cargo by water, air, rail, or land	
Express Courier Tracking Number	Mandatory for mail/express courier in lieu of AWB/BOL/Flight #	Mandatory for mail/express courier in lieu of AWB/BOL/Flight #	
Anticipated Arrival Date	Mandatory	Mandatory	Mandatory
Anticipated Arrival Time	Mandatory	Mandatory	Mandatory
Anticipated Port of Arrival	Mandatory	Mandatory	
Anticipated Port of Entry			Optional

Summary

- Know the product being imported and associated requirements
- Understand the data elements
- Provided correct and accurate information
- Give Entry Filers the information they need
- Obtain all necessary information from the Importer

NOTE: FDA will not be able to process an entry without this information. You can help expedite FDA's review of your imported product(s) by initially providing accurate and complete information and by responding quickly to requests from FDA for additional documents or information.

Common Reasons for Food Entry Processing Delays

Low Acid and Acidified Foods

- Failure to provide: FCE and SID; Container Dimensions or Volume; Lot Number
- Firm and/or Product incorrectly provided

Additional Resources

- For more information about Human and Animal Foods, visit http://www.fda.gov/Food/default.htm
- For more information about Registration of Food Facilities, visit https://www.fda.gov/food/guidanceregulation/foodfacilityregistration/default.htm
- For Prior Notice Q&As, visit https://www.fda.gov/Food/GuidanceRegulation/ImportsExports/Importing/ucm2006836.htm

Making ACE Work for You: Importing FDA Regulated Products

MEDICAL DEVICES

Submitting Medical Device Entries in ACE

- Know the Product Being Imported
- Information Needed for Submission
- Common Reasons for Medical Device Entry Processing Delays
- Additional Resources

DEV

Know the Product Being Imported

If a product is labeled, promoted or used in a manner that meets the following definition in section 201(h) of the Federal Food Drug & Cosmetic (FD&C) Act it will be regulated by the Food and Drug Administration (FDA) as a medical device and is subject to premarketing and post marketing regulatory controls.

DEV

FDA

Know the Product Being Imported

- ***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. (21 CFR 820.3(c))

- ***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. (21 CFR 820.3 (l))

Know the Product Being Imported

Examples of medical devices

- Tongue depressors and bedpans
- Myocardial and Epicardial leads
- Surgical lasers
- In vitro diagnostic test kits
- Reagents
- Diagnostic ultrasound products
- X-ray machines

DEV

Information Needed for Submission

Program & Processing Codes

Program Code for medical device commodities is **DEV**.

The **Processing Code** will be determined by the commodity sub-type:

PG01 - Government Agency Code	Commodity Type	PG01 - Government Agency Program Code	Commodity Sub-Type	PG01 - Government Agency Processing Code
FDA	Medical Devices	DEV	Radiation Emitting Devices *	RED
FDA	Medical Devices	DEV	Non-Radiation Emitting Devices	NED

DEV

Information Needed for Submission

Product Code Overview

Structure of the FDA Product Code					
Position	1-2	3	4	5	6-7
Name	Industry Code (N)	Class Code (A)	Sub Class Code (A or “-”)	Process Identification Code – PIC (A or “-”)	Product (AN)
Legend: N – Numeric; A – Alphabetic; AN - Alphanumeric					

- FDA Product Code errors are among the most common reasons for FDA Entry Rejections.
- Use a valid FDA Product Code per the FDA Product Code Builder.

DEV

Information Needed for Submission

Product Codes

- Product code is mandatory.

PG01: Program Code & Commodity	PG01: Processing Code & Commodity Subtype	PG02: Industry Code
DEV - Medical Device	NED - Non-Radiation Emitting Device	73-92
	RED - Radiation-Emitting Device	

DEV

FDA

Information Needed for Submission

Product Descriptions, Packaging and Condition

- Data requirements depend on whether the product is:
  - Radiation Emitting Device
  - Non-Radiation Emitting Device

Data Requirement	Radiation Emitting Devices	Non-radiation Emitting Devices
Commodity Characteristic Description	Mandatory	Mandatory
Quantity and Packaging* (if entered, the rules from the SG must be followed)	Mandatory if the product requires a 2877	Optional but encouraged
PGA Line Value	Optional but highly encouraged	Optional but highly encouraged

See the FDA Supplemental Guide for ACE for valid units of measure for medical device packaging containers.

DEV

Information Needed for Submission

Intended Use Codes and Affirmations of Compliance

- Intended Use Code is mandatory for medical devices.
- Affirmation of Compliance requirements depend on the Intended Use Code.

Intended Use Codes	Import Scenario	Affirmations of Compliance
081.001 or UNK	• Standard import of device, accessories, or components regulated as a finished device • Import of refurbished device • Import of a reprocessed device	Mandatory: DEV, DFE, LST Conditional: IRC, LWC, PM# Optional: DI
081.002*	Import of a device for domestic refurbishing	Mandatory: DEV, DFE, LST Conditional: IRC, LWC, PM# Optional: DI
081.003	Domestically manufactured device that is part of a medical device convenience kit	Mandatory: DDM, DFE, KIT, LST Conditional: IRC, LWC, PM# Optional: DI
081.004	Foreign manufactured device that is Part of a medical device convenience kit	Mandatory: KIT, DEV, DFE, LST Conditional: PM#, LWC; IRC Optional: DI

*Annotates that additional information may be needed at time of entry in order for FDA to make a final admissibility decision.

DEV

Information Needed for Submission

Intended Use Codes and Affirmations of Compliance

- Intended Use Code is mandatory for medical devices.
- Affirmation of Compliance requirements depend on the Intended Use Code.

Intended Use Codes	Import Scenario	Affirmations of Compliance
081.005	Device constituent part for drug-device combination product	Mandatory: DEV, DFE, LST Conditional: DA, IND
140.000	Import of a device for charity	Mandatory: DEV, DFE, LST Conditional: IRC, LWC, PM# Optional: DI
081.007	Component for further manufacturing into a finished medical device	Mandatory: CPT Optional: LST, PM#
081.008	Device component for use in a drug-device combination product	Mandatory: CPT Conditional: DA, IND
170.000	Repair of medical device and re-exportation	Mandatory: IFE Conditional: DFE, LST, IRC, LWC, PM#, DDM Optional: DI

DEV

Information Needed for Submission

Intended Use Codes and Affirmations of Compliance

- Intended Use Code is mandatory for medical devices.
- Affirmation of Compliance requirements depend on the Intended Use Code.

Intended Use Codes	Import Scenario	Affirmations of Compliance
180.010	Import of research or investigational use in vitro diagnostic device	
180.014*	• Import of a device for non-clinical use/bench testing • Import of device sample for customer evaluation	
180.015*	Import of a medical device for clinical investigational use	Mandatory: IDE
920.001	Import of a device that is US goods returned for refund/overstock (to manufacturer)	Mandatory: DDM, LST Conditional: DFE, IRC, LWC, PM# Optional: DI
920.002	Import of device that is US goods returned for sale to a third party	Mandatory: DFE, DDM, LST Conditional: IRC, LWC, PM# Optional: DI

*Annotates that additional information may be needed at time of entry in order for FDA to make a final admissibility decision.

DEV

Information Needed for Submission

Intended Use Codes and Affirmations of Compliance

- Intended Use Code is mandatory for medical devices.
- Affirmation of Compliance requirements depend on the Intended Use Code.

Intended Use Codes	Import Scenario	Affirmations of Compliance
950.001*	Import of a single-use device for domestic reprocessing	Mandatory: DDM, LST Conditional: DFE, IRC, LWC, PM# Optional: DI
950.002*	Import of a multi-use device for domestic reprocessing	Conditional: DDM, DFE, IRC, LST, LWC, PM# Optional: DI
970.000	Import for Export: • Import of a medical device for further processing and re-exportation • Importation of a medical device or accessory for further manufacturing into an export-only medical device	Mandatory: DEV, DFE, IFE, LST

*Annotates that additional information may be needed at time of entry in order for FDA to make a final admissibility decision.

DEV

Information Needed for Submission

Intended Use Codes and Affirmations of Compliance

- Intended Use Code is mandatory for medical devices.
- Affirmation of Compliance requirements depend on the Intended Use Code.

Intended Use Codes	Import Scenario	Affirmations of Compliance
970.001	Import for Export: • Importation of a medical device component for further manufacturing into an export-only medical device	Mandatory: IFE, CPT, DDM, LST
100.000*	Device For Personal Use	
110.000*	Public Exhibition/Trade Show	
940.000*	Compassionate Use/Emergency device	

*Annotates that additional information may be needed at time of entry in order for FDA to make a final admissibility decision.

DEV

FDA

Information Needed for Submission

Entities

Entity Role (Code)	Entity Name	Entity Address	Individual Name, Tel# and eMail
Manufacturer (**MF**)	Mandatory	Mandatory	
Shipper (**DEQ**)	Mandatory	Mandatory	
FDA Importer (**FD1**)	Mandatory	Mandatory	Mandatory
Device Initial Importer (**DII**)	Mandatory	Mandatory	
Delivered to Party (**DP**)	Mandatory	Mandatory	
Filer's/Broker's Point of Contact (**PK**)	Optional but encouraged	Optional but encouraged	Optional but encouraged

- FEI number is preferred and DUNS number is encouraged when FEI number is unknown.

DEV

Information Needed for Submission

Origin and Arrival

Data Requirement	Medical Devices
Country of Production for a finished product or Country of Source for a component	Mandatory
Country of Refusal	Mandatory if refused by other country(-ies)

Anticipated Arrival Date	Mandatory
Anticipated Arrival Time	Mandatory
Anticipated Port of Entry	Optional

Summary

- Know the product being imported and associated requirements
- Understand the data elements
- Provided correct and accurate information
- Give Entry Filers the information they need
- Obtain all necessary information from the Importer

NOTE: FDA will not be able to process an entry without this information. You can help expedite FDA's review of your imported product(s) by initially providing accurate and complete information and by responding quickly to requests from FDA for additional documents or information.

DEV

FDA

Common Reasons for Medical Device Entry Processing Delays

- Required Affirmation of Compliance (A of C) Codes incomplete or incorrect (LST, DEV, DFE, etc.)
- Firm Name does not match A of C
- Device Initial Importer Entity
- Product Code Incorrect
- Country Code U.S
- Transmitting “UNK” as intended use code

DEV

Additional Resources

- For more information about medical devices, visit http://www.fda.gov/medicaldevices/deviceregulationandguidance/overview/classifyyourdevice/ucm051512.htm
- For examples of accessories to medical devices, visit https://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM429672.pdf
- Device Advise, visit https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/default.htm
- CDRH Learn, visit https://www.fda.gov/Training/CDRHLearn/default.htm
- Device Registration Database, visit https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfRL/rl.cfm
- Premarket Approval Database , visit https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMA/pma.cfm
- Product Classification Database, visit https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPCD/classification.cfm
- Who Must Register and List, visit https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/RegistrationandListing/ucm053165.htm

Making ACE Work for You: Importing FDA Regulated Products

TOBACCO

TOB

Submitting Tobacco Entries in ACE

- Know the Product Being Imported
- Information Needed for Submission
- Additional Resources

TOB

FDA

Know the Product Being Imported

- The Federal Food, Drug, and Cosmetic Act defines “tobacco product” as “any part made or derived from tobacco that is intended for human consumption, including any component, part, or accessory of a tobacco product (except for raw materials other than tobacco used in manufacturing a component, part, or accessory of a tobacco product).

TOB

FDA

Know the Product Being Imported

Example of tobacco products

- Cigarettes, cigarette tobacco and roll-your-own tobacco
- Smokeless tobacco (e.g. snuff and chewing tobacco)
- Electronic cigarettes
- Cigars
- Hookah
- Pipe tobacco
- Their components and parts, but not their accessories

TOB

Information Needed for Submission

Program & Processing Codes

Program Code for tobacco commodities is **TOB**.

The **Processing Code** will be determined by the commodity sub-type:

PG01 - Government Agency Code	Commodity Type	PG01 - Government Agency Program Code	Commodity Sub-Type	PG01 - Government Agency Processing Code
FDA	Tobacco	TOB	Consumer Use	CSU
FDA	Tobacco	TOB	For Further Manufacturing	FFM
FDA	Tobacco	TOB	Investigational	INV

TOB

Information Needed for Submission

Product Code Overview

Structure of the FDA Product Code					
Position	1-2	3	4	5	6-7
Name	Industry Code (N)	Class Code (A)	Sub Class Code (A or “-”)	Process Identification Code – PIC (A or “-”)	Product (AN)
Legend: N – Numeric; A – Alphabetic; AN - Alphanumeric					

- FDA Product Code errors are among the most common reasons for FDA Entry Rejections.
- Use a valid FDA Product Code per the FDA Product Code Builder.

TOB

Information Needed for Submission

Product Codes

- Product code is mandatory.

PG01: Program Code & Commodity	PG01: Processing Code & Commodity Subtype	PG02: Industry Code
TOB - Tobacco	CSU - Consumer Use	98
	FFM - For further manufacturing	
	INV - Investigational	

TOB

Information Needed for Submission

Product Descriptions, Packaging and Condition

Data Requirement	Tobacco
Commodity Characteristic Description	Mandatory
Trade Name/Brand Name	Required if the product is intended for consumer use (agency processing code CSU)
Quantity and Packaging* (if entered, the rules from the SG must be followed)	Optional but encouraged
PGA Line Value	Optional but highly encouraged

* See FDA Supplemental Guide for ACE for valid units of measure for Tobacco Packaging Containers.

TOB

FDA

Information Needed for Submission

Intended Use Codes and Affirmations of Compliance

- Intended Use Codes are conditional for tobacco products.

Intended Use Code	Intended Use Description
150.000	For commercial process as non-food
155.000	For Commercial Assembly as a Non-Food Product to be consumed
180.001	For Research and Development as a non-Food Product - Animal or plant for biomedical research
180.000	For Research and Development as a non-Food Product – All other Uses
110.000	For Public Exhibition or Display as a Non-Food Product
130.000	For Consumer Use as a Non- Food Product
140.000	For Charitable Organization Use as Non-Food Product
130.037	For re-packaging and re-labelling**

TOB

Information Needed for Submission

Affirmations of Compliance

- Affirmations of Compliance are optional for tobacco products.

- Please see the FDA Supplemental Guide for ACE for applicable codes.

TOB

FDA

Information Needed for Submission

Entities

Entity Role (Code)	Entity Name	Entity Address	Individual Name, Tel# and eMail
Manufacturer (**MF**)	Mandatory	Mandatory	
Shipper (**DEQ**)	Mandatory	Mandatory	
FDA Importer (**FD1**)	Mandatory	Mandatory	Mandatory
Delivered to Party (**DP**)	Mandatory	Mandatory	
Independent Third Party (**ITL**)	Conditional	Conditional	
Laboratory or Clinical Site (**LAB**)	Conditional	Conditional	
Retailer/Distributor (**RD**)	Optional	Optional	
Submitter (**TB**)	Optional	Optional	
Filer's/Broker's Point of Contact (**PK**)	Optional but encouraged	Optional but encouraged	Optional but encouraged

- DUNS and FEI are optional, but encouraged.

TOB

Information Needed for Submission

Origin and Arrival

Data Requirement	Tobacco
Country of Production or Place of Growth or Harvested or Country of Source	Mandatory
Country of Refusal	Mandatory if refused by other country(-ies)

Anticipated Arrival Date	Mandatory
Anticipated Arrival Time	Mandatory
Anticipated Port of Entry	Optional

TOB

Summary

- Know the product being imported and associated requirements
- Understand the data elements
- Provided correct and accurate information
- Give Entry Filers the information they need
- Obtain all necessary information from the Importer

NOTE: FDA will not be able to process an entry without this information. You can help expedite FDA's review of your imported product(s) by initially providing accurate and complete information and by responding quickly to requests from FDA for additional documents or information.

TOB

FDA

Additional Resources

- For more general information about tobacco products, visit https://www.fda.gov/TobaccoProducts/default.htm
- Information on FDA's New Tobacco Rule, visit https://www.fda.gov/ForConsumers/ConsumerUpdates/ucm506676.htm
- FDA's New Regulations for E-Cigarettes, Cigars, and All Other Tobacco Products, visit https://www.fda.gov/TobaccoProducts/Labeling/RulesRegulationsGuidance/ucm394909.htm

Making ACE Work for You: Importing FDA Regulated Products

RADIATION EMITTING PRODUCTS

Submitting Radiation Emitting Device Entries in ACE

- Know the Product Being Imported
- Information Needed for Submission
- Common Reasons for Radiation Emitting Device Entry Processing Delays
- Additional Resources

Know the Product Being Imported

Examples of radiation emitting products

- Diagnostic x-ray systems
- Cabinet x-ray systems
- Microwave ovens
- Laser products
- Sunlamp products
- High-intensity mercury vapor discharge lamps
- Ultrasonic therapy products

RAD

FDA

Information Needed for Submission

Program & Processing Codes

Program Code for radiation emitting commodities is **RAD**.

The **Processing Code** will be determined by the commodity sub-type:

PG01 - Government Agency Code	Commodity Type	PG01 - Government Agency Program Code	Commodity Sub-Type	PG01 - Government Agency Processing Code
FDA	Radiation Emitting Products	RAD	Non-Medical Radiation Emitting Products	REP

RAD

FDA

Information Needed for Submission

Product Code Overview

Structure of the FDA Product Code					
Position	1-2	3	4	5	6-7
Name	Industry Code (N)	Class Code (A)	Sub Class Code (A or “-”)	Process Identification Code – PIC (A or “-”)	Product (AN)
Legend: N – Numeric; A – Alphabetic; AN - Alphanumeric					

- FDA Product Code errors are among the most common reasons for FDA Entry Rejections.
- Use a valid FDA Product Code per the FDA Product Code Builder.

RAD

Information Needed for Submission

Product Codes

- Product code is mandatory.

PG01: Program Code & Commodity	PG01: Processing Code & Commodity Subtype	PG02: Industry Code
RAD - Radiation-Emitting Products	REP - Non-Medical Radiation-Emitting Product	94-97

RAD

FDA

Information Needed for Submission

Product Descriptions, Packaging and Condition

Data Requirement	Radiation Emitting Product
Commodity Characteristic Description	Mandatory
Trade Name/Brand Name	Mandatory if product requires a 2877
Quantity and Packaging* (when entered, the rules from the SG must be followed)	Mandatory if product requires a 2877
PGA Line Value	Optional but highly encouraged

* See the FDA Supplemental Guide for ACE for valid units of measure for Radiation Emitting Product Packaging Containers.

RAD

FDA

Information Needed for Submission

Intended Use Codes

- Intended Use Code is mandatory for radiation emitting products.

Intended Use Codes	Import Scenario
085.000	Veterinary Medical Use as a Non-Food Product under Controlled Distribution
090.000	Military Use as a Non- Food Product
100.000	Personal Use as a Non- Food Product
110.000	Public Exhibition or Display as a Non-Food Product
120.000	Public Safety Use as a Non-Food Product
130.000	Consumer Use as a Non- Food Product
140.000	Charitable Organization Use as Non-Food Product
150.000	Commercial Processing as a Non-Food Product
155.000	Commercial Assembly as a Non-Food Product
170.000	Repair of a Non-Food Product
180.000	Research and Development as a Non-Food Product
970.000	Import Export
980.000	Other Use

RAD

FDA

Information Needed for Submission

Affirmations of Compliance

- These Affirmations of Compliance are conditional for radiation emitting products requiring a 2877.

AoC Code	Description	Requirement
RA1, RA2, RA3, RA4, RA5, RA6 and RA7	EPRC Radiation - emitting Products. Use if FDA compliance is non-applicable. See Form FDA 2877.	Conditional
RB1	EPRC Radiation - emitting Products. Use if product is FDA compliant. See Form FDA 2877 (must transmit with ANC or ACC).	Conditional
RB2, RC1*	EPRC Radiation products. Use if product is FDA compliant. See Form FDA 2877.	Conditional
RC2	EPRC Product Declaration C2 (FDA 2877).	Conditional
RD1*, RD2*, RD3	EPRC Radiation products. Use if product is non-compliant but will be re-conditioned under bond and Form FDA766. See Form FDA 2877.	Conditional
ACC	EPRC (Electronic Product Radiation Control) Accession Number	Conditional
ANC	PRC Radiation - emitting Products Annual Report Accession Number	Conditional

Information Needed for Submission

Affirmations of Compliance

- The following Affirmations of Compliance are optional for radiation emitting products.

AoC Code	Description	Requirement
MDL	Model Number of the Product	Optional
ERR	Entry Review Requested	Optional
IFE	Import For Export	Optional
CCM	Name of the Certified Component Manufacturer	Optional

RAD

FDA

Information Needed for Submission

Entities

Entity Role (Code)	Entity Name	Entity Address	Individual Name, Tel# and eMail
Manufacturer (**MF**)	Mandatory	Mandatory	
Shipper (**DEQ**)	Mandatory	Mandatory	
FDA Importer (**FD1**)	Mandatory	Mandatory	Mandatory
Delivered to Party (**DP**)	Mandatory	Mandatory	
Filer's/Broker's Point of Contact (**PK**)	Optional but encouraged	Optional but encouraged	Optional but encouraged

- DUNS and FEI are optional, but encouraged.

Information Needed for Submission

Origin and Arrival

Data Requirement	Radiation Emitting Products
Country of Production or Country of Source	Mandatory
Country of Refusal	Mandatory if refused by other country(-ies)

Anticipated Arrival Date	Mandatory
Anticipated Arrival Time	Mandatory
Anticipated Port of Entry	Optional

Summary

- Know the product being imported and associated requirements
- Understand the data elements
- Provided correct and accurate information
- Give Entry Filers the information they need
- Obtain all necessary information from the Importer

NOTE: FDA will not be able to process an entry without this information. You can help expedite FDA's review of your imported product(s) by initially providing accurate and complete information and by responding quickly to requests from FDA for additional documents or information.

Common Reasons for Radiation Emitting Device Entry Processing Delays

- No Affirmation of Compliance Codes or incorrectly provided
  - Accession Number (ACC)
  - Annual Report Accession Number (ANC)

Additional Resources

- For more general information about radiation emitting products, visit https://www.fda.gov/Radiation-EmittingProducts/default.htm

- For additional information concerning Radiation Emitting Electronic Product Codes, visit https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPCD_RH/classification.cfm

Making ACE Work for You: Importing FDA Regulated Products

ANIMAL DRUGS & DEVICES

VME

Submitting Animal Drug and Device Entries in ACE

- Know the Product Being Imported
- Information Needed for Submission
- Additional Resources

VME

FDA

Know the Product Being Imported

FD&C Act defines “drug” as “articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease" and "articles (other than food) intended to affect the structure or any function of the body of man or other animals“.

A “new animal drug” means any drug intended for use for animals other than man, including any drug intended for use in animal feed but some exclusions do apply.

Animal/Veterinary medical devices

Know the Product Being Imported

Examples of animal drugs

- Penicillin G Benzathine
- Butorphanol Tartrate
- Gentamicin Sulfate
- Tetracycline and Monensin

Examples of devices for use on animals

- Immobilizer
- Scales
- X-ray systems
- Capnography and oxygen monitors

VME

Information Needed for Submission

Program & Processing Codes

Program Code for animal drug and device commodities is **VME**.

The **Processing Code** will be determined by the commodity sub-type:

PG01 - Government Agency Code	Commodity Type	PG01 - Government Agency Program Code	Commodity Sub-Type	PG01 - Government Agency Processing Code
FDA	Animal Drugs and Devices	VME	Animal Drugs	ADR
FDA	Animal Drugs and Devices	VME	Animal Devices	ADE

VME

FDA

Information Needed for Submission

Product Code Overview

Structure of the FDA Product Code					
Position	1-2	3	4	5	6-7
Name	Industry Code (N)	Class Code (A)	Sub Class Code (A or "-")	Process Identification Code – PIC (A or "-")	Product (AN)
Legend: N – Numeric; A – Alphabetic; AN - Alphanumeric					

- FDA Product Code errors are among the most common reasons for FDA Entry Rejections.
- Use a valid FDA Product Code per the FDA Product Code Builder.

VME

Information Needed for Submission

Product Codes

- Product code is mandatory.

PG01: Program Code & Commodity	PG01: Processing Code & Commodity Subtype	PG02: Industry Code
VME - Animal Drug or Device*	ADR - Animal Drug	54, 56, 60, 61, 62, 63, 64, 65, 66 or 67
	ADE - Animal Device	68

*Subject to additional rules based on FDA Program/Processing/Product codes. See PG02 in individual chapters of the Supplemental guide.

VME

FDA

Information Needed for Submission

Product Descriptions, Packaging and Condition

Data Requirement	Animal Drugs and Devices
Commodity Characteristic Description	Mandatory
Quantity and Packaging* (if entered, the rules from the SG must be followed)	Optional but encouraged
PGA Line Value	Optional but highly encouraged

* See FDA Supplemental Guide for ACE for valid units of measure for Animal Drug and Device Packaging Containers.

VME

Information Needed for Submission

Intended Use Codes and Affirmations of Compliance

- Intended Use Code is mandatory for animal drugs (VME/ADR).
- Affirmation of Compliance requirements depend on the Intended Use Code.

Intended Use Codes	Import Scenario	Affirmations of Compliance
085.003	Drug subject of a new animal drug application, conditionally approved application, or Index listing	Mandatory: REG, NDC, and VAN, or VNA Optional: VFL, VFD
100.000	Importation for Personal Use	
150.013	Active Pharmaceutical Ingredient / Bulk Drug Substance to be used for Pharmacy Compounding	Mandatory: REG, NDC
150.020	Active Pharmaceutical Ingredient / Bulk Drug Substance used to be further manufactured into a finished drug subject of a new animal drug application, conditionally approved application, or Index listing	Mandatory: REG, NDC, and VAN, or VNA

VME

Information Needed for Submission

Intended Use Codes and Affirmations of Compliance

- Intended Use Code is mandatory for animal drugs (VME/ADR).
- Affirmation of Compliance requirements depend on the Intended Use Code.

Intended Use Codes	Import Scenario	Affirmations of Compliance
180.009	For research and development in a pharmaceutical product – clinical investigations in animals (INAD)	Mandatory: VIN
180.018	For research and development in a pharmaceutical product – for tests in-vitro or in laboratory research animals.	Optional: VIN
920.000	US Goods Returned	
970.000	Import for Export	
980.000	For Other Use: (APIs or Finished Drugs not elsewhere classified)	Mandatory: REG, NDC Optional: VAN, VNA, VFL, VFD

VME

FDA

Information Needed for Submission

Entities

Entity Role (Code)	Entity Name	Entity Address	Individual Name, Tel# and eMail
Manufacturer (**MF**)	Mandatory	Mandatory	
Shipper (**DEQ**)	Mandatory	Mandatory	
FDA Importer (**FD1**)	Mandatory	Mandatory	Mandatory
Delivered to Party (**DP**)	Mandatory	Mandatory	
Producer (**GD**)	Optional	Optional	
Filer's/Broker's Point of Contact (**PK**)	Optional but encouraged	Optional but encouraged	Optional but encouraged

- DUNS and FEI are optional, but encouraged.

VME

Information Needed for Submission

Origin and Arrival

Data Requirement	Animal Drugs and Devices
Country of Production or Country of Source	Mandatory
Country of Refusal	Mandatory if refused by other country(-ies)

Anticipated Arrival Date	Mandatory
Anticipated Arrival Time	Mandatory
Anticipated Port of Entry	Optional

VME

FDA

Summary

- Know the product being imported and associated requirements
- Understand the data elements
- Provided correct and accurate information
- Give Entry Filers the information they need
- Obtain all necessary information from the Importer

NOTE: FDA will not be able to process an entry without this information. You can help expedite FDA's review of your imported product(s) by initially providing accurate and complete information and by responding quickly to requests from FDA for additional documents or information.

VME

FDA

Additional Resources

- For more general information about animal drug and device products, visit https://www.fda.gov/AnimalVeterinary/default.htm

INFORMATION AND RESOURCES FOR ALL FDA REGULATED PRODUCTS

Avoiding Delays with FDA

- Delays occur when:
  - Inaccurate information such as incorrect product code are submitted
  - Intended Use Code qualifier “UNK” (Unknown)

- To expedite FDA review:
  - All information provided should be complete and accurate
  - Provide **conditional data elements** if applicable to the product being declared
  - Provide **optional data elements** such as:
    - FEI and/or DUNS
    - Quantity and Unit of Measure

Use the FDA Supplemental Guide

- Review each of the PG records until all required information is understood and has been provided by the importer
- Each section identifies:
  - mandatory, optional, and conditional data elements
  - codes and code descriptions
  - length/class (syntax) for data element types
- Follow any instructions provided by your software vendor to ensure all data elements are entered for transmission.

Summary

- Know the product being imported and associated requirements
- Understand the data elements
- Provided correct and accurate information
- Give Entry Filers the information they need
- Obtain all necessary information from the Importer

Frequently Asked Question

Q: If I transmit an FDA entry, does ACE allow me to correct the data if I realize I made a mistake?

A: When CBP receives an entry, it will automatically send the entry to FDA to process in real time if the entry is within five days of arrival. Unless CBP or FDA rejected the entry, no corrections can be made. If CBP or FDA did reject your entry, work with your ABI representative to send a correction.

Frequently Asked Question

Q: When does FDA receive the entry data from CBP? I have had an "FDA Review Message" for several days.

A: Once the entry is accepted by CBP, CBP sends out a generic message that says "DATA UNDER PGA REVIEW." This is not a confirmation that the data was sent to FDA. CBP will only send the entry to FDA, if the transmitted arrival date is within five days. If it is more than five days out, CBP will wait until it is within that timeframe to send it to FDA.

If it is within five days of arrival and you have not received any FDA response **within your usual turnaround time**, contact FDA's ACE Help Desk at ACE_Support@fda.hhs.gov and your CBP Client Representative.

Frequently Asked Question

Q: Does FDA prefer DUNS or FEI numbers for entity identification codes (PG19)?

A: FEI and DUNS are optional, but encouraged.

Note: As of 5/30/2017, the DUNS will be required for the FSVP importer for each line entry of food, unless they are subject to exemption and/or modified requirements. For additional information, visit https://www.fda.gov/Food/NewsEvents/ConstituentUpdates/ucm549668.htm.

Frequently Asked Questions

Q: Is the Drug Registration number an FEI number?

A: The Drug Registration Number (REG) is the 9-digit DUNS number the firm has on file with FDA Center for Drugs, Evaluation, and Research (CDER) Drug Registration (eDRLS). Only those DUNS numbers on file with eDRLS are Drug Registration Numbers (REG).

These can be found at on the **Drug Firm Registration Lookup** webpage**:**
http://www.accessdata.fda.gov/scripts/cder/drls/default.cfm

Frequently Asked Question

Q: Why can't I see the status of my entry in ITACS? Why does it say "FDA entry status information is not available pending receipt of conveyance arrival notification" when the shipment has arrived?

A: CBP is not consistently sending arrival notifications to FDA upon arrival of a shipment. Without receipt of that notification, ITACS will display the above message. This does not affect the ability to submit documents, submit availability information, or FDA's ability to review the entry.

Reference: CSMS #16-001003

Frequently Asked Question

Q: What are the lessons learned for how ACE changed filing for FDA?

A: Communicate early and often about FDA requirements. (Importer, Broker, and Software Vendor).

Delays and rejects occur when inaccurate information is provided, such as invalid product code or an unknown intended use code.

Use FDA as a resource. Attend webinars or request a training session. We are here to help.

Frequently Asked Questions

Q: Is “UNK” (Unknown) still allowed as an Intended Use Code?

A: UNK is still allowed as an Intended Use Code when the IUC is mandatory. If “UNK” is declared, CBP will not reject the entry if Affirmations of Compliance are not provided.

FDA highly encourages the transmission of complete data, including the correct Intended Use Code and Affirmations of Compliance. Refer to the FDA Supplemental Guide for a full list of requirements based on the import scenario.

UNK should only be used if information is not able to be obtained. Utilizing this code may lead to manual reviews and delayed processing by FDA.

Resources

- CSMS #16-000557, FDA ACE Entries: Common Errors
  https://csms.cbp.gov/viewmssg.asp?Recid=21913&page=&srch_argv=16-000557&srchtype=&btype=&sortby=&sby=

- CSMS #16-000741, FDA ACE Reject Document Posted to FDA.gov
  https://csms.cbp.gov/viewmssg.asp?Recid=22092&page=&srch_argv=16-000741&srchtype=&btype=&sortby=&sby=

Resources Available Online

- FDA ACE Affirmations of Compliance and Affirmations of Compliance Quick Reference at http://www.fda.gov/forindustry/importprogram/entryprocess/entrysubmissionprocess/ucm461234.htm

- FDA ACE/ITDS Webpage (including FDA Supplemental Guide) at https://www.fda.gov/industry/import-systems/automated-commercial-environmentinternational-trade-data-system-aceitds

- FDA DUNS Portal at https://fda.dnb.com/FDAUI/login.aspx and FDA Guide at https://www.fda.gov/media/95828/download

- Product Code Builder Tool and Tutorial at https://www.accessdata.fda.gov/scripts/ora/pcb/index.cfm

- For more information about FDA's Import Program, visit http://www.fda.gov/forindustry/importprogram/default.htm

- For information about ACE Quantity Data Instructions, visit https://www.fda.gov/downloads/ForIndustry/ImportProgram/EntryProcess/ImportSystems/UCM487256.pdf

Resources

Contact the **FDA Imports Inquiry Team** for questions regarding FDA import operations and policy, product coding, FD flags associated with HTS codes, entry declaration requirements for determining admissibility, if a product is regulated by FDA and other general import questions.

FDAImportsInquiry@fda.hhs.gov

301-796-0356

Resources

Contact **FDA ACE Support Center** for technical questions related to the FDA Supplemental Guide, required data elements, ACE entries, rejects, and errors.

ACE_Support@fda.hhs.gov
877-345-1101 (domestic toll-free)
571-620-7320 (local or international)

CSMS #17-000162: The ACE Support Center operates from 6 a.m. to 10 p.m. EST seven days per week.

Always keep your CBP Client Representative on all ACE-related email traffic

FDA Points of Contact for Imports

FDA Unit	Contact Information	Areas of Focus
ACE Support Center	ACE_Support@fda.hhs.gov Toll Free: 877-345-1101 Local/International: 571-620-7320	Technical issues related to the FDA supplemental guide, required data elements, and general ACE submission questions, including entry submissions rejected by FDA.
FDA Imports Inquiry	FDAImportsInquiry@fda.hhs.gov 301-796-0356	General questions regarding FDA import operations and policy, including product classification (program, processing, product and HTS codes) and declaration
Local FDA Office	http://www.fda.gov/ForIndustry/ImportProgram/ucm319216.htm	First-line support for product coding and entry-specific questions, including working through the FDA entry admissibility process, once the entry is successfully transmitted to FDA and accepted
Division of Food Defense Targeting	Prior.Notice@fda.hhs.gov 866-521-2297 http://www.fda.gov/Food/GuidanceRegulation/ImportsExports/Importing/ucm2006836.htm	General questions regarding Prior Notice for food shipments

Questions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