ACE

FDA data elements

June 2016

Note: This guide is an abridged version that contains the most common types of information. For a complete version, please contact the U.S. Food and Drug Administration - www.fda.gov

LIVINGSTON Simplify Trade

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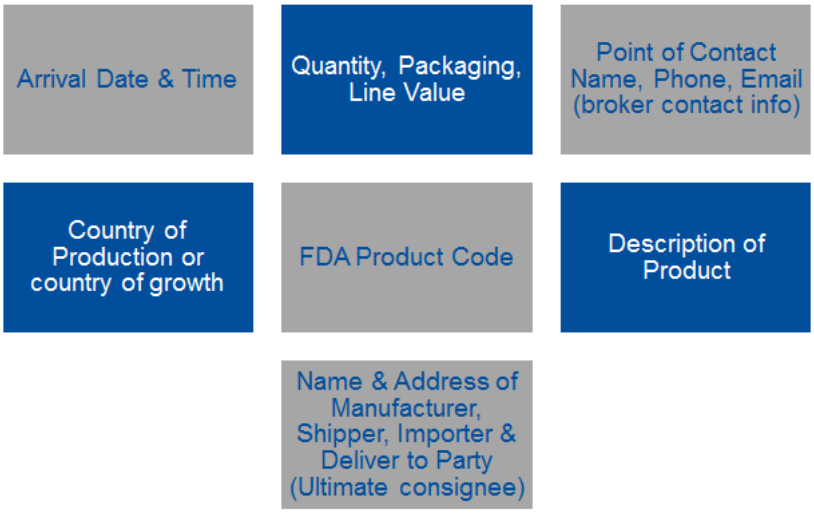
Introduction

This guide was put together as an additional resource, aside from the UPKs, including each FDA Program group, to address areas within FDA that now require decision making based upon the product you have as to what will be required by CBP/FDA. Each program group will have its own requirements, so the sections will look a bit different from each other.

With these new ACE requirements for FDA, some information is mandatory, some is conditional and some is optional. We will focus on the mandatory and conditional elements that are new/different than before. This guide will not contain system specific information, as this is available in the UPKs.

Required Data for all FDA Products



FDA Party Matrix

Program Codes	Manufacturer (MF)	Grower (DFI)	Consolidator (FDC)	Shipper (DEQ)	Owner (DFP)	FDA Importer (Importer of Record (FD1)	Ultimate Consignee (UC)*	Delivered to Party (DP)*	Submitter	Transmitter	Device Initial Importer (DII)	Sponsor
Biologics	X			X		X		X				
Cosmetics	X			X		X		X				
Medical Devices	X			X		X		X			X	
Drugs	X			X		X		X				X
Radiation Emitting Products	X			X		X		X				
Tobacco	X			X		X		X	X			
Veterinary Medications	X			X		X		X				
Food _Prior Notice	PN 1/3	PN 2/3	PN 3/3	X	X	X	X		PN X	PN X		

* Take notice that for food the consignee is represented by UC (ultimate consignee). For all other commodities, it is DP (deliver to party).

Criteria for selecting Parties for Food Prior Notice

Manufacturer for processed food; Grower or Consolidator for natural state food
Prior Notice Regulation requires one of the following:

Manufacturer (MF)	Grower (DFI)	Consolidator (FDC)
Use if food/feed is not in its natural state	Use if food/feed is in its natural state and the grower(s) is/are known	Use if food/feed is in its natural state and the grower(s) is/are unknown
The PN submission allows you to provide the Manufacturers Food Facility Registration number and the name, city and country, the full address is required	If known, full address of the growing location	Full address of the firm or person who consolidated the articles of food from the grower(s)
Food Facility registration numbers are entered in Affirmations of Compliance: PFR	Growers are not required to be registered. But if registered you may provide the Grower's Food Facility Registration number	A consolidator must have a Food Facility Registration number. Food Facility registration numbers are entered in Affirmations of Compliance: PFR

Distinction Submitter and Transmitter

Submitter (PNS) Prior Notice Submitter And Tobacco	Transmitter (PNT) Prior Notice Transmitter
PNS is the party with first-hand knowledge of the food product	PN Transmitter is the customs broker transmitting the entry (for example, if the PN is filed with the entry)
Use name, address, and contact information from the Importer of Record for the entry	
Point of Contact A person's name, phone, and e-mail address is required A fax number is not required	

FDA Data Requirements

Food

Data Fields	Qualifier	Definition	New Under ACE
Main Tab			
Commercial Description	Free Form	Commercial Description	N
Agency Program Code	FOO	Food	Y
Processing code	NSF	Natural State Food	Y
	PRO	Processed Food	Y
	FEE	Animal Feed	Y
	ADD	Additives & Colors	Y
	DSU	Dietary Supplements	Y
	CCW	Ceramic ware	Y
FDA Product code	Alpha-numeric FDA product code	Product code	N
Product description	Free form	Description of product	N
Estimated Date and time of Arrival	Numeric	Anticipated time of arrival in military time, eastern standard time	N
Quantity		Broken down to base unit	N
Lot Number		Lot number for FCE products only	Y
Can dimensions		Container dimensions for FCE (Food Canning Establishment)	Y- formerly voluntary, now mandatory for FCE products
			(See Food Can Dimensions to see how to calculate)
Countries Tab			
Origin	39	Country of Production	N
	262	Place of Growth	Y
	294	Country of Refusal	Y
(See Food Source Processing Chart below to determine which counties are required to be declared)			
Country of Shipping	CSH	Country of shipping	N

Parties Tab			
Parties Required for Food with prior Notice Transmission	(1) PNS	Prior Notice Submitter	N
	(2) PNT	Prior Notice Transmitter	N
	(3) MF OR	Manufacturer	N
	FDC OR	FDA Consolidator	Y
	DFI OR	Grower	Y
	(4) DEQ	Shipper	N
	(5) FD1	Importer of Record	Y
	(6) UC	Ultimate Consignee	N
	(7) DFP	Owner	N
Point of Contact	PK	Point of Contact	Y – needed for FD1 Food: PNS, PNT
Affirmation of Compliance Tab			
	PFR	FDA Registration Number	N
	FME	Facility Exemption number	N

Food Can Dimensions

Can Dimension #	Length	Definition
1	4N	The first dimension of the container. If the container is rectangle, the dimension is in width, height, and length order. If the container is cylindrical, the dimensions are in diameter and height order. Container dimension information is restricted to use with acidified and low acid canned foods. The first two spaces are inches. The second two positions are in 16ths.
2	4N	The second dimension of the container. If the container is rectangle, the dimension is in width, height, and length order. If the container is cylindrical, the dimensions are in diameter and height order. The first two spaces are inches. The second two positions are in 16ths.
3	4N	The third dimension. If the container is rectangle, the dimension is in width, height, and length order. The first two spaces are inches. The second two positions are in 16ths.

Low- Acid Canned Food or Acidified Food

Note 1:
IF Government Agency Program Code = FOO and
If the product is Low-Acid Canned Food (LACF) or Acidified Food (AF), one of the following must be provided:
1. Container Measurements in PG28 (either height and diameter or height/length, width and thickness OR
2. Container Volume (VOL) in PG23
Note 2:
If the container is rectangular, the dimensions are in width, height & length order. Each dimension is expressed as a four-digit number. The first 2 digits give the number of whole inches. The next two digits give the additional fraction of the dimension expressed as sixteenths of an inch.

E.g. 1404 x 0800 x 0608 represents 14 4/16" width, 8" height and 6 8/16" length.

If the container is cylindrical the dimensions are in diameter & height order. Each dimension is expressed as a three-digit number. The first digit gives the number of whole inches. The next two digits give the additional fraction of the dimension expressed as sixteenths of an inch.

E.g. 300 x 108 represents 3" diameter & 1 8/16" height.

Food Source Processing

Program Code/Processing Code	Source Type Code	Definition	Mandatory
FOO + NSF	262	Place of Growth	Y
FOO + CCW, PRO, FEE, ADD or DSU	39	Country of Production	Y
Any when obtaining prior notice	CSH	Country of Shipment	Y
Any if refused by another government's food agency	294	Country of Refusal	Y – if actually previously refused

Processing code NSF

Natural State Food is only used when the food is totally unprocessed and in natural state. Examples: apples, potatoes, unprocessed seafood. [Seafood may be gutted or de-headed and still be natural state but cooked, or filleted fish is considered processed food].
If using NSF Natural state food, you must also use for the country field 262 Place of Growth and either DFI Grower OR FDC Consolidator.

Food Affirmations of Compliance

AOC	Description	Syntax	Business Rules	New Under ACE
FCE	Food Canning Establishment	5N- 10N	IF Government Agency Program Code = FOO AND the product is either LACF or AF THEN FCE must be entered.	N
SID	Schedule Identifier Number	11N	IF Government Agency Program Code = FOO AND the product is LACF or AF THEN AoC Code 'SID' must be entered. Format: CCYYMMDDnnn.	N
VOL	LACF/AF Volume	LACF/AF Volume	IF Government Agency Program Code = FOO AND the product is AF THEN VOL must be entered.	N
FME or	Food facility Exemption code	1A	Either FME or PFR is required when the Manufacturer or Consolidator are transmitted. If both FME and PFR are submitted, FDA will review the registration. FME (or a registration) is no longer required if DFI Grower is used.	N – but new as an AOC
PFR	Mfr food facility reg #	11N	Manufacturer registration number is required unless FME and Reason code is submitted or consolidator / grower role code is submitted in lieu of manufacturer for food in its natural state.	N – but new as an AOC
RNO	Rail Car Number		Required If MOT = Rail or MOT = Containerized Rail. For multiple Rail Car Numbers, repeat PG23 as needed. If the Rail Car Number is not available, enter 'Does Not Exist'.	
CAN	Carrier Name		If using a PG13 record OR if the SCAC or IATA are not provided this AoC value is required.	
VFT	Voyage, Trip, Flight Number		If the article of food is arriving by express consignment operator or carrier and neither the PN submitter or PN transmitter is the express consignment operator or carrier, the express consignment operator or carrier tracking number may be submitted in lieu of the flight number. Otherwise, VFT is required if MOT = Air, Rail, Truck or Ocean if it exists.	

			If the Trip Number is not available, enter 'Does Not Exist'.	
VES	Vessel Name		Required If MOT = Ocean	

Drugs

Data Fields	Qualifier	Definition	New Under ACE
Main Tab			
Commercial Description	Product Description	Product Description	N
Government Agency Code	FDA	Food & Drug Admin	Y
Agency Program Code	DRU	Drugs	Y
Processing code	PRE	Prescription	Y
	OTC	Over the Counter	Y
	INV	Investigational	Y
	PHN	Pharmaceutical Necessity	Y
	RND	Research and Development	Y
FDA Product code	Alpha numeric FDA product code	Product code	N
Product Description	Free form	Product Description	N
Intended Use Code	Intended Use Code (See Drugs Intended Use Chart below)	Intended Use Code	Y
Trade Name/Brand Name	Name of Product	Trade Name/Brand Name	Y
Quantity	numeric broken into data pairs	Quantity	N
Anticipated Arrival Date and time	Numeric	Anticipated arrival time in military time EST	N
Country Tab			
Origin	39	Country of Production	N
	30	Country of source	Y
	294	Country of refusal	Y
Parties Tab			
	1) MF	Manufacturer	N
	2) DEQ	Shipper	N
	3) FD1	FDA Importer of Record (Requires PK information)	Y

	4) DP	Deliver to Party	Y
	5) SPO (only req if different than MF or FD1)	Sponsor	Y
Affirmation of Compliance Tab			
	Alpha	(Refer to Drugs Affirmation of Compliance Chart Below)	
Ingredients Tab			
Active Ingredient	Check Mark	for PRE OTC INV RND	Y
	No is indicated by a blank	for PHN	Y
	(See Drugs Ingredients Chart below)		
Name of Ingredient	Name of active ingredient	Name of active ingredient	Y
Quantity of Ingredient	Quantity of active ingredient	Total amount by unit of measure	Y
Unit of measure	Base unit of measure	Weight/volume	Y
Percent of Ingredient	Percent	% of Active ingredient	Y

Drugs Intended Use

Intended Use	Qualifier
080.000	For Human Medical Use as a Non-Food Product under Controlled Distribution - PRE Prescription
130.000	For Consumer Use as a Non-food Product - OTC Over the Counter
150.007	Active Pharmaceutical Ingredient/ bulk drug substance for processing into a pharmaceutical product
180.009	Chemical for research and development in a pharmaceutical product - investigational new drugs, clinical trials or other human/animal ingestion
180.017	Chemical for research and development in a pharmaceutical product - laboratory testing only-- no human/animal ingestion
970.000	Import for Export - program
100.000	Importation for personal Use
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
150.017	Importation of a drug component (API) for use in a medical product regulated under device (CDRH) - combination product
150.018	Active Pharmaceutical ingredient/ bulk drug substance to be used for pharmacy compounding
UNK	Unknown (Temporarily Acceptable)
Applicable Intended uses per Processing code	
Prescription - Finished form	

	080.000 For medical use under controlled distribution (PRE Prescription)
	970.000 Import for export
	100.000 Importation for Personal Use
	155.009 Drug to be used as constituent part in Medical Device
Prescription - Not Finished Form Active Pharmaceutical Ingredient - Bulk Drug Substance	
	150.007 Active Pharmaceutical Ingredient/ Bulk drug substance for processing
	150.013 Active Pharmaceutical Ingredient/ for pharmaceutical compounding
	970.000 Import for Export
	150.017 Drug to be used as a component of a medical device
Over the Counter - Finished form	
	130.000 For consumer use – OTC over the counter
	970.000 Import for Export
	100.000 Personal Use
	155.009 Drug to be used as a constituent part of a medical device
Over the Counter - not Finished form	
	150.007 Active Pharmaceutical ingredient / bulk drug substance
	150.013 Active Pharmaceutical ingredient / for pharmaceutical compounding
	970.000 Import for Export
	150.017 Drug to be used as a component in a medical device
Research and Development INV	
	180.009 Chemical for research & development – clinical trial or human/animal use
Research and Development - RND	
	180.017 Chemical for research & development- laboratory testing only, no human/animal use
Pharmaceutical Necessities - no intended used code for this commodity sub-type	

Drugs Ingredients

IF Government Agency Program Code = DRU
AND If Government Agency Processing Code = PRE or OTC or INV or RND
THEN Constituent Active Ingredient Qualifier and Name of the Constituent Element are entered.

Applicable rules for API quantities/percentages per processing code/intended use:

Form	Intended Use	Processing Code/Product	What is entered
Finished Dosage Form Drugs	080.000	PRE	Either the quantity and Unit of Measurement are entered OR the Percent Constituent Element is entered
	130.000	OTC	Either the quantity and Unit of Measurement are entered OR the Percent Constituent Element is entered
	155.009	Drug to be used as a constituent part in a Medical Device (Finished Dosage Form Drug)	Either the quantity and Unit of Measurement are entered OR the Percent Constituent Element is entered
	180.009	INV	Either the quantity and Unit of Measurement are entered OR the Percent Constituent Element is entered
	180.017	RND	Either the quantity and Unit of Measurement are entered OR the Percent Constituent Element is entered
Active Pharmaceutical Ingredients (API)			
	080.000	Active Pharmaceutical Ingredient / Bulk Drug Substance for processing into a pharmaceutical product	The quantity, Unit of Measurement and the Percent Constituent Element are entered.
	130.000	Active Pharmaceutical Ingredient to be used in drug compounding	The quantity, Unit of Measurement and the Percent Constituent Element are entered.
	155.009	Drug to be used as a component in a Medical Device (Active Pharmaceutical Ingredient / Bulk Drug Substance)	The quantity, Unit of Measurement and the Percent Constituent Element are entered.
	180.009	INV	The quantity, Unit of Measurement and the Percent Constituent Element are entered.
	180.017	RND	The quantity, Unit of Measurement and the Percent Constituent Element are entered.

Drugs Trade/Brand Name

Finished	Processing Code	Intended Use	Mandatory
Y	PRE		Y
Y	OTC		Y
	INV	180.009	Y
	API/Bulk		N
	RND		N
	PHN		N

Note: UNK for Unknown is acceptable temporarily.

Drugs Affirmations of Compliance

The FDA Affirmation of Compliance Codes and their descriptions are listed in the Appendix PGA (Food & Drug Affirmation of Compliance, FDA Affirmation of Compliance Codes) of ACE ABI CATAIR publication. The list of AOC codes applicable to FDA Drugs Message Sets is below:

*** Exemptions from providing Affirmations of Compliance ***
*** Pharmaceutical Necessities & Containers and Research & Development products do not need AOCs

For Government Program Code = DRU AND Government Processing Code =

- PHN: Pharmaceutical Necessities, Containers, Inactive Pharmaceutical Ingredients and Excipients; or
- RND: Research and Development

THEN AOC is not required

*** Import For Export entries, and Personal Importations do not require AOCs ***
For Government Program Code = DRU AND Intended Use code =

- 100.000: Importation for Personal Use; OR
- 970.000: Import For Export

THEN AOC is not required

AOC	Description	Syntax	New under ACE	Scenario Use
DA	New drug application number or Abbreviated New Drug Application number or Therapeutic Biologic application number	6N	N	IF Government Agency Program Code = DRU AND Government Agency Processing Code = 'PRE' AND Intended Use Code NOT = 100.000, 130.000, 180.009, 180.017, or 970.00 THEN DA IS MANDATORY IF Government Agency Program Code = DRU AND Government Agency Processing Code = ' 'OTC' THEN DA IS OPTIONAL The DA AOC includes all the previous AOC codes, NDA, ANDA and BLA.
REG	Drug Registration number	9N	Y	IF Government Agency Program Code = DRU and IF

				Government Agency Processing Code is PRE or OTC AND Intended Use Code NOT = 100.000, 180.009, 180.017, or 970.000 THEN REG IS MANDATORY
DLS	Drug Listing number	10N	N	IF Government Agency Program Code = DRU and IF Government Agency Processing Code is PRE or OTC, AND Intended Use Code NOT = 100.000, 180.009, 180.017, or 970.000 THEN DLS IS MANDATORY unless affirmation “PLR” is declared. The DLS AOC includes both the previous NDC and DLS AOC codes.
IND	Investigational new drug number	6N	N	IF Government Agency Program Code = DRU and IF Government Agency Processing Code is PRE or OTC or INV AND Intended Use Code = 180.009 THEN IND is MANDATORY

Medical Devices

Data Fields	Abbreviation	Definition	New Under ACE
Main Tab			
Commercial Invoice Description		Commercial Invoice Description	N
Agency Program Code	DEV	Medical Devices	Y
Processing code	RED	Radiation emitting devices	Y
	NED	Non-Radiation emitting devices	Y
FDA Product code	Alpha numeric code	FDA Product Code	N
Product description	free-form	Description of Product	N
Intended Use Code	Numeric code	6 digit intended Use Code (See Chart below)	Y
Trade/ Brand Name		Trade/Brand Name	Y
Anticipated Date and time of arrival	Numeric	Anticipated Time of Arrival in military time EST	N
Quantity	Numeric broken into pairs	Quantity	N
Countries Tab			
Origin	30	Country of Source	N
	39	Country of origin	N
	294	Country of refusal	Y

Parties Tab			
Required entities	MF	Manufacturer of good	N
	DEQ	Shipper of goods	N
	FD1	Importer of Record (PK information required)	N
	DII	Device Initial Importer	N
	DP	Deliver to Party	N
Affirmations of Compliance Tab		(See Affirmation of Compliance Chart to see when to use each code)	
	PM#	Device Premarket Number	N
	DDM	Device Domestic Manufacturer	N
	DFE	Device Foreign Exporter Registration number	N
	DI	Device identifier	N
	CPT	Component Identifier (indicator only)	N
	IFE	Import for Export (indicator only)	N
	LST	Device listing number	N
	DA	New Drug application number	N
	IND	Investigation New Drug Application	N
	LWC	Electrode Lead Wire or Patient Cable (indicator only)	N
	DI	Device Identifier (part of the Unique Device Identifier, UDI)	N
	DEV	Device Registration from Manufacturer	N

Medical Devices Intended Use

Intended Use Code	Intended Use Definition Relevant Medical Device Import Scenarios	Import Scenarios	Mandatory and Conditional Affirmations of Compliance per Intended Use
081.001	For Human Medical use as a medical device	Standard import of a medical device, accessories, or components regulated as a finished device, Import of refurbished device OR Import of a reprocessed device	DEV, DFE, LST (Mandatory); IRC, LWC, PM# (Conditional)
081.002	For Human Medical Use as a Medical Device for Domestic Refurbishing		DEV, DFE, LST (Mandatory); IRC, LWC, PM# (Conditional)
081.003	For Human Medical Use as Medical Device–domestically manufactured device that is part of a medical device		DDM, DFE, KIT, LST (Mandatory); IRC, LWC, PM#

	convenience kit		(Conditional)
081.004	For Human Medical Use as a Medical Device –foreign manufactured device that is part of a medical device convenience kit		KIT, DEV, DFE, LST (Mandatory); PM#, LWC;IRC (Conditional)
081.005	Importation of a device constituent part (finished device) for use in a medical product regulated under a drug (CDER) application type (e.g., for use in an NDA/ANDA/BLA drug-device combination product).		DEV, DFE, LST (Mandatory); DA, IND (Conditional)
081.006	Import of a medical device under enforcement discretion provisions per final guidance: http://www.fda.gov/ucm/groups/fdagov-public/@fdagov-meddev-gen/documents/document/ucm401996.pdf	Applicable product codes for CBP business rule: 80O - - UG; 86N - - FF 86N - - FG; 80N - - XQ 90L - - MB; 90L - - MD	
100.000	For Personal Use as a Non-Food Product – for personal use as a medical device		
110.000	For Public Exhibition or Display as a Non-Food Product	Includes import of device for trade show	
140.000	For Charitable Organization Use as a Non-Food Product		DEV, DFE, LST (Mandatory); IRC, LWC, PM# (Conditional)
081.007	Component for further manufacturing into a finished medical device		CPT (Mandatory)
081.008	Importation of a device component for use in a medical product regulated under a drug (CDER) application type (e.g., for use in an NDA/ANDA/BLA drug-device combination product).		CPT (Mandatory); DA, IND (Conditional)
170.000	For Repair of a Non-Food Product	Repair of medical device and re-exportation	DDM, IFE (Mandatory); DFE, LST, IRC, LWC, PM# (Conditional)
180.010	For Research and Development as a Non-Food Product - For research and development as a medical device	For Research and Development as a Non-Food Product - For research and development as a medical device	
180.014	For Research and Development as a Non-Food Product – for bench testing or nonclinical research use	Import of a device for non-clinical use/bench testing OR Import of device sample for	

		customer evaluation	
180.015	For Research and Development as a Non-Food Product – import of a medical device for clinical investigational use		IDA (Mandatory)
920.001	Import of a device that is US goods returned for refund/overstock (to manufacturer)	Refund/overstock OR Bench Testing OR Corrective Action Prevention Action (CAPA) OR Plan Investigation OR Recall	DDM, LST (Mandatory); DFE, IRC, LWC, PM# (Conditional)
920.002	Import of a device that is US goods returned for sale to a third party		DFE, DDM, LST (Mandatory); IRC, LWC, PM# (Conditional)
940.000	Import of a Compassionate Use/Emergency Use Device		
950.001*	Import of a single-use device for domestic reprocessing		DDM, LST (Mandatory); DFE, IRC, LWC, PM# (Conditional)
950.002*	Import of a multi-use device for domestic reprocessing		DDM, DFE, IRC, LST, LWC, PM# (Conditional)
970.000	Import for export	Import of a medical device for further processing and re-exportation OR Import of medical device or accessory for further manufacturing into an export only medical device	DEV, DFE, IFE, LST (Mandatory)
970.001	Import for export	Import of a medical device component for further manufacturing into an export only medical device	IFE, CPT, DDM, LST (Mandatory)
UNK	Unknown (Temporarily Acceptable)		

Medical Devices Affirmations of Compliance

AOC	Definition	Syntax	New Under ACE – Applicable by intended use chart
PM#	Device Premarket Number	Any of the following: P+6N; N+4N, 5N, or 6N; D+6N; H+6N; K+6N; DEN+6N; BP + 4-6N; BK + 6N; BH + 6N; BM + 6N; BR + 6N; DK + 6N; BD+6N	N
DDM	Device Domestic Manufacturer	1 - 10N	N
DEV	Device Registration from Manufacturer	1 - 10N	N
DFE	Device Foreign Exporter Registration number	1 - 10N	N
DI	Device identifier	6-23X	N
CPT	Component Identifier	Indicator only	N
IFE	Import for Export	Indicator only	N
IDE	Investigational Device Exemption Number	G+6N OR "NSR"	N
IRC	Device Impact Resistance Lens Certification	Indicator only	N
KIT	Device Imported Kit of Finished Device	Indicator only	N
LST	Device listing number	A+6N; B+6N; C+6N; D+6N; E+6N; L+6N; Q+6N; R+6N UNK - temporary	N
DA	New Drug application number	BA+4-6N or BN + 5-6 N or 6N	N
IND	Investigation New Drug Application	4-6N	N
LWC	Electrode Lead Wire or Patient Cable	Indicator only	N

Biologics

Data Fields	Qualifier	Definition	New Under ACE
Main Tab			
Commercial Description	Free Form	Commercial Description of Product	N
Government Agency Code	FDA	Food & Drug Admin	Y
Agency Program Code	BIO	Biologics	Y
Processing Codes	ALG	Allergens	Y
	BLO	Blood and Blood products	Y
	CGT	Cell & Gene Therapy	Y
	HCT	Human Cells & tissue	Y
	VAC	Vaccines	Y
	XEN	Xenotransplant	Y
	BDP	Blood Derivatives	Y
	BLD	Licensed Devices	Y
	BBA	Blood bag with anti-coagulant	Y
	PVE	Plasma volume expanders	Y
	BRD	Biologics regulated devices not subject to licensure	Y
Product Description	Description	Description of product	N
Intended Use Code	Intended Use Code	Intended Use Code (See Biologics Intended Use Chart below)	Y
Anticipated Date/Time of Arrival	Numeric	Anticipate time of arrival in military time EST	N
Trade/Brand Name	Name of Product	Trade/Brand Name of Product (see chart below)	N
Quantity	Numeric	Quantity broken down into data pairs	N
Countries Tab			
Origin	39	Country of Production	N
	30	Country of source	Y
	294	Country of refusal	Y
Parties Tab			
Required			

Entities/Parties			
	1) MF	Manufacturer	N
	2) DEQ	Shipper	N
	3) FD1	FDA Importer of Record (PK information required)	Y
	4) DP	Deliver to Party	Y
Affirmations of Compliance	3N or 2n+#	Affirmation of Compliance Code (See Biologics Affirmations of Compliance Chart below)	Y

Biologics Intended Use

Intended use code	CBER Regulated Products import scenario	CBP Intended Use name
080.000	CBER-regulated final product ready for use	For Humans Medical use under controlled distribution
081.000	CBER-regulated product for processing into a medical device	For processing into a medical device
082.000	Human cells, tissues, and cellular tissue based products for implant, transplant, infusion or transfer into human recipient	for immediate use by authorized medical officials in treatment of humans
100.000	Importation for personal use	For private, non-commercial use under FDA personal importation policy (PIP)
110.000	Import of biological drug or device for trade show	For public exhibition or display as a non-food product
140.000	Standard import of a biological drug or device for non-commercial distribution in organization support program	For improving living conditions during a natural disaster
150.007	Bulk drug substance for processing into a pharmaceutical product	For commercial processing as a non-food product; for processing into a pharmaceutical product
155.000	CBER product for further manufacturer of a licensed biological product under a short supply agreement (21CFR 601.22)*	For processing into a pharmaceutical product
170.000	Import of biological product, drug, or device that is US goods returned to manufacturer	For reconditioning or repair
180.000	Import of biologic for NON-clinical research use only. Bench testing etc	For research and development

180.009	Import of biological or chemical for research and development into a pharmaceutical product	For research and development
180.010	Import of a biological or chemical for research and development into a medical device	For research and development
180.016	CBER product sample for testing or lot release	For processing samples submitted to CBER for lot release
940.000	Compassionate use/emergency use	Compassionate or emergency use
970.000	CBER-Import for Export	Import for Export
UNK	Unknown (Temporarily Acceptable)	

Biologics Trade Name

Processing Code	Description	Trade Name Mandatory
VAC, BDP, BLD	Vaccines, Blood Derivatives and Licensed Devices	Y
All Other		N – but should include when applicable

Note: UNK for unknown is temporarily acceptable.

Biologics Affirmations of Compliance

Affirmations of Compliance	Description	Syntax	New under ACE	Scenario Use
			NOTE: Affirmations of Compliance were voluntary under OGA, now mandatory under PGA	
BLN	Biologic license number	4N		Required if intended use is 080.000 or 081.016, and if processing code is ALG, BDP, BLD,BLO, CGT,VAC, OR XEN (BLN AND/OR STN ARE MANDAT0RY). Required if intended use is 140.000 and processing code is as above or PVE. Required if intended use is 155.000 and if processing

				code is as above or BBA or PVE.
CPT	Component identifier			Required if intended use is 081.000 and the product is a component under processing code BRD
DA	Biologics New Drug or Abbreviated New Drug Application number or Therapeutic biologic application number	BA+4-6N or BN + 5-6 N or 6N		Required if intended use is 080.000, and if processing code is BBA or PVE
DEV	Device foreign manufacturer registration number	1-10N		Required if intended use is 080.000 or 081.000 and processing code BRD
DLS	Drug listing number	10N		Optional only for intended use 155.000 or 080.000 not mandatory
HCT	Human Cells & Tissue	Indicator only		Required if intended use is 082.000 and processing code is HCT,
HRN	Biologic cells, tissues product establishment registration	10N		Required if intended use is 082.000, and processing code is HCT
IDE	Biologics investigation device exemption	4-5N		Required if intended use is 180.010, and processing code is BRD
IFE	Import For Export	Indicator Only		Required if intended use code is 970.000 and the processing code is ALG, BBA, BRD, BDP, BLD, BLO, CGT, PVE, VAC or XEN.

IND	Biologic investigation new drug application number	4-6N		Required if intended use is 180.009, and if processing code = ALG, BBA, BDP, CGT, PVE, VAC, OR XEN
LST	Device listing number	A+6N; B+6N; C+6N; D+6N; E+6N; L+6N; Q+6N; R+6N; UNK can be used temporarily		Required if intended use is 080.000 or 081.000 and processing code BRD,
PM#	Biologics premarket notification number 510k	Any of the following: BP + 4-6N; BK + 6N; BH+6N; BR+6N; DK+6N; P+6N; D+6N; K+6N DEN+6N; BM+6N; BD+6N		Required if intended use is 080.000 or 081.000 and processing code BRD
REG	Drug Registration number	4-10N		Required if intended use is 080.000, and if processing code is BBA or PVE
STN	Biologic submission tracking number	6N		Required if intended use is 080.000 180.016, and if processing code is ALG, BDP, BLD,BLO, CGT,VAC, OR XEN (BLN AND/OR STN ARE MANDATORY. Required if intended use is 140.000 and processing code is as above or PVE. Required if intended use is 155.000 and if processing code is as above or BBA or PVE.

Cosmetics

Data Fields	Qualifier	Definition	New Under ACE
Main			
Commercial Description	Free Form	Commercial Description of Merchandise	N
Government Agency Code	FDA	Food & Drug Admin	Y
Government Agency Program Code	COS	Cosmetics	Y
Processing code		[none]	
FDA Product code	Alpha-numeric FDA product code	Product code	N
Product Description	Free form	Product description	N
Anticipated Date/Time of Arrival	numeric	Anticipate time of arrival in military time	N
Quantity	numeric broken into data pairs	quantity	N
Countries Tab			
Origin	39	Country of Production	N
	294	Country of Refusal	Y
Parties Tab			
Required entities	1) MF	Manufacturer	N
	2) DEQ	Shipper	N
	3) FD1 (Requires PK information)	FDA Importer of Record	Y
	4) DP	Deliver to Party	Y

Tobacco

Data Fields	Abbreviation	Definition	New Under ACE
Main Tab			
Commercial Invoice Description		Commercial Invoice Description	N
Government Agency Code	FDA	Food and drug Admin	Y
Program Code	TOB	Tobacco	Y
Processing code	CSU	Consumer Use	Y
	FFM	Further manufacturing	Y
	INV	Investigational	Y
		Description of product	N
FDA Product code	Alpha-numeric FDA product code	Product code	N
Product description	free form	Product Description	N
Intended Use Code		Only required for INV (See Tobacco Intended Use Code Chart below)	
Trade/Brand Name	Free Form	Trade/Brand Name (See Tobacco Trade Name Chart below to see when this is applicable)	Y
Anticipated Date/Time of Arrival	Numeric	Anticipated time of arrival in military time EST	N
Quantity	Numeric	quantity broken into data pairs	N
Countries Tab			
Origin	39	Country of Production	N
	262	Place of Growth	Y
	294	Country of Refusal	Y
		(See Source Processing Chart below to determine when each code applies)	
Parties Tab			
	1) MF	Manufacturer	N
	2) DEQ	Shipper	N
	3) FD1	FDA Importer of Record	Y
	4) DP	Deliver to Party	Y
	5) TB	Tobacco Submitter	Y

	6) ITL	Independent 3rd party lab OR	Y – only if processing code INV
	LAB	Lab or Clinical site	Y – only if processing code INV
Point of Contact	PK	Point of Contact (FD1)	Y
	or RD	Retail Distributor	Y

Tobacco Intended Use (Applicable if Processing Code = INV (Investigational)

Intended Use Code	Description
150.000	Commercial Use
155.000	Commercial assembly to be consumed
180.001	Research and development - animal or plant biomedical
180.000	Research and development - all other uses
110.000	Public Exhibition or display
130.000	Consumer use
140.000	Charitable organization
130.037	Repackaging and relabeling
UNK	Unknown (Temporarily Acceptable)

Tobacco Source Processing

Source Code	Description	Mandatory
39	Country of Production	Y
262	Place of Growth	N, but may be entered if available
30	Country of Source	N, but may be entered if available
294	Country of Refusal	Y – if product refused

Tobacco Trade Name

Processing Code	Description	Trade Name Mandatory
INV	Investigational **	Y
CSU	Consumer Use	Y
FFM	For Further Manufacturing	N

Note: UNK for unknown is temporarily acceptable.

**Note: If processing code INV Investigational is used, then an additional entity/party must be entered:

ITL Independent 3rd party lab

LAB Laboratory or Clinical site

Electronics (Radiation Emitting Products)

Data Fields	Qualifier	Definition	New Under ACE
Main Tab			
Commercial Invoice Description	Free Form	Commercial Invoice Description	N
Government Agency Code	FDA	Food & Drug Admin	Y
Agency Program Code	RAD	Radiation Emitting Products	Y
Processing code	REP	Non-medical radiation emitting products	Y
FDA Product code	Alpha-numeric FDA product code	Product code	N
Product Description	Free form	Product Description	N
Intended Use Base	numeric	3 digit Intended use Base code (See Electronics Intended Use Chart below)	Y
Intended Use Sub	numeric	3 digit Intended use Sub code (See Electronics Intended Use Chart below)	Y
Trade/Brand Name	Free form	Trade name of product	Y UNK is temporarily acceptable
Anticipated Date/time of arrival	numeric	Anticipated time of arrival in military time	N
Quantity	numeric	Quantity broken down into data pairs	N
Countries Tab			
Origin	39	Country of Production	N
	30	Country of source	N
	294	Country of Refusal	Y
Parties Tab			
Required Parties	1) MF	Manufacturer	N
	2) DEQ	Shipper	N
	3) FD1	FDA Importer of Record (Requires PK information)	Y
	4) DP	Deliver to Party	Y
Affirmations of Compliance Tab		(See Electronics Affirmations of Compliance Chart Below)	Y

Electronics Intended Use

Intended Use Code	Description	New Under ACE
085.000	For Veterinary Medical Use as a Non-Food Product under Controlled Distribution	Y
090.000	For Military Use as a Non- Food Product	Y
100.000	For Personal Use as a Non- Food Product	Y
110.000	For Public Exhibition or Display as a Non-Food Product	Y
120.000	For Public Safety Use as a Non-Food Product	Y
130.000	For Consumer Use as a Non- Food Product	Y
140.000	For Charitable Organization Use as Non-Food Product	Y
150.000	For Commercial Processing as a Non-Food Product	Y
155.000	For Commercial Assembly as a Non-Food Product	Y
170.000	For Repair of a Non-Food Product	Y
180.000	For Research and Development as a Non-Food Product	Y
970.000	For Import For Export	Y
980.000	For Other Use	Y
UNK	Unknown (Temporarily Acceptable)	

Electronics Affirmation of Compliance

Affirmation	Qualifier	Examples	Additional affirmations required	Corresponds to this text on FDA 2877 form
RA1	date	mm/yyyy		1. Were manufactured prior to the effective date of any applicable standard. Date of manufacture:
RA2	text	reason for exclusion		2. Are excluded by the applicability clause or definition n the standard or by FDA written guidance. Specify reason:
RA3	none			3. Are personal household goods of an individual entering the US or being returned to a US resident (Limit 3 of each product type)

RA4*	none			4. Are property of a party residing outside the US and will be returned to the owner after repair or servicing
RA5*	text	description of the end product		5. Are components or subassemblies to be used in manufacturing or as replacement parts
RA6	none			6. Are prototypes intended for ongoing product development by the importing firms, are labeled "for test/evaluation only"
				and will be exported, destroyed, or held for future testing, quantity limit stated on back of 2877 form
RA7*	text	description of the end product		7. Are being reprocessed in accordance with PL 104-134 or other FDA guidance, are labeled "for export only" and will not be
				sold, distributed, or transferred without FDA approval.
RB1*	none		If RB1 then ACC (product report accession number) OR ANC (annual report accession number) must be provided	B.1. Comply with the performance stands 1. Last annual report

RB2*	text	reason product complies		B2. Comply with performance standards 2. Unknown manufacture/report number State reason
RC1*	none			C1. Do not comply with performance standards; TIB, will be exported or destroyed under CBP supervision 1. Research, investigation, 766 form required
RC2	text	text is dates and use restriction		C2. Do not comply with performance standards, held under bond, 766 form required
RD1*	none			D1. Do not comply with performance standards, held under bond, Approved 766 petition attached
RD2*	none			D2. Do not comply with performance standards, held under bond, 766 Petition request attached
RD3*	date	date 766 form will be submitted		D3. Do not comply, held under bond, 766 petition to be submitted within 60 days

* Denotes that additional information may be required at time of entry for FDA to make a final decision on admissibility.

Non-Medical Electronic products which require a 2877 form

Non-medical electronic products which require a 2877 form	
Veterinary Therapy ultrasonic products	Other demonstration laser products
Non-medical cabinet x-ray systems	Other laser products
Cold-cathode gas discharge tubes	Positioning medical laser products
TV receivers and products containing same (not flat screen, plasma)	Research, scientific, laboratory laser products
Microwave ovens	Safety, security, surveillance laser products
Data measurement, transmit, control laser products	Surveying, leveling, alignment laser products
Laser light show display products	Toy, novelty, play laser products
Material processing laser products	Utility/ Peripheral Laser products
Mercury vapor lamps	

Veterinary

Data Fields	Qualifier	Definition	New Under ACE
Main Tab			
Commercial Description	Free form	Commercial Description	N
Agency Program Code	VME	Veterinary Drugs and Devices	Y
Processing code	ADR	Animal Drugs	Y
	ADE	Animal Devices	Y
FDA Product code	Alpha-numeric FDA product code	Product code	N
Product Description	Free form	Product description	N
Trade/Brand Name	Free form	Trade/Brand name	Y (Vet Drugs only) UNK is temporarily acceptable
Quantity	numeric	Quantity broken down into data pairs	N
Anticipated Date/Time of Arrival	numeric	Anticipated time of arrival in military time	N
Countries Tab			
Origin	39	Country of Production	N
	30	Country of source	N
	294	Country of Refusal	Y
Parties Tab			
Required Parties	1) MF	Manufacturer	N
	2) DEQ	Shipper	N
	3) FD1	FDA Importer of Record (PK information required)	Y
	4) DP	Deliver to Party	Y
Affirmations of Compliance Tab			
	Alpha	(See Veterinary Affirmation of Compliance Chart below to determine when AoC is required)	Y

Veterinary Affirmations of Compliance

AOC	Description	Syntax	Conditions
REG	Animal Drug Registration number	9N	IF Government Agency Program Code = VME and Government Agency Processing Code = 'ADR' THEN REG is MANDATORY.
VAN	Veterinary Abbreviated New Animal Drug Number ANADA	6N	IF Government Agency Program Code = VME AND PROCESSING CODE IS ADR THEN EITHER VNA, VIN or VAN is MANDATORY
VIN	Animal investigational new animal drug number (INAD) and JNIDA	6N	IF Government Agency Program Code = VME AND PROCESSING CODE IS ADR THEN EITHER VNA, VIN or VAN is MANDATORY
VNA	Animal new animal drug application number (NADA), legally marketing Unapproved New animal indexed drugs for minor species (MSIF)	4N or 6N	IF Government Agency Program Code = VME AND PROCESSING CODE IS ADR THEN EITHER VNA, VIN or VAN is MANDATORY
NDC	National drug Code	10N	OPTIONAL: IF Government Agency Program Code = VME AND Government Agency Processing Code = ADR THEN NDC may be entered.
DLS	Drug listing number	10N	OPTIONAL: IF Government Agency Program Code = VME AND Government Agency Processing Code = ADR THEN DLS may be entered.