U.S. FOOD & DRUG ADMINISTRATION

Industry Quick Reference Guide to the FDA ACE Supplemental Guide

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INTRODUCTION

What is the Industry Quick Reference Guide to the FDA ACE SG?

The Industry Quick Reference Guide to the FDA ACE SG is a resource to help importers and filers understand the information reported to FDA for FDA-regulated products offered for import into the United States. This document highlights information that is mandatory, as well as the information that is helpful to the FDA's review process.

This Industry Quick Reference Guide is a high-level document; it does not replace or provide all of the details included in the FDA Supplemental Guide for the Automated Commercial Environment/ International Trade Data System (FDA Supplemental Guide for ACE). This document does not include:

- technical specifications for transmitting data;
- information for determining if FDA regulates a product,
- information on the Harmonized Tariff Schedule; or
- information on disclaiming a product.

Full details on the information collected for each commodity are available in the respective "Commodity Data Elements and Values" section of the FDA Supplemental Guide for ACE. Note that the FDA Partner Government Agency (PGA) message set, excluding Stand-alone Prior Notice, must be submitted with an ACE Cargo Release or ACE Entry Summary certified for cargo release transaction.

CBP's ACE CATAIR Cargo Release Chapter is available at:
https://www.cbp.gov/document/guidance/ace-catair-cargo-release-chapter.

CBP's ACE CATAIR Entry Summary Create/Update document is available at:
https://www.cbp.gov/document/technical-documentation/entry-summary-createupdate.

How do I use the Industry Quick Reference Guide to the FDA ACE SG?

This document is divided into ten commodity chapters, following the structure of the FDA ACE SG, and four appendices. Fully consider each question below, while working through the appropriate commodity chapter and referencing the appropriate appendices and links. This will help importers and filers collect the information to report to FDA for FDA-regulated products offered for import into the United States.

- **WHAT?** What is being offered for import (commodity, product code, description, quantity and packaging, and value)?
- **WHY?** Why is the product being imported or offered for import (intended use)?
- **HOW?** How can commodity-specific requirements be verified (Affirmations of Compliance)?
- **WHO?** Who are the entities involved with each entry line?
- **WHEN?** When is the anticipated arrival (date and time) of the entry line?
- **WHERE?** Where is the product origin? Where is the port of arrival?

Each product category or commodity is a chapter in this document. Click on a commodity page number to go to detailed information on the data FDA collects.

Commodities	Page Number	Description and Link to FDA Webpage
Biologics	Page 4	Biologic products such as human blood, blood donor screening tests, human tissue, embryos, human plasma, and medical devices for use in blood banking operations | Click for more BIO info.
Cosmetics	Page 8	Cosmetic products such as shampoo and make-up | Click for more COS info.
Human Drugs	Page 9	Active pharmaceutical ingredients, finished dosage drugs, and pharmaceutical necessities. Drugs include both prescription and over-the-counter medications. | Click for more DRU info.
Human and Animal Foods – Stand-alone Prior Notice	Page 12	Foods for human and animal consumption, including dietary supplements, and color additives. Prior Notice data requirements | Click for Human info. | Click for Animal info.
Human and Animal Foods – Combined Entry (801(a) and Prior Notice)	Page 15	Foods for human and animal consumption, including dietary supplements, and color additives. Combined Prior Notice and 801(a) data requirements | Click for Human info. | Click for Animal info.
Human and Animal Foods - Non- Prior Notice and Prior Notice Previously Met	Page 18	Foods for human and animal consumption, including dietary supplements, and color additives. Products that do not require Prior Notice data as ceramicware/food contact substance (CCW) or PN requirements previously met | Click for Human info. | Click for Animal info.
Medical Devices	Page 20	Medical devices such as first aid kits, pacemakers, surgical instruments, and sunglasses for human use | Click for more DEV info.
Tobacco Products	Page 23	Tobacco products such as cigarettes and its component parts, smokeless tobacco, and e-cigarettes | Click for more TOB info.
Radiation-Emitting Products	Page 25	Radiation-emitting products such as x-ray machines, microwave ovens, CD-ROMs, and laser pointers | Click for more RAD info.
Animal Drugs and Devices	Page 27	Animal drugs and medical devices for veterinary use | Click for more VME info.
Appendices	Page 29	Information on: Entities; Food Processing Codes; Program, Processing, and Product Codes; “UNK” in Lieu of an Intended Use Code; Helpful Links and Contacts

1. BIOLOGICS

See the FDA Supplemental Guide for ACE for full Biologics requirements.

Biologics **program information** is noted in the table below.

Program Code or Commodity	Processing Code or Commodity Subtype	Product Industry Code*	Status
BIO - Biologic	ALG - Allergenics	57	Program Code + One Processing Code + Product Code are Mandatory
	BBA - Blood Bag with Anti-coagulant		
	BDP - Blood Derivatives		
	BLD - Licensed Devices		
	BLO - Blood and Blood Products		
	CGT - Cell and Gene Therapy		
	HCT - Human Cells and Tissue		
	PVE - Plasma Volume Expanders		
	VAC - Vaccines		
	XEN - Xenotransplants		

*Note: The Industry Code is the first two digits of the product code. For full product code details visit the FDA Product Code Builder.

Biologics **product information** is noted in the table below.

Product Information	Status
Product Description	Mandatory
Trade Name/Brand Name	Optional for processing code HCT; Conditional for all other processing codes
Quantity and Packaging	Optional, but encouraged
PGA Line Value	

Valid FDA **Units of Measure (UOM)** for Biologics Packaging Containers and **UOM for the Base Unit** (Last Quantity Transmitted) for Biologics are noted below.

UOM Code	Description
AE	Aerosol
AM	Ampoule, Non-protected
AP	Ampoule, Protected
AT	Atomizer
BA	Barrel
BC	Bottle crate, Bottle rack
BG	Bag
BO	Bottle, Non-Protected, Cyl
BQ	Bottle, Protected, Cylindrical

Base UOM Code	Description
AU	Allergy Units (ml or tablet)
BAU	Bioequivalent Allergy Units (ml or tablet)
CAP	Capsule
CG	Centigrams
FOZ	Ounces, fluid
G	Grams
GAL	Gallons (US)
KG	Kilograms
L	Liters

UOM Code	Description
BS	Bottle, Non-protected, Bulbous
BV	Bottle, Protected Bulbous
BX	Box
CA	Can, Rectangular
CI	Canister
CON	Container
CS	Case
CT	Carton
CX	Can, Cylindrical
CY	Cylinder
DR	Drum
EN	Envelope
FD	Framed Crate
GB	Gas Bottle
MB	Bag, Multi-ply
PAL	Pallet
PC	Parcel
PK	Package
SY	Syringe
VI	Vial
TU	Tube
VP	Vacuum Packed
VL	Bulk Liquid

Base UOM Code	Description
LB	Pounds (avdp)
MG	Milligrams
ML	Milliliters
MCG	Micrograms
NO	Number
OZ	Ounces, weight (avdp)
PCS	Pieces
PNU	Protein Nitrogen Units
PTL	Pints, liquid (US)
QTL	Quarts, liquid (US)
TAB	Tablets

Intended Use Codes (IUCs) and **Affirmations of Compliance (AofCs)** for each Biologics Intended Use Code import scenario are noted in the table below. Refer to the FDA ACE AofCs document for more information and examples of AofCs. See Appendix C for information about "UNK".

Import Scenario	Processing Codes	IUC	AofCs
Biological or chemical for research and development into a pharmaceutical product – Investigational New Drugs (IND); clinical trials or other human/animal use	ALG, BBA, BDP, BLD CGT, PVE, VAC, BLD, XEN	180.009	Mandatory: IND Optional: REG
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.	ALG, BDP, BLD, BLO, CGT, VAC, or XEN	080.000	Mandatory: BLN or STN or both Optional: DLS, REG
CBER-regulated Final product; ready for use. Importation of drug regulated by CBER.	BBA, PVE	080.000	Mandatory: DA, REG, (DA includes NDA & ANDA only) Optional: DLS
Human Cells, tissues, and cellular and tissue based products (HCT/Ps) for implant,	HCT	082.000	Mandatory: HCT (No

Import Scenario	Processing Codes	IUC	AofCs
transplant, infusion, or transfer into a human recipient. The HCT affirmation should be used to indicate the HCT/Ps being imported or offered for import are in compliance with all applicable requirements of 21 CFR 1271.			Qualifier Needed for HCT)
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.	HCT	082.000	Mandatory: HRN Optional: HCT
CBER Product sample for testing or lot release	ALG, BDP, BLD, BLO, CGT, VAC, or XEN	180.016	Mandatory: BLN or STN or both Optional: DLS, REG
CBER product for further manufacture of a licensed biological product under a short supply agreement (21 CFR 601.22)	ALG, BDP, BLD, BLO, CGT. VAC, or XEN	155.000	Mandatory: BLN or STN or both Optional: DLS, REG
Importation for personal use	ALG, BBA, BDP, BLD, BLO, CGT, PVE, VAC, or XEN	100.000	N/A
Bulk biological drug substance for processing into a pharmaceutical product	ALG, BDP, BLD, BLO, CGT, VAC, or XEN	150.007	Mandatory: BLN or STN or both Optional: DLS, IND, REG
Bulk drug substance for processing into a pharmaceutical product	BBA or PVE	150.007	Mandatory: DA Optional: DLS, IND, REG
Standard import of a biological drug or device for non-commercial distribution in government and non-government support program.	ALG, BBA, BDP, BLD, BLO, CGT, PVE, VAC, or XEN	140.000	Optional: BLN, DA, IND, STN
Import of a biological drug or device for trade show	ALG, BBA, BDP, BLD, BLO, CGT, PVE, VAC, or XEN	110.000	Optional: BLN, DA, IND, STN
For reconditioning or repair of a non-food product	ALG, BBA, BDP, BLD, BLO, CGT, HCT, PVE, VAC, or XEN	170.000	Optional: BLN, DA, HCT, HRN, IND, STN
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.	ALG, BBA, BDP, BLD, BLO, CGT, PVE, VAC, or XEN	970.000	Mandatory: IFE (No qualifier required)

Import Scenario	Processing Codes	IUC	AofCs
Import of a biologic for non-clinical research use only, bench testing, etc. These entries could be disclaimed if the HTS code allows it.	ALG, BBA, BDP, BLD, BLO, CGT, HCT, PVE, VAC, or XEN	180.000	N/A
Importation of a drug (including a biological product) or device for compassionate use/emergency use	ALG, BBA, BDP, BLD, BLO, CGT, HCT, PVE, VAC, or XEN,	940.000	Optional: BLN, DA, HCT, HRN, IND, STN
Import of US Goods Returned	ALG, BBA, BDP, BLD, BLO, CGT, HCT, PVE VAC, or XEN,	920.000	N/A

An additional optional Biologics AofC is Entry Review Requested (ERR).

Biologics **entity information** is noted in the table below. Refer to Appendix A: Entity Glossary for more information.

Entity Role (Code)	Entity Name and Entity Address	Individual Name, Tel# and Email	Entity ID Code and Number: DUNS or FEI
Manufacturer (MF)	Mandatory	N/A	Optional, but encouraged
Shipper (DEQ)		N/A	
FDA Importer (FD1)		Mandatory	
Delivered to Party (DP)		N/A	
Filer's/Broker's Point of Contact (PK)	Optional, but encouraged		

"Optional, but encouraged" information assists in matching firms in the FDA database and/or facilitates the entry review process. FDA CBER prefers FEIs for biologics. See the Blood Establishment Registration (BER) Database and Human Cell and Tissue Establishment Registration Public Query for public FEIs and information.

Biologics **arrival** and **product origin information** are noted below.

Arrival Information	Status
Anticipated Arrival Date AND Time at Port of Entry	Mandatory
FTZ Information	Conditional

Product Origin Information	Status
Country of Production OR Country of Source	Mandatory
Country of Prior Refusal	Optional

2. COSMETICS

See the FDA Supplemental Guide for ACE for full Cosmetics requirements.

Cosmetics **program information** is noted in the table below.

Program Code or Commodity	Processing Code or Commodity Subtype	Product Industry Code*	Status
COS - Cosmetics	N/A	50 or 53	Program Code + Product Code are Mandatory

*Note: The Industry Code is the first two digits of the product code. For full product code details visit the FDA Product Code Builder.

Cosmetics **product information** is noted in the table below.

Product Information	Status
Product Description	Mandatory
Quantity and Packaging	Optional, but encouraged; Refer to Appendix D of the FDA Supplemental Guide for ACE.
PGA Line Value	Optional, but encouraged

Optional Cosmetics **Affirmation of Compliance (AofCs)** data requirements are noted below.

- Cosmetic Registration Number (COS)
- Entry Review Requested (ERR)

Cosmetics **entity information** is noted in the table below. Refer to Appendix A: Entity Glossary for more information.

Entity Role (Code)	Entity Name and Entity Address	Individual Name, Tel# and Email	Entity ID Code and Number: DUNS or FEI
Manufacturer (MF)	Mandatory	N/A	Optional, but encouraged
Shipper (DEQ)		N/A	
FDA Importer (FD1)		Mandatory	
Delivered to Party (DP)		N/A	
Filer's/Broker's Point of Contact (PK)	Optional, but encouraged		

"Optional, but encouraged" information assists in matching firms in the FDA database and/or facilitates the entry review process.

Cosmetics **arrival** and **product origin information** are noted below.

Arrival Information	Status
Anticipated Arrival Date AND Time at Port of Entry	Mandatory
FTZ Information	Conditional

Product Origin Information	Status
Country of Production	Mandatory
Country of Prior Refusal	Optional

3. HUMAN DRUGS

See the FDA Supplemental Guide for ACE for full Human Drugs requirements.

Human Drugs **program information** is noted in the table below.

Program Code or Commodity	Processing Code or Commodity Subtype	Product Industry Code*	Status
DRU – Drug	INV - Investigational	54, 56, 58, 60, 61, 62, 63, 64, 65, or 66	Program Code + One Processing Code + Product Code are Mandatory
	OTC - Over the Counter		
	PRE - Prescription		
	RND - Research and Development		
	PHN - Pharmaceutical Necessities	55, various codes could apply	
	804 – Section 804 Importation Program	54, 56, 60, 61, 62, 63, 64, 65, or 66	

*Note: The Industry Code is the first two digits of the product code. For full product code details visit the FDA Product Code Builder.

Human Drugs **product information** is noted in the table below.

Product Information	Status
Product Description	Mandatory
Quantity and Packaging	Optional, but encouraged
PGA Line Value	
Product Constituent Element	
Product Trade Name	
Production Condition	

Valid FDA **UOM for the Base Unit** (Last Quantity Transmitted) for Human Drugs are noted below. Refer to Appendix D of the FDA Supplemental Guide for ACE for valid units of measure for drugs packaging containers.

Base UOM Code	Description
BBL	Barrel (42 Gallons Ea)
BOL	Boluses
CAP	Capsules (Dosage)
CFT	Cubic Feet
CG	Centigrams
CM	Centimeters
CM3	Cubic Centimeters
CYD	Cubic Yard
FOZ	Ounces, fluid (Volume)

Base UOM Code	Description
LNM	Linear Meter
M	Meter
M2	Square Meter
M3	Cubic Meter
MG	Milligrams
MCG	Micrograms
ML	Milliliters
OZ	Ounces
PCS	Pieces

Base UOM Code	Description
FT	Feet
G	Grams
GAL	Gallons
KG	Kilograms (Weight)
KM	Kilometer
KM2	1000 Square Meters
KM3	1000 Cubic Meters
L	Liter
LB	Pounds (avdp) (Weight)

Base UOM Code	Description
PTL	Pints
QTL	Quarts
STN	Short Ton
SUP	Suppositories
T	Metric Ton
TAB	Tablets
TON	Long Ton
TOZ	Ounces, Troy

The only **Intended Use Codes (IUCs)** and **Affirmations of Compliance (AofCs)** to be used for Human Drugs are noted in the table below. Refer to the FDA ACE AofCs document for more information and examples of AofCs. See Appendix C for information about "UNK".

Human Drug Import Scenarios	IUC	AofCs
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	080.012	Mandatory: DA, Conditional: DLS, REG, FSR, PRN Optional: PLR (not available for Processing Code 804)
Importation for Personal Use	100.000	N/A
For Consumer Use as a Non-Food Product – Over the Counter (OTC)	130.000	Mandatory: DLS, REG Optional: DA
Active Pharmaceutical Ingredient / Bulk Drug Substance for processing into a pharmaceutical product	150.007	Mandatory: REG, DLS Conditional: DA
Active Pharmaceutical Ingredient / Bulk Drug Substance to be used for Pharmacy Compounding	150.013	Mandatory: DLS, REG
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)	150.017	Mandatory: DLS, REG Optional: DA, IDE, LST, PM#
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).	155.009	Mandatory: REG, DLS Optional: DA, IDE, LST, PM#
Chemical for research and development of a pharmaceutical product – subject of an Investigational New Drug application (IND), including Placebos	180.009	Mandatory: IND
Chemical for research and development of a pharmaceutical product – laboratory testing only, no human/animal use	180.017	N/A

Human Drug Import Scenarios	IUC	AofCs
Chemical for research and development; investigational use in animals	180.018	N/A
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.	180.026	N/A
US Goods Returned	920.000	Optional: DA, DLS, IND, REG,
Import for Export	970.000	N/A
For Other Use (APIs or Finished Drugs not elsewhere classified)	980.000	Mandatory: DLS, REG

Human Drugs **entity information** is noted in the table below. Refer to Appendix A: Entity Glossary for more information.

Entity Role (Code)	Entity Name and Entity Address	Individual Name, Tel# and Email	Entity ID Code and Number: DUNS or FEI
Manufacturer (MF)	Mandatory	N/A	Optional, but encouraged
Shipper (DEQ)		N/A	
FDA Importer (FD1)		Mandatory	
Delivered to Party (DP)		N/A	
Filer's/Broker's Point of Contact (PK)	Optional, but encouraged	Optional, but encouraged	
Sponsor of IND - If different than MF or FD1 (SPO)		N/A	
Producer (Producer of API) (GD)		N/A	

"Optional, but encouraged" information assists in matching firms in the FDA database and/or facilitates the entry review process, particularly submission of Sponsor and Producer information. See the Drug Establishments Current Registration Site for public DUNS and FEI numbers and information.

Human Drugs **arrival** and **product origin information** are noted below.

Arrival Information	Status
Anticipated Arrival Date AND Time at Port of Entry	Mandatory
FTZ Information	Conditional

Product Origin Information	Status
Country of Production OR Country of Source	Mandatory
Country of Prior Refusal	Optional

4. HUMAN AND ANIMAL FOODS – STAND-ALONE PRIOR NOTICE

See the FDA Supplemental Guide for ACE for full "Stand-alone" PN requirements.

Human and Animal Foods – Stand-alone PN **program information** is noted below. Refer to Appendix B: Food Processing Codes for additional program information.

Program Code or Commodity	Processing Code or Commodity Subtype	Product Industry Code*	Status
FOO – Food	ADD - Additives and Colors	02-05, 07, 09, 12-18, 20-42, 45-46, 50, 52**, 54**, 69, 70, 71 or 72	Program Code + One Processing Code + Product Code are Mandatory
	DSU - Dietary Supplements		
	FEE - Animal Food		
	NSF - Natural State Food		
	PRO - Processed Food		

*Note: The Industry Code is the first two digits of the product code. For full product code details visit the FDA Product Code Builder.

**See the FDA Supplemental Guide for ACE for more information on class rules for Industry Code 52 and subclass rules for Industry Code 54.

Human and Animal Foods – Stand-alone PN **product information** is noted in the table below.

Product Information	Status
Product Description	Mandatory
Quantity and Packaging	Mandatory; Refer to Stand-alone section of the FDA Supplemental Guide for ACE for valid units
License Information	Conditional for Carriers that are Privately Owned Vehicles (POV)
Shipping Container Information	Conditional for containerized cargo arriving by water, air, rail or land
Express Courier Information	Conditional

Intended Use Codes (IUCs) are optional for Prior Notice. See Appendix C for information about "UNK".

Conditional and optional Human and Animal Foods – Stand-alone PN **Affirmation of Compliance (AofCs) information** is noted below. Refer to the FDA ACE AofCs document for detailed information and examples of AofCs.

AofC Codes	Status
CAN, FME, PFR, RNO, VFT, VES	Conditional
CFR, GFR, IFR, LFR, ORN, SFR, SRN, TFR, UFR	Optional

Human and Animal Foods – Stand-alone PN **entity information** is noted below. Refer to Appendix A: Entity Glossary for more information.

Entity Role (Code)	Entity Name	Entity Address	Individual Name, Tel# and Email	Entity ID Code and Number: DUNS or FEI
PN Submitter (PNS)	Mandatory	Mandatory, except if the PN Submitter's 'SRN' is transmitted, then the address line 1 is optional.	Mandatory	Optional, but encouraged
PNT Transmitter (PNT)	Mandatory	Mandatory, except if the PN Transmitter's 'TFR' is transmitted, then the address line 1 is optional.	Mandatory	
Choose one: 1. Manufacturer (MF) or 2. FDA Consolidator (FDC) or 3. Grower (DFI)	Mandatory	Mandatory, except if the manufacturer's (MF) 'PFR' is transmitted, then the address line 1 is optional.	N/A	
Shipper (DEQ)	Mandatory	Mandatory	N/A	
Location of Goods (Secure Holding Facility for PN Purposes) (LG)	Conditional	Conditional	N/A	
FDA Importer (Importer of Record) (FD1)	Conditional	Conditional	Optional, but encouraged	
Ultimate Consignee* (Delivered to Party) (UC)	Conditional	Conditional	N/A	
Owners (DFP)	Conditional	Conditional	N/A	
Filer's/Broker's Point of Contact (PK)	Optional, but encouraged			

*Ultimate Consignee (Deliver To Party), Importer and Owner info is not required IF the product is imported for the transportation and exportation (T&E) entry type. Refer to the FDA Supplemental Guide for ACE additional information.

"Optional, but encouraged" information assists in matching firms in the FDA database.

Human and Animal Foods – Stand-alone PN **arrival** and **product origin information** are noted below.

Arrival Information	Status
Anticipated Arrival Date at Port of Arrival	Mandatory
Anticipated Arrival Time at Port of Arrival	Mandatory
Anticipated Port of Arrival	Mandatory

Product Origin Information	Status
Country of Shipment	Mandatory
Choose one: 1. Place of Growth or 2. Country of Production	Mandatory
Country of Prior Refusal	Conditional

5. HUMAN AND ANIMAL FOODS – COMBINED ENTRY (801(A) AND PRIOR NOTICE)

See the FDA Supplemental Guide for ACE for full "Combined Entry" requirements.

The Human and Animal Foods – Combined Entry **program information** is noted in the table below. Refer to Appendix B: Food Processing Codes for additional program information.

Program Code or Commodity	Processing Code or Commodity Subtype	Product Industry Code*	Status
FOO – Food	ADD - Additives and Colors	02-05, 07, 09, 12-18, 20-42, 45-46, 50, 52**, 54**, 69, 70, 71 or 72	Program Code + One Processing Code + Product Code are Mandatory
	DSU - Dietary Supplements		
	FEE - Animal Food		
	NSF - Natural State Food		
	PRO - Processed Food		

*Note: The Industry Code is the first two digits of the product code. For full product code details visit the FDA Product Code Builder.

**See the FDA Supplemental Guide for ACE for more information on class rules for Industry Code 52 and subclass rules for Industry Code 54.

Human and Animal Foods – Combined Entry **product information** is noted in the table below.

Product Information	Status
Product Description	Mandatory
Quantity and Packaging	Mandatory; Refer to Combined Entry section of the FDA Supplemental Guide for ACE for valid units.
License Information	Conditional for Carriers that are Privately Owned Vehicles (POV).
Shipping Container Information	Conditional for containerized cargo arriving by water, air, rail or land
Express Courier Information	Conditional
PGA Line Value	Optional, but encouraged

Intended Use Codes (IUCs) are optional for Human and Animal Foods – Combined 801(a) and Prior Notice. See Appendix C for information about "UNK".

Conditional and optional Human and Animal Foods – Combined Entry **Affirmation of Compliance (AofCs) information** is noted below. Refer to the FDA ACE AofCs document for detailed information and examples of AofCs.

AofC Codes	Status
CAN, FCE, FME, FSX, PFR, RNE, RNO, SID, VES, VFT, VOL	Conditional
AIN, CFR, CIN, ERR, FAP, FCC, GFR, IBP, IFE, IFR, JIF, LFR, ORN, PKC, REG, SFR, SIF, SRN, TFR, UFR, VFD, VFL, VQI	Optional

Human and Animal Foods – Combined Entry **entity information** is noted below. Refer to Appendix A: Entity Glossary for more information.

Entity Role (Code)	Entity Name	Entity Address	Individual Name, Tel# and Email	Entity ID Code and Number: DUNS or FEI
PNT Submitter (PNS)	Mandatory	Mandatory, except if the PN Submitter's 'SRN' is transmitted, then the address line 1 is optional.	Mandatory	Optional, but encouraged
PNT Transmitter (PNT)	Mandatory	Mandatory, except if the PN Transmitter's 'TFR' is transmitted, then the address line 1 is optional.	Mandatory	Optional, but encouraged
Choose one: 1. Manufacturer (MF) or 2. FDA Consolidator (FDC) or 3. Grower (DFI)	Mandatory	Mandatory	N/A	Optional, but encouraged
Shipper (DEQ)	Mandatory	Mandatory	N/A	Optional, but encouraged
FDA Importer (Importer of Record) (FD1)	Mandatory	Mandatory	Optional, but encouraged	Optional, but encouraged
Owners (DFP)	Mandatory	Mandatory	N/A	Optional, but encouraged
Ultimate Consignee (Delivered to Party) (UC)	Mandatory	Mandatory	N/A	Optional, but encouraged
Location of Goods (Secure Holding Facility for PN Purposes) (LG)	Conditional	Conditional	N/A	Optional, but encouraged

Entity Role (Code)	Entity Name	Entity Address	Individual Name, Tel# and Email	Entity ID Code and Number: DUNS or FEI
Foreign Supplier Verification Program Importer (FSV)	Conditional*	Conditional*	Email is Mandatory if FSV is provided Individual Name and Telephone Number are Optional, but encouraged	DUNS is Mandatory if FSV is provided
Filer's/Broker's Point of Contact (PK)	Optional, but encouraged			Optional, but encouraged

*Mandatory, unless Industry Codes 16 or 32 are present in PG02 or an exemption is declared in the AoC using either codes FSX (FSVP Exempt) or RNE (Research and Evaluation).

"Optional, but encouraged" information assists in matching firms in the FDA database and/or facilitates the entry review process.

Human and Animal Foods – Combined Entry **arrival** and **product origin information** are noted below.

Arrival Information	Status
Anticipated Arrival Date at Port of Arrival	Mandatory
Anticipated Arrival Time at Port of Arrival	Mandatory
Anticipated Port of Arrival	Mandatory

Product Origin Information	Status
Country of Shipment	Mandatory
Choose one: 1. Place of Growth or 2. Country of Production	Mandatory
Country of Prior Refusal	Conditional

6. HUMAN AND ANIMAL FOODS - NON-PRIOR NOTICE AND PRIOR NOTICE PREVIOUSLY MET

See the FDA Supplemental Guide for ACE for full Non-PN and PN Previously Met requirements.

Human and Animal Foods – Non-PN and PN Previously Met **program information** is noted below. Refer to Appendix B: Food Processing Codes for additional program information.

Program Code or Commodity	Processing Code or Commodity Subtype	Product Industry Code*	Status
FOO – Food	ADD - Additives and Colors	02-05, 07, 09, 12-18, 20-42, 45-46, 50, 52, 54, 69, 70, 71 or 72	Program Code + One Processing Code + Product Code are Mandatory
	DSU - Dietary Supplements		
	FEE - Animal Food		
	NSF - Natural State Food		
	PRO - Processed Food		
	CCW - Ceramicware and Food Contact Substances	52	

*Note: The Industry Code is the first two digits of the product code. For full product code details visit the FDA Product Code Builder.

Human and Animal Foods – Non-PN and PN Previously Met **product information** is noted in the table below.

Product Information	Status
Product Description	Mandatory
Prior Notice Confirmation Number	Mandatory for foods with a previously submitted Prior Notice
Quantity and Packaging	Optional, but encouraged; Refer to Non-PN and PN Previously Met section of the FDA Supplemental Guide for ACE for valid units.
PGA Line Value	Optional, but encouraged

Intended Use Codes (IUCs) are optional or Human and Animal Foods - Non-Prior Notice and Prior Notice previously met. See Appendix C for information about “UNK”.

Conditional and optional Human and Animal Foods – Non-PN and PN Previously Met **Affirmation of Compliance (AofCs) information** is noted below. Refer to the FDA ACE AofCs document for more information.

AofC Codes	Status
FCE, FSX, RNE, SID, VOL	Conditional
CCC, CIN, ERR, FAP, FCC, AIN, VQI, JIF, SIF, IBP, IFE, PKC, REG, VFD, VFL	Optional

Human and Animal Foods – Non-PN and PN Previously Met **entity information** is noted below. Refer to Appendix A: Entity Glossary for more information.

Entity Role (Code)	Entity Name	Entity Address	Individual Name, Tel# and Email	Entity ID Code and Number: DUNS or FEI
Manufacturer (MF)	Mandatory	Mandatory	N/A	Optional, but encouraged
Shipper (DEQ)	Mandatory	Mandatory	N/A	
FDA Importer (Importer of Record) (FD1)	Mandatory	Mandatory	Optional, unless filing a CCW for food contact service, Mandatory.	
Delivered To Party (DP)	Mandatory	Mandatory	N/A	
Foreign Supplier Verification Program Importer (FSV)	Conditional	Conditional	Email is Mandatory if FSV is provided Individual Name and Telephone Number are Optional, but encouraged	DUNS is Mandatory if FSV is provided
Filer's/Broker's Point of Contact (PK)	Optional, but encouraged			

"Optional, but encouraged" information assists in matching firms in the FDA database and/or facilitates the entry review process.

Human and Animal Foods – Non-PN and PN Previously Met **arrival** and **product origin information** are noted below.

Arrival Information	Status
Anticipated Arrival Date AND Time at Port of Entry	Mandatory
FTZ Information	Conditional

Product Origin Information	Status
Place of Growth OR Country of Production	Mandatory
Country of Prior Refusal	Optional

7. MEDICAL DEVICES

See the FDA Supplemental Guide for ACE for full Medical Devices requirements.

The Medical Devices **program information** is noted in the table below.

Program Code or Commodity	Processing Code or Commodity Subtype	Product Industry Code*	Status
DEV - Medical Device	NED - Non-Radiation Emitting Device	73-92	Program Code + One Processing Code + Product Code are Mandatory
	RED - Radiation-Emitting Device		

*Note: The Industry Code is the first two digits of the product code. For full product code details visit the FDA Product Code Builder.

Medical Devices **product information** are noted in the table below.

Product Information	Radiation-Emitting Device	Non-Radiation Emitting Device
Product Description	Mandatory	Mandatory
Quantity and Packaging	Mandatory if the product requires FDA Form 2877, otherwise optional, but encouraged	Optional, but encouraged
PGA Line Value	Optional, but encouraged	Optional, but encouraged

Valid FDA **Units of Measure (UOM)** and **UOM for the Base Unit** (Last Quantity Transmitted) for Medical Devices are noted below.

UOM Code	Description
CS	Case
CT	Carton
BX	Box
PK	Package

Base UOM Code	Description
PCS	Pieces (Count)

Intended Use Codes (IUCs) and **Affirmations of Compliance (AofCs)** for each Medical Device import scenario are noted in the table below. The conditional AofCs are mandatory if the associated regulatory requirements apply to the product being offered for import. For example, if the product requires premarket clearance (e.g. submission of a 510(k) as notification to FDA), then PM# must be provided. See FDA ACE AofCs for more information. See Appendix C for information about “UNK”.

Medical Device Import Scenarios	IUC	AofCs
• Standard import of a foreign manufactured device, accessories, or components regulated as a finished device • Import of refurbished device • Import of a reprocessed device	081.001	Mandatory: DEV, DFE, LST Conditional: IRC, LWC, PM# Optional: DI
Import of a foreign manufactured device for domestic refurbishing	081.002	Mandatory: DEV, DFE, LST Conditional: IRC, LWC, PM# Optional: DI
Domestically manufactured device that is part of a medical device convenience kit	081.003	Mandatory: DDM, DFE, KIT, LST Conditional: IRC, LWC, PM# Optional: DI
A foreign manufactured device that is Part of a medical device convenience kit	081.004	Mandatory: DEV, DFE, KIT, LST Conditional: IRC, LWC; PM# Optional: DI
Device constituent part for drug-device combination product	081.005	Conditional: DA, DEV, DFE, IND, LST
Import under enforcement discretion provisions per final guidance Import of a General Wellness Product per final guidance:	081.006	N/A
Component for further manufacturing into a finished medical device	081.007	Mandatory: CPT Optional: LST, PM#
Device component for use in a drug-device combination product	081.008	Mandatory: CPT Conditional: DA, IND
Device for Personal Use	100.000	N/A
Public Exhibition/Trade Show	110.000	N/A
Import of a device for charity	140.000	Mandatory: DEV, DFE, LST Conditional: IRC, LWC, PM# Optional: DI
Repair of medical device and re-exportation	170.000	Mandatory: IFE Conditional: DDM, DFE, IRC, LST, LWC, PM# Optional: DI
Import of research or investigational use in vitro diagnostic device	180.010	N/A
• Import of a device for non-clinical use/bench testing • Import of device sample for customer evaluation	180.014	N/A
Import of a medical device for clinical investigational use	180.015	Mandatory: IDE
Import of a device that is US goods returned for refund/overstock (to manufacturer)	920.001	Mandatory: DDM, LST Conditional: DFE, IRC, LWC, PM# Optional: DI

Medical Device Import Scenarios	IUC	AofCs
Import of device that is US goods returned for sale to a third party	920.002	Mandatory: DDM, DFE, LST Conditional: IRC, LWC, PM# Optional: DI
Compassionate Use/Emergency Device	940.000	N/A
Import of a single-use device for domestic reprocessing	950.001	Mandatory: DDM, LST Conditional: DFE, IRC, LWC, PM# Optional: DI
Import of a multi-use device for domestic reprocessing	950.002	Conditional: DDM, DFE, IRC, LST, LWC, PM# Optional: DI
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	970.000	Mandatory: DEV, DFE, IFE, LST
Import for Export: • Importation of a medical device component for further manufacturing into an export-only medical device	970.001	Mandatory: IFE, CPT, DDM, LST

Additional optional Medical Devices AofCs are: Device Identifier (DI) and Entry Review Requested (ERR).

Medical Device **entity information** is noted in the table. Refer to Appendix A: Entity Glossary for more information.

Entity Role (Code)	Entity Name and Entity Address	Individual Name, Tel# and Email	Entity ID Code and Number: DUNS or FEI
Manufacturer (MF)	Mandatory	N/A	Optional, but encouraged
Shipper (DEQ)		N/A	
FDA Importer (FD1)		Mandatory	
Device Initial Importer (DII)		N/A	
Delivered to Party (DP)		N/A	
Filer's/Broker's Point of Contact (PK)	Optional, but encouraged		

"Optional, but encouraged" information assists in matching firms in the FDA database and/or facilitates the entry review process. FDA CDRH prefers FEIs for devices. See Establishment Registration & Device Listing for public FEIs and information.

Medical Devices **arrival** and **product origin information** noted below.

Arrival Information	Status
Anticipated Arrival Date AND Time at Port of Entry	Mandatory
FTZ Information	Conditional

Product Origin Information	Status
Country of Production OR Country of Source	Mandatory
Country of Prior Refusal	Optional

8. TOBACCO PRODUCTS

See the FDA Supplemental Guide for ACE for full Tobacco Products requirements.

Tobacco **program information** is noted in the table below.

Program Code or Commodity	Processing Code or Commodity Subtype	Product Industry Code*	Status
TOB - Tobacco	CSU - Consumer Use	98	Program Code + One Processing Code + Product Code are Mandatory
	FFM - For Further Manufacturing		
	INV - Investigational		

*Note: The Industry Code is the first two digits of the product code. For full product code details visit the FDA Product Code Builder.

Tobacco **product information** is noted in the table below.

Product Information	Status
Product Description	Mandatory
Trade Name/Brand Name	Mandatory for processing code CSU
Quantity and Packaging	Optional, but encouraged
PGA Line Value	Optional, but encouraged

Valid FDA **Units of Measure (UOM)** for Packaging Containers and **UOM for the Base Unit** (Last Quantity Transmitted) for Tobacco Products are noted below.

UOM Code	Description
AT	Atomizer
BL	Bale, Compressed
BN	Bale, Non-Compressed
BX	Box
CON	Container
CS	Case
CT	Carton
CTR	Cartridge
DR	Drum
KIT	Kit
PK	Package
VI	Vial
VL	Bulk Liquid

Base UOM Code	Description
BBL	Barrels (42 Gallons Ea)
DOZ	Dozen
DPC	Dozen Pieces
FOZ	Ounces, fluid
GAL	Gallons (US)
L	Liters
ML	Milliliters
NO	Number
PCS	Pieces
PTL	Pints, liquid (US)
QTL	Quarts, liquid (US)
G	Grams
KG	Kilograms
LB	Pounds (avdp)

Conditional **Intended Use Codes (IUCs)** for Tobacco Products are noted below. See Appendix C for information about “UNK”.

IUC	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

Optional Tobacco Products **Affirmations of Compliance (AofC)** are noted below. Refer to the FDA ACE AofCs document for detailed information and examples of AofCs.

Tobacco Products AofCs	Status
ILS, CMT, ERR, EXE, HPC, PMT, SE, TST	Optional

Tobacco Products **entity information** is noted in the table below. Refer to Appendix A: Entity Glossary for more information.

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

"Optional, but encouraged" information assists in matching firms in the FDA database and/or facilitates the entry review process.

Tobacco Products **arrival** and **product origin information** are noted below.

Arrival Information	Status
Anticipated Arrival Date AND Time at Port of Entry	Mandatory
FTZ Information	Conditional

Product Origin Information	Status
Place of Growth OR Harvested OR Country of Source	Mandatory
Country of Prior Refusal	Optional

9. RADIATION-EMITTING PRODUCTS

See the FDA Supplemental Guide for ACE for full Radiation-Emitting Products requirements. Some Radiation-Emitting Products are Medical Devices. If the product is also a Medical Device,

then all Medical Device data elements noted in the Medical Device chapter of the FDA Supplemental Guide for ACE are also required.

Radiation-Emitting **program information** is noted in the table below.

Program Code or Commodity	Processing Code or Commodity Subtype	Product Industry Code*	Status
RAD - Radiation-Emitting Products	REP - Non-Medical Radiation-Emitting Product	94-97	Program Code + One Processing Code + Product Code are Mandatory

*Note: The Industry Code is the first two digits of the product code. For full product code details visit the FDA Product Code Builder.

Radiation-Emitting **product information** is noted in the table below.

Product Information	Status
Product Description	Mandatory
Trade Name/Brand Name	Conditional: mandatory for articles required to submit form FDA 2877
Quantity and Packaging	
PGA Line Value	Optional, but encouraged

Valid FDA **Units of Measure (UOM)** and **UOM for the Base Unit** (Last Quantity Transmitted) for Radiation-Emitting Products are noted below.

UOM Code	Description
CS	Case
CT	Carton
BX	Box
PK	Package

Base UOM Code	Description
PCS	Pieces (Count)

Intended Use Codes (IUCs) for Radiation Emitting Products are noted below. See Appendix C for information about “UNK”.

IUC	Description
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

Below are **Affirmations of Compliance (AofC)** that may be used if Form FDA 2877 is Mandatory. Refer to the FDA ACE AofCs document for detailed information and examples.

AofC	Description	Status
RA1, RA2, RA3, RA4, RA5, RA6 and RA7	EPRC Radiation - emitting Products. Use if FDA compliance is non-applicable. Refer to Form FDA 2877	Conditional
RB1, RB2	EPRC Radiation – emitting Products. Use if product is FDA compliant. Refer to Form FDA 2877	
RC1, RC2	EPRC Product Declaration Form FDA 2877)	
RD1, RD2, RD3	EPRC Radiation products. Use if product is non-compliant but will be re-conditioned under bond and Form FDA766. Refer to Form FDA 2877	
ACC	EPRC (Electronic Product Radiation Control) Accession Number	
ANC	PRC Radiation - emitting Products Annual Report Accession Number	
MDL	Model Number of the Product	Optional
ERR	Entry Review Requested	
IFE	Import For Export	
CCM	Name of the Certified Component Manufacturer	

Radiation-Emitting Products **entity information** is noted in the table below. Refer to Appendix A: Entity Glossary for more information.

Entity Role (Code)	Entity Name and Entity Address	Individual Name, Tel# and Email	Entity ID Code and Number: DUNS or FEI
Manufacturer (MF)	Mandatory	N/A	Optional, but encouraged
Shipper (DEQ)		N/A	
FDA Importer (FD1)		Mandatory	
Delivered to Party (DP)		N/A	
Filer's/Broker's Point of Contact (PK)	Optional, but encouraged		

"Optional, but encouraged" information assists in matching firms in the FDA database and/or facilitates the entry review process.

Radiation-Emitting Products **arrival** and **product origin information** are noted below.

Arrival Information	Status
Anticipated Arrival Date AND Time at Port of Entry	Mandatory
FTZ Information	Conditional

Product Origin Information	Status
Country of Production OR Country of Source	Mandatory
Country of Prior Refusal	Optional

10. ANIMAL DRUGS AND DEVICES

See the FDA Supplemental Guide for ACE for full Animal Drugs and Devices requirements.

The Animal Drugs and Devices **program information** is noted in the table below.

Program Code and Commodity	Processing Code and Commodity Subtype	Product Industry Code*	Status
VME - Animal Drug or Device	ADR - Animal Drug	54, 56, 58, 60, 61, 62, 63, 64, 65, 66 or 67	Program Code + One Processing Code + Product Code are Mandatory
	ADE - Animal Device	68	

*Note: The Industry Code is the first two digits of the product code. For full product code details visit the FDA Product Code Builder.

Animal Drugs and Devices **product information** is noted in the table below.

Product Information	Status
Product Description	Mandatory
PGA Line Value	Optional, but encouraged
Quantity and Packaging	Optional, but encouraged; Refer to Appendix D of the FDA Supplemental Guide for ACE.
Product Constituent Element for ADR	Optional, but encouraged

Intended Use Codes (IUCs) and **Affirmations of Compliance (AofCs)** for each Animal Drug import scenario is noted in the table below. Refer to the FDA ACE AofCs document for more information and examples of AofCs. See Appendix C for information about "UNK".

Animal Drugs Import Scenarios	IUC	AofCs
Drug subject of a new animal drug application, conditionally approved application, or Index listing	085.003	Mandatory: NDC, REG, and either VAN or VNA Optional: VFD, VFL,
Importation for Personal Use	100.000	N/A
Active Pharmaceutical Ingredient / Bulk Drug Substance to be used for Pharmacy Compounding	150.013	Mandatory: NDC, REG
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	150.020	Mandatory: NDC, REG, and either VAN or VNA
For research and development in a pharmaceutical product – clinical investigations in animals (INAD)	180.009	Mandatory: VIN
For research and development in a pharmaceutical product – for tests in-vitro or in laboratory research animals.	180.018	Optional: VIN
US Goods Returned	920.000	N/A
Import for Export	970.000	N/A
For Other Use (APIs or Finished Drugs not elsewhere classified)	980.000	Mandatory: NDC, REG, Optional: VAN, VFD, VFL, VNA,

Animal Drugs and Devices **entity information** is noted in the table below. Refer to Appendix A: Entity Glossary for more information.

Entity Role (Code)	Entity Name and Entity Address	Individual Name, Tel# and Email	Entity ID Code and Number: DUNS or FEI
Manufacturer (MF)	Mandatory	N/A	Optional, but encouraged
Shipper (DEQ)		N/A	
FDA Importer (FD1)		Mandatory	
Delivered to Party (DP)		N/A	
Producer of API (GD)	Optional	N/A	
Filer's/Broker's Point of Contact (PK)	Optional, but encouraged		

"Optional, but encouraged" information assists in matching firms in the FDA database and/or facilitates the entry review process.

Animal Drugs and Devices **arrival** and **product origin information** are noted below.

Arrival Information	Status
Anticipated Arrival Date AND Time at Port of Entry	Mandatory
FTZ Information	Conditional

Product Origin Information	Status
Country of Production OR Country of Source	Mandatory
Country of Prior Refusal	Optional

11. Appendix A: Entity Glossary

For full definitions in FDA laws and regulations, see the FDA Regulatory Information webpage.

Entity Name	Description
Manufacturer of goods ('MF')	The FDA Manufacturer is the site-specific location where the product is manufactured, produced or grown.
Shipper ('DEQ')	The shipper is the firm or individual responsible for introducing merchandise into interstate commerce by way of transport and that does not act as a manufacturer, repacker, distributor.
FDA Importer of Record ('FD1')	The individual responsible for assuring that imported goods are in compliance with all laws affecting the importation. While the importer may authorize others to carry out certain tasks such as filing, the importer of record holds the bond and is ultimately responsible for the entry.
Device Initial Importer ('DII')	The initial importer is any importer who furthers the marketing of a device from a foreign manufacturer to the person who makes final delivery or sale of the device to the ultimate consumer or user, but does not repackage, or otherwise change the container, wrapper, or labeling of the device or device package. The initial importer must have a physical address in the United States staffed by individuals responsible for ensuring the compliance of imported devices with all applicable FDA laws and regulations.
Delivered to Party ('DP')	The site where the goods are to be delivered. It represents the facility to physically receive the goods after arrival in the US. The 'UC' is applicable for Prior Notice data and is synonymous to 'DP'
Ultimate Consignee ('UC')	
Point of Contact ('PK')	The individual who can respond to FDA's questions on a specific shipment, usually the broker or entry filer.
Prior Notice Submitter ('PNS')	The PNS is any person with knowledge of the required information may submit prior notice for an article of food. The person is the submitter.
Prior Notice Transmitter ('PNT')	The PN Submitter may also use another person to transmit the required information on his or her behalf. The person who transmits the information is the transmitter. The submitter and transmitter may be the same person (21 CFR 1.278).
Owner ('DFP')	The term *owner* or *consignee* means the person who makes entry under the provisions of section 484 of the Tariff Act of 1930, as amended (19 U.S.C. 1484), namely, the "importer of record."
Grower ('DFI')	Grower means a person who engages in growing and harvesting or collecting crops (including botanicals), raising animals (including fish, which includes seafood), or both.
Consolidator ('FDC')	The firm that has consolidated the articles of food from different growers or different growing locations.

12. Appendix B: Food Processing Codes

For definitions in FDA laws and regulations, see the FDA Regulatory Information webpage.

Processing Code	Description
Natural State Food (NSF)	21 USC 321(r)-The term ‘‘raw agricultural commodity’’ means any food in its raw or natural state, including all fruits that are washed, colored, or otherwise treated in their unpeeled natural form prior to marketing.[1] Note (1): This includes vegetables and grains, as well as whole fish headed, eviscerated or frozen attendant to harvest. Note (2): No longer in its natural state means that an article of food has been made from one or more ingredients or synthesized, prepared, treated, modified, or manipulated. Examples of activities that render food no longer in its natural state are cutting, peeling, trimming, washing, waxing, eviscerating, rendering, cooking, baking, freezing, cooling, pasteurizing, homogenizing, mixing, formulating, bottling, milling, grinding, extracting juice, distilling, labeling, or packaging. Crops that have been cleaned (e.g., dusted, washed), trimmed, or cooled attendant to harvest or collection or treated against pests, or polished are still in their natural state for purposes of this subpart. Whole fish headed, eviscerated, or frozen attendant to harvest are still in their natural state for purposes of this subpart.
Processed Food (PRO)	21 USC 321(gg)-The term "processed food" means any food other than a raw agricultural commodity and includes any raw agricultural commodity that has been subject to processing, such as canning, cooking, freezing, dehydration, or milling.
Animal Food (FEE)	21 USC 321(w)-The term "animal feed", means an article which is intended for use for food for animals other than man and which is intended for use as a substantial source of nutrients in the diet of the animal, and is not limited to a mixture intended to be the sole ration of the animal.
(Food)Additives and Colors (ADD)	21 USC 321(s) and 21 USC 321(t) The term "food additive" means any substance the intended use of which results or may reasonably be expected to result, directly or indirectly, in its becoming a component or otherwise affecting the characteristics of any food (including any substance intended for use in producing, manufacturing, packing, processing, preparing, treating, packaging, transporting, or holding food; and including any source of radiation intended for any such use), if such substance is not generally recognized, among experts qualified by scientific training and experience to evaluate its safety, as having been adequately shown through scientific procedures (or, in the case of a substance used in food prior to January 1, 1958, through either scientific procedures or experience based on common use in food) to be safe under the conditions of its intended use; except that such term does not include— (1) a pesticide chemical residue in or on a raw agricultural commodity or processed food; or (2) a pesticide chemical; or (3) a color additive; or (4) any substance used in accordance with a sanction or approval granted prior to September 6, 1958, pursuant to this chapter, the Poultry Products Inspection Act [21 U.S.C. 451 et seq.] or the Meat Inspection Act of March 4, 1907, as amended and extended [21 U.S.C. 601 et seq.]; (5) a new animal drug; or

Processing Code	Description
	(6) an ingredient described in paragraph (ff) in, or intended for use in, a dietary supplement. (t)(1) The term "color additive" means a material which— (A) is a dye, pigment, or other substance made by a process of synthesis or similar artifice, or extracted, isolated, or otherwise derived, with or without intermediate or final change of identity, from a vegetable, animal, mineral, or other source, and (B) when added or applied to a food, drug, or cosmetic, or to the human body or any part thereof, is capable (alone or through reaction with other substance) of imparting color thereto; except that such term does not include any material which the Secretary, by regulation, determines is used (or intended to be used) solely for a purpose or purposes other than coloring.
Dietary Supplement (DSU)	21 USC 321(ff)-The term "dietary supplement"— (1) means a product (other than tobacco) intended to supplement the diet that bears or contains one or more of the following dietary ingredients: (A) a vitamin; (B) a mineral; (C) an herb or other botanical; (D) an amino acid; (E) a dietary substance for use by man to supplement the diet by increasing the total dietary intake; or (F) a concentrate, metabolite, constituent, extract, or combination of any ingredient described in clause (A), (B), (C), (D), or (E);
Ceramicware and other Food Contact Substances (CCW)	21 USC 348(h)(6)-The term "food contact substance" means any substance intended for use as a component of materials used in manufacturing, packing, packaging, transporting, or holding food if such use is not intended to have any technical effect in such food.

13. Appendix C: “UNK” in Lieu of an Intended Use Code

If after consultation with the importer, who should know the intended use of the product, the filer still ***does not know*** the intended use of the product, “UNK” may be used in lieu of an IUC. In most cases, the line will be subject to manual review, and may result in a request for documentation and/or additional information about the product as the product offered for import will be treated as a standard import. Ensure the IUC (reason for importation) is transmitted to avoid delays. As per the ACE Rule, if “UNK” is submitted as the IUC for the article, the ACE filer is still responsible for submitting the other required data elements in this rule that are applicable to that article, at the time of entry. In the future, if those other data elements are not submitted in ACE at the time of entry, the entry may be transmitted by ACE to FDA for admissibility review, but FDA may reject the entry. If FDA rejects an entry filing, the ACE filer will need to resubmit the entry with complete and accurate information.

14. Appendix D: Helpful Links and Contacts

Below are helpful links and contact Information for importers and filers.

Helpful Links and Contact Information
FDA Supplemental Guide for ACE
FDA Affirmations of Compliance for ACE
FDA Affirmations of Compliance - Quick Reference
Drug Establishments Current Registration Site
Device Establishment Registration and Device Listing
FDA Establishment Identifier Portal
Product Code Builder
Information for FDA Entry Filings

Contact Information:
▪ FDA Import Contacts and Office Locations
▪ FDA Import Offices and Ports of Entry
  ○ 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
▪ ACE Support Desk:
  ○ ACE_Support@fda.hhs.gov
  ○ Contact for questions regarding this Industry Quick Reference Guide, technical issues related to the FDA supplemental guide, required data elements, and general ACE submission questions, including entry submissions rejected by FDA.
▪ Division of Import Operations (DIO):
  ○ FDAImportsInquiry@fda.hhs.gov
  ○ 301-796-0356
  ○ Contact for general questions regarding FDA import operations and policy, including product classification (program, processing, product and HTS codes) and declaration