CBP and Trade Automated Interface Requirements

FDA Supplemental Guidance for the Automated Commercial Environment/International Trade Data System (ACE/ITDS) Version 2.4

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U.S. Customs and Border Protection

FDA Supplemental Guidance

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Change Log

Date	Version No.	Description	Page Number	Author
11/25/2014	1	Initial Version	129	FDA
1/02/2015	1.2	Updated all mandatory record types to match FDA business rules for CBP processing	Multiple pages	FDA
1/22/2015	1.3	Updates based on feedback from Trade in the 1/6 and 1/13 meetings; based on feedback from FDA's review of draft. Added Commodity type to Commodity sub-type mapping table.	Multiple pages	FDA
2/9/2015	1.4	Updates based on feedback from CDRH on Medical Devices and from CBP on all chapters; enforced consistence of same PG record types across commodities where there is no special handling from one commodity to another (example, PG06, PG20, PG21); updates based on feedback from Trade in the 1/20, 1/27 and 2/3 meeting.	Multiple pages	FDA
3/5/2015	1.6	Updates to Drugs chapter based on CBP's feedback; removed references to MID as the identifier for Trade; re-aligned the Processing Codes for Medical Devices	Multiple pages	FDA
3/19/2015	1.7	Removed references to ESS, SSN & TIN in PG19; Added 'DP' to PG19; the mandatory LOT# related fields in PG25 are now conditional; Improved rules for Item Type in PG02 record; Updates to Drugs chapter based on meeting with Philadelphia District Office; PG06 Notes are made consistent across all the commodities; added new Processing Codes for Radiation Emitting Products	Multiple pages	FDA
4/2/2015	1.8	For VME, PG07 is conditional; for Cosmetics, Cosmetic Registration Number (COS) is optional; for FOO, PG23 AoC Codes FCE/SID requirements are updated; for DRU PG23, REG is not required for PHN; updated the processing codes for drugs; PG25 – all values except PGA Line value are now optional for all commodities; PG27 record is now mandatory for PN but is optional for all commodities; PG26 is optional and PG29 is conditional for Drugs; added Appendix C for DRU;	Multiple pages	FDA

Date	Version No.	Description	Page Number	Author
4/11/2015	1.9	Additional text added for PG30 record description based on the March 25th release of CATAIR; adjusted list of intended use codes for PG01 in Radiation Emitting Products chapter per Amy Gomez, CDRH; changes to Drugs chapter PG01, PH02, PG04, PG19 and PG23 based on feedback from John Verbeten CDER; updates to Biologics chapter based on feedback from CBER;	Multiple pages	FDA
4/27/2015	2.0	Updated PG19 Entity identification criteria across all commodities; added subtypes to Tobacco; added PG04 to Tobacco and included feedback from CTP; includes CBER feedback in Biologics; added the new chapter on Device and Drug Combination Products chapter; added the new chapter for Prior Notice; included additional text to Food chapter to connect PN and Food chapters; updated the context of the PN and Food chapters to describe a stand-alone PN entry in the PN chapter and a combination entry (801a and 801m) in the Food chapter.	Multiple pages	FDA
5/12/2015	2.1	Updated **Drugs** chapter using 4/30/2015 & 5/8/2015 feedback from CDER; updated **Tobacco** chapter using 5/1/2015, 5/2/2015 & 5/7/2015 feedback from CTP; updated **Veterinary Medicine** chapter using 5/5/2015 & 5/8/2015 feedback from CVM; updated the **Biologics** chapter using 5/6/2015 feedback from CBER; updated Disclaimer in PG01 consistently across all the commodities; updated **Medical Devices** chapter using ACE ITDS Import Scenario Mapping19.xlsx from CDRH; updated **Cosmetics** chapter using feedback from CFSAN; updated **Radiation Emitting Products** chapter based on 5/7/2015 feedback from CDRH; updated **Prior Notice** chapter using 5/7/2015 feedback from DFDT;	Multiple pages	FDA
5/18/2015	2.1.1	Updates to PG30 to make mandatory for anticipated arrival time. Updated Prior Notice section to include data elements in the PE records. Various cosmetic and formatting updates	Multiple pages	FDA

Date	Version No.	Description	Page Number	Author
6/12/2015	2.2	PG55 is not supported at this time for all FDA commodities; CBER AoC codes & business rules updated; PG25 - line value is required in all the PG25 records (repeated for multiple lot #); FDA product code = 7 characters; Added references to a new entity role code: FDC = FDA Consolidator; Valid list of port codes link added to PG30; Medical Devices - PG01 Intended Use codes and sub-codes – updated; Radiation Emitting Products - PG01 Intended Use codes and sub-codes – updated; PG20 is mandatory with additional notes for all commodities; dropped Remarks Code and clarified the Note in PG24 for all commodities; added Prior Notice Non-PGA Data Elements by Mode of Transportation to PN chapters; external sample file is referenced to provide samples for all commodities; included additional rules for entering PG19 entity role codes;	Multiple pages	FDA
8/18/2015	2.3.1	Updated **PN**-related chapters based on feedback from DFDT's FDA Supplemental Guide Release 2 2 DFDT Edits 07-02-15.docx, FDA Supplemental Guide Release 2 3 draft DFDT Edits 7-13-15.docx, FDA Supplemental Guide Release 2 3 with tracking DFDT Edits 7-20-15.docx and FDA Supplemental Guide Release 2 3 with tracking DFDT Edits 7-24-15.docx; updated **Medical Devices** and **Radiation Editing Products** chapters based on feedback from CDRH's FDA Supplemental Guide Release 2.2 abg.docx and final - FDA Supplemental Guide Release 2 3 with tracking - Device Chapter_abg + ja 150814abg.docx; changed the use of FD1 entity role code to DII for **CDRH** use; updated **PG26** across all commodities based on CBP's new descriptions of product packaging; updated **PG05-06-07-10** throughout the document to reference the most recent PG02; re-arranged the appendices and updated their references throughout the document; updated the validation criteria for **FEI** numbers across all commodities based on its current range of values in FDA's databases; clarified the text for **PG21** and **PG30** record across all commodities; clarified the references to PE10 and SE15 in conjunction with the PG Message Set in the **PN-related** chapters; in the **Drugs** chapter, added BLA to the scope of the AoC code DA (formerly NDA and AND); removed the use of Intended Use Codes for Food-related commodities and added logic depending on parts of product codes at group	Multiple pages	FDA

Date	Version No.	Description	Page Number	Author
		level; **PG01** is not repeatable for different Intended Use Codes; added the FDA Product Code structure to all commodities and included logic based on product codes in **Food-related** chapters; renamed veterinary medicine chapter to **Animal Drugs and Devices** per feedback from CVM and replaced references to veterinary medications by animal drugs in the entire document; updated **Tobacco** chapter based on feedback in Tobacco Data Elements - June 2015 exw jw jma.doc; updated **Biologics** chapter using feedback from FDA Supplemental Guide Release 2 3 CBER Edits.docx; updated Devices and Drug chapters in lieu of the **Device+Drug Combination** chapter before removing it; updated Devices and Biologics chapters in lieu of the **Device+Biologics Combination** chapter before removing it; added business rules for **PG24**; added Appendix E showing the use of PG04 both at Product-level and at Constituent Element-level and updated all commodities accordingly; added new AoC codes in the **Tobacco** chapter; added new UoM codes for **Drugs**;		
10/26/2015	2.3.2	**For all commodities:** Intended Use Description is optional; added Appendix F for the list of Unit of Measurement codes and included its reference in PG26 and PG29; PG29 is not supported by the FDA at this time; clarified the use of PG04 for multiple constituent elements under PG02 and corrected Appendix E accordingly; Line value in PG25 must be greater than zero; Quantity in PG26 must be greater than zero; PG19:Entity Number is optional; PG19:Entity Identification Code is Mandatory if PG19:Entity Number is entered; PG21:Telephone Number is 15X (alpha-numeric) to include global telephone numbers; added a national and an international telephone number as examples in PG21; At least one PG21 record is required;	Multiple pages	FDA

Date	Version No.	Description	Page Number	Author
		For specific commodities: Government Agency Processing codes have changed for VME; reviewed and corrected the Intended Use Codes for BIO, DRU, DEV and VME – these changes will be in line with the next release of Schedule R by the CBP; corrected a typo in DRU:PG07; corrected Note3 text for Radiation Emitting Products:PG01; PG23:AoC codes are adjusted for BIO, DRU, DEV and VME; updated the mapping between the AoC codes and import scenarios for BIO and DRU chapters; PG01:Note3 for Cosmetics is deleted; PG04 is required for all DRU messages except PHN; Note5 is new in DRU:PG04; added the new AoC code PLR for drugs; added references to Carrier Name to PN-related chapters – the new AoC code CAN is added to PG23 for PN; Bulk (230.005) is not a valid IUC code for Food; all references to the AoC code PND are deleted in the Food chapters; clarified the rules for PG06, PG13 and PG14 for Food chapters; PG21:PK reference is added to all Food chapters; Food UoM tables are added to FOO chapters; PG28 is conditional for non-PN chapters – Note1 includes additional clarifications; for TOB:PG26, it is not required to enter 20 cigarettes in a pack – it may be entered if		

Date	Version No.	Description	Page Number	Author
		desired by the filer; IUC codes are optional for VME; the AoC code VMS is deleted from VME chapter; Clarified that ONE of MF/DFI/FDC is required for PN and only one of them is allowed; PG30 is used to collect Foreign Trade Zone (FTZ) information for the **FOO+PNC** chapter.		
10/29/2015	2.4	Corrected the footnotes in PG19 for Prior Notice chapters; clarified the percentage of constituent element in PG04 and added examples for DRU and VME chapters; AofC code is conditional for RAD chapter; new IUC codes are ordered to match the next release of Schedule R by CBP. Updated PG30 record for FOO+PNC chapter;	Multiple pages	FDA

General Introduction

This document is intended as a supplemental guide to the CBP Customs and Trade Automated Interface Requirements (CATAIR), PGA Message Set chapter (also referred to as an implementation guide).

The PGA Message Set chapter/implementation guide and its related Appendix PGA can be found on CBP.gov at: http://www.cbp.gov/document/guidance/appendix-pga

The ACE ABI CATAIR – Custom and Trade Automated Interface Requirements: http://www.cbp.gov/document/guidance/pga-message-set

Appendix V Government Agency Codes: http://www.cbp.gov/document/guidance/appendix-v-government-agency-codes

Appendix R Intended Use Codes for ACE: http://www.cbp.gov/document/guidance/appendix-r-intended-use-codes-ace

Appendix B Valid Codes: http://www.cbp.gov/document/guidance/appendix-b-valid-codes

Appendix C: http://www.cbp.gov/document/guidance/appendix-c-tariff-abbreviations

There are times when FDA and CBP reporting may require the same data. In those instances, FDA will not ask for the data to be provided again in the PGA Message Set, if it is already collected by CBP. That is, the PGA Message Set data requirements for FDA will not duplicate those common data elements. Instead, the PGA Message Set is used to provide specific data elements required for FDA reporting

FDA Overview

FDA is responsible for:

- Protecting the public health by assuring that foods (except for meat from livestock, poultry and some egg products which are regulated by the U.S. Department of Agriculture) are safe, wholesome, sanitary and properly labeled; ensuring that human and animal drugs, and vaccines and other biological products and medical devices intended for human use are safe and effective,
- Protecting the public from electronic product radiation,
- Assuring cosmetics and dietary supplements are safe and properly labeled,
- Regulating tobacco products, and
- Advancing the public health by helping to speed product innovations.

Primary responsibility for administering the nation's laws relating to import, export, and the collection of duties is given to the United States Customs and Border Protection (CBP). FDA, however, is responsible for determining whether or not an article offered for importation is in compliance with or in violation of the acts enforced by the FDA. This includes the responsibility of determining whether or not a violative article may be brought into compliance with the appropriate statute and/or regulations, and authorizing reconditioning in order to bring an article into compliance.
In order to fulfill their respective responsibilities, CBP and FDA must work in close cooperation.

Points of Contact

If you have technical questions about the content of this Supplemental Guide, please email FDA at ACE_Support@fda.hhs.gov.

If you have other questions about this Guide or its data examples, please contact:

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Legends

Field Requirements

Abbreviation	Name	Description
M	Mandatory	This data element is required under all circumstances
C	Conditional	This data element is required under certain circumstances based on business rules
O	Optional	This data element is not compulsory under all circumstances

Field Data Types

Abbreviation	Name	Description
A	Alpha	Letters A-Z
N	Numeric	Numbers 0-9
AN	Alphanumeric	Letters A-Z and Numbers 0-9
X	Alphanumeric and Special Characters	Letters A-Z, Numbers 0-9, special characters (*,!,@, etc.)

Required (Mandatory and/or Conditional)Data Elements for all FDA Commodities

Level of Data	Record ID	Data Element	Length/ Class	Position	Field Type
Entry	OI	Record Identifier			
Line	PG01	PGA Line Number	3N	5-7	incremental
Line	PG01	Government Agency Code	3AN	8-10	code
Line	PG01	Government Agency Program Code*	3X	11-13	code
Line	PG01	Government Agency Processing Code*	3AN	14-16	code
Line	PG02	Item Type	1A	5	code
Line	PG02	Product Code Qualifier	4AN	6-9	code
Line	PG02	Product Code Number	19X	10-28	text
Line	PG06	Source Type Code	3AN	5-7	code
Line	PG06	Country Code	2X	8-9	code
Line	PG10	Product Description	57X	24-80	text
Line	PG19	Entity Role Code	3AN	5-7	code
Line	PG19	Entity Name	32X	26-57	text
Line	PG19	Entity Address 1	23X	58-80	text
Line	PG26	Packaging Qualifier	1N	5	code
Line	PG26	Quantity	12N	6-17	number
Line	PG26	Unit of Measure (Packaging Level)	5X	18-22	code
Line	PG30	Inspection/ Laboratory Testing Status	1A	5	code
Line	PG30	Anticipated Arrival date	8N	6-13	date
Line	PG30	Anticipated Arrival time	4N	14-17	time

*Not Required for a Disclaimed entry

FDA Commodities and Commodity Sub-Types

Govt. Agency Code	Commodity Type	Govt. Agency Program Code	Commodity Sub-Type	Govt. Agency Processing Code
FDA	Biologics	BIO	Allergens	ALG
FDA	Biologics	BIO	Blood and Blood Products	BLO
FDA	Biologics	BIO	Cell & Gene Therapy	CGT
FDA	Biologics	BIO	Human Cells & Tissue	HCT
FDA	Biologics	BIO	Vaccines	VAC
FDA	Biologics	BIO	Xenotransplant	XEN
FDA	Biologics	BIO	Blood Derivatives	BDP
FDA	Biologics	BIO	Licensed Devices	BLD
FDA	Biologics	BIO	Blood Bag with Anti-coagulant	BBA
FDA	Biologics	BIO	Plasma Volume Expanders	PVE
FDA	Biologics	BIO	Biologics Regulated Devices (Not subject to licensure)	BRD
FDA	Cosmetics	COS	All Products	
FDA	Medical Devices	DEV	Radiation Emitting Devices	RED
FDA	Medical Devices	DEV	Non-Radiation Emitting Devices	NED
FDA	Drugs	DRU	Investigational	INV
FDA	Drugs	DRU	Research and Development	RND
FDA	Drugs	DRU	Pharmaceutical Necessities & Containers	PHN
FDA	Drugs	DRU	Over the Counter	OTC
FDA	Drugs	DRU	Prescription	PRE
FDA	Foods	FOO	Additives and Colors	ADD
FDA	Foods	FOO	Dietary Supplements	DSU
FDA	Foods	FOO	Animal Food (includes pet food, medicated feed and feeds)	FEE
FDA	Foods	FOO	Ceramic ware and other food contact substances	CCW
FDA	Foods	FOO	Natural State Food	NSF
FDA	Foods	FOO	Processed Food	PRO
FDA	Radiation Emitting Products	RAD	Non-Medical Radiation Emitting Products	REP
FDA	Tobacco	TOB	Consumer Use	CSU
FDA	Tobacco	TOB	For Further Manufacturing	FFM
FDA	Tobacco	TOB	Investigational	INV
FDA	Animal Drugs and Devices	VME	Animal Drugs	ADR
FDA	Animal Drugs and Devices	VME	Animal Devices	ADE

Biologics Commodity Data Elements and Values

Biologics commodities can be broken down into the following categories using the existing Government Agency data elements available in the PG01 message

PG01 - Government Agency Code	Commodity Type	PG01 - Government Agency Program Code	Commodity Sub-Type	PG01 - Government Agency Processing Code
FDA	Biologics	BIO	Allergens	ALG
FDA	Biologics	BIO	Vaccines	VAC
FDA	Biologics	BIO	Human Cells & Tissue	HCT
FDA	Biologics	BIO	Xenotransplant	XEN
FDA	Biologics	BIO	Cell & Gene Therapy	CGT
FDA	Biologics	BIO	Blood and Blood Products	BLO
FDA	Biologics	BIO	Licensed Devices	BLD
FDA	Biologics	BIO	Blood Derivatives	BDP
FDA	Biologics	BIO	Blood Bag with Anti-coagulant	BBA
FDA	Biologics	BIO	Plasma Volume Expanders	PVE
FDA	Biologics	BIO	Biologics Regulated Devices (Not subject to licensure)	BRD

Table 1 – Biologics commodity hierarchy

The following are the potential PGA records associated with submitting Biologics data:

PG Record	Description
OI	The commercial description of the shipment is provided.
PG01	The shipment is regulated by the FDA program office within FDA and the intended use is provided.
PG02	The item type and Product Code detail are provided.
PG04	Product Constituent Active Ingredient
PG05	Scientific Genus Names
PG06	Product Source information is provided
PG07	Trade/Brand Name
PG10	Description of items in the lot number
PG19	Entity Role (manufacturer, consignee, shipper, etc.) Entity Identification, Entity Name, and Entity Address 1 are provided.

PG Record	Description
PG20	Additional address data on the entity in PG19 is provided
PG21	The entity (manufacturer, consignee, shipper, etc.) of Record's individual point of contact, phone number and email is given.
PG23	FDA affirmation of Compliance criteria is provided
PG24	Remarks
PG25	Temperature qualifier, Lot#, Production dates, PGA Line Value and PGA Unit Value are provided
PG26	Packaging qualifier and quantity of the shipment are provided
PG27	Additional data on Container number
PG29	Weight of lot number
PG30	Inspection location, date and time
PG55	Additional roles performed by entity or individual
PG00	Data Substitution

Biologics Example

Biologic Message Set Layout for Sample

Please refer to the external file: **FDA SG 2.4 Example PG Message Sets.xlsx** Tab: ***Biologics***

Because of the flexibility of the PGA Message set, the PGA Records and Data Elements that are required may vary both from program to program and within a single program. For a more expansive set of examples of FDA PGA Message Sets, please refer to the above document.

Record Identifier OI (Record Identifier)

This is a mandatory PGA line item description input record that provides the description of the item. This record precedes the Record Identifiers for the PGA Message set.

Record Identifier OI (Record Identifier)					
Data Element	**Length/ Class**	**Position**	**Status**	**Description**	**Note**
Control Identifier	2A	1-2	M	Must be “OI”	
Filler	8X	3-10	M	Space filled.	
Commercial Description	70X	11-80	M	The commercial description of the product. This can be the importer’s product description used in ACS currently. For example, BLOOD DERIVATIVES	

Record Identifier PG01 (Record Identifier)

This is a mandatory PGA input record that provides data pertaining to the PGA Line Number, Government Agency Code, Government Agency Program Code, Globally Unique Product Identification Code, Intended Use Code, Intended Use Description, and Disclaimer.

Record Identifier PG01 (*Record Identifier*)					
Data Element	**Length/ Class**	**Position**	**Status**	**Description/Required Value**	**Note**
Control Identifier	2A	1-2	M	"PG"	
Record Type	2N	3-4	M	"01"	
PGA Line Number	3N	5-7	M	"001"	
Government Agency Code	3AN	8-10	M	"FDA"	
Government Agency Program Code	3X	11-13	C	"BIO"	1, 2
Government Agency Processing Code	3AN	14-16	C	Allowed values for Biologics sub-types: ALG, VAC, HCT, XEN, CGT, BLO, BLD, BDP, BBA, PVE and BRD.	1, 2
Intended Use Code	16X	42-57	C		3, 4
Intended Use Description	22X	58-79	O		
Disclaimer	1A	80	C	A code of A (= product is not regulated by this agency) or B (= data is not required per agency guidance) indicating there is no agency declaration requirement. Or this field is left blank for no disclaimer. No other code is accepted	

Note 1

See Table 1 above for the commodity hierarchy for Biologic commodities

Note 2

If the Disclaimer is 'A' or 'B' then these data elements should both be populated with FDA. Otherwise the Government Agency Program Code and Government Agency Processing Code are mandatory.

Note 3

If the Disclaimer is 'A' or 'B' then these data elements are optional; otherwise the Intended Use Code is conditional.

Note 4:

CBER Regulated Products Import Scenario	**Intended Use Code**	**CBP Intended Use Name**
CBER-regulated Final product; ready for use	**080.000**	For Human Medical Use as a Non-Food Product under Controlled Distribution

CBER Regulated Products Import Scenario	Intended Use Code	CBP Intended Use Name
Human Cells, tissues, and cellular and tissue based products (HCT/Ps) for implant, transplant, infusion, or transfer into a human recipient	**082.000**	For Immediate use by authorized medical officials in the medical treatment of humans
CBER-regulated product – for commercial processing as a non-food product	**150.000**	For further processing into non-medicinal and medicinal products
CBER-regulated product- for processing into a medical device	**150.013**	For processing into a medical device
CBER-regulated product For further manufacture including IFE components	**150.007**	For processing into a pharmaceutical product
CBER Product Sample for testing or lot release	**180.016**	For processing samples submitted to CBER for lot release testing.
Bulk Drug Substance for processing into a pharmaceutical product.	**150.007**	For commercial processing as a Non Food product; for processing into a pharmaceutical product.
CBER product For further manufacture of a licensed biological product under a short supply agreement (21 CFR 601.22)*	**150.007**	For processing into a pharmaceutical product
Importation for Personal Use	**100.000**	For private non-commercial use under the FDA personal importation policy (PIP)
Standard import of a biological drug or device for non-commercial distribution in government and non-government organization support program	**140.000**	For improving living conditions during a natural disaster.
Import of biological device (not IVD) for investigational use under IDE, or not requiring an IDE	**180.000**	For Research and Development as a Non-Food Product
Import of a biological or chemical for research and development into a pharmaceutical product	**180.009**	For Research and Development of a pharmaceutical product
Import of a biological or chemical for research and development into a medical device	**180.010**	For Research and Development of a medical device
Import of biological device (not IVD) for non-clinical research use only, bench testing, etc.	**180.000**	For Research and Development as a Non-Food Product
Import of Biological IVD for research use only or investigational use only	**180.000**	For Research and Development as a Non-Food Product
Import of biological drug or device for trade show	**110.000**	For Public Exhibition or Display as a Non-Food Product
Import of a biological device manufactured outside US that is part of a medical device convenience kit	**080.000**	For Human Medical Use as a Non-Food Product under Controlled Distribution
import of a biological product, drug or device that is US goods returned (to manufacturer)	**170.000**	For reconditioning or repair of a Non-Food Product

Record Identifier PG02 (Product Identifier)

This mandatory PGA input record is used to indicate whether or not the information being provided relates to a product (P) or a component (C) of a product.

Record Identifier PG02 (Product Identifier)					
Data Element	**Length/ Class**	**Position**	**Status**	**Description**	**Note**
Control Identifier	2A	1-2	M	"PG"	
Record Type	2N	3-4	M	"02"	
Item Type	1A	5	M	Code identifying the following records as pertaining to the product. Enter P for product. No other values are allowed. Only one 'P' record is allowed for the same PGA Line # in PG01.	
Product Code Qualifier	4AN	6-9	M	"FDP" (FDA Product)	
Product Code Number	19X	10-28	M	FDA Product Code Must be equal 7 characters	

Product Code Qualifiers and their descriptions can be found in Appendix PGA (PG02 – Product Code Qualifiers) of the ACE ABI CATAIR publication. For FDA, this is currently always 'FDP' for all FDA products.

Only one FDA Product Code Number per product is allowed.

FDA Product Code Structure:

Position	1-2	3	4	5	6-7
Name	Industry Code (N)	Class Code (A)	Sub Class Code (A or '-')	Process Identification Code - PIC (A or '-')	Product (AN)

Legend - N: Numeric; A:Alphabetic; AN:AlphaNumeric

Record Identifier PG04 (Product Constituent Element)

This is an optional PGA input record that provides data pertaining to Constituent Active Ingredient Qualifier, Name of the Constituent Element, Quantity of Constituent Element, Unit of Measure, and Percent of Constituent Element for the product identified by Product Code Number in PG02. This record can be repeated.

See Appendix E for an example of how PG04 can be used at the Product-level for multiple Constituent Elements.

Record Identifier PG04 (Product Constituent Element)					
Data Element	**Length/ Class**	**Position**	**Status**	**Description**	**Note**
Control Identifier	2A	1-2	M	"PG".	
Record Type	2N	3-4	M	"04".	
Constituent Active Ingredient Qualifier	1A	5	O	Active ingredient = "*Y*" if yes, blank if no.	1
Name of the Constituent Element	51X	6-56	O		1
Quantity of Constituent Element	12N	57-68	O	2 decimal places are implied	1
Unit of Measure (Constituent Element)	5AN	69-73	O		1
Percent of Constituent Element	7N	74-80	O	4 decimal places are implied. 18.2% is entered as 0182000.	1, 2

Note 1
Some of the Biologics products may not have a defined active ingredient. Even when an active ingredient is known, it may be in a descriptive form. For example, the multiple active ingredients in the MMR Vaccine are expressed in detail in the Prescribing information.

Note 2
Examples of Percentages:

1000000	=	100%
0990000	=	99%
0090000	=	9%
0009000	=	.9%
0000900	=	.09%
0000090	=	.009%
0000009	=	.0009%

Record Identifier PG05 (Scientific Genus Names)

This is an optional PGA input record that provides data pertaining to Scientific Genus Names, Scientific Species, Scientific Sub Species Name, Scientific Species Code, and FWS Description Code for the product identified by Product Code Number in PG02.

Using a Drug example, Appendix E shows how PG04 can be used at the Product-level for multiple Constituent Elements. **The FDA will process PG05-PG06-PG07-PG08-PG10 records only at the Product-level (when they are under a PG02) at this time**.

Record Identifier PG05 (Scientific Genus Names)					
Data Element	**Length /Class**	**Position**	**Status**	**Description**	**Note**
Control Identifier	2A	1-2	O	“PG”.	
Record Type	2N	3-4	O	“05”.	
Scientific Genus Name	22X	5-26	O	Scientific Genus Name of the merchandise being entered.	1
Scientific Species Name	22X	27-48	O	Scientific Species Name of the merchandise being entered.	1
Scientific Sub Species Name	18X	49-66	O	Scientific Sub Species Name of the merchandise being entered.	1

Note 1
This PG only can apply to products with a Government Agency Processing code = XEN.

Record Identifier PG06 (Product Origin)

This is a mandatory PGA input record that provides data pertaining to Source Type (Origin) - other than the CBP Country of Origin - for the product identified by Product Code Number in PG02 in addition to Processing dates, Processing Type and Processing Description.

Using a Drug example, Appendix E shows how PG04 can be used at the Product-level for multiple Constituent Elements. **The FDA will process PG05-PG06-PG07-PG08-PG10 records only at the Product-level (when they are under a PG02) at this time.**

For the Lacey Act, the filer must submit a corresponding genus/species (PG05/PG06) for each Country of Harvest.

Record Identifier PG06 (Product Origin)					
Data Element	**Length/ Class**	**Position**	**Status**	**Description**	**Note**
Control Identifier	2A	1-2	M	“PG”.	
Record Type	2N	3-4	M	“06”.	
Source Type Code	3AN	5-7	M	Mandatory valid value is 39 (Country of Production) or 30 (Country of Source). 294 (Country of Refusal) is MANDATORY if previously refused. There would be at least one PG06 with source type code of 30 or 39. If previously refused, then trade would also provide another PG06 with source type code 294.	1
Country Code	2X	8-9	M	Country of production or source is required for Biologics.	2

Note 1

Source Type Codes and their descriptions can be found in Appendix PGA (PG06 – Source Type Codes) of the ACE ABI CATAIR publication.

Note 2

Any of the country codes from Appendix B (ISO Country and Currency Codes) in the ACS ABI CATAIR can be entered.

Record Identifier PG07 (Product Trade Names)

For Biologics, this is a conditional PGA input record that provides data pertaining to Trade or Brand Name of the product identified by Product Code Number in PG02.

Using a Drug example, Appendix E shows how PG04 can be used at the Product-level for multiple Constituent Elements. **The FDA will process PG05-PG06-PG07-PG08-PG10 records only at the Product-level (when they are under a PG02) at this time.**

Record Identifier PG07 (Product Trade Names)					
Data Element	**Length /Class**	**Position**	**Status**	**Description**	**Note**
Control Identifier	2A	1-2	M	“PG”.	
Record Type	2N	3-4	M	“07”.	
Trade Name/Brand Name	35X	5-39	C	The make of the product (or component) by manufacturer or distributor from the label or invoice.	1

Note 1:

If a product is licensed, Trade Name or Proper Name is mandatory. Vaccines (VAC), Blood Derivatives (BDP) and Licensed Devices (BLD) are required to include Trade/Brand Name if it exists. If no Trade Name is available then its Proper Name should be provided.
Per 21CFR600.3 (k), *Proper name is defined* as the name designated in the product license, for use upon each package of the product.

Tissues and cells only have product description (HCT).

All other commodity sub-types should include Trade/Brand Name, if applicable.

Record Identifier PG10 (Product Characteristics)

For Biologics this is a mandatory PGA input record that allows for importer to report the description of the product identified by Product Code Number in PG02 at the line level to capture the information currently collected in multiple OI records. This record can be repeated if there are more Commodity Characteristic Descriptions.

Using a Drug example, Appendix E shows how PG04 can be used at the Product-level for multiple Constituent Elements. **The FDA will process PG05-PG06-PG07-PG08-PG10 records only at the Product-level (when they are under a PG02) at this time.**

Record Identifier PG10 (Product Characteristics)					
Data Element	**Length/ Class**	**Position**	**Status**	**Description**	**Note**
Control Identifier	2A	1-2	M	“PG”.	
Record Type	2N	3-4	M	“10”.	
Commodity Characteristic Description	57X	24-80	M	Include proper name (if applicable) OR invoice description here - NOT product code description. See Appendix A for the use of PG10 to capture the information currently collected in multiple OI records.	

Record Identifier PG19 (Entity Data)

For Biologics, this is a mandatory PGA input record that provides FDA with data pertaining to Entity Role and conditionally the following data elements; Entity Identification, Entity Name, and Entity Address 1.

Record Identifier PG19 (Entity Data)					
Data Element	**Length /Class**	**Position**	**Status**	**Description**	**Note**
Control Identifier	2A	1-2	M	"PG"	
Record Type	2N	3-4	M	"19"	
Entity Role Code	3AN	5-7	M	Code identifying the role of the entity being provided. For example, IM.	1
Entity Identification Code	3AN	8-10	C	Code identifying the Entity Identification is entered. For example: 16, 47. Mandatory, if Entity Number is entered.	2
Entity Number	15X	11-25	O	The Entity Number of the entity based on the above Entity Identification Code is entered; must conform to the descriptions in Note 2	2
Entity Name	32X	26-57	M	The name of the entity is required. See validation criteria below.	2
Entity Address 1	23X	58-80	M	The address of the entity is required. See validation criteria below.	2

Note 1
Entity Role Codes and their descriptions can be found in Appendix PGA (PG19 – Entity Role Codes) of the ACE ABI CATAIR publication. List of Entity Role codes mandatory to FDA Biologics Message Sets is below. One of each of these is mandatory for EACH LINE:

Data Element	***Code***	***Description***
Entity Role Codes§	MF	Manufacturer of goods
	DEQ	Shipper
	FD1	FDA Importer (Importer of Record)
	DP	Delivered To Party±

§ Same Role Code cannot be entered more than once.

± Even though Title 19 141.19 (CBP) addresses - Consignee -, Title 21, Requires Prior Notice information about the - Ultimate Consignee - and Title 19 (CBP) defines - Ultimate Consignee -, FDA acknowledges that these terms cause confusion and would like to simplify and harmonize said data elements under the ACE environment.

Hence, the FDA has elected to utilize the data element --- "Deliver to Party" --- , U.S party that physically receives the good(s). The FDA's PG Message Set will, therefore, incorporate the deliver to party as issued in the ITDS Standard Data Set under the auspices of the ITDS Board of Directors. FDA's Prior Notice requirement for ultimate consignee is synonymous with deliver to party.

List of Entity Role codes also applicable to FDA Biologics Message Sets is below:

Data Element	***Code***	***Description***
Entity Role Codes	AAR	All Applicable Roles

Data Element	Code	Description
	APP	Applicant
	CE	Certifying Entity
	CO	Certifying Official
	CN	Consignee**
	CR	Consolidator
	CZ	Consignor
	DDF	Primary electronic business contact
	DDG	Alternate electronic business contact
	DDH	Primary government business contact
	DDI	Alternate government business contact
	DEI	Means of transport operator
	DFP	Owner
	EX	Exporter
	EXE	Exporting Establishment
	FCI	FDA Clinical Investigator
	FD2	FDA Importer 2
	FD3	FDA Importer 3
	FG	Foreign Government
	GC	Goods custodian
	INC	Inspection Contact
	ITL	Independent Third Party Laboratory
	LAB	Laboratory
	LAP	LPCO Authorized Party
	LG	Location of Goods immediately after Entry Release
	LIP	LPCO Issuing Agency
	MF	Manufacturer of goods
	OV	Transport means owner
	PE	Producing Establishment
	PES	Packing Establishment
	PK	Point of Contact
	PRE	Preparer
	PRO	Processing Establishment
	RD	Retailer/Distributor
	RGO	Responsible Government Official
	SE	Seller
	SIG	Signer
	SOE	Source Establishment
	STL	Storage location
	TB	Submitter
	VW	Responsible party

Note 2

Entity Identification Codes and their descriptions can be found in Appendix PGA (PG19 – Entity Identification Codes) of the ACE ABI CATAIR publication. List of Entity Identification codes applicable to FDA Biologics Message Sets is below:

Data Element	Code	Description	Length/ Class
Entity Identification Codes	16	D&B-assigned (DUNS number); must be 9 digits	9N
	47	FDA-assigned (FEI number); must be from 4 to 10 digits	4-10N

FDA ENTITY IDENTIFICATION CODE AND ENTITY NUMBER SELECTION AND VALIDATION CRITERIA

FDA requires Entity Name and Entity Address. Additionally, FDA prefers to use DUNS numbers for identifying the Entity; IF DUNS is not available THEN may provide FEI.

Entity Name <>NULL AND Entity Address 1 <>NULL AND
IF Entity Identification Code =16 (DUNS) THEN Entity Number MUST BE Length = 9 and Type = N
ELSE IF Entity Identification Code =47 (FEI) THEN Entity Number MUST BE Length from 4 to 10 and Type = N

Record Identifier PG20 (Entity Address)

This is a mandatory PGA input record that provides additional data pertaining to Entity identification such as Entity Address line 2, Apartment/Suite, City, State, and Zip/Postal Code. This record is used when additional address information for the entity needs to be entered.

Record Identifier PG20 (Entity Address)					
Data Element	**Length /Class**	**Position**	**Status**	**Description**	**Note**
Control Identifier	2A	1-2	M	“PG”.	
Record Type	2N	3-4	M	“20”.	
Entity Address 2	32X	5-36	C	Address Line 2 for the Entity.	1
Entity Apartment Number/Suite Number	5X	37-41	C	Apartment/Suite number of the entity.	1
Entity City	21X	42-62	M	City of the entity.	
Entity State/Province	3AN	63-65	C	State/Province of the entity. See Appendix B in the ACS ABI CATAIR for valid codes.	2
Entity Country	2A	66-67	M	ISO Country Code. See Appendix B in the ACS ABI CATAIR for valid codes.	
Entity Zip/Postal Code	9X	68-76	C	Zip/Postal Code of the entity.	2
Filler	4X	77-80	M	Space fill	

Note 1: If the Entity Address 1 in PG19 is longer than the allocated 23 characters then utilize these fields.

Note 2: Populated if US or Canada based entities

Record Identifier PG21 (Point of Contact)

This is a mandatory PGA input record that provides data about an Individual and may also be related to an entity (the party) in the preceding PG19 record. Included in this record are the Individual Name, Telephone Number, Fax Number, and Email address. If multiple Individuals related to a single entity are required by an agency, this record can be repeated and should follow each entity designated in the PG19 record. This record can also be repeated in cases where multiples of these data elements need to be reported for a single Individual. (For example, for reporting two phone numbers or an email and fax number). A typical example is a POC for the Filer.

At least one PG21 record is required.

Record Identifier PG21 (Point of Contact)					
Data Element	**Length/ Class**	**Position**	**Status**	**Description**	**Note**
Control Identifier	2A	1-2	M	“PG”.	
Record Type	2N	3-4	M	“21”.	
Individual Qualifier	3AN	5-7	M	Identify the type of party or facility the Individual represents. For example, person is associated to the grower, producer, I-house or filer, etc. For valid codes, use the Entity Role Codes from PG19 (See Appendix PGA of this publication.)	
Individual Name	23X	8-30	M	Name of the Individual. If the name will not fit, complete PG24 and fill out the remarks code (Individual name) and then enter the name in the remarks text field.	
Telephone Number of the Individual	15X	31-45	M	Telephone number of the Individual. For example, (713)555-8765 in US or (+65)9052-3529 in Singapore	
Email Address or Fax Number for the Individual	35X	46-80	M	Option to either submit the Fax number or Email Address of the individual.	

Record Identifier PG23 (Affirmation of Compliance)

For Biologics, it is a conditional PGA input record that provides data pertaining to Food and Drug Administration Affirmation of Compliance Criteria. This record is typically only used by FDA. This record is repeatable.

Record Identifier PG23 (Affirmation of Compliance)					
Data Element	**Length/ Class**	**Position**	**Status**	**Description**	**Note**
Control Identifier	2A	1-2	M	"PG".	
Record Type	2N	3-4	M	"23".	
Affirmation of Compliance Code	5X	5-9	C	A code used to affirm compliance with FDA requirements. See Appendix PGA (Food & Drug Affirmation of Compliance Codes) of this publication for valid codes.	1
Affirmation of Compliance Qualifier	30AN	10-39	C	Text describing the information required by the FDA. This could include a number or a country code, etc. Also, see Appendix PGA (Food & Drug Affirmation of Compliance Qualifier Codes) of this publication for valid codes related to certain specific Affirmation of Compliance codes.	

Note 1
The list of Affirmation of Compliance codes for FDA-Biologics Message Sets is below followed by the scenarios when the AofCs must be provided:

Data Element	***Code***	***Description***	***Syntax***	***Business Rules***
	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	If government agency code= BIO and the government agency processing code = BBA or PVE then the code and the qualifier in the syntax must be provided.
	HDE	Humanitarian Device Exemption	BH+6N	If government agency code= BIO and the government agency processing code = BRD then the code and the qualifier in the syntax may be applicable.
	PM#	Biologics Pre-Market Approval Number	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	If government agency code= BIO and the government agency processing code = BRD then the code and the qualifier in the syntax must be provided. This includes PMA and PMN.

Data Element	Code	Description	Syntax	Business Rules
	HRN	Biologics Human Cells, Tissues/ Cellular and Tissue-Based Product Establishment Registration Number (HCT/P Registration Numbers)	10N	If government agency code= BIO and the government agency processing code = HCT then the code and the qualifier in the syntax must be provided.
	IND	Biologics Investigation New Drug Application Number	4-6N	If government agency code= BIO and the government agency processing code = ALG, VAC, CGT, BLO, BDP, BLD, BBA, or PVE, and then the code and the qualifier in the syntax must be provided.
	IDE	Biologics Investigational Device Exemption	4-5N	If government agency code= BIO and the government agency processing code = BRD then the code and the qualifier in the syntax must be provided.
	BLN	Biologics License Number	4N	If government agency code= BIO and the government agency processing code = ALG, VAC, CGT, BLO, BLD, BDP, BBA, or PVE and then the code and the qualifier in the syntax must be provided.
	STN	Biologics Submission Tracking Number	6N	If government agency code= BIO and the government agency processing code = ALG, VAC, CGT, BLO, BLD, BDP, BBA, or PVE and then the code and the qualifier in the syntax must be provided.
	CPT	Component Identifier		If government agency code= BIO and the government agency processing code = BRD then the AoC code. Indicator Only.
	REG	Drug Registration Number	9N	If government agency code= BIO and the government agency processing code = ALG, VAC, XEN, CGT, BLO, BLD, BDP, BBA, or PVE, then the code and the qualifier in the syntax must be provided.
	DEV	Device Foreign Manufacturer Registration Number	1-10N	If government agency code= BIO and the government agency processing code = BRD then the AoC code and the qualifier in the syntax must be provided.
	LST	Device Listing Number	A+6N; B+6N; C+6N; D+6N; E+6N; L+6N; Q+6N; R+6N	If government agency code= BIO and the government agency processing code = BRD then the AoC code and the qualifier in the syntax must be provided.

Note * - Is required if Device & Biologic combination product with the scenario of importation of a device component to be further processed then included in a CBER-lead combination product.

Scenario based on mandatory (M), conditional (C) and optional (O) AoC codes

CBER/Biologics Imports Scenario	DA	PM#	HRN	IND	IDE	BLN	STN	HDE	CPT	REG	DEV	LST
Importation of biological human drug The qualifier requires BA or BN prefix followed by the abbreviated new drug application number or new drug application number	M							O		M		
Importation of Biological Device. The qualifier requires BP or BM prefix followed by Biologics Device Pre-Market Approval Number		M						O	C		M	M
Importation of Human Cells, Tissues and Cellular and Tissue-based Products. This 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. No qualifier is required.								O				
Importation of Human Cells, Tissues and Cellular and Tissue-Based Product where the establishment is registered with the FDA. establishment is registered with the FDA			M					O				
Importation of a Biologics Investigational New Drug. The qualifier should be the Investigational New Drug Application Number				M				O				
Importation of Biologics Investigational Device and the qualifier should be the be the Investigational Device Exemption Number					M			O				
Importation of a licensed biological product. The Biologics License Number is the U.S. license number (not the STN number). An STN number for the product can also be provided along with its qualifier.						M	O	O				
Importation of a licensed biological product using the submission tracking number. The Submission Tracking number is the biologics license application (BLA) number. The STN is associated with the manufacturer and a specific product, and the first six digits represent the original submission tracking number (“XXXXXX”). An applicant license number could also be						O	M	O				

CBER/Biologics Imports Scenario	DA	PM#	HRN	IND	IDE	BLN	STN	HDE	CPT	REG	DEV	LST
provided.												
Importation of a Biologics Device associated with a Pre-Market Notification Number 510(k)		M						O	C		M	M
Importation of non-compliant articles (including drug, blood, blood components, Source Plasma, Source Leukocytes, and device components) under the import-for-export provisions of the FD&C Act								O				
Establishment Registration Number/Facility identifier for Manufacturers								O				
Import of Biologics Regulated Devices (Not subject to licensure) (BIO/BRD)								M				

The list of AoC codes **optional** to FDA Biologics Message Sets is below:

Data Element	***Code***	***Description***	***Syntax***	***Business Rules***
Affirmation of Compliance	CCN	Carrier ISO Country Code	2A	ISO Country code
	ERR	Entry Review Requested	indicator only	ERR is just used as an indicator, no data will follow
	FTZ	FTZ Admission Number		Note: May be used when the E214 is deployed automating the existing FTZ processes.
	HTS	Harmonized Tariff Number	4N 10N-12N	
	IFE	Import For Export	indicator only	

Record Identifier PG24 (Remarks)

This is an optional PGA input record that provides data pertaining to Remarks Codes, and Text of Remarks. Remark Type Code should be either GEN or NAM.

If GEN, the PG24 is applicable to the preceding PG02. Only one GEN:PG24 is allowed per PG02 (this is to avoid multiple GEN:PG24 records without a guaranteed sequencing as intended by the filer). This may be expanded in future with sufficient sequencing control to receive multiple GEN:PG24 records in the same order in which the Filer entered remarks.

If NAM, the PG24 is applicable to the preceding PG21. This structure simply allows the entry of 68 characters in addition to 23 characters afforded by PG21 for the Individual Name field in PG21. When a NAM-PG24 is present, the Individual Name field in PG21 is concatenated with Remarks Text field in PG24, to the full name in the format "*Last Name, First Name Middle Name*" for a potential 91 characters. Only one NAM:PG24 is allowed per PG21.

Record Identifier PG24 (Input)					
Data Element	**Length /Class**	**Position**	**Status**	**Description**	**Note**
Control Identifier	2A	1-2	M	Must always equal PG.	
Record Type	2N	3-4	M	Must always be 24.	
Remarks Type Code	3X	5-7	O	A code indicating the type of remarks. Valid codes are listed in Appendix PGA (Remarks Type Code) of this publication. FDA uses either NAM or GEN as its valid values.	1
Remarks Text	68X	13-80	O	Free form text relevant to the shipment or the commodity.	

Note 1

If an individual's Name in the preceding PG21 is longer than 23 characters, the Remarks Type Code should be identified as NAM (Full name of the Individual) then the Remarks Text can be used to indicate the full name of that individual. Individual's Name should still follow the same format when using PG24, as following:

Last Name, First Name Middle Name

If submitting general comments then use the Remarks Type Code = GEN (General Remarks)

Record Identifier PG25 (Product Condition)

For Biologics, it is a conditional PGA input record that provides data pertaining to: Temperature Qualifier, Degree Type, Actual Temperature, Lot Number, Production, Date, Range of the Lot, PGA Line Value, and PGA Unit Value. This record is repeatable for multiple Lot Number Qualifiers and Lot Numbers but the line value MUST be included on each record.

Record Identifier PG25 (Product Condition)					
Data Element	**Length/ Class**	**Position**	**Status**	**Description**	**Note**
Control Identifier	2A	1-2	M	"PG".	
Record Type	2N	3-4	M	"25".	
Temperature Qualifier	1A	5	O	Temperature Category being reported for quality control or preservation purposes. A= Ambient, F=Frozen R=Refrigerated/Chilled, D=Dry Ice H=Fresh, U=Uncontrolled P=Flashpoint	
Degree Type	1A	6	O	F = Fahrenheit, C = Celsius , K = Kelvin	
Negative Number	1A	7	O	If the actual temperature is in the negative numbers use an "X".	
Actual Temperature	6N	8-13	O	Reported temperature. Two decimals places are implied.	
Location of Temperature Recording	1A	14	O	Identifies recorded temperature is for A = product B = container C = conveyance	
Lot Number Qualifier	1AN	15	C	Code of the entity that assigned the Lot number. For Biologics the only valid value is: 1 = Manufacturer	
Lot Number	25X	16-40	C	The lot number that the manufacturer/ producer/grower assigned to the product.	1
Production Start date of the Lot	8N	41-48	O	The date when the production for the Lot started. A numeric date in MMDDCCYY (month, day, century, year) format.	
Production End Date of the Lot	8N	49-56	O	The date when the production for the Lot ended. A numeric date in MMDDCCYY (month, day, century, year) format.	
PGA Line Value	12N	57-68	M	The value associated with the PGA line number in whole dollars. It must be right-justified with preceding zeros. Must be greater than zero.	
PGA Unit Value	12N	69-80	O	The value of the lowest unit of measure reported in PG26. Two decimal places are implied.	

Note 1
Lot Number is Mandatory for Blood Derivatives; otherwise Optional for other Biologics such as Plasma Derivatives and finished products.

Record Identifier PG26 (Product Packaging)

For Biologics, this is a mandatory PGA Record that provides data pertaining to Packaging Qualifier, Quantity and Unit of Measure. This record can be repeated up to six times per unique package size. The first record is used to describe the largest container (outermost container) and the number of containers. The second record is used to describe the contents of the next smallest container. If needed, records 2-6 are used in a similar manner (largest to smallest container). The last quantity record used must describe the actual amount of the product in the smallest container.

When reporting a different package size of the same product, repeat this record using the method described above.

The appearance of any 'Packaging Qualifier' number level requires all levels under it to be represented. For instance, level 3 can't be present unless levels 1 and 2 are present.

Record Identifier PG26 (Packaging Data)					
Data Element	**Length /Class**	**Position**	**Status**	**Description**	**Note**
Control Identifier	2A	1-2	M	"PG".	
Record Type	2N	3-4	M	"26".	
Packaging Qualifier	1N	5	M	This code identifies the level of packaging for the product. Outermost (largest=1) packages to the innermost (smallest=6) packages. There can be up to 6 levels of packaging. If reporting only one level, show the total quantity for the item and report that as level 1.	1,4
Quantity	12N	6-17	M	The total quantity for the packaging level. Must be greater than zero. Two decimal places are implied. The base quantity must always be the last quantity transmitted.	2,4
Unit of Measure (Packaging Level)	5X	18-22	M	Type of packaging / packaging level. For example, BX.	3,4

Note 1
This code identifies the level of packaging for the product. Valid values are 1, 2, 3, 4, 5 and 6: Outermost (largest=1) packages to the innermost (smallest=6) packages. There can be up to 6 levels of packaging.

Note 2
There are two implied decimal points when writing the quantity in Units of Measure for the Base Unit (Last Quantity Transmitted). In this example, 4 pieces are represented as 000000000400, with the nine leading zeroes as "fill" and two decimal places following the value. The quantity for packaging containers will be in whole numbers with no decimal places. The sample shows 1 carton containing 10 boxes and each box containing 4 pieces.

Note 3
List of Unit of Measure codes applicable to FDA-Biologics Message Sets
For a full list of applicable Unit of Measure codes, please refer to the Appendix F in this document or to Appendix PGA (PG26 – Unit of Measure - Valid FDA Units of Measure for Packaging Containers) and Appendix PGA (PG26 – Unit of Measure -Valid FDA Units of Measure for the Base Unit (Last Quantity Transmitted)) of the CATAIR.

Below are FDA valid units of measure for Biologics:

Code	Code Name
AE	Aerosol
AM	Ampoule, Nonprotected
AP	Ampoule, Protected
AT	Atomizer
BA	Barrel
BC	Bottle crate, Bottle rack
BQ	Bottle, Protected, Cylindrical
BS	Bottle, Nonprotected, Bulbous
BV	Bottle, Protected Bulbous
BX	Box
CA	Can, Rectangular
CG	Centigrams (Weight)
CI	Canister
CON	Container
CS	Case
CT	Carton
CX	Can, Cylindrical
CY	Cylinder
DR	Drum
EN	Envelope
FD	Framed Crate
FOZ	Ounces, fluid (Volume)
G	Grams (Weight)
GAL	Gallons (US) (Volume)
GB	Gas Bottle
KG	Kilograms (Weight)
L	Liters (Volume)
LB	Pounds (avdp) (Weight)
MB	Bag, Multi-ply
MG	Milligrams (Weight)
ML	Milliliters (Volume)
NO	Number (Count)
OZ	Ounces, weight (avdp) (Weight)
PAL	Pallet
PCS	Pieces (Count)
PK	Package
PTL	Pints, liquid (US) (Volume)
QTL	Quarts, liquid (US) (Volume)
SY	Syringe
VI	Vial

TU	Tube

Note 4

Quantity Data provides additional information to FDA about the product and how it is packaged. The basic format for Quantity Data is in multiple pairs of data – quantity and unit of measure, i.e., 500 cases, 12 ounces, fluid, 1000 cartons, etc. Up to 6 data pairs may be submitted, beginning with the 1st pair for the outermost packaging when Packaging Qualifier = 1. The first pairs may describe the largest container and the last pair must describe the amount of product in the smallest container.

For example: Blood Derivatives: 25 boxes, 8 bottles/box, 1pint each bottle:

Units 1-Quantity= 25
Units 1-Measure =BX
Units 2-Quantity=8
Units 2-Measure=BO
Units 3-Quantity=1
Units 3-Measure=PTL

Record Identifier PG27 (Container Information)

This is an optional PGA input record that provides data pertaining to issued Container Number. The Number of the shipping container is included in the Bill of Lading. Hence this record is not needed.

Record Identifier PG27 (Container Information)					
Data Element	**Length /Class**	**Position**	**Status**	**Description**	**Note**
Control Identifier	2A	1-2	O	“PG”.	
Record Type	2N	3-4	O	“27”.	
Container Number (Equipment ID)	20AN	5-24	O	The number of the shipping container as entered in the Bill of Lading.	
Filler	7X	74-80	O	Space fill	

Record Identifier PG29 (Unit of Measure)

This is an optional PGA input record that provides data pertaining to the net or gross unit of measure of the commodity. This can be provided at the overall PGA Line Number and/or the Individual Unit level.

Record Identifier PG29 (Unit of Measure)					
Data Element	**Length /Class**	**Position**	**Status**	**Description**	**Note**
Control Identifier	2A	1-2	M	“PG”.	
Record Type	2N	3-4	M	“29”.	
Unit of Measure (PGA line - net)	3AN	5-7	O	Pertaining to the overall PGA Line Number, the indication of the unit of measurement in which weight, capacity, length, area, volume or other quantity is expressed. “Unit of Measure (PGA line - net)” in this position is associated with “Commodity Net Quantity (PGA line - net)” and is required when “Commodity Net Quantity (PGA line - net)” is reported. Valid Unit of Measure codes are listed in Appendix C in the ACS ABI CATAIR.	
Commodity Net Quantity (PGA line - net)	12N	8-19	O	Pertaining to the overall PGA Line Number, excluding all packing and packaging. Two decimals are implied. “Commodity Net Quantity (PGA line - net)” is required when “Unit of Measure (PGA line - net)” is reported in positions 5-7 of this record.	
Unit of Measure (PGA line - gross)	3AN	20-22	O	Pertaining to the overall PGA Line Number, the indication of the unit of measurement in which weight, capacity, length, area, volume or other quantity is expressed. “Unit of Measure (PGA line - gross)” in this position is associated with “Commodity Gross Quantity (PGA line - gross)” and is required when “Commodity Gross Quantity (PGA line - gross)” is reported. Valid Unit of Measure codes are listed in Appendix F in this document or in Appendix C in the ACS ABI CATAIR.	
Commodity Gross Quantity (PGA line - gross)	12N	23-34	O	Pertaining to the overall PGA Line Number, including any packaging, but excluding weight of the carrier's equipment. Two decimals are implied. “Commodity Gross Quantity (PGA line - gross)” is required when “Unit of Measure (PGA line - gross)” is reported in positions 20-22 of this record.	

Record Identifier PG29 (Unit of Measure)					
Data Element	**Length /Class**	**Position**	**Status**	**Description**	**Note**
Unit of Measure (Individual Unit - net)	3AN	35-37	O	Pertaining to the Individual unit (net), the indication of the unit of measurement in which weight, capacity, length, area, volume or other quantity is expressed. "Unit of Measure (Individual unit - net)" in this position is associated with "Commodity Net Quantity (Individual unit - net)" and is required when "Commodity Net Quantity (Individual unit - net)" is reported. Valid Unit of Measure codes are listed in Appendix F in this document or in Appendix C in the ACS ABI CATAIR.	
Commodity Net Quantity (Individual Unit - net)	12N	38-49	O	Pertaining to the Individual unit, excluding all packing and packaging. Two decimals are implied. "Commodity Net Quantity (Individual unit - net)" is required when "Unit of Measure (Individual unit - net)" is reported in positions 35-37 of this record.	
Unit of Measure (Individual Unit - gross)	3AN	50-52	O	Pertaining to the Individual unit (gross), the indication of the unit of measurement in which weight, capacity, length, area, volume or other quantity is expressed. "Unit of Measure (Individual unit - gross)" in this position is associated with "Commodity Gross Quantity (Individual unit - gross)" and is required when "Commodity Gross Quantity (Individual unit - gross)" is reported. Valid Unit of Measure codes are listed in Appendix F in this document or in Appendix C in the ACS ABI CATAIR.	
Commodity Gross Quantity (Individual Unit - gross)	12N	53-64	O	Pertaining to the Individual unit, including any packaging, but excluding weight of the carrier's equipment. Two decimals are implied. "Commodity Gross Quantity (Individual unit - gross)" is required when "Unit of Measure (Individual unit - gross)" is reported in positions 50-52 of this record.	
Filler	16X	65-80	M	Space fill	

Record not supported by FDA at this time

Record Identifier PG30 (Anticipated Arrival Information)

This is a mandatory PGA input record that provides data pertaining to the date, time and location of the anticipated arrival information for all FDA products. While other PGAs may use PG30 to Collect Inspection and Lab information, currently FDA will utilize this record to collect Anticipated Arrival Information at this time.

For each line a PG30 record with an "A" (Anticipated arrival information) code, date and time of arrival is Mandatory.

Record Identifier PG30 (Inspection and Lab Information)					
Data Element	**Length/ Class**	**Position**	**Status**	**Description**	**Note**
Control Identifier	2A	1-2	M	“PG”.	
Record Type	2N	3-4	M	“30”.	
Inspection/ Laboratory Testing Status	1A	5	M	A is the ONLY valid code for FDA: A = Anticipated arrival information	
Anticipated Arrival date	8N	6-13	M	A numeric date in MMDDCCYY (month, day, century, year) format.	
Anticipated Arrival time	4N	14-17	M	Military time HHMM in (hour, minute) format. (Example: 1015, this represents 10:15 a.m.). For midnight, use 2400 (0000 is invalid).	
Arrival Location Code	4AN	18-21	O	For valid port codes, refer to note 1.	1
Arrival Location	50X	22-71	O	Code or free form text indicating site of inspection.	
Filler	8X	72-80	M	Space fill	

Note 1:
Refer to List of Valid Port Codes:
http://www.cbp.gov/sites/default/files/documents/CBP%20Port%20Codes%20041014_1.pdf

Record Identifier PG55 (Additional Entity Roles)

This is an optional PGA input record used to provide additional roles performed by an entity or individual.

The PG55 record is not supported by FDA at this time. Multiple PG19 records should be used to input more than one Entity-Role combination. Refer to the PG19 section for details.

Record Identifier PG55 (Additional Entity Roles)					
Data Element	**Length /Class**	**Position**	**Status**	**Description**	**Note**
Control Identifier	2A	1-2	M	“PG”.	
Record Type	2N	3-4	M	“55”.	
Entity Role Code	3AN	5-7	O	Additional role of the entity.	
Entity Role Code	3AN	8-10	O	Additional role of the entity.	
Entity Role Code	3AN	11-13	O	Additional role of the entity.	
Entity Role Code	3AN	14-16	O	Additional role of the entity.	
Entity Role Code	3AN	17-19	O	Additional role of the entity.	
Entity Role Code	3AN	20-22	O	Additional role of the entity.	
Entity Role Code	3AN	23-25	O	Additional role of the entity.	
Entity Role Code	3AN	26-28	O	Additional role of the entity.	
Entity Role Code	3AN	29-31	O	Additional role of the entity.	
Entity Role Code	3AN	32-34	O	Additional role of the entity.	
Filler	8X	72-80	M	Space fill	

Not supported by FDA at this time

Record Identifier PG00 (Data Substitution)

This is an optional record used at the CBP entry (or entry summary) header, CBP entry (or entry summary) line and/or PGA message set levels to indicate data substitution.

Currently, the PG00 record is implemented only at the CBP entry header level. Future implementation will allow for submission at the CBP entry line and PGA Message Set level.

Record Identifier PG00 (Data Substitution)					
Data Element	**Length /Class**	**Position**	**Status**	**Description**	**Note**
Control Identifier	2A	1-2	M	“PG”.	
Record Type	2N	3-4	M	“00”.	
Substitution Indicator	1X	5	O	Identifies either the start or end of the substitution group, or the location of where to place the substitute data within the PGA Message Set. The following codes are allowed: S=Start of the substitution group E=End of the substitution group R=Replace this record with the substitution group indicated by the Substitution Number	
Substitution Number	4AN	6-9	O	Sequential number assigned to, or referring to, a specific substitution group of data provided at the header level. This data element is mandatory when using the S or R substitution indicator.	
Filler	71X	10-80	M	Space fills.	

Cosmetics Commodity Data Elements and Values

Cosmetic commodities can be broken down into the following categories using the existing Government Agency data elements available in the PG01 message

PG01 - Government Agency Code	Commodity Type	PG01 - Government Agency Program Code	Commodity Sub-Type	PG01 - Government Agency Processing Code
FDA	Cosmetics	COS	None	

Table 2 – Cosmetics commodity hierarchy

The following are the potential PGA records associated with submitting Cosmetics:

PG Record	Description
OI	The commercial description of the shipment is provided.
PG01	The shipment is regulated by the FDA program office within FDA and the intended use is provided.
PG02	The item type and Product Code detail are provided.
PG06	Source Type(origin) other than the CBP country of origin is provided
PG07	The Trade/Brand Name, Model and Year of Manufacture are provided
PG10	Description of items in the lot number
PG19	The entity (manufacturer, consignee, shipper, etc.) of Record's identification information is provided.
PG20	Additional address data on the entity in PG19 is provided
PG21	The entity (manufacturer, consignee, shipper, etc.) of Record's individual point of contact, phone number and email is given.
PG23	FDA's Affirmation of Compliance Criteria is provided.
PG24	Remarks
PG25	Temperature qualifier, Lot#, Production dates, PGA Line Value and PGA Unit Value are provided
PG26	Packaging qualifier and quantity of the shipment are provided
PG27	Additional data on Container number
PG29	Weight of lot number
PG30	Inspection location, date and time
PG55	Additional roles performed by entity or individual
PG00	Data Substitution

Cosmetics Example

Cosmetics Message Set Layout for Sample

Please refer to the external file: **FDA SG 2.4 Example PG Message Sets.xlsx** Tab: ***Cosmetics***

Because of the flexibility of the PGA Message set, the PGA Records and Data Elements that are required may vary both from program to program and within a single program. For a more expansive set of examples of FDA PGA Message Sets, please refer to the above document.

Record Identifier OI (Record Identifier)

This is a mandatory PGA line item description input record that provides the description of the item. This record precedes the Record Identifiers for the PGA Message set.

Record Identifier OI (Record Identifier)					
Data Element	**Length /Class**	**Position**	**Status**	**Description**	**Note**
Control Identifier	2A	1-2	M	“OI”	
Filler	8X	3-10	M	Space filled.	
Commercial Description	70X	11-80	M	The commercial description of the product. For example, FINE EYELINER	

Record Identifier PG01 (PGA Identifier)

This is a mandatory PGA input record that provides data pertaining to the PGA Line Number, Government Agency Code, Government Agency Program Code, Globally Unique Product Identification Code, Intended Use Code, Intended Use Description, and Disclaimer.

Record Identifier PG01 (PGA Identifier)					
Data Element	**Length /Class**	**Position**	**Status**	**Description/Required Value**	**Note**
Control Identifier	2A	1-2	M	"PG"	
Record Type	2N	3-4	M	"01"	
PGA Line Number	3N	5-7	M	"001"	
Government Agency Code	3AN	8-10	M	"FDA"	
Government Agency Program Code	3X	11-13	C	"COS"	1, 2
Government Agency Processing Code	16AN	14-16	C		1, 2
Intended Use Code	16X	42-57	O		
Intended Use Description	22X	58-79	O		
Disclaimer	1A	80	C	A code of A (= product is not regulated by this agency) or B (= data is not required per agency guidance) indicating there is no agency declaration requirement. Or this field is left blank for no disclaimer. No other code is accepted	

Note 1
See Table 2 above for the commodity hierarchy for Cosmetic commodity.

Note 2

If the Disclaimer is 'A' or 'B' then these data elements should both be populated with FDA. Otherwise, the Government Agency Program Code and Government Agency Processing Code are mandatory.

Record Identifier PG02 (Product Identifier)

This mandatory PGA input record is used to indicate whether or not the information being provided relates to a product (P) or a component (C) of a product.

Record Identifier PG02 (Product Identifier)					
Data Element	**Length /Class**	**Position**	**Status**	**Description**	**Note**
Control Identifier	2A	1-2	M	"PG"	
Record Type	2N	3-4	M	"02"	
Item Type	1A	5	M	Code identifying the following records as pertaining to P=Product. No other values accepted. Only one 'P' record is allowed for the same PGA Line # in PG01.	
Product Code Qualifier	4AN	6-9	M	"FDP"	1
Product Code Number	19X	10-28	M	FDA Product Code Must be equal to 7 characters	1

Note 1

Product Code Qualifiers and their descriptions can be found in Appendix PGA (PG02 – Product Code Qualifiers) of the ACE ABI CATAIR publication. For FDA, this is currently always 'FDP' for all FDA products.

Only one FDA Product Code Number per product is allowed.

FDA Product Code Structure:

Position	1-2	3	4	5	6-7
Name	Industry Code (N)	Class Code (A)	Sub Class Code (A or '-')	Process Identification Code - PIC (A or '-')	Product (AN)

Legend - N: Numeric; A:Alphabetic; AN:AlphaNumeric

Record Identifier PG06 (Product Origin)

This is a mandatory PGA input record that provides data pertaining to Source Type (Origin) other than the CBP Country of Origin, in addition to Processing dates, Processing Type and Processing Description.

Record Identifier PG06 (Product Origin)					
Data Element	**Length/ Class**	**Position**	**Status**	**Description**	**Note**
Control Identifier	2A	1-2	M	“PG”.	
Record Type	2N	3-4	M	“06”.	
Source Type Code	3AN	5-7	M	Mandatory valid values are 30 (Country of Source) or 39 (Country of Production). 294 (Country of Refusal) if previously refused.	1
Country Code	2X	8-9	M	Country of production or source is required for Cosmetics.	2

Note 1

Source Type Codes and their descriptions can be found in Appendix PGA (PG06 – Source Type Codes) of the ACE ABI CATAIR publication.

Note 2

Any of the country codes from Appendix B (ISO Country and Currency Codes) in the ACS ABI CATAIR can be entered.

Record Identifier PG07 (Product Trade Names)

This is an optional PGA input record that provides data pertaining to Trade or Brand Name, Model, Manufacture Year, Item Identity Number Qualifier and Item Identity Numbers.

Record Identifier PG07 (Product Trade Names)					
Data Element	**Length/ Class**	**Position**	**Status**	**Description**	**Note**
Control Identifier	2A	1-2	O	“PG”	
Record Type	2N	3-4	O	“07”	
Trade Name/Brand Name	35X	5-39	O	Trade or Brand name of the Cosmetic product is entered	

Record Identifier PG10 (Product Characteristics)

This is a mandatory PGA input record that allows for reporting codes that provide additional characteristics of a product or component, not reported elsewhere in the PG Message Set. For example, this record can be used to provide the model year of an automobile, which can be different from the year of manufacture provided in the PG07. This record can be repeated if there are more qualifiers or categories.

Record Identifier PG10 (Product Characteristics)					
Data Element	**Length /Class**	**Position**	**Status**	**Description**	**Note**
Control Identifier	2A	1-2	M	“PG”.	
Record Type	2N	3-4	M	“10”.	
Commodity Characteristic Description	57X	24-80	M	Free form description (invoice description NOT product code description) of the item. See Appendix A for the use of PG10 to capture the information currently collected in multiple OI records.	

Record Identifier PG19 (Entity Data)

For Cosmetics, this is a mandatory PGA input record that provides FDA with data pertaining to Entity Role and conditionally the following data elements; Entity Identification, Entity Name, and Entity Address 1.

Record Identifier PG19 (Entity Data)					
Data Element	**Length /Class**	**Position**	**Status**	**Description**	**Note**
Control Identifier	2A	1-2	M	"PG"	
Record Type	2N	3-4	M	"19"	
Entity Role Code	3AN	5-7	M	Code identifying the role of the entity being provided. For example: MF, UC	1, 3
Entity Identification Code	3AN	8-10	C	Code identifying the Entity Identification is entered. For example: 16, 47. Mandatory, if Entity Number is entered.	2
Entity Number	15X	11-25	O	The Entity Number of the entity based on the above Entity Identification Code is entered; must conform to the descriptions in Note 2	2
Entity Name	32X	26-57	M	The name of the entity is required. See validation criteria below.	2
Entity Address 1	23X	58-80	M	Must be entered.. See validation criteria below.	2

Note 1

Entity Role Codes and their descriptions can be found in Appendix PGA (PG19 – Entity Role Codes) of the ACE ABI CATAIR publication. List of Entity Role codes mandatory to FDA Cosmetics Message Sets is below:

Data Element	***Code***	***Description***
Entity Role Codes§	MF	Manufacturer of goods
	DEQ	Shipper
	FD1	FDA Importer (Importer of Record)
	DP	Delivered To Party±

§ Same Role Code cannot be entered more than once.

± Even though Title 19 141.19 (CBP) addresses - Consignee -, Title 21, Requires Prior Notice information about the - Ultimate Consignee - and Title 19 (CBP) defines - Ultimate Consignee -, FDA acknowledges that these terms cause confusion and would like to simplify and harmonize said data elements under the ACE environment.

Hence, the FDA has elected to utilize the data element --- "Deliver to Party" --- , U.S party that physically receives the good(s). The FDA's PG Message Set will, therefore, incorporate the deliver to party as issued in the ITDS Standard Data Set under the auspices of the ITDS Board of Directors. FDA's Prior Notice requirement for ultimate consignee is synonymous with deliver to party.

List of Entity Role codes also applicable to FDA Cosmetics Message Sets is below:

Data Element	***Code***	***Description***
Entity Role Codes	AAR	All Applicable Roles

Data Element	Code	Description
	APP	Applicant
	CE	Certifying Entity
	CO	Certifying Official
	CN	Consignee**
	CR	Consolidator
	CZ	Consignor
	DDF	Primary electronic business contact
	DDG	Alternate electronic business contact
	DDH	Primary government business contact
	DDI	Alternate government business contact
	DEI	Means of transport operator
	DFP	Owner
	EX	Exporter
	EXE	Exporting Establishment
	FCI	FDA Clinical Investigator
	FD2	FDA Importer 2
	FD3	FDA Importer 3
	FG	Foreign Government
	GC	Goods custodian
	INC	Inspection Contact
	ITL	Independent Third Party Laboratory
	LAB	Laboratory
	LAP	LPCO Authorized Party
	LG	Location of Goods immediately after Entry Release
	LIP	LPCO Issuing Agency
	OV	Transport means owner
	PCK	Packer
	PE	Producing Establishment
	PES	Packing Establishment
	PK	Point of Contact
	PRE	Preparer
	PRO	Processing Establishment
	RD	Retailer/Distributor
	RGO	Responsible Government Official
	SE	Seller
	SIG	Signer
	SOE	Source Establishment
	STL	Storage location
	TB	Submitter
	VW	Responsible party

Note 2

Entity Identification Codes and their descriptions can be found in Appendix PGA (PG19 – Entity Identification Codes) of the ACE ABI CATAIR publication. List of Entity Identification codes applicable to FDA Drug Message Sets is below:

Data Element	Code	Description	Length/ Class
Entity Identification Codes	16	D&B-assigned (DUNS number)	9N
	47	FDA-assigned	4-10N

FDA ENTITY IDENTIFICATION CODE AND ENTITY NUMBER SELECTION AND VALIDATION CRITERIA

FDA requires Entity Name and Entity Address. Additionally, FDA prefers to use DUNS numbers for identifying the Entity; IF DUNS is not available THEN FEI.

Entity Name <>NULL AND Entity Address 1 <>NULL AND
IF Entity Identification Code =16 (DUNS) THEN Entity Number MUST BE Length = 9 and Type = N
ELSE IF Entity Identification Code =47 (FEI) THEN Entity Number MUST BE Length from 4 to 10 and Type = N

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Record Identifier PG20 (Entity Address)

This is a mandatory PGA input record that provides additional data pertaining to Entity identification such as Entity Address line 2, Apartment/Suite, City, State, and Zip/Postal Code. This record is used when additional address for the entity needs to be entered.

Record Identifier PG20 (Entity Address)					
Data Element	**Length /Class**	**Position**	**Status**	**Description**	**Note**
Control Identifier	2A	1-2	M	“PG”.	
Record Type	2N	3-4	M	“20”.	
Entity Address 2	32X	5-36	C	Address Line 2 for the Entity.	1
Entity Apartment Number/Suite Number	5X	37-41	C	Apartment/Suite number of the entity.	1
Entity City	21X	42-62	M	City of the entity.	
Entity State/Province	3AN	63-65	C	State/Province of the entity. See Appendix B in the ACS ABI CATAIR for valid codes.	2
Entity Country	2A	66-67	M	ISO Country Code. See Appendix B in the ACS ABI CATAIR for valid codes.	
Entity Zip/Postal Code	9X	68-76	C	Zip/Postal Code of the entity.	2
Filler	4X	77-80	M	Space fill	

Note 1: If the Entity Address 1 in PG19 is longer than the allocated 23 characters then utilize these fields.

Note 2: Populated if US or Canada based entities

Record Identifier PG21 (Point of Contact)

This is a mandatory PGA input record that provides data about an Individual and may also be related to an entity (the party) in the preceding PG19 or record. Included in this record are the Individual Name, Telephone Number, Fax Number, and Email address. If multiple Individuals related to a single entity are required by an agency, this record can be repeated and should follow each entity designated in the PG19 record. This record can also be repeated in cases where multiples of these data elements need to be reported for a single Individual. (For example, for reporting two phone numbers or an email and fax number). A typical example is a POC for the Filer.

At least one PG21 record is required.

Record Identifier PG21 (Point of Contact)					
Data Element	**Length /Class**	**Position**	**Status**	**Description**	**Note**
Control Identifier	2A	1-2	M	“PG”.	
Record Type	2N	3-4	M	“21”.	
Individual Qualifier	3AN	5-7	M	Identify the type of party or facility the Individual represents. For example, person is associated to the grower, producer, I-house or filer, etc. For valid codes, use the Entity Role Codes from PG19 (See Appendix PGA of this publication.)	
Individual Name	23X	8-30	M	Name of the Individual. If the name will not fit, complete PG24 and fill out the remarks code (Individual name) and then enter the name in the remarks text field.	
Telephone Number of the Individual	15X	31-45	M	Telephone number of the Individual. For example, (713)555-8765 in US or (+65)9052-3529 in Singapore	
Email Address or Fax Number for the Individual	35X	46-80	M	Option to either submit the Fax number or Email Address of the individual.	

Record Identifier PG23 (Affirmation of Compliance)

For Cosmetics, this is an optional PGA input record that provides data pertaining to Food and Drug Administration Affirmation of Compliance Criteria. This record is repeatable.

Record Identifier PG23 (Affirmation of Compliance)					
Data Element	**Length/ Class**	**Position**	**Status**	**Description**	**Note**
Control Identifier	2A	1-2	M	"PG".	
Record Type	2N	3-4	M	"23".	
Affirmation of Compliance Code	5X	5-9	O	A code used to affirm compliance with FDA requirements. . See Appendix PGA (Food & Drug Affirmation of Compliance Codes) of this publication for valid codes.	1
Affirmation of Compliance Qualifier	30AN	10-39	O	Text describing the information required by the PGA. This could include a number or a country code, etc. Also, see Appendix PGA (Food & Drug Affirmation of Compliance Qualifier Codes) of this publication for valid codes related to certain specific Affirmation of Compliance codes.	1

Note 1

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. List of Affirmation of Compliance codes CONDITIONALLY MANDATORY (see note 1.1) to FDA-Cosmetics Message Sets:

The list of AoC codes **optional** to FDA Cosmetic Message Sets is below:

Data Element	***Code***	***Description***	***Syntax***	***Business Rules***
Affirmation of Compliance Code	COS	Cosmetic Registration Number	7N or 10N	IF Government Agency Program Code = COS THEN COS IS Optional (voluntarily entered)
	CCN	Carrier ISO Country Code	2A	ISO Country code
	ERR	Entry Review Requested	indicator only	ERR is just used as an indicator, no data will follow
	HTS	Harmonized Tariff Number	10N-12N	
	IFE	Import For Export	indicator only	
	UFC	Unacceptable to Foreign Country (Products other than food)	2A	ISO Country code of Appendix B

Record Identifier PG24 (Remarks)

This is an optional PGA input record that provides data pertaining to Remarks Codes, and Text of Remarks. Remark Type Code should be either GEN or NAM.

If GEN, the PG24 is applicable to the preceding PG02. Only one GEN:PG24 is allowed per PG02 (this is to avoid multiple GEN:PG24 records without a guaranteed sequencing as intended by the filer). This may be expanded in future with sufficient sequencing control to receive multiple GEN:PG24 records in the same order in which the Filer entered remarks.

If NAM, the PG24 is applicable to the preceding PG21. This structure simply allows the entry of 68 characters in addition to 23 characters afforded by PG21 for the Individual Name field in PG21. When a NAM-PG24 is present, the Individual Name field in PG21 is concatenated with Remarks Text field in PG24, to the full name in the format "*Last Name, First Name Middle Name*" for a potential 91 characters. Only one NAM:PG24 is allowed per PG21.

Record Identifier PG24 (Input)					
Data Element	**Length /Class**	**Position**	**Status**	**Description**	**Note**
Control Identifier	2A	1-2	M	Must always equal PG.	
Record Type	2N	3-4	M	Must always be 24.	
Remarks Type Code	3X	5-7	O	A code indicating the type of remarks. Valid codes are listed in Appendix PGA (Remarks Type Code) of this publication. FDA uses either NAM or GEN as its valid values.	1
Remarks Text	68X	13-80	O	Free form text relevant to the shipment or the commodity.	

Note 1
If an individual's Name in the preceding PG21 is longer than 23 characters, the Remarks Type Code should be identified as NAM (Full name of the Individual) then the Remarks Text can be used to indicate the full name of that individual. Individual's Name should still follow the same format when using PG24, as following:

Last Name, First Name Middle Name

If submitting general comments then use the Remarks Type Code = GEN (General Remarks)

Record Identifier PG25 (Product Condition)

For Cosmetics, it is an optional PGA input record that provides data pertaining to: Temperature Qualifier, Degree Type, Actual Temperature, Lot Number, Production Date, Range of the Lot, PGA Line Value, and PGA Unit Value. This record is repeatable for multiple Lot Number Qualifiers and Lot Numbers but the line value MUST be included on each record.

Record Identifier PG25 (Product Condition)					
Data Element	**Length/ Class**	**Position**	**Status**	**Description**	**Note**
Control Identifier	2A	1-2	O	“PG”.	
Record Type	2N	3-4	O	“25”.	
Temperature Qualifier	1A	5	O	Temperature Category being reported for quality control or preservation purposes. A= Ambient, F=Frozen, D=Dry Ice, R=Refrigerated/Chilled, H=Fresh, U=Uncontrolled, P=Flashpoint	
Degree Type	1A	6	O	Optional F = Fahrenheit, C = Celsius , K = Kelvin	
Negative Number	1A	7	O	Optional. If the actual temperature is in the negative numbers use an “X”.	
Actual Temperature	6N	8-13	O	Optional. Required if Degree Type is entered. Reported temperature. Two decimals places are implied.	
Location of Temperature Recording	1A	14	O	Optional. Identifies recorded temperature is for A=product, B=container and C= conveyance	
Lot Number Qualifier	1AN	15	O	Includes Lots and/or Batches Lot Number Qualifier = 1	
Lot Number	25X	16-40	O	The lot number that the manufacturer assigned to the product.	
Production Start date of the Lot	8N	41-48	O	The date when the production for the Lot started. A numeric date in MMDDCCYY (month, day, century, year) format.	
Production End Date of the Lot	8N	49-56	O	The date when the production for the Lot ended. A numeric date in MMDDCCYY (month, day, century, year) format.	
PGA Line Value	12N	57-68	O	The value associated with the PGA line number in whole dollars. If entered, it must be right-justified with preceding zeros and greater than zero.	
PGA Unit Value	12N	69-80	O	The value of the lowest unit of measure reported in PG26. Two decimal places are implied.	

Record Identifier PG26 (Product Packaging)

This is a mandatory PGA input record that provides FDA with data pertaining to Packaging Qualifier, Quantity, Unit of Measure, Package Identifier, Packaging Method, Package Material, and Packaging Filler. This record can be repeated up to six (6) times, once for each unique packaging level. The first record is used to describe the largest (outermost) container and the number of containers at this packaging level. The second record is used to describe the contents of the next smallest container. If needed, qualifiers 2-6 are used in a similar manner (largest to smallest container). The final record must describe the actual amount of the product in the smallest container.

The appearance of any 'Packaging Qualifier' number level requires all levels under it to be represented. For instance, level 3 can't be present unless levels 1 and 2 are present.

Record Identifier PG26 (Product Packaging)					
Data Element	**Length /Class**	**Position**	**Status**	**Description**	**Note**
Control Identifier	2A	1-2	M	"PG"	
Record Type	2N	3-4	M	"26"	
Packaging Qualifier	1N	5	M	Code identifying the level of packaging. For example, 4. If reporting only one level, show the total quantity for the item and report that as level 1.	1
Quantity	12N	6-17	M	"Quantity of the packaging level, For example, 000000000400. Must be greater than zero.	2
Unit of Measure (Packaging Level)	5X	18-22	M	Type of packaging / packaging level. For example, BX.	3

Note 1
This code identifies the level of packaging for the product. Valid values are 1, 2, 3, 4, 5 and 6: Outermost (largest=1) packages to the innermost (smallest=6) packages. There can be up to 6 levels of packaging.

Note 2
There are two implied decimal points when writing the quantity in Units of Measure for the Base Unit (Last Quantity Transmitted). In this example, 4 pieces are represented as 000000000400, with the nine leading zeroes as "fill" and two decimal places following the value. The quantity for packaging containers will be in whole numbers with no decimal places. The sample shows 1 carton containing 10 boxes and each box containing 4 pieces.

Note 3
List of Unit of Measure codes applicable to FDA-Cosmetics Message Sets
For a full list of applicable Unit of Measure codes, please refer to Appendix F in this document or to the Appendix PGA (PG26 – Unit of Measure - Valid FDA Units of Measure for Packaging Containers) and Appendix PGA (PG26 – Unit of Measure -Valid FDA Units of Measure for the Base Unit (Last Quantity Transmitted)) of the CATAIR.

Valid FDA Units of Measure for Packaging Containers

Code	Name
AE	Aerosol
AT	Atomizer

Code	Name
BA	Barrel
BC	Bottle crate, Bottle rack
BO	Bottle, Nonprotected, Cylindrical
BQ	Bottle, Protected, Cylindrical
BS	Bottle, Nonprotected, Bulbous
BV	Bottle, Protected Bulbous
BX	Box
CA	Can, Rectangular
CG	Centigrams (Weight)
CI	Canister
CON	Container
CS	Case
CT	Carton
CX	Can, Cylindrical
CY	Cylinder
DR	Drum
EN	Envelope
FD	Framed Crate
FOZ	Ounces, fluid (Volume)
G	Grams (Weight)
GAL	Gallons (US) (Volume)
KG	Kilograms (Weight)
L	Liters (Volume)
LB	Pounds (avdp) (Weight)
MB	Bag, Multi-ply
MG	Milligrams (Weight)
ML	Milliliters (Volume)
NO	Number (Count)
OZ	Ounces, weight (avdp) (Weight)
PAL	Pallet
PCS	Pieces (Count)
PK	Package
PTL	Pints, liquid (US) (Volume)
QTL	Quarts, liquid (US) (Volume)

Note 4

Quantity Data provides additional information to FDA about the product and how it is packaged. The basic format for Quantity Data is in multiple pairs of data – quantity and unit of measure, i.e., 500 cases, 12 ounces, fluid, 1000 cartons, etc. Up to 6 data pairs may be submitted, beginning with the 1st pair for the outermost packaging when Packaging Qualifier = 1. The first pairs may describe the largest container and the last pair must describe the amount of product in the smallest container.

For example: Bubble bath: 25 boxes, 4 bottles/box, 28 fluid oz. each bottle:

Units 1-Quantity= 25
Units 1-Measure =BX
Units 2-Quantity=4
Units 2-Measure=BO
Units 3-Quantity=28
Units 3-Measure=FOZ

Record Identifier PG27 (Container Information)

This is an optional PGA input record that provides data pertaining to issued Container Number. The Number of the shipping container is included in the Bill of Lading. Hence this record is not needed.

Record Identifier PG27 (Container Information)					
Data Element	**Length /Class**	**Position**	**Status**	**Description**	**Note**
Control Identifier	2A	1-2	O	“PG”.	
Record Type	2N	3-4	O	“27”.	
Container Number (Equipment ID)	20AN	5-24	O	The number of the shipping container as entered in the Bill of Lading.	
Filler	7X	74-80	O	Space fill	

Record Identifier PG29 (Unit of Measure)

This is an optional PGA input record that provides data pertaining to the net or gross unit of measure of the commodity. This can be provided at the overall PGA Line Number and/or the Individual Unit level.

Record Identifier PG29 (Unit of Measure)					
Data Element	**Length /Class**	**Position**	**Status**	**Description**	**Note**
Control Identifier	2A	1-2	M	“PG”.	
Record Type	2N	3-4	M	“29”.	
Unit of Measure (PGA line - net)	3AN	5-7	O	Pertaining to the overall PGA Line Number, the indication of the unit of measurement in which weight, capacity, length, area, volume or other quantity is expressed. “Unit of Measure (PGA line - net)” in this position is associated with “Commodity Net Quantity (PGA line - net)” and is required when “Commodity Net Quantity (PGA line - net)” is reported. Valid Unit of Measure codes are listed in Appendix F in this document or in Appendix C in the ACS ABI CATAIR.	
Commodity Net Quantity (PGA line - net)	12N	8-19	O	Pertaining to the overall PGA Line Number, excluding all packing and packaging. Two decimals are implied. “Commodity Net Quantity (PGA line - net)” is required when “Unit of Measure (PGA line - net)” is reported in positions 5-7 of this record.	
Unit of Measure (PGA line - gross)	3AN	20-22	O	Pertaining to the overall PGA Line Number, the indication of the unit of measurement in which weight, capacity, length, area, volume or other quantity is expressed. “Unit of Measure (PGA line - gross)” in this position is associated with “Commodity Gross Quantity (PGA line - gross)” and is required when “Commodity Gross Quantity (PGA line - gross)” is reported. Valid Unit of Measure codes are listed in Appendix F in this document or in Appendix C in the ACS ABI CATAIR.	
Commodity Gross Quantity (PGA line - gross)	12N	23-34	O	Pertaining to the overall PGA Line Number, including any packaging, but excluding weight of the carrier's equipment. Two decimals are implied. “Commodity Gross Quantity (PGA line - gross)” is required when “Unit of Measure (PGA line - gross)” is reported in positions 20-22 of this record.	

Record Identifier PG29 (Unit of Measure)					
Data Element	**Length /Class**	**Position**	**Status**	**Description**	**Note**
Unit of Measure (Individual Unit - net)	3AN	35-37	O	Pertaining to the Individual unit (net), the indication of the unit of measurement in which weight, capacity, length, area, volume or other quantity is expressed. "Unit of Measure (Individual unit - net)" in this position is associated with "Commodity Net Quantity (Individual unit - net)" and is required when "Commodity Net Quantity (Individual unit - net)" is reported. Valid Unit of Measure codes are listed in Appendix F in this document or in Appendix C in the ACS ABI CATAIR.	
Commodity Net Quantity (Individual Unit - net)	12N	38-49	O	Pertaining to the Individual unit, excluding all packing and packaging. Two decimals are implied. "Commodity Net Quantity (Individual unit - net)" is required when "Unit of Measure (Individual unit - net)" is reported in positions 35-37 of this record.	
Unit of Measure (Individual Unit - gross)	3AN	50-52	O	Pertaining to the Individual unit (gross), the indication of the unit of measurement in which weight, capacity, length, area, volume or other quantity is expressed. "Unit of Measure (Individual unit - gross)" in this position is associated with "Commodity Gross Quantity (Individual unit - gross)" and is required when "Commodity Gross Quantity (Individual unit - gross)" is reported. Valid Unit of Measure codes are listed in Appendix F in this document or in Appendix C in the ACS ABI CATAIR.	
Commodity Gross Quantity (Individual Unit - gross)	12N	53-64	O	Pertaining to the Individual unit, including any packaging, but excluding weight of the carrier's equipment. Two decimals are implied. "Commodity Gross Quantity (Individual unit - gross)" is required when "Unit of Measure (Individual unit - gross)" is reported in positions 50-52 of this record.	
Filler	16X	65-80	M	Space fill	

Not supported by FDA at this time

Record Identifier PG30 (Anticipated Arrival Information)

This is a mandatory PGA input record that provides data pertaining to the date, time and location of the anticipated arrival information for all FDA products. While other PGAs may use PG30 to Collect Inspection and Lab information, currently FDA will utilize this record to collect Anticipated Arrival Information at this time.

For each line a PG30 record with an "A" (Anticipated arrival information) code, date and time of arrival is Mandatory.

Record Identifier PG30 (Inspection and Lab Information)					
Data Element	**Length/ Class**	**Position**	**Status**	**Description**	**Note**
Control Identifier	2A	1-2	M	“PG”.	
Record Type	2N	3-4	M	“30”.	
Inspection/ Laboratory Testing Status	1A	5	M	A is the only valid code for FDA:: A = Anticipated arrival information	
Anticipated Arrival date	8N	6-13	M	A numeric date in MMDDCCYY (month, day, century, year) format.	
Anticipated Arrival time	4N	14-17	M	Military time HHMM in (hour, minute) format. (Example: 1015, this represents 10:15 a.m.). For midnight, use 2400 (0000 is invalid).	
Arrival Location Code	4AN	18-21	O	For valid port codes, refer to note 1.	1
Arrival Location	50X	22-71	O	Code or free form text indicating site of inspection.	
Filler	8X	72-80	M	Space fill	

Note 1:
Refer to List of Valid Port Codes:
http://www.cbp.gov/sites/default/files/documents/CBP%20Port%20Codes%20041014_1.pdf

Record Identifier PG55 (Additional Entity Roles)

This is an optional PGA input record used to provide additional roles performed by an entity or individual.

The PG55 record is not supported by FDA at this time. Multiple PG19 records should be used to input more than one Entity-Role combination. Refer to the PG19 section for details.

Record Identifier PG55 (Additional Entity Roles)					
Data Element	**Length /Class**	**Position**	**Status**	**Description**	**Note**
Control Identifier	2A	1-2	M	“PG”.	
Record Type	2N	3-4	M	“55”.	
Entity Role Code	3AN	5-7	O	Additional role of the entity.	
Entity Role Code	3AN	8-10	O	Additional role of the entity.	
Entity Role Code	3AN	11-13	O	Additional role of the entity.	
Entity Role Code	3AN	14-16	O	Additional role of the entity.	
Entity Role Code	3AN	17-19	O	Additional role of the entity.	
Entity Role Code	3AN	20-22	O	Additional role of the entity.	
Entity Role Code	3AN	23-25	O	Additional role of the entity.	
Entity Role Code	3AN	26-28	O	Additional role of the entity.	
Entity Role Code	3AN	29-31	O	Additional role of the entity.	
Entity Role Code	3AN	32-34	O	Additional role of the entity.	
Filler	46X	35-80	M	Space fills.	

Not supported by FDA at this time

Record Identifier PG00 (Data Substitution)

This is an optional record used at the CBP entry (or entry summary) header, CBP entry (or entry summary) line and/or PGA message set levels to indicate data substitution.

Currently, the PG00 record is implemented only at the CBP entry header level. Future implementation will allow for submission at the CBP entry line and PGA Message Set level.

See the 'usage notes' in this chapter for more detailed information.

Record Identifier PG00 (Data Substitution)					
Data Element	**Length /Class**	**Position**	**Status**	**Description**	**Note**
Control Identifier	2A	1-2	M	"PG".	
Record Type	2N	3-4	M	"00".	
Substitution Indicator	1X	5	O	Identifies either the start or end of the substitution group, or the location of where to place the substitute data within the PGA Message Set. The following codes are allowed: S=Start of the substitution group E=End of the substitution group R=Replace this record with the substitution group indicated by the Substitution Number	
Substitution Number	4AN	6-9	O	Sequential number assigned to, or referring to, a specific substitution group of data provided at the header level. This data element is mandatory when using the S or R substitution indicator.	
Filler	71X	10-80	M	Space fills.	

Drug Commodity Data Elements and Values

Drug commodities can be broken down into the following categories using the existing Government Agency data elements available in the PG01 message

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

Table 3 – Drug commodity hierarchy

The following are the potential PGA records associated with submitting Drug:

PG Record	Description
OI	The commercial description of the shipment
PG01	The shipment is regulated by the FDA program office within FDA and the intended use is provided.
PG02	Product Identifier; the item type and Product Code detail are provided.
PG04	Product Constituent Active Ingredient
PG06	Product Source information is provided
PG07	The Trade/Brand Name
PG10	Product/Component Reporting Code
PG19	Entity Role (manufacturer, consignee, shipper, etc.) Entity Identification, Entity Name, and Entity Address 1 are provided.
PG20	Additional Entity Identification (Address line 2, Apartment/Suite, City, State, and Zip/Postal Code).
PG21	Additional Entity Role
PG23	FDA's Affirmation of Compliance Criteria is provided.
PG24	Remarks
PG25	Temperature qualifier, Lot#, Production dates, PGA Line Value and PGA Unit Value are provided
PG26	Packaging qualifier and quantity of the shipment are provided

PG Record	Description
PG29	Data pertaining to the net or gross unit of measure of the commodity
PG30	Product pertaining to the pertaining to the date, time and location of inspection; previous laboratory testing; inspection location; and anticipated arrival information for FDA
PG55	Additional roles performed by an entity or individual
PG00	Data Substitution

Drug Example

Drug message set layout sample below:

Please refer to the external file: **FDA SG 2.4 Example PG Message Sets.xlsx** Tab: ***Drugs***

Drugs Message Set Description

Because of the flexibility of the PGA Message set, the PGA Records and Data Elements that are required may vary both from program to program and within a single program. For a more expansive set of examples of FDA PGA Message Sets, please refer to the above document.

Record Identifier OI (Record Identifier)

This is a mandatory PGA line item description input record that provides the description of the item. This record precedes the Record Identifiers for the PGA Message set.

Record Identifier OI (Record Identifier)					
Data Element	**Length/ Class**	**Position**	**Status**	**Description**	**Note**
Control Identifier	2A	1-2	M	“OI”	
Filler	8X	3-10	M	Space filled.	
Commercial Description	70X	11-80	M	The commercial description of the product. For example, Amoxicillin	

Record Identifier PG01 (PGA Identifier)

This is a mandatory PGA input record that provides data pertaining to the PGA Line Number, Government Agency Code, Go**v**ernment Agency Program Code, Globally Unique Product Identification Code, Intended Use Code, Intended Use Description, and Disclaimer. The Intended Use Code allows FDA to identify whether the imported commodity is restricted by a consumption allowance or not.

Record Identifier PG01 (PGA Identifier)					
Data Element	**Length/ Class**	**Position**	**Status**	**Description/Required Value**	**Note**
Control Identifier	2A	1-2	M	“PG”	
Record Type	2N	3-4	M	“01”.	
PGA Line Number	3N	5-7	M	“001”	
Government Agency Code	3AN	8-10	M	“FDA”	
Government Agency Program Code	3X	11-13	C	“DRU”	1, 2, 4
Government Agency Processing Code	3AN	14-16	C	Allowed values: PRE, OTC, INV, PHN, RND	1, 2, 4
Intended Use Code	16X	42-57	C		3, 4
Intended Use Description	22X	58-79	O		3, 4
Disclaimer	1A	80	C	A code of A (= product is not regulated by this agency) or B (= data is not required per agency guidance) indicating there is no agency declaration requirement. Or this field is left blank for no disclaimer. No other code is accepted	2

Note 1

Refer to Table 3 above for commodity type and sub-type for Drugs

Note 2

If the Disclaimer is ‘A’ or ‘B’ then these data elements should both be populated with FDA. Otherwise the Government Agency Program Code and Government Agency Processing Code are mandatory.

Note 3

If the Disclaimer is ‘A’ or ‘B’ then these data elements are optional; otherwise the Intended Use Code is conditional.

Note 4

This is the list of intended use codes available for Government Agency Program Code = “DRU”.

Intended Use Code	Intended Use Description
080.000	For Human Medical Use as a Non-Food Product under Controlled Distribution – Prescription (PRE)
130.000	For Consumer Use as a Non- Food Product – Over the Counter (OTC)

Intended Use Code	Intended Use Description
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 use
180.017	Chemical for research and development in a pharmaceutical product – laboratory testing only, no human/animal use
970.000	Import for Export
100.000	Importation for Personal Use
155.012	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 a device (CDRH) application type (e.g., for use in a PMA/510(k) drug-device combination product)
150.018	Active Pharmaceutical Ingredient / Bulk Drug Substance to be used for Pharmacy Compounding

Please see the Intended Use codes applicable for Forms and Types:

<u>Prescription (PRE)</u>

Finished Form:

080.000 For Human Medical Use as a Non-Food Product under Controlled Distribution – Prescription (PRE)

970.000 Import for Export
100.000 Importation for Personal Use
155.012 Drug to be used as a constituent part in a Medical Device (Finished Dosage Form Drug)

Not Finished Form Active Pharmaceutical Ingredient / Bulk Drug Substance:

150.007 Active Pharmaceutical Ingredient / Bulk Drug Substance for processing into a pharmaceutical product

970.000 Import for Export
150.017 Drug to be used as a component in a Medical Device (Active Pharmaceutical Ingredient / Bulk Drug Substance)

<u>Over the Counter (OTC)</u>

Finished Form:

130.000 For Consumer Use as a Non-Food Product – Over the Counter (OTC)

970.000 Import for Export
100.000 Importation for Personal Use
155.012 Drug to be used as a constituent part in a Medical Device (Finished Dosage Form Drug)

Not finished form: Active Pharmaceutical Ingredient / Bulk Drug Substance:

150.007 Active Pharmaceutical Ingredient / Bulk Drug Substance for processing into a pharmaceutical product

970.000 Import for Export
150.017 Drug to be used as a component in a Medical Device (Active Pharmaceutical Ingredient / Bulk Drug Substance)

Pharmaceutical Necessities & Containers (PHN)
No intended use codes for this Commodity Sub-Type

Research and Development (INV)
180.009 Chemical for research and development in a pharmaceutical product **– clinical trial or other human/animal use**

Research and Development (RND)
180.017 Chemical for research and development in a pharmaceutical product – **laboratory testing only, no human/animal use**
.

Also see Appendix B and Appendix C for Decision Trees for required data elements based on Form and Type

Record Identifier PG02 (Product Identifier)

This mandatory PGA input record is used to indicate whether or not the information being provided relates to a product (P) or a component (C) of a product. For Drugs entries, the Product Code Number is provided within this record.

Record Identifier PG02 (Product Identifier)					
Data Element	**Length/ Class**	**Position**	**Status**	**Description**	**Note**
Control Identifier	2A	1 2	M	“PG”.	
Record Type	2N	3-4	M	“02”.	
Item Type	1A	5	M	Code identifying the following records as pertaining to P=Product. No other values are allowed. Only one ‘P’ record is allowed for the same PGA Line # in PG01.	
Product Code Qualifier	4AN	6-9	M	“FDP”.	
Product Code Number	19X	10-28	M	FDA Product Code Must be equal to 7 characters	

Only one FDA Product Code Number per product is allowed.

FDA Product Code Structure:

Position	1-2	3	4	5	6-7
Name	Industry Code (N)	Class Code (A)	Sub Class Code (A or '-')	Process Identification Code - PIC (A or '-')	Product (AN)

Legend - N: Numeric; A:Alphabetic; AN:AlphaNumeric

<u>*** Edit to limit Industry Codes, dependent upon the Commodity Sub-Type ***</u>

IF Commodity Sub-Type = PRE, OTC, INV or RND
THEN PRODUCT.CODE.INDUSTRY = 56, 60, 61, 62, 63, 64, 65, or 66

IF Commodity Sub-Type = PHN
THEN PRODUCT.CODE.INDUSTRY = 55

<u>*** Edit to limit Subclass, dependent upon the Commodity Sub-Type:</u>
C & D are the Subclasses for Rx products;
A & B are the Subclasses for OTC products;
I is the Subclass for Investigational New Drug products ***

IF Commodity Sub-Type = PRE or OTC
AND PG01 Intended Use Code INCLUDES 180.009
THEN PRODUCT.CODE.SUBCLASS = “I”

IF Commodity Sub-Type = PRE
AND PG01 Intended Use Code DOES NOT INCLUDE 180.009
THEN PRODUCT.CODE.SUBCLASS = ‘C’ or ‘D’

IF Commodity Sub-Type = OTC
AND PG01 Intended Use Code DOES NOT INCLUDE 180.009
THEN PRODUCT.CODE.SUBCLASS = ‘A’ or ‘B’

*** Edit to limit Process Indicator Code (PIC) for Active Pharmaceutical Ingredients ***

IF Commodity Sub-Type = PRE or OTC
AND PG01 Intended Use Code = 150.007 or PG01 Intended Use Code = 155.017 Drug to be used as a component in a Medical Device (Active Pharmaceutical Ingredient / Bulk Drug Substance)
THEN PRODUCT.CODE.PIC = ‘S’ or ‘T’

For compounding PRODUCT.CODE.PIC = ‘T’

Record Identifier PG04 (Product Constituent Element)

For Drugs, Government Agency Processing Codes – PRE, OTC, RND and INV - require this PGA input record which provides data pertaining to Constituent Active Ingredient Qualifier, Name of the Constituent Element, Quantity of Constituent Element, Unit of Measure, and Percent of Constituent Element for the product identified by Product Code Number in PG02. This record can be repeated.

Using a Drug example, Appendix E shows how PG04 can be used at the Product-level for multiple Constituent Elements. The FDA will process PG05-PG06-PG07-PG08-PG10 records only at the Product-level (when they are under a PG02) at this time.

Record Identifier PG04 (Product Constituent Element)					
Data Element	**Length/ Class**	**Position**	**Status**	**Description**	**Note**
Control Identifier	2A	1 2	M	"PG".	
Record Type	2N	3-4	M	"04".	
Constituent Active Ingredient Qualifier	1A	5	C	If commodity sub-type = PRE, OTC, INV or RND then YES = "*Y*" if yes, blank (= NO)	1
Name of the Constituent Element	51X	6-56	C	IF FINISHED: Name of Active Ingredient contained in the dosage form IF ACTIVE PHARMACEUTICAL INGREDIENT/BULK DRUG SUBSTANCE: name of the Active Pharmaceutical Ingredient (API)	1, 2 3
Quantity of Constituent Element	12N	57-68	C	IF FINISHED – amount of active ingredient per dose IF API/BULK DRUG SUBSTANCE: total volume of API 2 decimal places are implied	1, 2 3
Unit of Measure (Constituent Element)	5AN	69-73	C	IF FINISHED: Unit of measure for Quantity of Constituent Element IF API/BULK DRUG SUBSTANCE: Unit of measure for Quantity of Constituent Element	1, 2 3
Percent of Constituent Element	7N	74-80	C	Only needed for Active Pharmaceutical Ingredients otherwise left blank. 4 decimal places are implied.	1, 3, 4,

Note 1

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 Mandatory.

Either the quantity and Unit of Measurement should be entered OR the Percent Constituent Element should be entered.

For Government Program Code = DRU AND Government Processing Code = PHN THEN PG04 is not required

Note 2

*** Rules for Finished Dosage Form Drugs ***

IF PG01 Intended Use Code =

080 For Human Medical Use as a Non-Food Product under Controlled Distribution – Prescription (PRE)
OR
130 For Consumer Use as a Non- Food Product – Over the Counter (OTC)
OR
150.100 Drug to be used as a constituent part in a Medical Device (Finished Dosage Form Drug)
OR
180.009 Chemical for research and development in a pharmaceutical product – clinical trials or other human/animal use - Research and Development (INV)
OR
180.017 Chemical for research and development in a pharmaceutical product – laboratory testing only, no human/animal use – Research and Development (RND)

THEN:

Constituent Active Ingredient Qualifier and Name of the Constituent Element are Mandatory.

Either the quantity and Unit of Measurement should be entered OR the Percent Constituent Element should be entered.

REPEAT for EACH Active Pharmaceutical Ingredient in the dosage form

Example1: Ibuprofen, 200mg tablets

Name of the Constituent Element = Ibuprofen
Quantity of Constituent Element = 200 and Unit of Measure = milligrams

Example2: Degree Expert Protection

Name of the Constituent Element = aluminum zirconimum tetrachlorohydrex
Percent of Constituent Element 18.2% (entered as 0182000)

Note 3

*** Rules for Active Pharmaceutical Ingredients (API) ***

IF PG01 Intended Use Code =

150.007 Active Pharmaceutical Ingredient / Bulk Drug Substance for processing into a pharmaceutical product
OR
150.100 Drug to be used as a component in a Medical Device (Active Pharmaceutical Ingredient / Bulk Drug Substance)
OR
180.009 Chemical for research and development in a pharmaceutical product – clinical trials or other human/animal use - Research and Development (INV)
OR
180.017 Chemical for research and development in a pharmaceutical product – laboratory testing only, no human/animal use – Research and Development (RND)

THEN

Constituent Active Ingredient Qualifier and Name of the Constituent Element are Mandatory.

Either the quantity and Unit of Measurement should be entered OR the Percent Constituent Element should be entered.

Name of the Constituent Element = Active Pharmaceutical Ingredient name
Quantity of Constituent Element = Total Amount (by Unit of Measure) of the Active Pharmaceutical Ingredient
Unit of Measure = base unit of measure weight/volume
Percent of Constituent Element = percent identification of the Active Pharmaceutical Ingredient.

REPEAT for EACH Active Pharmaceutical Ingredient in the dosage form

Example1: Ephedrine Hydrochloride 99%, USP, 2 – 25 KG drums
Name of the Constituent Element = Ephedrine HCl
Quantity of Constituent Element = 50 and Unit of Measure = KG

Example2: Degree Expert Protection
Name of the Constituent Element = aluminum zirconimum tetrachlorohydrex
Percent of Constituent Element 18.2% (entered as 0182000)

Note 4

Examples of Percentages:

1000000	=	100%
0990000	=	99%
0090000	=	9%
0009000	=	.9%
0000900	=	.09%
0000090	=	.009%
0000009	=	.0009%

Record Identifier PG06 (Product Origin)

This is a mandatory PGA input record that provides data pertaining to Source Type (Origin) -other than the CBP Country of Origin – for the product identified by Product Code Number in PG02.

Using a Drug example, Appendix E shows how PG04 can be used at the Product-level for multiple Constituent Elements. **The FDA will process PG05-PG06-PG07-PG08-PG10 records only at the Product-level (when they are under a PG02) at this time.**

Record Identifier PG06 (Product Origin)					
Data Element	**Length/ Class**	**Position**	**Status**	**Description**	**Note**
Control Identifier	2A	1 2	M	“PG”.	
Record Type	2N	3-4	M	“06”.	
Source Type Code	3AN	5-7	M	Mandatory valid values are 30 (Country of Source) or 39 (Country of Production). 294 (Country of Refusal) if previously refused. There would be at least one PG06 with source type code of 30 or 39. If previously refused, then provide another PG06 with source type code 294.	1
Country Code	2X	8-9	M	Country of production or source is required for Drugs	2

Note 1

Source Type Codes and their descriptions can be found in Appendix PGA (PG06 – Source Type Codes) of the ACE ABI CATAIR publication.

Note 2

Any of the country codes from Appendix B (ISO Country and Currency Codes) in the ACS ABI CATAIR can be entered.

Record Identifier PG07 (Product Trade Names)

This is a conditional PGA input record that provides data pertaining to Trade or Brand Name for the product identified by Product Code Number in PG02.

Using a Drug example, Appendix E shows how PG04 can be used at the Product-level for multiple Constituent Elements. **The FDA will process PG05-PG06-PG07-PG08-PG10 records only at the Product-level (when they are under a PG02) at this time.**

Record Identifier PG07 (Product Trade Names)					
Data Element	**Length /Class**	**Position**	**Status**	**Description**	**Note**
Control Identifier	2A	1 2	M	“PG”	
Record Type	2N	3-4	M	“07”	
Trade Name/Brand Name	35X	5-39	C	If Government Agency Program Code = ‘DRU’ and [if PG01 Intended use code = 150.007 (indicates API/Bulk) or Agency Processing Code = ‘PHN’ OR ‘RND’] then Trade/Brand Name of the Drug is optional; otherwise, the Trade/Brand Name of the Drug is MANDATORY.	

Finished – Mandatory (PRE, OTC)
Investigation (intended use code – 180.009 – Mandatory (if no trade name then provide the existing compound name)

API/Bulk - Optional
RND – Optional
PHN – Optional

Record Identifier PG10 (Product Characteristics)

This is a mandatory PGA input record that allows for reporting codes that provide additional characteristics of a product or component identified by Product Code Number in PG02, not reported elsewhere in the PG Message Set.

Using a Drug example, Appendix E shows how PG04 can be used at the Product-level for multiple Constituent Elements. **The FDA will process PG05-PG06-PG07-PG08-PG10 records only at the Product-level (when they are under a PG02) at this time.**

Record Identifier PG10 (Product Characteristics)					
Data Element	**Length/ Class**	**Position**	**Status**	**Description**	**Note**
Control Identifier	2A	1-2	M	“PG”.	
Record Type	2N	3-4	M	“10”.	
Commodity Characteristic Description	57X	24-80	M	This should be Invoice Description NOT product code description. See Appendix A for the use of PG10 to capture the information currently collected in multiple OI records.	

Record Identifier PG19 (Entity Data)

For Drugs, this is a mandatory PGA input record that provides FDA with data pertaining to Entity Role and conditionally the following data elements; Entity Identification, Entity Name, and Entity Address 1.

Record Identifier PG19 (Entity Data)					
Data Element	**Length/ Class**	**Position**	**Status**	**Description**	**Note**
Control Identifier	2A	1-2	M	"PG"	
Record Type	2N	3-4	M	"19"	
Entity Role Code	3AN	5-7	M	Code identifying the role of the entity being provided. For example, MF.	1,2,
Entity Identification Code	3AN	8-10	C	Code identifying the Entity Identification is entered. For example, 16. Mandatory, if Entity Number is entered.	3
Entity Number	15X	11-25	O	The Entity Number of the entity based on the above Entity Identification Code is entered; must conform to the descriptions in Note 2	3
Entity Name	32X	26-57	M	The name of the entity is required. See validation criteria below.	3
Entity Address 1	23X	58-80	M	The address of the entity is required. See validation criteria below.	3

Note 1

Entity Role Codes and their descriptions can be found in Appendix PGA (PG19 – Entity Role Codes) of the ACE ABI CATAIR publication. List of Entity Role codes mandatory to FDA Drugs Message Sets is below:

Data Element	***Code***	***Description***
Entity Role Codes§	MF	Manufacturer of goods (Final producer for the final drug product). If the product is a bulk API, use "MF" as the Entity Role Code (rather than "GD – Producer of API); If the product is in finished form, provide MF of final product *and* GD for each API.
	DEQ	Shipper
	FD1	FDA Importer (Importer of Record)
	DP	Delivered To Party±

§ Same Role Code cannot be entered more than once.

± Even though Title 19 141.19 (CBP) addresses - Consignee -, Title 21, Requires Prior Notice information about the - Ultimate Consignee - and Title 19 (CBP) defines - Ultimate Consignee -, FDA acknowledges that these terms cause confusion and would like to simplify and harmonize said data elements under the ACE environment.

Hence, the FDA has elected to utilize the data element --- "Deliver to Party" --- , U.S party that physically receives the good(s). The FDA's PG Message Set will, therefore, incorporate the deliver to party as issued in the ITDS Standard Data Set under the auspices of the ITDS Board of Directors. FDA's Prior Notice requirement for ultimate consignee is synonymous with deliver to party.

Note 2

Entity Role Codes and their descriptions can be found in Appendix PGA (PG19 – Entity Role Codes) of the ACE ABI CATAIR publication. List of Entity Role codes conditional to FDA Drugs Message Sets is below:

Data Element	***Code***	***Description***
Entity Role Codes	GD	Producer (Producer of the API*)
	SPO	Sponsor (New) – if different then MF or FD1

*API – Active Pharmaceutical Ingredient

*** Rules for Finished Dosage Form Drugs ***
IF PG01 Intended Use Code =
080 For Human Medical Use as a Non-Food Product under Controlled Distribution – Prescription (PRE)
OR
130 For Consumer Use as a Non- Food Product – Over the Counter (OTC)
THEN: must include MF and at least one GD

REPEAT for EACH Active Pharmaceutical Ingredient in the dosage form

List of Entity Role codes <u>also applicable</u> to FDA Drugs Message Sets is below:

Data Element	***Code***	***Description***
Entity Role Codes	AAR	All Applicable Roles
	APP	Applicant
	CE	Certifying Entity
	CO	Certifying Official
	CN	Consignee**
	CR	Consolidator
	CZ	Consignor
	DDF	Primary electronic business contact
	DDG	Alternate electronic business contact
	DDH	Primary government business contact
	DDI	Alternate government business contact
	DEI	Means of transport operator
	DFP	Owner
	EX	Exporter
	EXE	Exporting Establishment
	FCI	FDA Clinical Investigator
	FD2	FDA Importer 2
	FD3	FDA Importer 3
	FG	Foreign Government
	GC	Goods custodian
	INC	Inspection Contact
	ITL	Independent Third Party Laboratory
	LAB	Laboratory
	LAP	LPCO Authorized Party
	LG	Location of Goods immediately after Entry Release
	LBR	Labeler (New)
	LIP	LPCO Issuing Agency
	OV	Transport means owner
	PE	Producing Establishment
	PES	Packing Establishment
	PK	Point of Contact

Data Element	Code	Description
	PCK	Packer
	PRE	Preparer
	PRO	Processing Establishment
	RD	Retailer/Distributor
	RGO	Responsible Government Official
	SE	Seller
	SIG	Signer
	SOE	Source Establishment
	STL	Storage location
	TB	Submitter
	VW	Responsible party

Note 3

Entity Identification Codes and their descriptions can be found in Appendix PGA (PG19 – Entity Identification Codes) of the ACE ABI CATAIR publication. List of Entity Identification codes applicable to FDA Drug Message Sets is below:

Data Element	Code	Description	Length/ Class
Entity Identification Codes	16	D&B-assigned (DUNS number); must be 9 digits	9N
	47	FDA-assigned (FEI number); must be from 4 to 10 digits	4-10N

FDA SELECTION CRITERIA

FDA requires Entity Name and Entity Address. Additionally, FDA prefers to use DUNS numbers for identifying the Entity; IF DUNS is not available THEN FEI.

Entity Name <>NULL AND Entity Address 1 <>NULL AND
IF Entity Identification Code =16 (DUNS) THEN Entity Number MUST BE Length = 9 and Type = N
ELSE IF Entity Identification Code =47 (FEI) THEN Entity Number MUST BE Length from 4 to10 and Type = N

Record Identifier PG20 (Entity Address)

This is a mandatory PGA input record that provides additional data pertaining to Entity identification such as Entity Address line 2, Apartment/Suite, City, State, and Zip/Postal Code. This record is used when additional address for the entity needs to be entered.

Record Identifier PG20 (Entity Address)					
Data Element	**Length/ Class**	**Position**	**Status**	**Description**	**Note**
Control Identifier	2A	1-2	M	“PG”	
Record Type	2N	3-4	M	“20”	
Entity Address 2	32X	5-36	C	Address Line 2 for the Entity.	1
Entity Apartment Number/Suite Number	5X	37-41	C	Apartment/Suite number of the entity.	1
Entity City	21X	42-62	M	City of the entity.	
Entity State/Province	3AN	63-65	C	State/Province of the entity.	2
Entity Country	2A	66-67	M	ISO Country Code.	
Entity Zip/Postal Code	9X	68-76	C	Zip/Postal Code of the entity.	2
Filler	4X	77-80	M	Space fills.	

Note 1: If the Entity Address 1 in PG19 is longer than the allocated 23 characters then utilize these fields.

Note 2: Populated if US or Canada based entities

Record Identifier PG21 (Point of Contact)

This is a mandatory PGA input record that provides data about an Individual and may also be related to an entity (the party) in the preceding PG19 record. Included in this record are the Individual Name, Telephone Number, Fax Number, and Email address. If multiple Individuals related to a single entity are required by an agency, this record can be repeated and should follow each entity designated in the PG19 record. This record can also be repeated in cases where multiples of these data elements need to be reported for a single Individual. (For example, for reporting two phone numbers or an email and fax number). A typical example is a POC for the Filer.

At least one PG21 record is required.

Record Identifier PG21 (Point of Contact)					
Data Element	**Length/ Class**	**Position**	**Status**	**Description**	**Note**
Control Identifier	2A	1-2	M	“PG”.	
Record Type	2N	3-4	M	“21”.	
Individual Qualifier	3AN	5-7	M	Identify the type of party or facility the Individual represents.	
Individual Name	23X	8-30	M	Name of the Individual. If the name will not fit, complete PG24 and fill out the remarks code (Individual name) and then enter the name in the remarks text field.	
Telephone Number of the Individual	15X	31-45	M	Telephone number of the Individual. For example, (713)555-8765 in US or (+65)9052-3529 in Singapore	
Email Address or Fax Number for the Individual	35X	46-80	M	Option to either submit the Fax number or Email Address of the individual.	

Record Identifier PG23 (Affirmation of Compliance)

This is a conditional PGA input record that provides data pertaining to Food and Drug Administration Affirmation of Compliance Criteria. This record is typically only used by FDA. This record is repeatable.

Record Identifier PG23 (Affirmation of Compliance)					
Data Element	**Length/ Class**	**Position**	**Status**	**Description**	**Note**
Control Identifier	2A	1-2	M	"PG".	
Record Type	2N	3-4	M	"23".	
Affirmation of Compliance Code	5X	5-9	C	A code used to affirm compliance with FDA requirements. See Appendix PGA PG23 – Food & Drug Affirmation of Compliance, FDA Affirmation of Compliance Codes of ACE ABI CATAIR publication.	1
Affirmation of Compliance Qualifier	30AN	10-39	C	Text describing the information required by the PGA. This could include a number or a country code, etc. Also, see Appendix PGA (Food & Drug Affirmation of Compliance Qualifier Codes) of this publication for valid codes related to certain specific Affirmation of Compliance codes.	

Note 1

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 AofCs ***
For Government Program Code = DRU AND Government Processing Code =

- PHN: Pharmaceutical Necessities & Containers; or
- RND: Research and Development

THEN PG23 is not required

*** R&D products, Import For Export entries, and Personal Importations do not require AofCs ***
For Government Program Code = DRU AND Intended Use code =

- 180.100: Chemical for research and development in a pharmaceutical product – laboratory testing only, no human/animal ingestion; OR
- 100.000: Importation for Personal Use; OR
- 970.001: Import For Export

THEN PG23 is not required

When several PG23 records are included in the Message Set, the same AoC Code can be entered only once.

The list of AoC codes **conditional** to FDA Drugs Message Sets is below:

Data Element	***Code***	***Description***	***Syntax***	***Business Rules***
Affirmation of	DA	New Drug	6N	IF Government Agency Program Code =

Compliance Code		Application Number or Abbreviated New Drug Application Number or Therapeutic Biologic Application Number		DRU AND Government Agency Processing Code = 'PRE' AND Intended Use Code NOT = 180.009 THEN DA IS MANDATORY IF Government Agency Program Code = DRU AND Government Agency Processing Code = ' 'OTC' THEN DA IS OPTIONAL The DA AofC includes all the previous AoC codes, NDA, ANDA and BLA.
	REG	Drug Registration Number	9N	IF Government Agency Program Code = DRU and IF Government Agency Processing Code is PRE or OTC AND Intended Use Code NOT = 180.009 THEN REG IS MANDATORY
	DLS	Drug Listing Number	10N	IF Government Agency Program Code = DRU and IF Government Agency Processing Code is PRE or OTC,AND Intended Use Code NOT = 180.009 THEN DLS IS MANDATORY unless affirmation "PLR" is declared
	IND	Investigational New Drug Number	6N	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

The list of AoC codes **optional** to FDA Drugs Message Sets is below:

Data Element	***Code***	***Description***	***Syntax***	***Business Rules***
Affirmation of Compliance Code	ERR	Entry Review Requested	Indicator only	ERR is just used as an indicator, no data will follow
	HDE	Humanitarian Device Exemption	H followed by 6 digits	IF Government Agency Program Code = DRU THEN HDE IS ALLOWED
	UFC	Unacceptable to Foreign Country (Products other than food)	2A	ISO Country code
	PLR	Used to identify the shipment as a PLAIR import shipment	Indicator only	Used as an indicator, no data will follow.
	LST	Device Listing Number		IF Government Agency Program Code = DRU AND Intended Use Code = 150.100 [Component/Constituent Part of a Medical Device] THEN Device Listing is Optional
	PM#	Device Premarket Number	Any of the following: P+6N; N+4N, 5N, or 6N; D+6N;	IF Government Agency Program Code = DRU AND Intended Use Code = 150.100 [Component/Constituent Part of a Medical Device] THEN Device Premarket Application is Optional

			H+6N; K+6N; DEN+6N;	
	IDE	Investigational Device Exemption Number	G+6N OR "NSR"	

Record Identifier PG24 (Remarks)

This is an optional PGA input record that provides data pertaining to Remarks Codes, and Text of Remarks. Remark Type Code should be either GEN or NAM.

If GEN, the PG24 is applicable to the preceding PG02. Only one GEN:PG24 is allowed per PG02 (this is to avoid multiple GEN:PG24 records without a guaranteed sequencing as intended by the filer). This may be expanded in future with sufficient sequencing control to receive multiple GEN:PG24 records in the same order in which the Filer entered remarks.

If NAM, the PG24 is applicable to the preceding PG21. This structure simply allows the entry of 68 characters in addition to 23 characters afforded by PG21 for the Individual Name field in PG21. When a NAM-PG24 is present, the Individual Name field in PG21 is concatenated with Remarks Text field in PG24, to the full name in the format "*Last Name, First Name Middle Name*" for a potential 91 characters. Only one NAM:PG24 is allowed per PG21.

Record Identifier PG24 (Input)					
Data Element	**Length /Class**	**Position**	**Status**	**Description**	**Note**
Control Identifier	2A	1-2	M	Must always equal PG.	
Record Type	2N	3-4	M	Must always be 24.	
Remarks Type Code	3X	5-7	O	A code indicating the type of remarks. Valid codes are listed in Appendix PGA (Remarks Type Code) of this publication. FDA uses either NAM or GEN as its valid values.	1
Remarks Text	68X	13-80	O	Free form text relevant to the shipment or the commodity.	

Note 1
If an individual's Name in the preceding PG21 is longer than 23 characters, the Remarks Type Code should be identified as NAM (Full name of the Individual) then the Remarks Text can be used to indicate the full name of that individual. Individual's Name should still follow the same format when using PG24, as following:

Last Name, First Name Middle Name

If submitting general comments then use the Remarks Type Code = GEN (General Remarks)

Record Identifier PG25 (Product Condition)

This is a mandatory PGA input record that provides data pertaining to: Temperature Qualifier, Degree Type, Actual Temperature, Lot Number, Production Date Range of the Lot, PGA Line Value, and PGA Unit Value. This record is repeatable for multiple Lot Number Qualifiers and Lot Numbers but the line value MUST be included on each record.

Record Identifier PG25 (Product Condition)					
Data Element	**Length/ Class**	**Position**	**Status**	**Description**	**Note**
Control Identifier	2A	1-2	M	“PG”.	
Record Type	2N	3-4	M	“25”.	
Temperature Qualifier	1A	5	O	Temperature Category being reported for quality control or preservation purposes. A= Ambient, F=Frozen R=Refrigerated/Chilled, D=Dry Ice H=Fresh, U=Uncontrolled P=Flashpoint	
Degree Type	1A	6	O	F = Fahrenheit, C = Celsius , K = Kelvin	
Negative Number	1A	7	O	If the actual temperature is in the negative numbers use an “X”.	
Actual Temperature	6N	8-13	O	Reported temperature. Two decimals places are implied.	
Location of Temperature Recording	1A	14	O	Identifies recorded temperature is for A = product B = container C = conveyance	
Lot Number Qualifier	1AN	15	O	Code of the entity that assigned the Lot number. For Drugs the only valid value is: 1 = Manufacturer	
Lot Number	25X	16-40	O	The lot number that the manufacturer/ producer/grower assigned to the product.	
Production Start date of the Lot	8N	41-48	O	The date when the production for the Lot started. A numeric date in MMDDCCYY (month, day, century, year) format.	
Production End Date of the Lot	8N	49-56	O	The date when the production for the Lot ended. A numeric date in MMDDCCYY (month, day, century, year) format.	
PGA Line Value	12N	57-68	M	The value associated with the PGA line number in whole dollars. It must be right-justified with preceding zeros. Must be greater than zero.	
PGA Unit Value	12N	69-80	O	The value of the lowest unit of measure reported in PG26. Two decimal places are implied.	

Record Identifier PG26 (Product Packaging)

For Drugs, this is a conditional PGA input record that provides FDA with data pertaining to Packaging Qualifier, Quantity and Unit of Measure. Must provide either PG26 packaging information to the lowest level or PG29 Unit of Measure.

This record can be repeated up to six (6) times, once for each unique packaging level. The first record is used to describe the largest (outermost) container and the number of containers at this packaging level. The second record is used to describe the contents of the next smallest container. If needed, qualifiers 2-6 are used in a similar manner (largest to smallest container). The final record must describe the actual amount of the product in the smallest container.

The appearance of any 'Packaging Qualifier' number level requires all levels under it to be represented. For instance, level 3 can't be present unless levels 1 and 2 are present.

Record Identifier PG26 (Product Packaging)					
Data Element	**Length/ Class**	**Position**	**Status**	**Description**	**Note**
Control Identifier	2A	1-2	M	"PG"	
Record Type	2N	3-4	M	"26"	
Packaging Qualifier	1N	5	C	Code identifying the level of packaging. For example, 4. If reporting only one level, show the total quantity for the item and report that as level 1.	1,4,5
Quantity	12N	6-17	C	"Quantity of the packaging level, For example, 000000000400. Must be greater than zero.	2,4,5
Unit of Measure (Packaging Level)	5X	18-22	C	Type of packaging / packaging level. For example, BX.	3,4,5

Note 1
This code identifies the level of packaging for the product. Valid values are 1, 2, 3, 4, 5 and 6: Outermost (largest=1) packages to the innermost (smallest=6) packages. There can be up to 6 levels of packaging

Note 2
There are two implied decimal points when writing the quantity in Units of Measure for the Base Unit (Last Quantity Transmitted). In this example, 4 pieces are represented as 000000000400, with the nine leading zeroes as "fill" and two decimal places following the value. The quantity for packaging containers will be in whole numbers with no decimal places. The sample shows 1 carton containing 10 boxes and each box containing 4 pieces.

Note 3
List of Unit of Measure codes applicable to FDA-Drug Message Sets
For a full list of applicable Unit of Measure codes, please refer to Appendix F in this document or to the Appendix PGA (PG26 – Unit of Measure - Valid FDA Units of Measure for Packaging Containers) and Appendix PGA (PG26 – Unit of Measure -Valid FDA Units of Measure for the Base Unit (Last Quantity Transmitted)) of the CATAIR.

Valid FDA Units of Measure for the Base Unit (Last Quantity Transmitted)

Code	Code Name
AE	Aerosol

Code	Code Name
AM	Ampoule, Nonprotected
AP	Ampoule, Protected
AT	Atomizer
BG	Bag
BA	Barrel
BC	Bottle crate, Bottle rack
BO	Bottle, Nonprotected, Cylindrical
BQ	Bottle, Protected, Cylindrical
BS	Bottle, Nonprotected, Bulbous
BV	Bottle, Protected Bulbous
BX	Box
CA	Can, Rectangular
CG	Centigrams (Weight)
CI	Canister
CON	Container
CS	Case
CT	Carton
CX	Can, Cylindrical
CY	Cylinder
DR	Drum
EN	Envelope
FD	Framed Crate
FOZ	Ounces, fluid (Volume)
G	Grams (Weight)
GAL	Gallons (US) (Volume)
GB	Gas Bottle
KG	Kilograms (Weight)
L	Liters (Volume)
LB	Pounds (avdp) (Weight)
MB	Bag, Multi-ply
MG	Milligrams (Weight)
MCG	Micrograms (Weight)
ML	Milliliters (Volume)
NO	Number (Count)
OZ	Ounces, weight (avdp) (Weight)
PAL	Pallet
PCS	Pieces (Count)
PK	Package
PTL	Pints, liquid (US) (Volume)
QTL	Quarts, liquid (US) (Volume)
SUP	Suppositories (Dosage)
SY	Syringe
TAB	Tablets (Dosage)
TU	Tube

Note 4

Quantity Data provides additional information to FDA about the product and how it is packaged. The basic format for Quantity Data is in multiple pairs of data – quantity and unit of measure, i.e., 500 cases, 12 ounces, fluid, 1000 cartons, etc. Up to 6 data pairs may be submitted, beginning with the 1st pair for the outermost packaging when Packaging Qualifier = 1. The first pairs may describe the largest container and the last pair must describe the amount of product in the smallest container. For example:

100 Cartons 24 Aspirin 100 tablets 325 mg

Units 1-Quantity	100
Units 1-Measure	CT
Units 2-Quantity	24
Units 2-Measure	BO
Units 3-Quantity	100
Units 3-Measure	TAB

In this case, the invoice description contains the strength of the aspirin tablets. The product quantity is listed using the "Tablets" quantity unit code.

Record Identifier PG29 (Unit of Measure)

This is a conditional PGA input record that provides data pertaining to the net or gross unit of measure of the commodity. This can be provided at the overall PGA Line Number and/or the Individual Unit level.

Record Identifier PG29 (Unit of Measure)					
Data Element	**Length/ Class**	**Position**	**Status**	**Description**	**Note**
Control Identifier	2A	1-2	M	"PG".	
Record Type	2N	3-4	M	"29".	
Unit of Measure (PGA line - gross)	3AN	20-22	O	Pertaining to the overall PGA Line Number, the indication of the unit of measurement in which weight, capacity, length, area, volume or other quantity is expressed. "Unit of Measure (PGA line - gross)" in this position is associated with "Commodity Gross Quantity (PGA line - gross)" and is required when "Commodity Gross Quantity (PGA line - gross)" is reported. Valid Unit of Measure codes are listed in Appendix F in this document or in Appendix C in the ACS ABI CATAIR.	1
Commodity Gross Quantity (PGA line - gross)	12N	23-34	O	Pertaining to the overall PGA Line Number, including any packaging, but excluding weight of the carrier's equipment. Two decimals are implied. "Commodity Gross Quantity (PGA line - gross)" is required when "Unit of Measure (PGA line - gross)" is reported in positions 20-22 of this record.	1
Unit of Measure (Individual Unit - gross)	3AN	50-52	O	Pertaining to the Individual unit (gross), the indication of the unit of measurement in which weight, capacity, length, area, volume or other quantity is expressed. "Unit of Measure (Individual unit - gross)" in this position is associated with "Commodity Gross Quantity (Individual unit - gross)" and is required when "Commodity Gross Quantity (Individual unit - gross)" is reported. Valid Unit of Measure codes are listed in Appendix F in this document or in Appendix C in the ACS ABI CATAIR.	
Commodity Gross Quantity (Individual Unit - gross)	12N	53-64	O	Pertaining to the Individual unit, including any packaging, but excluding weight of the carrier's equipment. Two decimals are implied. "Commodity Gross Quantity (Individual unit - gross)" is required when "Unit of Measure (Individual unit - gross)" is reported in positions 50-52 of this record.	
Filler	16X	65-80	M	Space fill	

Valid FDA Units of Measure for Packaging Containers

Code	*Description*
BX	Box
CS	Case
CT	Carton
CX	Can, Cylindrical
DR	Drum
MB	Bag, Multi-ply
PK	Package
PO	Pouch

Valid FDA Units of Measure for the Base Unit (Last Quantity Transmitted)

Code	*Description*
DOZ	Dozen (Count)
DPC	Dozen Pieces (Count)
NO	Number (Count)
PCS	Pieces (Count)
CAP	Capsules (Dosage)
SUP	Suppositories (Dosage)
TAB	Tablets (Dosage)
BBL	Barrels (42 Gallons ea.) (Volume)
FOZ	Ounces, fluid (Volume)
GAL	Gallons (US) (Volume)
L	Liters (Volume)
ML	Milliliters (Volume)
PTL	Pints, liquid (US) (Volume)
QTL	Quarts, liquid (US) (Volume)
CG	Centigrams (Weight)
G	Grams (Weight)
KG	Kilograms (Weight)
LB	Pounds (avdp) (Weight)
MG	Milligrams (Weight)
MCG	Micrograms (Weight)
OZ	Ounces, weight (avdp) (Weight)
TU	Tube

Record not supported by FDA at this time

Record Identifier PG30 (Anticipated Arrival Information)

This is a mandatory PGA input record that provides data pertaining to the date, time and location of the anticipated arrival information for all FDA products. While other PGAs may use PG30 to Collect Inspection and Lab information, currently FDA will utilize this record to collect Anticipated Arrival Information at this time.

For each line a PG30 record with an "A" (Anticipated arrival information) code, date and time of arrival is Mandatory.

Record Identifier PG30 (Inspection and Lab Information)					
Data Element	**Length/ Class**	**Position**	**Status**	**Description**	**Note**
Control Identifier	2A	1-2	M	“PG”.	
Record Type	2N	3-4	M	“30”.	
Inspection/ Laboratory Testing Status	1A	5	M	A is the ONLY valid code for FDA:: A = Anticipated arrival information	
Anticipated Arrival date	8N	6-13	M	A numeric date in MMDDCCYY (month, day, century, year) format.	
Anticipated Arrival time	4N	14-17	M	Military time HHMM in (hour, minute) format. (Example: 1015, this represents 10:15 a.m.). For midnight, use 2400 (0000 is invalid).	
Arrival Location Code	4AN	18-21	O	For valid port codes, refer to note 1.	1
Arrival Location	50X	22-71	O	Code or free form text indicating site of inspection.	
Filler	8X	72-80	M	Space fill	

Note 1:
Refer to List of Valid Port Codes:
http://www.cbp.gov/sites/default/files/documents/CBP%20Port%20Codes%20041014_1.pdf

Record Identifier PG55 (Additional Entity Roles)

This is an optional PGA input record used to provide additional roles performed by an entity or individual.

The PG55 record is not supported by FDA at this time. Multiple PG19 records should be used to input more than one Entity-Role combination. Refer to the PG19 section for details.

Record Identifier PG55 (Additional Entity Roles)					
Data Element	**Length/ Class**	**Position**	**Status**	**Description**	**Note**
Control Identifier	2A	1-2	M	“PG”.	
Record Type	2N	3-4	M	“55”.	
Entity Role Code	3AN	5-7	O	Additional role of the entity.	
Entity Role Code	3AN	8-10	O	Additional role of the entity.	
Entity Role Code	3AN	11-13	O	Additional role of the entity.	
Entity Role Code	3AN	14-16	O	Additional role of the entity.	
Entity Role Code	3AN	17-19	O	Additional role of the entity.	
Entity Role Code	3AN	20-22	O	Additional role of the entity.	
Entity Role Code	3AN	23-25	O	Additional role of the entity.	
Entity Role Code	3AN	26-28	O	Additional role of the entity.	
Entity Role Code	3AN	29-31	O	Additional role of the entity.	
Entity Role Code	3AN	32-34	O	Additional role of the entity.	
Filler	8X	72-80	M	Space fill	

Not supported by FDA at this time

Record Identifier PG00 (Data Substitution)

This is an optional record used at the CBP entry (or entry summary) header, CBP entry (or entry summary) line and/or PGA message set levels to indicate data substitution

Record Identifier PG00 (Data Substitution)					
Data Element	**Length/ Class**	**Position**	**Status**	**Description**	**Note**
Control Identifier	2A	1-2	M	“PG”.	
Record Type	2N	3-4	M	“00”.	
Substitution Indicator	1X	5	O	Identifies either the start or end of the substitution group, or the location of where to place the substitute data within the PGA Message Set. The following codes are allowed: S=Start of the substitution group E=End of the substitution group R=Replace this record with the substitution group indicated by the Substitution Number	
Substitution Number	4AN	6-9	O	Sequential number assigned to, or referring to, a specific substitution group of data provided at the header level. This data element is mandatory when using the S or R substitution indicator.	
Filler	71X	10-80	M	Space fills.	

Stand Alone Prior Notice Submission Data Elements and Values

This chapter describes the data elements and their business rules for a stand-alone Prior Notice submission. This chapter is consisting of Prior Notice Submission (801m) requirements and the PE record requirements.

Prior Notice Non-PGA Data Elements by Mode of Transportation (See Note)

MOT	Required Data Elements	Mapping	Mapping - Data Elements
AIR	IATA	PE10	Carrier
	Airway Bill Number	PE10	Ref Qual Code = AWB, Ref ID Num
	Flight Number	PG23	AofC - VFT - Voyage/Flight/Trip Number
	Container Number	PG27	Container Number
	Carrier Name	PG23	AofC - CAN – Carrier Name
OCEAN	Bill of Lading	PE10	Ref. Qual. Code 'BIL,' Bill Type Indicator 'R,' and report the Simple Bill of Lading Number in the Reference Identifier Number field
	Vessel Name	PG23	AofC – VES – Vessel Name
	Voyage Number	PG23	AofC - VFT - Voyage/Flight/Trip Number
	Container Number	PG27	Container Number
	Carrier Name	PG23	AofC - CAN – Carrier Name
LAND - Bus, Truck	Bill of Lading	PE10	Ref. Qual. Code 'BIL,' Bill Type Indicator 'R,' and report the Simple Bill of Lading Number in the Reference Identifier Number field
	Trip Number	PG23	AofC - VFT - Voyage/Flight/Trip Number
	SCAC	PE10	Carrier
	Container Number *	PG27	Container Number
	Carrier Name	PG23	AofC - CAN – Carrier Name
LAND - Rail	Bill of Lading	PE10	Ref Qual Code = BIL, Ref ID Num
	Trip Number	PG23	AofC - VFT - Voyage/Flight/Trip Number
	SCAC	PE10	Filer/SCAC Code, Ref ID Num
	Rail Car Number	PG23	AofC – RNO - Rail Car Number
	Container Number *	PG27	Container Number
Express Consignment Carrier	Tracking Number	PG28	Report Express Courier tracking number for the shipment as applicable.
	Carrier Name	PG23	AofC - CAN – Carrier Name

* if applicable

Note: The above table makes references to select **entry-level data elements** from the PE10 to provide the context and to identify from which data source FDA expects to receive a number of the required prior notice data elements for the specific modes of transportation. For additional information on the data elements found within the PE10 record, please refer to the relevant CBP documentation. This supplemental guidance document describes only **line-level data** within the structure of the FDA PG Message Set.

Food Commodity Data Elements and Values

Food commodities can be broken down into the following categories using the existing Government Agency data elements available in the PG01 message

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

Table 4a – Food commodity hierarchy

The following are the potential PGA records associated with submitting Prior Notice:

PG Record	Description
OI	Record Identifier (The general product description)
PG01	PGA Identifier (The shipment is regulated by the FDA program office within FDA and the Intended Use)
PG02	Product Identifier (FDA Product Code Information)
PG06	Product Origin (FDA Country of Production, Shipment, and Refusal)
PG10	Product Characteristics (Line level Item Common/Usual/Market Name Description)
PG13	License Plate Issuer [Privately Owned Vehicle (POV) Information]
PG14	License Plate Number [Privately Owned Vehicle (POV) Information]
PG19	Entity Data (Trade Entity's Transaction Role, Identification Type, Identification Number, and 1st Line of Address)
PG20	Entity Address (Continuation of Entity information including Address Line 2, City, State/Province, Country for entities provided in PG19)
PG21	Point of Contact [Individual (POC) Information, including Name, Phone Number, Fax Number, Email Address for trade entities]
PG23	Affirmation of Compliance [FDA's Affirmation of Compliance (AofC) Criteria including food facility registration and other Prior Notice information]

PG Record	Description
PG24	Remarks (Continuation of POC name as necessary)
PG25	Product Condition (Lot # of product as required by specific commodities)
PG26	Product Packaging (Packaging Qualifier And Quantity per line)
PG27	Container Information
PG28	Express Courier Tracking (Number)§
PG30	Anticipated Arrival Information
PG55	Additional Role(s) (for future use)
PG00	Data Substitution

§ CBP confirmed that the PE header can only be used to submit express courier tracking numbers in the air environment. Therefore, all express courier tracking numbers for PNs in the air environment should be submitted in the PE. Express courier tracking numbers for PNs for food shipments in the ground environment are to be reported in the PG28.

Prior Notice Example

Prior Notice message set layout sample below:

Please refer to the external file: **FDA SG 2.4 Example PG Message Sets.xlsx** Tab: ***PN Only***

Because of the flexibility of the PGA Message set, the PGA Records and Data Elements that are required may vary both from program to program and within a single program. For a more expansive set of examples of FDA PGA Message Sets, please refer to the above document.

Record Identifier OI (Record Identifier)

For Prior Notice, this is a mandatory record that provides the general description of the item. This record precedes the Record Identifiers for the PGA Message set.

Record Identifier OI (Input)					
Data Element	**Length /Class**	**Position**	**Status**	**Description**	**Note**
Control Identifier	2A	1-2	M	"OI"	
Filler	8X	3-10	M	Space filled.	
Commercial Description	70X	11-80	M	The commercial description of the product. For example, Fruit Juice	

Record Identifier PG01 (PGA Identifier)

For Prior Notice, this is a mandatory input record that provides data pertaining to the PGA Line Number, Government Agency Code, Government Agency Program and Processing Codes, Intended Use Code, and Disclaim information.

Record Identifier PG01 (Input)					
Data Element	**Length /Class**	**Position**	**Status**	**Description**	**Note**
Control Identifier	2A	1-2	M	"PG"	
Record Type	2N	3-4	M	"01"	
PGA Line Number	3N	5-7	M	"001"	
Government Agency Code	3X	8-10	M	"FDA"	
Government Agency Program Code	3X	11-13	M	"FOO"	1
Government Agency Processing Code	3X	14-16	M	For allowed values Codes for Food see Note 1 below.	1
Intended Use Code	16X	42-57	O		2
Intended Use Description	22X	58-79	O		2

Note 1

See Table 4a above for the commodity hierarchy for Human Food and Animal Food commodities applicable for Prior Notice.

Note2

Choose one of these intended use codes, if applicable based on the product requirements. The submission of an Intended use code is not a requirement for prior notice.

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

Record Identifier PG02 (Product Identifier)

For Prior Notice, this mandatory input record is used to indicate whether or not the information being provided relates to a product (P) or a component (C) of a product. The Product Code Qualifier and Number can be used to provide FDA Product Code.

Record Identifier PG02 (Input)					
Data Element	**Length /Class**	**Position**	**Status**	**Description**	**Note**
Control Identifier	2A	1-2	M	"PG"	
Record Type	2N	3-4	M	"02"	
Item Type	1A	5	M	Code identifying the following records as pertaining to P=Product. No other values accepted. Only one 'P' record is allowed for the same PGA Line # in PG01	
Product Code Qualifier	4X	6-9	M	"FDP"	1
Product Code Number	19X	10-28	M	The FDA Product Code Must be equal to 7 characters	

Note 1

Product Code Qualifier is currently always 'FDP' for all FDA products.
Product Code Qualifiers and their descriptions can be found in Appendix PGA (PG02 – Product Code Qualifiers) of the ACE ABI CATAIR publication.

Only one Product Code Number per product is allowed.

FDA Product Code Structure:

Position	1-2	3	4	5	6-7
Name	Industry Code (N)	Class Code (A)	Sub Class Code (A or '-')	Process Identification Code - PIC (A or '-')	Group Code (AN)

Legend - N: Numeric; A:Alphabetic; AN:AlphaNumeric

A product is subject to Prior Notice requirements if the following condition is satisfied.

```
if industry_code IN ('48','49', '69', '70', '71', '72')
OR if industry_code BETWEEN '01' and '46'
OR if (industry_code+class_code+group_code) in ('52D01','52D99')
OR if (industry_code+class_code+group_code) in ('50A01','50B01')
OR if (industry code ='50' and class_code in ('C', 'D', 'E', 'F', 'G', 'L')
OR if  (industry_code = '54' and subclass_code in ('A','B','C','L','M','Y'))
```

Record Identifier PG06 (Product Origin)

For Prior Notice, this is a mandatory input record that provides data pertaining to Source Type (FDA country of production/growth and country from which the article was shipped) for the article of food. This record also provides the conditional PN data concerning the Country or Countries) who previously refused entry of the article of food. This record can be repeated to submit the countries required for PN as described in Note 1.

Record Identifier PG06 (Input)					
Data Element	**Length/ Class**	**Position**	**Status**	**Description**	**Note**
Control Identifier	2A	1-2	M	Must always equal PG.	
Record Type	2N	3-4	M	Must always be 06.	
Source Type Code	3X	5-7	M	Source Type Code must be selected using the following logic. 1) IF Government Agency Program Code = FOO and Government Agency Processing Code = NSF then use 262 (Place of growth) ELSE Source Type Code can be 39 (Country of Production). IF Government Agency Program Code = FOO, THEN Country of Shipment CSH is required. *2)* IF Government Agency Program Code = FOO then Country of Entry Refusal 294 is required, if previously refused from other country(s)	1
Country Code	2X	8-9	M	ISO country codes are allowed.	2

Note 1

Source Type Code from Appendix PGA, PG06 – Source Type Codes may be entered.
Prior Notice requires the following data elements:

1. **Country of Shipment**, Source Type Code = CSH
2. **All Natural State Human Food and Animal Food requires** the
   - **Country of Growth,** Source Type Code = 262 –the country where the article of food was grown - for fish/seafood caught outside the waters of the US = country in which the vessel who caught the fish/seafood is registered.
3. **Non-Natural State Human Food and Animal Food requires** the
   - **Country of Production**, Source Type Code = 39- the country where the article of food was made - if made from fish/seafood aboard a vessel = country in which the vessel is registered.
4. **Country of Entry Refusal**, if the article of food has been refused by other country(ies), provide the ISO country code(s) as a part of the Prior Notice submission. (Source Code Type = 294)

Note 2

ISO Country codes from Appendix D (ISO Country and Currency Codes) in the ACS ABI CATAIR must be entered.

Record Identifier PG10 (Product Characteristics)

For Prior Notice, this is a mandatory input record that provides common or usual name description of a product or component, not reported elsewhere in the PG Message Set.

Record Identifier PG10 (Input)					
Data Element	**Length /Class**	**Position**	**Status**	**Description**	**Note**
Control Identifier	2A	1-2	M	Must always equal PG.	
Record Type	2N	3-4	M	Must always be 10.	
Commodity Characteristic Description	57X	24-80	M	Common, market or usual name or description, NOT product code description of the product. Free form description of the item.	1

An example of the use of PG10 record is included in Appendix A.

Note 1

For PN at least one common, market or usual name in PG10 MUST be provided.

Record Identifier PG13 (License Plate Issuer)

For Prior Notice, this is a conditional input record that provides data pertaining to Licenses, Permits, Certificates or Other (LPCO). For Prior Notice submission, this PG record is only required when the carrier is a privately owned vehicle and does not have a SCAC or IATA. For this situation, this PG record allows for the submission of some of the license plate information for the subject privately owned vehicle. The data elements included in this record are Issuer and location of issuer of the LPCO. If using this record, a PG14 and PG23 (Carrier Name – CAN) are mandatory.

Record Identifier PG13 (Input)					
Data Element	**Length /**	**Position**	**Status**	**Description**	**Note**
Control Identifier	2A	1-2	M	Must always equal PG.	
Record Type	2N	3-4	M	Must always be 13.	
Issuer of LPCO	35X	5-39	O	Identifies the entity that issued the LPCO.	1
LPCO Issuer - Government Geographic Code Qualifier	3A	40-42	C	The code relating to the location of the issuer of the POV license plate. Select one: Canadian Province = PR Country Code = ISO Mexican State = MS US State = US	1
Location (Country/State/Province) of Issuer of the LPCO	3A	43-45	C	Identifies the location of the issuer of the POV license plate (ex: the US, Mexico or Canadian Province/State code or Foreign Country Code). Enter the appropriate code from Appendix B in the ACS ABI CATAIR.	1
Regional description of location of Agency Issuing the LPCO	25X	46-70	C	This description allows for the submission of a License Plate Issuer location when the Issuer is reported as an ISO and State or Province other than those from the US, Canada, or Mexico.	1
Filler	10X	71-80	M	Space fill	

Note 1

When the Carrier or the Transport Means Owner does not have SCAC or IATA, the following data requirements Prior Notice's privately owned vehicle (POV) license plate information should be submitted using PG13 and PG14. .

License Plate Number	**PG14 –** LPCO Number
License State (US)	**PG13** - LPCO Issuer - Location (Country/State/Province) of Issuer of the LPCO
License Province	**PG13** - LPCO Issuer - Location (Country/State/Province) of Issuer of the LPCO
License Country	**PG13** - LPCO Issuer - Government Geographic Code Qualifier

Record Identifier PG14 (License Plate Number)

Applicable for Prior Notice where the carrier is a privately owned vehicle, provide the Privately Owned Vehicle license plate information.

Record Identifier PG14 (Input)					
Data Element	**Length /Class**	**Position**	**Status**	**Description**	**Note**
Control Identifier	2A	1-2	M	Must always equal PG.	
Record Type	2N	3-4	M	Must always be 14.	
LPCO Transaction Type	1N	5	O	Leave blank - not required (reserved for future use)	
LPCO Type	3AN	6-8	C	Identifies Type Code for Privately Owned Vehicle license plate number as applicable. Use “POV” for Type	1
LPCO Number (or Name)	33X	9-41	C	Identifies the number that corresponds to the *PN Confirmation number or* Privately Owned Vehicle license plate number.	

Note 1

This information is only required in cases where the carrier is a privately owned vehicle, and PG 13 is used to report the issuer of the license plate, provide the Privately Owned Vehicle license plate information.
.

Record Identifier PG19 (Entity Data)

For Prior Notice, this is a mandatory input record that provides FDA with data pertaining to Entity Role, Entity Identification Code, Entity Identification Number, Entity Name, and Entity Address 1, specifying various trade entities involved in this transaction.

Record Identifier PG19 (Input)					
Data Element	**Length /Class**	**Position**	**Status**	**Description**	**Note**
Control Identifier	2A	1-2	M	"PG"	
Record Type	2N	3-4	M	"19"	
Entity Role Code	3X	5-7	M	Code identifying the role of the entity being provided. For example: MF, UC	1
Entity Identification Code	3X	8-10	C	Code identifying the Entity Type is entered. For example: 16 (DUNS), 47 (FEI) . Mandatory, if Entity Number is entered.	2
Entity Number	15X	11-25	O	The Entity Number of the entity based on the above Entity Identification Code is entered; must conform to the descriptions in Note 2	2
Entity Name	32X	26-57	M	The name of the entity is entered. See validation criteria below	2
Entity Address 1	23X	58-80	C	Conditional only for the Manufacturer, PN Transmitter, and/or PN Submitter entities if a Food Facility Registration number is included in PG23 . Mandatory for all other required entities. See Note 1 and validation criteria below.	1, 2

Note 1

Entity Role Codes and their descriptions can be found in Appendix PGA (PG19 – Entity Role Codes) of the ACE ABI CATAIR publication. List of Entity Role codes **MANDATORY** to FDA Prior Notice Message Sets is below:

Data Element	***Code***	***Description***	***Condition***
Entity Role Codes[§]	PNS	PN Submitter[1]	Provide DUNS, FEI number and/or full address in PG19 and PG20 or if the facility is registered you may provide the Submitter's FDA Food Facility Registration number in PG23, with the Name, City, and Country in lieu of the full address in PG19 and PG20. POC person's name, phone, fax, email address information is required for all PN in PG21.
	PNT	PN Transmitter[1]	PN Transmitter is required if the PN is not transmitted by the PN Submitter. • Provide DUNS, FEI number and/or full address in PG19 and PG20 or if the facility is registered you may provide the Transmitter's FDA Food Facility Registration number in PG23, with the Name, City, and Country in lieu of the full address in PG19 and PG20 POC person's name, phone, fax, email address information is required in PG21.
	MF[4]	Manufacturer[3]	Provide DUNS, FEI number and/or full address in PG19

Data Element	Code	Description	Condition
	-or- FDC[4] -or- DFI[4]		and PG20 of the manufacturer or person (if individual) as required when the food /feed is NOT in its natural state. Otherwise if you provide the AoC code PFR (manufacturer's Food Facility Registration number) in PG23, you may provide the manufacturer's Name, City, and Country in PG19 and PG20 in lieu of the full address
		FDA Consolidator[3]	Full address of the firm or person (if individual) who consolidated the articles of food from the grower(s) is required when the food/feed is in its natural state and the grower(s) is/are unknown. If registered you may provide the AoC Code CFR (FDA Consolidator's Food Facility Registration number) if available in PG23
		Grower[3]	If known, full address of the growing location of the grower or person (if individual) is required when the food/feed IS in its natural state. If registered you may provide the AoC code GFR (Grower's Food Facility Registration number) if available in PG23
	DEQ	Shipper	Full address of Shipper is required for all PN. Provide DUNS, FEI number with full address in PG19 and PG20, and if registered you may provide the Shipper's Food Facility Registration number if available in PG23

§ Same Role Code cannot be entered more than once.

List of Entity Role codes that are **CONDITIONALLY REQUIRED** to FDA Prior Notice Message Sets is below:

Data Element	Code	Description	Condition
	LG	Location of Goods Immediately after Entry Release	This entity is only required for PN when the article of food/feed was refused for inadequate PN and moved under CBP Supervision. This entity is the location and address where the refused food is held.
	FD1	FDA Importer (Importer of Record)	Except for T & E entries, full address of the Importer is required for all PN. Provide DUNS, FEI number with full address in PG19 and PG20, and if registered you may provide the Importer's Food Facility Registration number if available in PG23.
	UC	Ultimate Consignee (Delivered to Party)[2, 3]	Except for T & E entries, full address of the UC is required for all PN. Provide DUNS, FEI number with full address in PG19 and PG20, and if registered you may provide the Ultimate Consignee's Food Facility Registration number if available in PG23.
	DFP	Owner[2, 3]	Except for T & E entries, full address of the Owner is required by all PN. Provide DUNS, FEI number with full address in PG19 and PG20 and if registered you may provide the Owner's Food Facility Registration number in PG23.

[1] The Entity Role of Submitter and Transmitter requires the Firm/Entity info as well as a Point of Contact info which includes the Individual's Full Name, Phone Number(s), and Email Address in PG21.

[2] Ultimate Consignee (Deliver To Party – reference guidance), Importer and Owner info is not required IF the entry line product is imported for transportation and exportation, i.e. T&E entry type.

[3] The PN regulation requires **ONE** of the following:
IF the food/feed is NOT in natural state THEN Manufacturer (MF)
IF the food/feed is in natural state THEN Grower (DFI)
IF the food/feed is in natural state, and Grower is unknown THEN Consolidator (FDC)

[4] Only one of the Entity Role Codes MF/FDC/DFI is permitted. If AoC codes are entered along with one of these PG19 entity role codes, then only a PFR or FME shall be used along with MF; only a GFR may be used in conjunction with DFI; and only a CFR may be used in conjunction with FDC.

List of Entity Role codes **MAY BE APPLICABLE** to FDA Prior Notice Message Sets is below. These codes may not be used as a substitute for the mandatory or conditional entities listed above.

Data Element	***Code***	***Description***
Entity Role Codes	PK[1]	Point of Contact Any other additional POC's information may be provided using the Role Code PK

[1] For role code PK, PG20 and 21 would be required in order to submit the complete address (PG19, PG20) and name (PG21) of the individual. Also, Phone, Fax Number, Email address (PG21) may be additionally required depending on the individual's role in the Entry process.

Note 2

Entity Identification Codes and their descriptions can be found in Appendix PGA (PG19 – Entity Identification Codes) of the ACE ABI CATAIR publication. List of Entity Identification codes applicable to FDA Prior Notice Message Sets is below:

Data Element	***Code***	***Description***	***Length/ Class***
Entity Identification Codes[1]	16	D&B-assigned (DUNS number)	9N
	47	FDA-assigned (FEI number)	4- 10N

For PN purposes, FDA always requires Entity Name but the Entity Address 1 is optional for the Manufacturer, PN Submitter, and/or PN Transmitter entities if an associated Food Facility Registration number is included in PG23. Additionally, FDA prefers to use DUNS numbers for identifying the Entity; IF DUNS is not available THEN FEI.

IF Entity Identification Code =16 (DUNS) THEN Entity Number MUST BE Length = 9 and Type = N
ELSE IF Entity Identification Code =47 (FEI) THEN Entity Number MUST BE Length from 4 to 10 and Type = N

Record Identifier PG20 (Entity Address)

For Prior Notice, this is a mandatory PGA input record that provides additional data pertaining to Entity identification such as Entity Address line 2, Apartment/Suite, City, State, and Zip/Postal Code. This record is used with the PG19 and may be repeated if PG19 is repeated.

Record Identifier PG20 (Input)					
Data Element	**Length /Class**	**Position**	**Status**	**Description**	**Note**
Control Identifier	2A	1-2	M	Must always equal PG.	
Record Type	2N	3-4	M	Must always be 20.	
Entity Address 2	32X	5-36	C	Address Line 2 for the Entity.	1
Entity Apartment Number/Suite Number	5X	37-41	C	Apartment/Suite number of the entity.	1
Entity City	21X	42-62	M	City of the entity.	
Entity State/Province	3X	63-65	C	State/Province of the entity. See Appendix B in the ACS ABI CATAIR for valid codes.	2
Entity Country	2A	66-67	M	ISO Country Code. See Appendix B in the ACS ABI CATAIR for valid codes.	
Entity Zip/Postal Code	9X	68-76	C	Zip/Postal Code of the entity.	2
Filler	4X	77-80	M	Space fill	

Note 1: If the Entity Address 1 in PG19 is longer than the allocated 23 characters then utilize these fields.

Note 2: Populated if US or Canada based entities

Record Identifier PG21 (Point of Contact)

For Prior Notice, this is a mandatory PG input record that provide2 data about an Individual POC's information. The contact may also be related to an entity (the party) in the preceding PG19 record. Included in this record are the Individual Name, Telephone Number, Fax Number, and Email address.

If multiple Individuals related to a single entity are required by an agency, this record can be repeated and should follow each entity designated in the PG19 record. This record can also be repeated in cases where multiples of these data elements need to be reported for a single Individual. (For example, for reporting two phone numbers or an email and fax number).

Record Identifier PG21 (Input)					
Data Element	**Length /Class**	**Position**	**Status**	**Description**	**Note**
Control Identifier	2A	1-2	M	Must always equal PG.	
Record Type	2N	3-4	M	Must always be 21.	
Individual Qualifier	3X	5-7	M	Identify the type of party or facility the Individual represents. For example, person is associated to the PN Submitter and PN Transmitter. For valid codes, use the Entity Role Codes from PG19 (See Appendix PGA of this publication.)	1
Individual Name	23X	8-30	M	Name of the Individual. If the name will not fit, complete PG24 and fill out the remarks code (Individual name) and then enter the name in the remarks text field. For Example: SMITH, JOHN	1, 2, 3
Telephone Number of the Individual	15X	31-45	M	Telephone number of the Individual. For example, (713)555-8765 in US or (+65)9052-3529 in Singapore	1
Email Address or Fax Number for the Individual	35X	46-80	M	Either the Fax number or Email Address of the individual.	1

Note 1

Prior Notice regulation requires PG21 data for the Entity Roles of *PN Submitter, and PN Transmitter*. Other condition where PG21 information is required for Prior Notice is specified in PG19 mandatory and conditional data sections.

Data Element	***Code***	***Description***
Entity Role Codes	PK	Point of Contact

Note 2

Individual's Name should have the following format:

Last Name, First Name Middle Name

Note 3

If the individual's Name is longer than 23 characters, then the **PG24 Remarks** records should be used to indicate the full name of the individual. Individual's Name should still follow the same format when using PG24:

Last Name, First Name Middle Name

Record Identifier PG23 (Affirmation of Compliance)

For Prior Notice, these are conditional or optional PGA input records that provide data pertaining to Food and Drug Administration Affirmation of Compliance Criteria. This record is typically only used by FDA. This record is repeatable.

Record Identifier PG23 (Input)					
Data Element	**Length/ Class**	**Position**	**Status**	**Description**	**Note**
Control Identifier	2A	1-2	O	Must always equal PG.	
Record Type	2N	3-4	O	Must always be 23.	
Affirmation of Compliance Code	5X	5-9	C	A code used to affirm compliance with FDA requirements. If the merchandise is subject to BTA, use this field to report the appropriate affirmation of compliance information, not reported elsewhere. See Appendix PGA (Food & Drug Affirmation of Compliance Codes) of this publication for valid codes.	1,2
Affirmation of Compliance Qualifier	70X	10-79	C	Text describing the information required by the PGA. This could include a number or a country code, etc. Also, see Appendix PGA (Food & Drug Affirmation of Compliance Qualifier Codes) of this publication for valid codes related to certain specific Affirmation of Compliance codes.	1
Filler	1X	80	O	Space fill	

Note 1

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 **CONDITIONAL** AoC codes for the FDA Prior Notice Message Set is below:

Data Element	***Code***	***Description***	***Syntax***	***Business Rules***
Affirmation of Compliance Code	FME	Food Processing Facility Registration Exemption	Indicator	To be used when Food or Feed is no longer in its natural state or when the PFR number is not provided. See Appendix D at the end of this document for valid codes Either FME or PFR is required in the case of Manufacturer or when consolidator/grower is entered in lieu of manufacturer for food in natural state. If both are submitted, FME is not used by the FDA.
	RNO	Rail Car Number		Required If MOT = Rail
	CAN	Carrier Name		If using a PG13 record OR if the SCAC or IATA are not provided this AoC value is required.

Data Element	Code	Description	Syntax	Business Rules
	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 VFT is also required if MOT = Rail or Truck
	VES	Vessel Name		Required If MOT = Ocean
	PFR	Manufacturers food facility registration number	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. If both FME and PFR are submitted, FME is not used by the FDA.

Note 2

The list of **OPTIONAL** AoC codes for the FDA Prior Notice Message Set is below:

Data Element	Code	Description	Syntax	Business Rules
	SFR	Shippers food facility registration number	11N	optional
	UFR	Ultimate consignee food facility registration number	11N	optional
	IFR	Importers food facility registration number	11N	optional
	TFR	Transmitter food facility registration number	11N	optional
	ORN	Owners food facility registration number-	11N	optional
	SRN	Submitters food facility registration number	11N	optional
	CFR	FDA Consolidator food facility registration number	11N	optional
	GFR	Growers food facility registration number	11N	optional

Record Identifier PG24 (Remarks)

This is an optional PGA input record that provides data pertaining to Remarks Codes, and Text of Remarks.

Remark Type Code should be either GEN or NAM.

If GEN, the PG24 is applicable to the preceding PG02. Only one GEN:PG24 is allowed per PG02 (this is to avoid multiple GEN:PG24 records without a guaranteed sequencing as intended by the filer). This may be expanded in future with sufficient sequencing control to receive multiple GEN:PG24 records in the same order in which the Filer entered remarks.

If NAM, the PG24 is applicable to the preceding PG21. This structure simply allows the entry of 68 characters in addition to 23 characters afforded by PG21 for the Individual Name field in PG21. When a NAM-PG24 is present, the Individual Name field in PG21 is concatenated with Remarks Text field in PG24, to the full name in the format "*Last Name, First Name Middle Name*" for a potential 91 characters. Only one NAM:PG24 is allowed per PG21.

Record Identifier PG24 (Input)					
Data Element	**Length /Class**	**Position**	**Status**	**Description**	**Note**
Control Identifier	2A	1-2	M	Must always equal PG.	
Record Type	2N	3-4	M	Must always be 24.	
Remarks Type Code	3X	5-7	C	A code indicating the type of remarks. Valid codes are listed in Appendix PGA (Remarks Type Code) of this publication. FDA uses either NAM or GEN as its valid values.	1
Remarks Text	68X	13-80	C	Free form text relevant to the shipment or the commodity.	

Note 1
If an individual's Name in the preceding PG21 is longer than 23 characters, the Remarks Type Code should be identified as NAM (Full name of the Individual) then the Remarks Text can be used to indicate the full name of that individual. Individual's Name should still follow the same format when using PG24, as following:

Last Name, First Name Middle Name

If submitting general comments then use the Remarks Type Code = GEN (General Remarks)

Record Identifier PG25 (Product Condition)

For Prior Notice, this is a conditional input record that provides data pertaining to: Lot Number required by FDA regulations for Infant formula, Acidified Foods, and LACF products. This record is repeatable for multiple Lot Number Qualifiers and Lot Numbers but the line value MUST be included on each record.

Record Identifier PG25 (Temperature Qualifier)					
Data Element	**Length/ Class**	**Position**	**Status**	**Description**	**Note**
Control Identifier	2A	1-2	M	Must always equal PG.	
Record Type	2N	3-4	M	Must always be 25.	
Lot Number Qualifier	1AN	15	C	Includes Lots and/or Batches. Mandatory for Infant formula, Acidified Foods, and LACF/AF products. 1 = Manufacturer	
Lot Number	25X	16-40	C	The lot number that the manufacturer assigned to the product. Mandatory for Infant formula, Acidified Foods, and LACF products.	1

Note 1:

Using the FDA Product Code in PG02, the following classifications are made where specific imported food/feed products require the submission of lot or code numbers or other identifier with prior notice. These include:

LACF and Acidified:

Industry Codes: 02-39, 41, 71, & 72
With Process Indicator Code (PIC): Acidified-**I**, Aseptic-**F**, Commercially Sterile-**E**

Infant Formula:

Industry Code: 40
With Class:

- C-Formula Prod (Baby)
- N-Ready to Feed Formula Product
- O-Liquid Concentrate Formula Product
- P-Powder Formula Products
- R-Infant Formula for Sample Testing (not for sale)

Record Identifier PG26 (Product Packaging)

For Prior Notice, this is a mandatory input record that provides FDA with estimated quantity of food to be shipped by describing the Packaging Qualifier, Quantity, Unit of Measure, Package Identifier, Packaging Method, Package Material, and Packaging Filler. This record can be repeated up to six (6) times, once for each unique packaging level. The first record is used to describe the largest (outermost) container and the number of containers at this packaging level. The second record is used to describe the contents of the next smallest container. If needed, qualifiers 2-6 are used in a similar manner (largest to smallest container). The final record must describe the actual amount of the product in the smallest container.

The appearance of any 'Packaging Qualifier' number level requires all levels under it to be represented. For instance, level 3 can't be present unless levels 1 and 2 are present.

Record Identifier PG26 (Input)					
Data Element	**Length /Class**	**Position**	**Status**	**Description**	**Note**
Control Identifier	2A	1-2	M	"PG"	
Record Type	2N	3-4	M	"26"	
Packaging Qualifier	1N	5	M	Code identifying the level of packaging. For example, 4. If reporting only one level, show the total quantity for the item and report that as level 1.	1, 4
Quantity	12N	6-17	M	"Quantity of the packaging level, For example, 000000000400. Must be greater than zero.	2, 4
Unit of Measure (Packaging Level)	5X	18-22	M	Type of packaging / packaging level. For example, BX.	3, 4

Note 1
This code identifies the level of packaging for the product. Valid values are 1, 2, 3, 4, 5 and 6: Outermost (largest=1) packages to the innermost (smallest=6) packages. There can be up to 6 levels of packaging.

Note 2
There are two implied decimal points when writing the quantity in Units of Measure for the Base Unit (Last Quantity Transmitted). In this example, 4 pieces are represented as 000000000400, with the nine leading zeroes as "fill" and two decimal places following the value. The quantity for packaging containers will be in whole numbers with no decimal places. The sample shows 1 carton containing 10 boxes and each box containing 4 pieces.

Note 3
List of Unit of Measure codes applicable to FDA-Prior Notice Message Sets
For a full list of applicable Unit of Measure codes, please refer to Appendix F in this document or to the Appendix PGA (PG26 – Unit of Measure - Valid FDA Units of Measure for Packaging Containers) and Appendix PGA (PG26 – Unit of Measure -Valid FDA Units of Measure for the Base Unit (Last Quantity Transmitted)) of the CATAIR.

Valid FDA Food Units of Measure for Packaging Containers

Code	*Description*
AE	Aerosol

AM	Ampoule, Non-Protected
AP	Ampoule, Protected
AT	Atomizer
BA	Barrel (Container)
BB	Bobbin
BC	Bottlecrate, Bottlerack
BE	Bundle
BF	Balloon, Non-Protected
BG	Bag
BH	Bunch
BI	Bin
BJ	Bucket
BK	Basket
BL	Bale, Compressed
BN	Bale, Non-Compressed
BO	Bottle, Non-Protected,Cyl
BP	Balloon, Protected
BQ	Bottle, Protected, Cylnd
BR	Bar
BS	Bottle, Non-Prot Bulbous
BU	Butt
BV	Bottle, Protected Bulbous
BX	Box
BZ	Bars in Bundle/Bunch/Trus
CA	Can, Rectangular
CAG	Cage
CB	Crate, Beer
CC	Churn
CE	Creel
CF	Coffer
CH	Chest
CI	Canister
CJ	Coffin
CK	Cask
CL	Coil
CO	Carboy, Non-Protected
CON	Container
CP	Carboy, Protected
CR	Crate
CS	Case
CT	Carton
CU	Cup
CV	Cover

CX	Can, Cylindrical
CY	Cylinder
CZ	Canvas
DJ	Demijohn, Non-Protected
DP	Demijohn, Protected
DR	Drum
EN	Envelope
FC	Crate, Fruit
FD	Crate, Framed
FI	Firkin
FL	Flask
FO	Footlocker
FR	Frame
GB	Bottle, Gas
HG	Hogshead
HR	Hamper
JC	Jerrican, Rectangular
JG	Jug
JR	Jar
JT	Jutebag
JY	Jerrican, Cylindrical
KEG	Keg
KIT	Kit
MB	Bag, Multi-ply
MC	Crate, Milk
MS	Sack, Multiwall
MT	Mat
NE	Unpacked Or Unpackaged
NS	Nest
NT	Net
PA	Packet
PAL	Pallet
PC	Parcel
PH	Pitcher
PK	Package
PL	Pail
PO	Pouch
PT	Pot
PU	Tray or Tray Pack
PY	Plates in Bndl/Bnch/Truss
RG	Ring
RO	Roll
SA	Sack

SC	Crate, Shallow
SD	Spindle
SE	Sea-chest
SH	Sachet
SK	Case, Skeleton
SL	Slipsheet
SU	Suitcase
SW	Shrinkwrapped
SZ	Sheets in Bndl/Bnch/Truss
TB	Tub
TC	Tea-Chest
TD	Tube, Collapsible
TK	Tank, Rectangular
TN	Tin
TO	Tun
TR	Trunk
TS	Truss
TU	Tube
TY	Tank, Cylindrical
TZ	Tubes in Bndl/Bnch/Truss
VA	Vat
VG	Bulk Gas at 1031 MBAR
VI	Vial
VL	Bulk Liquid
VO	Bulk,Solid,Lg Particles
VP	Vacuum-packed
VQ	Bulk Liquified Gas
VR	Bulk,Solid,Granular Parti
VY	Bulk,Solid,Fine Particle
WB	Wickerbottle

Valid FDA Food Units of Measure for the Base Unit (Last Quantity Transmitted)

Code	***Description***	***Measure Type***
BBL	Barrels (42 Gallons Ea)	Volume
BOL	Boluses	Dosage
CAR	Carats	Weight
CAP	Capsules	Dosage
CFT	Cubic Feet	Volume
CG	Centigrams	Weight
CM3	Cubic Centimeters	Volume

CYD	Cubic Yards	Volume
DOZ	Dozen	Count
DPC	Dozen Pieces	Count
DPR	Dozen Pairs	Count
FOZ	Ounces, fluid	Volume
G	Grams	Weight
GAL	Gallons (US)	Volume
GR	Gross	Count
KG	Kilograms	Weight
KM3	1,000 Cubic Meters	Volume
L	Liters	Volume
LB	Pounds (avdp)	Weight
M3	Cubic Meters	Volume
MCG	Micrograms	Weight
MG	Milligrams	Weight
ML	Milliliters	Volume
NO	Number	Count
OZ	Ounces, weight (avdp)	Weight
PCS	Pieces	Count
PRS	Pairs	Count
PTL	Pints, liquid (US)	Volume
QTL	Quarts, liquid (US)	Volume
STN	Short ton (2000 LB)	Weight
T	Metric Ton	Weight
Tab	Tablets	Dosage
TON	Long Ton (2240 LB)	Weight
TOZ	Ounces, Troy or Apoth	Weight

Note 4
Quantity Data provides additional information to FDA about the product and how it is packaged. The basic format for Quantity Data is in multiple pairs of data – quantity and unit of measure, i.e., 500 cases, 12 ounces, fluid, 1000 cartons, etc. Up to 6 data pairs may be submitted, beginning with the 1st pair for the outermost packaging when Packaging Qualifier = 1. The first pair may describe the largest container and the last pair must describe the amount of product in the smallest container. For example:
Product: 1000 cases of mineral water, 24/12 ounce bottles in each case
Packaging Qualifier =1: 1000 CS (Case)
Packaging Qualifier =2: 24 BO (Bottle, Non-protected, Cyl)
Packaging Qualifier =3: 12 FOZ (Ounces, fluid)

Record Identifier PG27 (Container Information)

For Prior Notice, this is a conditional PGA input record that provides data pertaining to the Rail Car or Container Number. Data provided should match the Container number info included in the Bill of Lading.

Record Identifier PG27 (Container Information)					
Data Element	**Length/ Class**	**Position**	**Status**	**Description**	**Note**
Control Identifier	2A	1-2	M	“PG”.	
Record Type	2N	3-4	M	“27”.	
Container Number (Equipment ID)	20AN	5-24	C	The number of the shipping container (CNO) or Rail Car (RNO) as entered in the Bill of Lading based on the Mode of Transportation (MOT). This is applicable for food arriving as containerized cargo by water, air, rail, or land, the container number(s) is required for prior notice.	
Filler	7X	74-80	M	Space fill	

Record Identifier PG28 (Express Courier Tracking Number)

For Prior Notice if the Mode of Transportation is mail or express courier then Package Tracking Number Code and Package Tracking Number are conditionally required, i.e. may be submitted in PG28 in lieu of the airway bill or bill of lading and in lieu of the flight number in PG23.

Record Identifier PG28 (Input)					
Data Element	**Length/ Class**	**Position**	**Status**	**Description**	**Note**
Control Identifier	2A	1-2	M	"PG".	
Record Type	2N	3-4	M	"28".	
Package Tracking Number Code	3AN	17-19	C	Code indicating the tracking number used. • UPS = UPS • FEX = FedEx • DHL = DHLITN = International Tracking Number	1
Package Tracking Number	50AN	20-69	C	Tracking numbers used by FedEx, UPS, DHL, etc.	1

Note 1:

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 Airway Bill number(s) or Bill of Lading number(s), and in lieu of the flight number in PG23.

Record Identifier PG30 (Anticipated Arrival Info)

This is a mandatory PGA input record that provides data pertaining to the date, time and location of the anticipated arrival information for all FDA products. While other PGAs may use PG30 to Collect Inspection and Lab information, currently FDA will utilize this record to collect Anticipated Arrival Information at this time.

For Prior Notice, this is a mandatory PGA input record that provides data pertaining to the date, time and location of anticipated arrival information for FDA BTA.

Record Identifier PG30 (Input)					
Data Element	**Length /Class**	**Position**	**Status**	**Description**	**Note**
Control Identifier	2A	1-2	M	Must always equal PG.	
Record Type	2N	3-4	M	Must always be 30.	
Inspection/ Laboratory Testing Status	1A	5	M	A is the ONLY valid code for FDA:: A = Anticipated arrival information	1
Anticipated Arrival date	8N	6-13	M	A numeric date in MMDDCCYY (month, day, century, year) format.	2
Anticipated Arrival time	4N	14-17	M	Military time HHMM in (hour, minute) format. (Example: 1015, this represents 10:15 a.m.). For midnight, use 2400 (0000 is invalid).	2
Arrival Location Code	4AN	18-21	M	For valid port codes, refer to note 3.	3
Arrival Location	50X	22-71	O	Code or free form text indicating site of inspection or arrival.	3
Filler	9X	72-80	M	Space fill	

Note 1:
Status Code A to indicate BTA Anticipated Arrival information.

Note 2:
Indicates BTA Anticipated Date and Time of Arrival information.

Note 3:
Refer to List of Valid Port Codes:
http://www.cbp.gov/sites/default/files/documents/CBP%20Port%20Codes%20041014_1.pdf

Record Identifier PG55 (Additional Roles)

For Prior Notice, this is an optional input record used to provide additional roles performed by an entity or individual identified in PG19.

The PG55 record is not supported by FDA at this time. Multiple PG19 records should be used to input more than one Entity-Role combination. Refer to the PG19 section for details.

Record Identifier PG55 (Input)					
Data Element	**Length /Class**	**Position**	**Status**	**Description**	**Note**
Control Identifier	2A	1-2	M	Must always equal PG.	
Record Type	2N	3-4	M	Must always be 55.	
Entity Role Code	3AN	5-7	C	Additional role of the entity.	
Entity Role Code	3AN	8-10	C	Additional role of the entity.	
Entity Role Code	3AN	11-13	C	Additional role of the entity.	
Entity Role Code	3AN	14-16	C	Additional role of the entity.	
Entity Role Code	3AN	17-19	C	Additional role of the entity.	
Entity Role Code	3AN	20-22	C	Additional role of the entity.	
Entity Role Code	3AN	23-25	C	Additional role of the entity.	
Entity Role Code	3AN	26-28	C	Additional role of the entity.	
Entity Role Code	3AN	29-31	C	Additional role of the entity.	
Entity Role Code	3AN	32-34	C	Additional role of the entity.	
Filler	46X	35-80	M	Space fill.	

Record not supported by FDA at this time

Record Identifier PG00 (Data Substitution)

This is an optional record used at the CBP entry (or entry summary) header, CBP entry (or entry summary) line and/or PGA message set levels to indicate data substitution

Record Identifier PG00 (Data Substitution)					
Data Element	**Length /Class**	**Position**	**Status**	**Description**	**Note**
Control Identifier	2A	1-2	M	“PG”.	
Record Type	2N	3-4	M	“00”.	
Substitution Indicator	1X	5	O	Identifies either the start or end of the substitution group, or the location of where to place the substitute data within the PGA Message Set. The following codes are allowed: S=Start of the substitution group E=End of the substitution group R=Replace this record with the substitution group indicated by the Substitution Number	
Substitution Number	4AN	6-9	O	Sequential number assigned to, or referring to, a specific substitution group of data provided at the header level. This data element is mandatory when using the S or R substitution indicator.	
Filler	71X	10-80	M	Space fills.	

Food Commodity Combined Entry Submission - Data Elements and Values

In this scenario both 801a and 801m data elements will be submitted as a single message for an Entry.
Food commodities can be broken down into the following categories using the existing Government Agency data elements available in the PG01 message

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

Table 4b – Food commodity hierarchy

This chapter describes the data elements and their business rules for a 801A entry, with the Government Agency Program Code = 'FOO', which may be subject to PN regulations. To satisfy the PN requirements in a combined entry (801a and 801m), a PG14 record may be included in the combined entry in addition to all applicable PG records described in this chapter.

The following are the potential PGA records associated with submitting Foods with PN processing:

PG Record	Description
OI	Record Identifier (The commercial description of the shipment is provided)
PG01	PGA Identifier (The shipment is regulated by the FDA program office within FDA and the intended use is provided)
PG02	Product Identifier (The item type and the FDA Product Code details are provided)
PG05	Scientific Genus Name (Optional information related to the scientific species name and code)
PG06	Product Origin (FDA Country of Production, Shipment, and Refusal)
PG07	Product Trade Name (Conditional submission of product market name)
PG10	Product Characteristics (Line level item common/usual name)
PG13	License Plate Issuer [Privately Owned Vehicle (POV) Information]
PG14	License Plate Number [Privately Owned Vehicle (POV) Information]
PG19	Entity Data (Trade entity's Transaction Role, Identification Type, Identification Number, and 1st line of address)

PG Record	Description
PG20	Entity Address (Continuation of Entity information including Address line 2, City, State/Province, Country for entities provided in PG19)
PG21	Point of Contact [Individual (POC) Information including Name, Phone Number, FAX Number, Email address for trade entities]
PG23	Affirmation of Compliance [FDA's Affirmation of Compliance (AofC) Criteria including food facility registration, specific PN information, and other food related codes]
PG24	Remarks (Continuation of POC name as necessary)
PG25	Product Condition (Temperature qualifier, Lot#, Production dates, PGA Line Value and PGA Unit Value are provided)
PG26	Product Packaging (Packaging qualifier and quantity of the shipment are provided)
PG27	Container Number
PG28	Express Courier Tracking (Number) and Can Dimensions(LACF Only) **§**
PG29	Unit of Measure (Data pertaining to the net or gross unit of measure of the commodity)
PG30	Anticipated Arrival Information
PG55	Additional roles performed by entity or individual (future use)
PG00	Data Substitution

§ CBP confirmed that the SE header can only be used to submit express courier tracking numbers in the air environment. Therefore, all express courier tracking numbers for PNs in the air environment should be submitted in the SE. Express courier tracking numbers for PNs for food shipments in the ground environment are to be reported in the PG28.

Prior Notice Non-PGA Data Elements by Mode of Transportation (See Note)

MOT	Required Data Elements	Mapping	Mapping - Data Elements
AIR	IATA	SE15	Carrier
	Airway Bill Number	SE15	Ref Qual Code = AWB, Ref ID Num
	Flight Number	PG23	AofC - VFT - Voyage/Flight/Trip Number
	Container Number	PG27	Container Number
	Carrier Name	PG23	AofC - CAN - Carrier Name
OCEAN	Bill of Lading	SE15	Ref. Qual. Code 'BIL,' Bill Type Indicator 'R,' and report the Simple Bill of Lading Number in the Reference Identifier Number field
	Vessel Name	PG23	AofC – VES – Vessel Name
	Voyage Number	PG23	AofC - VFT - Voyage/Flight/Trip Number
	Container Number	PG27	Container Number
	Carrier Name	PG23	AofC - CAN - Carrier Name
LAND - Bus, Truck	Bill of Lading	SE15	Ref. Qual. Code 'BIL,' Bill Type Indicator 'R,' and report the Simple Bill of Lading Number in the Reference Identifier Number field
	Trip Number	PG23	AofC - VFT - Voyage/Flight/Trip Number
	SCAC	SE15	Carrier
	Container Number *	PG27	Container Number
	Carrier Name	PG23	AofC - CAN - Carrier Name
LAND - Rail	Bill of Lading	SE15	Ref Qual Code = BIL, Ref ID Num
	Trip Number	PG23	AofC - VFT - Voyage/Flight/Trip Number
	SCAC	SE15	Filer/SCAC Code, Ref ID Num
	Rail Car Number	PG23	AofC – RNO - Rail Car Number
	Container Number *	PG27	Container Number
Express Consignment Carrier	Tracking Number	PG28	Report Express Courier tracking number for the shipment as applicable.
	Carrier Name	PG23	AofC - CAN - Carrier Name

* if applicable

Note: The above table makes references to select entry-level data elements from the SE15 to provide the context and to identify from which data source FDA expects to receive a number of the required prior notice data elements for the specific modes of transportation. For additional information on the data elements found within the SE15 record, please refer to the relevant CBP documentation. This supplemental guidance document describes only line-level data within the structure of the FDA PG Message Set.

Prior Notice Combined Entry Example

Prior Notice Combined Entry message set layout sample below:

Please refer to the external file: **FDA SG 2.4 Example PG Message Sets.xlsx** Tab: ***FOO+PN***

Because of the flexibility of the PGA Message set, the PGA Records and Data Elements that are required may vary both from program to program and within a single program. For a more expansive set of examples of FDA PGA Message Sets, please refer to the above document.

Record Identifier OI (Record Identifier)

This is a mandatory PGA line item description input record that provides the general commercial description of the item. This record precedes the Record Identifiers for the PGA Message set.

Record Identifier OI					
Data Element	**Length/ Class**	**Position**	**Status**	**Description**	**Note**
Control Identifier	2A	1-2	M	“OI”	
Filler	8X	3-10	M	Space filled.	
Commercial Description	70X	11-80	M	The commercial description of the product. For example, NATURE’S FINEST REAL FRUIT JUICE, 12 OUNCE BOTTLES	

Record Identifier PG01 (PGA Identifier)

This is a mandatory PGA input record that provides data pertaining to the PGA Line Number, Government Agency Code, Government Agency Program Code, Globally Unique Product Identification Code, Intended Use Code, Intended Use Description, and Disclaimer. The Intended Use Code allows FDA to identify whether the imported commodity is restricted by a consumption allowance or not.

Record Identifier PG01 (PGA Identifier)					
Data Element	**Length/ Class**	**Position**	**Status**	**Description/Required Value**	**Note**
Control Identifier	2A	1-2	M	"PG"	
Record Type	2N	3-4	M	"01"	
PGA Line Number	3N	5-7	M	"001"	
Government Agency Code	3AN	8-10	M	"FDA"	
Government Agency Program Code	3X	11-13	C	"FOO"	1
Government Agency Processing Code	3AN	14-16	C	Allowed values: NSF, PRO, FEE, ADD, DSU, CCW	1
Intended Use Code	16X	42-57	O		2
Intended Use Description	22X	58-79	O		2
Disclaimer	1A	80	C	A code of A (= product is not regulated by this agency) or B (= data is not required per agency guidance) indicating there is no agency declaration requirement. Or this field is left blank for no disclaimer. No other code is accepted	

Refer to Table 4b above for commodity type and sub-type for Food.

Note 1
If the Disclaimer is 'A' or 'B' then these data elements should both be populated with FDA. otherwise the Government Agency Program Code, Government Agency Processing are mandatory.

Note 2
Choose one of these intended use codes based on the product requirements. The submission of an Intended use code is not a requirement for prior notice.

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

Record Identifier PG02 (Product Identifier)

This mandatory PGA input record is used to indicate whether or not the information being provided relates to a product (P) or a component (C) of a product.

Record Identifier PG02 (Product Identifier)					
Data Element	**Length/ Class**	**Position**	**Status**	**Description**	**Note**
Control Identifier	2A	1-2	M	"PG"	
Record Type	2N	3-4	M	"02"	
Item Type	1A	5	M	Code identifying the following records as pertaining to P=Product. No other values accepted. Only one 'P' record is allowed for the same PGA Line # in PG01.	
Product Code Qualifier	4AN	6-9	M	"FDP"	1
Product Code Number	19X	10-28	M	FDA Product Code Must be equal to 7 characters	

Note 1

Product Code Qualifiers and their descriptions can be found in Appendix PGA (PG02 – Product Code Qualifiers) of the ACE ABI CATAIR publication. For Food commodity, this is currently always 'FDP' for all FDA products.

Only one Product Code Number per product is allowed.

FDA Product Code Structure:

Position	1-2	3	4	5	6-7
Name	Industry Code (N)	Class Code (A)	Sub Class Code (A or '-')	Process Identification Code - PIC (A or '-')	Group Code (AN)

Legend - N: Numeric; A:Alphabetic; AN:AlphaNumeric

A product is subject to Prior Notice requirements if the following condition is satisfied.

```
if industry_code IN ('48','49', '69', '70', '71', '72')
OR if industry_code BETWEEN '01' and '46'
OR if (industry_code+class_code+group_code) in ('52D01','52D99')
OR if (industry_code+class_code+group_code) in ('50A01','50B01')
OR if (industry code ='50' and class_code in ('C', 'D', 'E', 'F', 'G', 'L')
OR if  (industry_code = '54' and subclass_code in ('A','B','C','L','M','Y'))
```

Record Identifier PG05 (Scientific Genus Names)

This is an optional PGA input record that provides data pertaining to Scientific Genus Names, Scientific Species, Scientific Sub Species Name, Scientific Species Code, and FWS Description Code.

Record Identifier PG05 (Scientific Genus Names)					
Data Element	**Length/ Class**	**Position**	**Status**	**Description**	**Note**
Control Identifier	2A	1-2	O	“PG”.	
Record Type	2N	3-4	O	“05”.	
Scientific Genus Name	22X	5-26	O	Scientific Genus Name of the merchandise being entered.	
Scientific Species Name	22X	27-48	O	Scientific Species Name of the merchandise being entered.	
Scientific Sub Species Name	18X	49-66	O	Scientific Sub Species Name of the merchandise being entered.	

Record Identifier PG06 (Product Origin)

For Prior Notice, this is a mandatory input record that provides data pertaining to Source Type (FDA country of production/growth and country from which the article was shipped) for the article of food. This record also provides the conditional PN data concerning the Country or Countries) who previously refused entry of the article of food. This record can be repeated to submit the countries required for PN as described in Note 1.

Record Identifier PG06 (Product Origin)					
Data Element	**Length/ Class**	**Position**	**Status**	**Description**	**Note**
Control Identifier	2A	1-2	M	"PG".	
Record Type	2N	3-4	M	"06".	
Source Type Code	3AN	5-7	M	Source Type Code must be selected using the following logic. 1) IF Government Agency Program Code = FOO and Government Agency Processing Code = NSF then use 262 (Place of growth) ELSE Source Type Code can be 39 (Country of Production). IF Government Agency Program Code = FOO, THEN Country of Shipment CSH is required. IF Government Agency Program Code = FOO then Country of Entry Refusal 294 is required, if previously refused from other country(s)	1
Country Code	2X	8-9	M	Foods require the harvesting or production location of the product.	2

Note 1
Source Type Code from Appendix PGA, PG06 – Source Type Codes may be entered.
Prior Notice requires the following data elements:

Country of Shipment, Source Type Code = CSH (required for Prior Notice)
All Natural State Human Food and Animal Food requires the

- **Country of Growth,** Source Type Code = 262 - if made from fish/seafood aboard a vessel = country in which the vessel is registered.

Non-Natural State Human Food and Animal Food requires the

- **Country of Production**, Source Type Code = 39- if made from fish/seafood aboard a vessel = country in which the vessel is registered.

Country of Entry Refusal, if the article of food has been refused by other country(ies), provide the ISO country code(s) and. (Source Code Type = 294)

Note 2
ISO Country codes from Appendix D (ISO Country and Currency Codes) in the ACS ABI CATAIR must be entered.

Record Identifier PG07 (Product Trade Names)

This is an optional PGA input record that provides data pertaining to Trade or Brand Name.

Record Identifier PG07 (Product Trade Names)					
Data Element	**Length/ Class**	**Position**	**Status**	**Description**	**Note**
Control Identifier	2A	1-2	C	“PG”	
Record Type	2N	3-4	C	“07”	
Trade Name/Brand Name	35X	5-39	O	Market, Trade, or Brand Name that describes the food or feed product at each line level	

.

Record Identifier PG10 (Product Characteristics)

For Food, this is a mandatory PGA input record that allows for importer to report the description of the product at the line level to capture the information currently collected in multiple OI records. This record can be repeated if there are more Commodity Characteristic Descriptions.

Record Identifier PG10 (Product Characteristics)					
Data Element	**Length/ Class**	**Position**	**Status**	**Description**	**Note**
Control Identifier	2A	1-2	M	“PG”.	
Record Type	2N	3-4	M	“10”.	
Commodity Characteristic Description	57X	24-80	M	Common, market or usual name or description, NOT product code description of the product. Free form description of the item.	1

Record Identifier PG13 (License Plate Issuer)

For Prior Notice, this is a conditional input record that provides data pertaining to Licenses, Permits, Certificates or Other (LPCO). For Prior Notice submission, this PG record is only required when the carrier is a privately owned vehicle and does not have a SCAC or IATA. For this situation, this PG record allows for the submission of some of the license plate information for the subject privately owned vehicle. The data elements included in this record are Issuer and location of issuer of the LPCO. If using this record, a PG14 and PG23 (Carrier Name – CAN) are mandatory.

Record Identifier PG13 (Input)					
Data Element	**Length/ Class**	**Position**	**Status**	**Description**	**Note**
Control Identifier	2A	1-2	M	Must always equal PG.	
Record Type	2N	3-4	M	Must always be 13.	
Issuer of LPCO	35X	5-39	O	Identifies the entity that issued the LPCO.	1
LPCO Issuer - Government Geographic Code Qualifier	3A	40-42	C	The code relating to the location of the issuer of the POV license plate. Select one: Canadian Province = PR Country Code = ISO Mexican State = MS US State = US	1
Location (Country/State/Province) of Issuer of the LPCO	3A	43-45	C	Identifies the location of the issuer of the POV license plate (ex: the US, Mexico or Canadian Province/State code or Foreign Country Code). Enter the appropriate code from Appendix B in the ACS ABI CATAIR.	1
Regional description of location of Agency Issuing the LPCO	25X	46-70	C	This description allows for the submission of a License Plate Issuer location when the Issuer is reported as an ISO and State or Province other than those from the US, Canada, or Mexico.	1
Filler	10X	71-80	M	Space fill	

Note 1

When the Carrier or the Transport Means Owner does not have SCAC or IATA, the following data requirements Prior Notice's privately owned vehicle (POV) license plate information should be submitted using PG13 and PG14.

License Plate Number	**PG14 –** LPCO Number
License State (US)	**PG13** - LPCO Issuer - Location (Country/State/Province) of Issuer of the LPCO
License Province	**PG13** - LPCO Issuer - Location (Country/State/Province) of Issuer of the LPCO
License Country	**PG13** - LPCO Issuer - Government Geographic Code Qualifier

Record Identifier PG14 (License Plate Number)

As applicable for Prior Notice where the carrier is a privately owned vehicle, provide the Privately Owned Vehicle license plate information.

Record Identifier PG14 (Input)					
Data Element	**Length /Class**	**Position**	**Status**	**Description**	**Note**
Control Identifier	2A	1-2	M	Must always equal PG.	
Record Type	2N	3-4	M	Must always be 14.	
LPCO Transaction Type	1N	5	O	Leave blank - not required (reserved for future use)	
LPCO Type	3AN	6-8	C	Identifies Type Code for Privately Owned Vehicle license plate number as applicable. Use “POV” for Type	1
LPCO Number (or Name)	33X	9-41	C	Privately Owned Vehicle license plate number.	

Note 1

This information is only required in cases where the carrier is a privately owned vehicle, and PG 13 is used to report the issuer of the license plate, provide the Privately Owned Vehicle license plate information.

Record Identifier PG19 (Entity Data)

For Foods, this is a mandatory PGA input record that provides FDA with data pertaining to Entity Role and conditionally the following data elements; Entity Identification, Entity Name, and Entity Address 1.

Record Identifier PG19 (Input)					
Data Element	**Length /Class**	**Position**	**Status**	**Description**	**Note**
Control Identifier	2A	1-2	M	"PG"	
Record Type	2N	3-4	M	"19"	
Entity Role Code	3X	5-7	M	Code identifying the role of the entity being provided. For example: MF, UC	1
Entity Identification Code	3X	8-10	C	Code identifying the Entity Type is entered. For example: 16 (DUNS), 47 (FEI) . Mandatory, if Entity Number is entered.	2
Entity Number	15X	11-25	O	The Entity Number of the entity based on the above Entity Identification Code is entered; must conform to the descriptions in Note 2	2
Entity Name	32X	26-57	M	The name of the entity is entered. See validation criteria below.	2
Entity Address 1	23X	58-80	C	Conditional only for the PN Transmitter and PN Submitter entities if a Food Facility Registration number is included in PG23. Mandatory for all other required entities. See Note 1 for validation criteria below.	1, 2

Note 1

Entity Role Codes and their descriptions can be found in Appendix PGA (PG19 – Entity Role Codes) of the ACE ABI CATAIR publication. List of Entity Role codes **MANDATORY** to FDA Prior Notice Message Sets is below:

Data Element	***Code***	***Description***	***Condition***
Entity Role Codes[§]	PNS	PN Submitter[1]	Provide DUNS, FEI number and/or full address in PG19 and PG20 or if the facility is registered you may provide the Submitter's FDA Food Facility Registration number in PG23, with the Name, City, and Country in lieu of the full address in PG19 and PG20. POC person's name, phone, fax, email address information is required for all PN in PG21.
	PNT	PN Transmitter[1]	PN Transmitter is required if the PN is not transmitted by the PN Submitter. • Provide DUNS, FEI number and/or full address in PG19 and PG20 or if the facility is registered you may provide the Transmitter's FDA Food Facility Registration number in PG23, with the Name, City, and Country in lieu of the full address in PG19 and PG20 POC person's name, phone, fax, email address

Data Element	Code	Description	Condition
			information is required in PG21.
	MF[4] -or- FDC[4] -or- DFI[4]	Manufacturer[3]	Provide DUNS, FEI number and/or full address in PG19 and PG20 of the manufacturer or person (if individual) as required when the food /feed is NOT in its natural state. Although the PN submission allows you to provide the manufacturer's Food Facility Registration number in PG23, and the manufacturer's Name, City, and Country in PG19 and PG20 in lieu of the full address, the full address is required to satisfy FDA 801(a) requirements.
		FDA Consolidator[3]	Full address of the firm or person (if individual) who consolidated the articles of food from the grower(s) is required when the food/feed is in its natural state and the grower(s) is/are unknown. If registered you may provide the FDA Consolidator's Food Facility Registration number if available in PG23
		Grower[3]	If known, full address of the growing location of the grower or person (if individual) is required when the food/feed IS in its natural state. If registered you may provide the Grower's Food Facility Registration number if available in PG23
	DEQ	Shipper	Full address of Shipper is required for all PN. Provide DUNS, FEI number with full address in PG19 and PG20, and if registered you may provide the Shipper's Food Facility Registration number if available in PG23
	FD1	FDA Importer 1 (Importer of Record)	Full address of the Importer is required for all PN and entries. Provide DUNS, FEI number with full address in PG19 and PG20, and if registered you may provide the Importer's Food Facility Registration number if available in PG23
	DFP	Owner[2,]	Full address of the Owner is required for all PN. Provide DUNS, FEI number with full address in PG19 and PG20 and if registered you may provide the Owner's Food Facility Registration number in PG23.
	UC	Ultimate Consignee (Delivered to Party)[2,]	Full address of the UC is required for all PN and entries. Provide DUNS, FEI number with full address in PG19 and PG20, and if registered you may provide the Ultimate Consignee's Food Facility Registration number if available in PG23

§ Same Role Code cannot be entered more than once.

[1] The Entity Role of Submitter and Transmitter require the Firm/Entity info as well as a Point of Contact info which includes the Individual's Full Name, Phone Number(s), and Email Address in PG21.

[2] Ultimate Consignee (Deliver To Party – reference guidance) and Owner info is not required IF the entry line product is imported for transportation and exportation, i.e. T&E entry type.

[3] The PN regulation requires **ONE** of the following:
IF the food/feed is NOT in natural state THEN Manufacturer
IF the food/feed is in natural state THEN Grower
IF the food/feed is in natural state, and grower is unknown THEN Consolidator

[4] Only one of the Entity Role Codes MF/FDC/DFI is permitted. If AoC codes are entered along with one of these PG19 entity role codes, then only a PFR or FME shall be used along with MF; only a GFR may be used in conjunction with DFI; and only a CFR may be used in conjunction with FDC.

Even though Title 19 141.19 (CBP) addresses - Consignee -, Title 21, Requires Prior Notice information about the - Ultimate Consignee - and Title 19 (CBP) defines - Ultimate Consignee -, FDA acknowledges that these terms cause confusion and would like to simplify and harmonize said data elements under the ACE environment.

Hence, the FDA has elected to utilize the data element --- "Deliver to Party" ---, U.S party that physically receives the good(s). The FDA's PG Message Set will, therefore, incorporate the deliver to party as issued in the ITDS Standard Data Set under the auspices of the ITDS Board of Directors. FDA's Prior Notice requirement for ultimate consignee is synonymous with deliver to party.

List of Entity Role codes that are **CONDITIONALLY REQUIRED** to FDA Prior Notice Message Sets is below:

Data Element	*Code*	*Description*	*Condition*
Entity Role Codes			
	LG	Location of Goods Immediately after Entry Release	Location of Goods Immediately after Entry Release

List of Entity Role codes **MAY BE APPLICABLE** to FDA Prior Notice Message Sets is below. These codes may not be used as a substitute for the mandatory or conditional entities listed above.

Data Element	*Code*	*Description*
Entity Role Codes	PK[1]	Point of Contact Any other additional POC's information may be provided using the Role Code PK. This is in lieu of IATA or SCAC information.

[1] For role code PK, PG20 and PG21 would be required in order to submit the complete address (PG19, PG20) and name (PG21) of the individual. Also, Phone, Fax Number, Email address (PG21) may be additionally required depending on the individual's role in the Entry process.

Note 2

Entity Identification Codes and their descriptions can be found in Appendix PGA (PG19 – Entity Identification Codes) of the ACE ABI CATAIR publication. List of Entity Identification codes applicable to FDA Prior Notice Message Sets is below:

Data Element	***Code***	***Description***	***Length/ Class***
Entity Identification Codes[1]	16	D&B-assigned (DUNS number)	9N
	47	FDA-assigned (FEI number)	4- 10N

For PN (801m) purposes, FDA always requires Entity Name but the Entity Address 1 for Manufacturer, PN Submitter and PN Transmitter is optional if an Food Facility Registration number is included in PG23. However, for Manufacturer, Entity Address 1 is required to satisfy 801a regulations. Additionally, FDA prefers to use DUNS numbers for identifying the Entity; IF DUNS is not available THEN FEI.

Entity Name <>NULL AND Entity Address 1 <>NULL AND
IF Entity Identification Code =16 (DUNS) THEN Entity Number MUST BE Length = 9 and Type = N
ELSE IF Entity Identification Code =47 (FEI) THEN Entity Number MUST BE Length from 4 to 10 and Type = N

Record Identifier PG20 (Entity Address)

This is a mandatory PGA input record that provides additional data pertaining to the Entity identified in the preceding PG19 record; such as Entity Address line 2, Apartment/Suite, City, State, and Zip/Postal Code. This record is used when additional address for the entity needs to be entered.

Record Identifier PG20 (Entity Address)					
Data Element	**Length/ Class**	**Position**	**Status**	**Description**	**Note**
Control Identifier	2A	1-2	M	“PG”	
Record Type	2N	3-4	M	“20”	
Entity Address 2	32X	5-36	C	Address Line 2 for the Entity.	1
Entity Apartment Number/Suite Number	5X	37-41	C	For example, 102 A.	1
Entity City	21X	42-62	M	For example, SUGARLAND	
Entity State/Province	3AN	63-65	C	For example, TX.	2
Entity Country	2A	66-67	M	For example, US.	
Entity Zip/Postal Code	9X	68-76	C	For example, 77004.	2
Filler	4X	77-80	C	Space fill	

Note 1: If the Entity Address 1 in PG19 is longer than the allocated 23 characters then utilize these fields.

Note 2: Populated if US or Canada based entities

Record Identifier PG21 (Point of Contact)

This is a mandatory PGA input record that provides FDA with data about an Individual Point of Contact (POC) related to the Entity (the party) in the preceding PG19 record. Included in this record are the Individual Name, Telephone Number, Fax Number, and Email address. A typical example is a POC for the Filer.

At least one PG21 record is required.

Record Identifier PG21 (Point of Contact)					
Data Element	**Length/ Class**	**Position**	**Status**	**Description**	**Note**
Control Identifier	2A	1-2	M	"PG"	
Record Type	2N	3-4	M	"21"	
Individual Qualifier	3AN	5-7	M	Code identifying which entity the Point of Contact is related to. Use PK	1
Individual Name	23X	8-30	M	Name of the Individual. If the name will not fit, complete PG24 and fill out the remarks code (Individual name) and then enter the name in the remarks text field. For example, SMITH, JOHN	1,2,3
Telephone Number of the Individual	15X	31-45	M	For example, (713)555-8765 in US or (+65)9052-3529 in Singapore	1
Email Address or Fax Number for the Individual	35X	46-80	M	For example, T.FREDERI@OJANDMORE.COM.	1

Note 1

Prior Notice regulation requires PG21 data for the Entity Roles of *PN Submitter, and PN Transmitter*. Other condition where PG21 information is required for Prior Notice is specified in PG19 mandatory and conditional data sections.

Data Element	***Code***	***Description***
Entity Role Codes	PK	Point of Contact

Note 2

Individual's Name should have the following format:

Last Name, First Name Middle Name

Note 3

If the individual's Name is longer than 23 characters, then the **PG24 Remarks** records should be used to indicate the full name of the individual. Individual's Name should still follow the same format when using PG24:

Last Name, First Name Middle Name

Record Identifier PG23 (Affirmation of Compliance)

These are conditional or optional PGA input records that provide data pertaining to Food and Drug Administration Affirmation of Compliance Criteria. This record is typically only used by FDA. This record is repeatable.

Record Identifier PG23 (Affirmation of Compliance)					
Data Element	**Length/ Class**	**Position**	**Status**	**Description**	**Note**
Control Identifier	2A	1-2	M	"PG".	
Record Type	2N	3-4	M	"23".	
Affirmation of Compliance Code	5X	5-9	C	A code used to affirm compliance with FDA requirements. See Appendix PGA (Food & Drug Affirmation of Compliance Codes) of this publication for valid codes.	1, 2, 3, 4, 5
Affirmation of Compliance Qualifier	30AN	10-39	C	Text describing the information required by the PGA. This could include a number or a country code, etc. Also, see Appendix PGA (Food & Drug Affirmation of Compliance Qualifier Codes) of this publication for valid codes related to certain specific Affirmation of Compliance codes.	1

Note 1

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 **conditional** AoC codes for the FDA food **Prior Notice** Message Set is below:

Data Element	***Code***	***Description***	***Syntax***	***Business Rules***
Affirmation of Compliance Code	FME	Food Processing Facility Registration Exemption	Indicator	To be used when Food or Feed is no longer in its natural state or when PFR number is not provided. See Appendix D at the end of this document for valid codes Either FME or PFR is required in the case of Manufacturer or when consolidator/grower is entered in lieu of manufacturer for food in natural state. If both are submitted, FME is not used by the FDA.
	RNO	Rail Car Number		Required If MOT = Rail
	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

Data Element	Code	Description	Syntax	Business Rules
				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 VFT is also required if MOT = Rail or Truck
	VES	Vessel Name		Required If MOT = Ocean
	PFR	Manufacturers food facility registration number	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. See Appendix B of this document for valid codes If both FME and PFR are submitted, FME is not used by the FDA.

Note 2

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The list of **optional** AoC codes for the FDA food **Prior Notice** Message Set is below:

Data Element	Code	Description	Syntax	Business Rules
	SFR	Shippers food facility registration number	11N	Optional
	UFR	Ultimate consignee food facility registration number	11N	Optional
	IFR	Importers food facility registration number	11N	Optional
	TFR	Transmitter food facility registration number	11N	Optional
	ORN	Owners food facility registration number-	11N	Optional
	SRN	Submitters food facility registration number	11N	Optional
	CFR	FDA Consolidator food facility registration number	11N	optional
	GFR	Growers food facility registration number	11N	optional

Note 3

The list of **conditional** AoC codes for the FDA Food **(Non-PN)** Message Set is below:

Data Element	Code	Description	Syntax	Business Rules	Note
	FCE	Food Canning Establishment Number	7N or 10N	IF Government Agency Program Code = FOO AND the product is either LACF or AF THEN FCE may be entered. See Note 1.	5
	SID	Schedule Identifier Number		IF Government Agency Program Code = FOO AND the product is LACF or AF THEN AoC Code 'SID' may be entered. See Note 1.	5
	VOL	LACF/AF Volume		IF Government Agency Program Code = FOO AND the product is either LACF or AF THEN VOL IS ALLOWED. See Note 1.	5

Note 4

The list of **optional** AoC codes for the FDA Food **(Non-PN)** Message Set is below:

Data Element	Code	Description	Syntax	Business Rules	Note
Affirmation of Compliance Code	CCC	Chinese Ceramic Ware Factory Code	6AN	IF Government Agency Program Code = FOO AND Government Agency Processing Code = CCW THEN CCC IS ALLOWED	
	CCN	Carrier ISO Country Code	2A	ISO Country code	
	CIN	Color Identification Number	Text (30X max.)	IF Government Agency Program Code = FOO AND Government Agency Processing Code = ADD THEN CIN IS ALLOWED	
	ERR	Entry Review Requested	indicator only	ERR is just used as an indicator, no data will follow	
	FAP	Food Additive Petition Approval Number	6N	IF Government Agency Program Code = FOO AND Government Agency Processing Code = ADD THEN FAP IS ALLOWED	
	FCC	French Cheese Facility Certification Number	7N or 10N	IF Government Agency Program Code = FOO AND Government Agency Processing Code = PRO THEN FCC IS ALLOWED	
	IBP	Indian Black Pepper Certificate	text	IF Government Agency Program Code = FOO AND Government Agency Processing Code = NSF THEN IBP IS ALLOWED	
	IFE	Import For Export	indicator only		
	PKC	Package/Can Code		IF Government Agency	

Data Element	Code	Description	Syntax	Business Rules	Note
				Program Code = FOO THEN PKC IS ALLOWED	
	AIN	Food Additive Identification Number	6N or 8N or E+7N	IF Government Agency Program Code = FOO AND Government Agency Processing Code = ADD THEN AIN IS ALLOWED	
	JIF	Juice HACCP Importer Firm	7N or 10N	IF Government Agency Program Code = FOO AND the product is HACCP THEN JIF IS ALLOWED	
	SIF	Seafood HACCP Importer Firm	7N or 10N	IF Government Agency Program Code = FOO AND the product is HACCP THEN SIF IS ALLOWED	

Note 5:

Using the FDA Product Code in PG02, the following classifications are made where specific imported food/feed products require the submission of lot or code numbers or other identifier with prior notice. These include:

LACF and Acidified:

Industry Codes: 02-39, 41, 71, & 72
With Process Indicator Code (PIC): Acidified-**I**, Aseptic-**F**, Commercially Sterile-**E**

If the product is LACF, the can measurements (height and diameter) in PG28 must be provided unless both the FCE and SID are provided.

If Acidified Food (AF), one of the following must be provided unless FCE and SID are provided:

1. Can Measurements in PG28 (either height and diameter or height/length, width and thickness
2. Container Volume (VOL)

Record Identifier PG24 (Remarks)

This is an optional PGA input record that provides data pertaining to Remarks Codes, and Text of Remarks.

Remark Type Code should be either GEN or NAM.

If GEN, the PG24 is applicable to the preceding PG02. Only one GEN:PG24 is allowed per PG02 (this is to avoid multiple GEN:PG24 records without a guaranteed sequencing as intended by the filer). This may be expanded in future with sufficient sequencing control to receive multiple GEN:PG24 records in the same order in which the Filer entered remarks.

If NAM, the PG24 is applicable to the preceding PG21. This structure simply allows the entry of 68 characters in addition to 23 characters afforded by PG21 for the Individual Name field in PG21. When a NAM-PG24 is present, the Individual Name field in PG21 is concatenated with Remarks Text field in PG24, to the full name in the format "*Last Name, First Name Middle Name*" for a potential 91 characters. Only one NAM:PG24 is allowed per PG21.

Record Identifier PG24 (Input)					
Data Element	**Length /Class**	**Position**	**Status**	**Description**	**Note**
Control Identifier	2A	1-2	M	Must always equal PG.	
Record Type	2N	3-4	M	Must always be 24.	
Remarks Type Code	3X	5-7	C	A code indicating the type of remarks. Valid codes are listed in Appendix PGA (Remarks Type Code) of this publication. FDA uses either NAM or GEN as its valid values.	1
Remarks Text	68X	13-80	C	Free form text relevant to the shipment or the commodity.	

Note 1
If an individual's Name in the preceding PG21 is longer than 23 characters, the Remarks Type Code should be identified as NAM (Full name of the Individual) then the Remarks Text can be used to indicate the full name of that individual. Individual's Name should still follow the same format when using PG24, as following:

Last Name, First Name Middle Name

If submitting general comments then use the Remarks Type Code = GEN (General Remarks)

Record Identifier PG25 (Product Condition)

For Food, it is a mandatory PGA input record that provides data pertaining to: Temperature Qualifier, Degree Type, Actual Temperature, Lot Number, Production Date, Range of the Lot, PGA Line Value, and PGA Unit Value. This record is repeatable for multiple Lot Number Qualifiers and Lot Numbers but the line value MUST be included on each record. For Prior Notice, this is a conditional input record that provides data pertaining to: Lot Number required by FDA regulations for Infant formula, Acidified Foods, and LACF products.

Record Identifier PG25 (Product Condition)					
Data Element	**Length/ Class**	**Position**	**Status**	**Description**	**Note**
Control Identifier	2A	1-2	M	“PG”.	
Record Type	2N	3-4	M	“25”.	
Temperature Qualifier	1A	5	O	Temperature Category being reported for quality control or preservation purposes. A= Ambient, F=Frozen, D=Dry Ice, R=Refrigerated/Chilled, H=Fresh, U=Uncontrolled, P=Flashpoint	
Degree Type	1A	6	O	F = Fahrenheit, C = Celsius , K = Kelvin	
Negative Number	1A	7	O	If the actual temperature is in the negative numbers use an “X”.	
Actual Temperature	6N	8-13	O	Required if Degree Type is entered. Reported temperature. Two decimals places are implied.	
Location of Temperature Recording	1A	14	O	Identifies recorded temperature is for A=product, B=container and C= conveyance	
Lot Number Qualifier	1AN	15	C	Code of the entity that assigned the Lot number. 1 = Manufacturer and 3 = Grower . IF Government Agency Program Code = FOO and Government Agency Processing Code = NSF THEN Lot Number Qualifier = 3 ELSE Lot Number Qualifier = 1	
Lot Number	25X	16-40	C	The lot number that the manufacturer assigned to the product. Mandatory for Infant formula, Acidified Foods, and LACF products.	1
Production Start date of the Lot	8N	41-48	O	The date when the production for the Lot started. A numeric date in MMDDCCYY (month, day, century, year) format	
Production End Date of the Lot	8N	49-56	O	The date when the production for the Lot ended. A numeric date in MMDDCCYY (month, day, century, year) format.	
PGA Line Value	12N	57-68	M	The value associated with the PGA line number in whole dollars. It must be right-justified with preceding zeros. Must be greater than zero.	
PGA Unit Value	12N	69-80	O	The value of the lowest unit of measure reported in PG26. Two decimal places are implied. IF Government Agency Program Code = ‘FOO’ AND IF AoC Code = ‘IFE’	

				THEN this is MANDATORY	

Note 1:

Using the FDA Product Code in PG02, the following classifications are made where specific imported food/feed products require the submission of lot or code numbers or other identifier with prior notice. These include:

LACF and Acidified:

Industry Codes: 02-39, 41, 71, & 72
With Process Indicator Code (PIC): Acidified-**I**, Aseptic-**F**, Commercially Sterile-**E**

Infant Formula:

Industry Code: 40
With Class:

- C-Formula Prod (Baby)
- N-Ready to Feed Formula Product
- O-Liquid Concentrate Formula Product
- P-Powder Formula Products
- R-Infant Formula for Sample Testing (not for sale)

Record Identifier PG26 (Product Packaging)

For Food, this is a mandatory PGA input record that provides FDA with data pertaining to Packaging Qualifier, Quantity and Unit of Measure. This record can be repeated up to six (6) times, once for each unique packaging level. The first record is used to describe the largest (outermost) container and the number of containers at this packaging level. The second record is used to describe the contents of the next smallest container. If needed, qualifiers 2-6 are used in a similar manner (largest to smallest container). The final record must describe the actual amount of the product in the smallest container.

The appearance of any 'Packaging Qualifier' number level requires all levels under it to be represented. For instance, level 3 can't be present unless levels 1 and 2 are present.

Record Identifier PG26 (Product Packaging)					
Data Element	**Length /Class**	**Position**	**Status**	**Description**	**Note**
Control Identifier	2A	1-2	M	"PG"	
Record Type	2N	3-4	M	"26"	
Packaging Qualifier	1N	5	M	Code identifying the level of packaging. For example, 4. If reporting only one level, show the total quantity for the item and report that as level 1.	1, 4
Quantity	12N	6-17	M	"Quantity of the packaging level, For example, 000000000400. Must be greater than zero.	2, 4
Unit of Measure (Packaging Level)	5X	18-22	M	Type of packaging / packaging level. For example, BX.	3, 4

Note 1
This code identifies the level of packaging for the product. Valid values are 1, 2, 3, 4, 5 and 6: Outermost (largest=1) packages to the innermost (smallest=6) packages. There can be up to 6 levels of packaging.

Note 2
There are two implied decimal points when writing the quantity in Units of Measure for the Base Unit (Last Quantity Transmitted). In this example, 4 pieces are represented as 000000000400, with the nine leading zeroes as "fill" and two decimal places following the value. The quantity for packaging containers will be in whole numbers with no decimal places. The sample shows 1 carton containing 10 boxes and each box containing 4 pieces.

Note 3
List of Unit of Measure codes applicable to FDA-Devices Message Sets
For a full list of applicable Unit of Measure codes, please refer to Appendix F in this document or to the Appendix PGA (PG26 – Unit of Measure - Valid FDA Units of Measure for Packaging Containers) and Appendix PGA (PG26 – Unit of Measure -Valid FDA Units of Measure for the Base Unit (Last Quantity Transmitted)) of the CATAIR.

Valid FDA Food Units of Measure for Packaging Containers

Code	*Description*
AE	Aerosol
AM	Ampoule, Non-Protected
AP	Ampoule, Protected

AT	Atomizer
BA	Barrel (Container)
BB	Bobbin
BC	Bottlecrate, Bottlerack
BE	Bundle
BF	Balloon, Non-Protected
BG	Bag
BH	Bunch
BI	Bin
BJ	Bucket
BK	Basket
BL	Bale, Compressed
BN	Bale, Non-Compressed
BO	Bottle, Non-Protected,Cyl
BP	Balloon, Protected
BQ	Bottle, Protected, Cylnd
BR	Bar
BS	Bottle, Non-Prot Bulbous
BU	Butt
BV	Bottle, Protected Bulbous
BX	Box
BZ	Bars in Bundle/Bunch/Trus
CA	Can, Rectangular
CAG	Cage
CB	Crate, Beer
CC	Churn
CE	Creel
CF	Coffer
CH	Chest
CI	Canister
CJ	Coffin
CK	Cask
CL	Coil
CO	Carboy, Non-Protected
CON	Container
CP	Carboy, Protected
CR	Crate
CS	Case
CT	Carton
CU	Cup
CV	Cover
CX	Can, Cylindrical
CY	Cylinder

CZ	Canvas
DJ	Demijohn, Non-Protected
DP	Demijohn, Protected
DR	Drum
EN	Envelope
FC	Crate, Fruit
FD	Crate, Framed
FI	Firkin
FL	Flask
FO	Footlocker
FR	Frame
GB	Bottle, Gas
HG	Hogshead
HR	Hamper
JC	Jerrican, Rectangular
JG	Jug
JR	Jar
JT	Jutebag
JY	Jerrican, Cylindrical
KEG	Keg
KIT	Kit
MB	Bag, Multi-ply
MC	Crate, Milk
MS	Sack, Multiwall
MT	Mat
NE	Unpacked Or Unpackaged
NS	Nest
NT	Net
PA	Packet
PAL	Pallet
PC	Parcel
PH	Pitcher
PK	Package
PL	Pail
PO	Pouch
PT	Pot
PU	Tray or Tray Pack
PY	Plates in Bndl/Bnch/Truss
RG	Ring
RO	Roll
SA	Sack
SC	Crate, Shallow
SD	Spindle

SE	Sea-chest
SH	Sachet
SK	Case, Skeleton
SL	Slipsheet
SU	Suitcase
SW	Shrinkwrapped
SZ	Sheets in Bndl/Bnch/Truss
TB	Tub
TC	Tea-Chest
TD	Tube, Collapsible
TK	Tank, Rectangular
TN	Tin
TO	Tun
TR	Trunk
TS	Truss
TU	Tube
TY	Tank, Cylindrical
TZ	Tubes in Bndl/Bnch/Truss
VA	Vat
VG	Bulk Gas at 1031 MBAR
VI	Vial
VL	Bulk Liquid
VO	Bulk,Solid,Lg Particles
VP	Vacuum-packed
VQ	Bulk Liquified Gas
VR	Bulk,Solid,Granular Parti
VY	Bulk,Solid,Fine Particle
WB	Wickerbottle

Valid FDA Food Units of Measure for the Base Unit (Last Quantity Transmitted)

Code	***Description***	***Measure Type***
BBL	Barrels (42 Gallons Ea)	Volume
BOL	Boluses	Dosage
CAR	Carats	Weight
CAP	Capsules	Dosage
CFT	Cubic Feet	Volume
CG	Centigrams	Weight
CM3	Cubic Centimeters	Volume
CYD	Cubic Yards	Volume
DOZ	Dozen	Count

DPC	Dozen Pieces	Count
DPR	Dozen Pairs	Count
FOZ	Ounces, fluid	Volume
G	Grams	Weight
GAL	Gallons (US)	Volume
GR	Gross	Count
KG	Kilograms	Weight
KM3	1,000 Cubic Meters	Volume
L	Liters	Volume
LB	Pounds (avdp)	Weight
M3	Cubic Meters	Volume
MCG	Micrograms	Weight
MG	Milligrams	Weight
ML	Milliliters	Volume
NO	Number	Count
OZ	Ounces, weight (avdp)	Weight
PCS	Pieces	Count
PRS	Pairs	Count
PTL	Pints, liquid (US)	Volume
QTL	Quarts, liquid (US)	Volume
STN	Short ton (2000 LB)	Weight
T	Metric Ton	Weight
Tab	Tablets	Dosage
TON	Long Ton (2240 LB)	Weight
TOZ	Ounces, Troy or Apoth	Weight

Note 4

Quantity Data provides additional information to FDA about the product and how it is packaged. The basic format for Quantity Data is in multiple pairs of data – quantity and unit of measure, i.e., 500 cases, 12 ounces, fluid, 1000 cartons, etc. Up to 6 data pairs may be submitted, beginning with the 1st pair for the outermost packaging when Packaging Qualifier = 1. The first pair may describe the largest container and the last pair must describe the amount of product in the smallest container. For example:

Product: 1000 cases of mineral water, 24/12 ounce bottles in each case

Units 1-Quantity	1000
Units 1-Measure	CS
Units 2-Quantity	24
Units 2-Measure	BO
Units 3-Quantity	12
Units 3-Measure	FOZ

Record Identifier PG27 (Container Information)

For Prior Notice, this is a conditional PGA input record that provides data pertaining to the Rail Car or Container Number. Data provided should match the Container number info included in the Bill of Lading.

Record Identifier PG27 (Container Information)					
Data Element	**Length/ Class**	**Position**	**Status**	**Description**	**Note**
Control Identifier	2A	1-2	M	“PG”.	
Record Type	2N	3-4	M	“27”.	
Container Number (Equipment ID)	20AN	5-24	C	The number of the shipping container (CNO) or Rail Car (RNO) as entered in the Bill of Lading based on the Mode of Transportation (MOT). This is applicable for food arriving as containerized cargo by water, air, rail, or land; the container number(s) is required for prior notice.	
Filler	7X	74-80	M	Space fill	

Record Identifier PG28 Express Courier Tracking and Can Dimensions (Acidified and LACF)

For Acidified and Low Acid Canned Food (LACF) this is a conditional PGA input record that provides data pertaining to reporting Can Dimensions for the Food and Drug. For Prior Notice if the Mode of Transportation is mail or express courier then Package Tracking Number Code and Package Tracking Number are conditionally required, i.e. may be submitted in PG28 in lieu of the airway bill or bill of lading and in lieu of the flight number in PG23.

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Record Identifier PG28 (Tracking and/or Can Dimensions – LACF only)					
Data Element	**Length/ Class**	**Position**	**Status**	**Description**	**Note**
Control Identifier	2A	1-2	M	"PG".	
Record Type	2N	3-4	M	"28".	
Can Dimensions #1	4N	5-8	C	The first dimension of the can. If the container is rectangle, the dimension is in width, height, and length order. If the can is cylindrical, the dimensions are in diameter and height order. Can 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.	1, 2
Can Dimensions #2	4N	9-12	C	The second dimension of the container. If the container is rectangle, the dimension is in width, height, and length order. If the can is cylindrical, the dimensions are in diameter and height order. The first two spaces are inches. The second two positions are in 16ths.	1, 2
Can Dimension #3	4N	13-16	C	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.	1, 2
Package Tracking Number Code	3AN	17-19	C	Code indicating the tracking number used. • UPS = UPS • FEX = FedEx • DHL = DHL • ITN = International Tracking Number	3
Package Tracking Number	50AN	20-69	C	Tracking numbers used by FedEx, UPS, DHL, etc.	3

Note 1:

If the product is LACF, the can measurements (height and diameter) in PG28 must be provided unless both the FCE and SID are provided.

If Acidified Food (AF), one of the following must be provided unless FCE and SID are provided:

1. Can Measurements in PG28 (either height and diameter or height/length, width and thickness
2. Container Volume (VOL)

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 144/16” 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/`6” height.

Note 3:

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 Airway Bill number(s) or Bill of Lading number(s), and in lieu of the flight number in PG23.

Record Identifier PG29 (Unit of Measure)

This is an optional PGA input record that provides data pertaining to the net or gross unit of measure of the commodity. This can be provided at the overall PGA Line Number and/or the Individual Unit level.

Record Identifier PG29 (Unit of Measure)					
Data Element	**Length/ Class**	**Position**	**Status**	**Description**	**Note**
Control Identifier	2A	1-2	M	“PG”.	
Record Type	2N	3-4	M	“29”.	
Unit of Measure (PGA line - net)	3AN	5-7	O	Pertaining to the overall PGA Line Number, the indication of the unit of measurement in which weight, capacity, length, area, volume or other quantity is expressed. “Unit of Measure (PGA line - net)” in this position is associated with “Commodity Net Quantity (PGA line - net)” and is required when “Commodity Net Quantity (PGA line - net)” is reported. Valid Unit of Measure codes are listed in Appendix F in this document or in Appendix C in the ACS ABI CATAIR.	
Commodity Net Quantity (PGA line - net)	12N	8-19	O	Pertaining to the overall PGA Line Number, excluding all packing and packaging. Two decimals are implied. “Commodity Net Quantity (PGA line - net)” is required when “Unit of Measure (PGA line - net)” is reported in positions 5-7 of this record.	
Unit of Measure (PGA line - gross)	3AN	20-22	O	Pertaining to the overall PGA Line Number, the indication of the unit of measurement in which weight, capacity, length, area, volume or other quantity is expressed. “Unit of Measure (PGA line - gross)” in this position is associated with “Commodity Gross Quantity (PGA line - gross)” and is required when “Commodity Gross Quantity (PGA line - gross)” is reported. Valid Unit of Measure codes are listed in Appendix F in this document or in Appendix C in the ACS ABI CATAIR.	
Commodity Gross Quantity (PGA line - gross)	12N	23-34	O	Pertaining to the overall PGA Line Number, including any packaging, but excluding weight of the carrier's equipment. Two decimals are implied. “Commodity Gross Quantity (PGA line - gross)” is required when “Unit of Measure (PGA line - gross)” is reported in positions 20-22 of this record.	

Record Identifier PG29 (Unit of Measure)					
Data Element	**Length/ Class**	**Position**	**Status**	**Description**	**Note**
Unit of Measure (Individual Unit - net)	3AN	35-37	O	Pertaining to the Individual unit (net), the indication of the unit of measurement in which weight, capacity, length, area, volume or other quantity is expressed. "Unit of Measure (Individual unit - net)" in this position is associated with "Commodity Net Quantity (Individual unit - net)" and is required when "Commodity Net Quantity (Individual unit - net)" is reported. Valid Unit of Measure codes are listed in Appendix C in the ACS ABI CATAIR.	
Commodity Net Quantity (Individual Unit - net)	12N	38-49	O	Pertaining to the Individual unit, excluding all packing and packaging. Two decimals are implied. "Commodity Net Quantity (Individual unit - net)" is required when "Unit of Measure (Individual unit - net)" is reported in positions 35-37 of this record.	
Unit of Measure (Individual Unit - gross)	3AN	50-52	O	Pertaining to the Individual unit (gross), the indication of the unit of measurement in which weight, capacity, length, area, volume or other quantity is expressed. "Unit of Measure (Individual unit - gross)" in this position is associated with "Commodity Gross Quantity (Individual unit - gross)" and is required when "Commodity Gross Quantity (Individual unit - gross)" is reported. Valid Unit of Measure codes are listed in Appendix C in the ACS ABI CATAIR.	
Commodity Gross Quantity (Individual Unit - gross)	12N	53-64	O	Pertaining to the Individual unit, including any packaging, but excluding weight of the carrier's equipment. Two decimals are implied. "Commodity Gross Quantity (Individual unit - gross)" is required when "Unit of Measure (Individual unit - gross)" is reported in positions 50-52 of this record.	
Filler	16X	65-80	M	Space fill	

Record not supported by FDA at this time

Record Identifier PG30 (Anticipated Arrival Information)

This is a mandatory PGA input record that provides data pertaining to the date, time and location of the anticipated arrival information for all FDA products. While other PGAs may use PG30 to Collect Inspection and Lab information, currently FDA will utilize this record to collect Anticipated Arrival Information at this time.

For each line a PG30 record with an "A" (Anticipated arrival information) code, date, time and location of arrival is Mandatory.

Record Identifier PG30 (Inspection and Lab Information)					
Data Element	**Length/ Class**	**Position**	**Status**	**Description**	**Note**
Control Identifier	2A	1-2	M	“PG”.	
Record Type	2N	3-4	M	“30”.	
Inspection/ Laboratory Testing Status	1A	5	M	A is the ONLY valid code for FDA:: A = Anticipated arrival information	3
Anticipated Arrival date	8N	6-13	M	A numeric date in MMDDCCYY (month, day, century, year) format.	2
Arrival time	4N	14-17	M	Military time HHMM in (hour, minute) format. (Example: 1015, this represents 10:15 a.m.). For midnight, use 2400 (0000 is invalid).	2
Anticipated Arrival Location Code	4AN	18-21	M	For valid port codes, refer to note 1.	1
Arrival Location	50X	22-71	O	Code or free form text indicating site of inspection.	
Filler	8X	72-80	M	Space fill	

Note 1:
Refer to List of Valid Port Codes:
http://www.cbp.gov/sites/default/files/documents/CBP%20Port%20Codes%20041014_1.pdf

Note 2:
Indicates BTA Anticipated Date and Time of Arrival information.

Note 3:
Indicates BTA Anticipated Port of Arrival information.

- Domestic CBP Port – Schedule D

Record Identifier PG55 (Additional Entity Roles)

This is an optional PGA input record used to provide additional roles performed by an entity or individual.

The PG55 record is not supported by FDA at this time. Multiple PG19 records should be used to input more than one Entity-Role combination. Refer to the PG19 section for details.

Record Identifier PG55 (Additional Entity Roles)					
Data Element	**Length/ Class**	**Position**	**Status**	**Description**	**Note**
Control Identifier	2A	1-2	M	“PG”.	
Record Type	2N	3-4	M	“55”.	
Entity Role Code	3AN	5-7	O	Additional role of the entity.	
Entity Role Code	3AN	8-10	O	Additional role of the entity.	
Entity Role Code	3AN	11-13	O	Additional role of the entity.	
Entity Role Code	3AN	14-16	O	Additional role of the entity.	
Entity Role Code	3AN	17-19	O	Additional role of the entity.	
Entity Role Code	3AN	20-22	O	Additional role of the entity.	
Entity Role Code	3AN	23-25	O	Additional role of the entity.	
Entity Role Code	3AN	26-28	O	Additional role of the entity.	
Entity Role Code	3AN	29-31	O	Additional role of the entity.	
Entity Role Code	3AN	32-34	O	Additional role of the entity.	
Filler	46X	35-80	M	Space fills.	

Not supported by FDA at this time

Record Identifier PG00 (Data Substitution)

This is an optional record used at the CBP entry (or entry summary) header, CBP entry (or entry summary) line and/or PGA message set levels to indicate data substitution.

Currently, the PG00 record is implemented only at the CBP entry header level. Future implementation will allow for submission at the CBP entry line and PGA Message Set level.

See the 'usage notes' in this chapter for more detailed information.

Record Identifier PG00 (Data Substitution)					
Data Element	**Length/ Class**	**Position**	**Status**	**Description**	**Note**
Control Identifier	2A	1-2	M	"PG".	
Record Type	2N	3-4	M	"00".	
Substitution Indicator	1X	5	O	Identifies either the start or end of the substitution group, or the location of where to place the substitute data within the PGA Message Set. The following codes are allowed: S=Start of the substitution group E=End of the substitution group R=Replace this record with the substitution group indicated by the Substitution Number	
Substitution Number	4AN	6-9	O	Sequential number assigned to, or referring to, a specific substitution group of data provided at the header level. This data element is mandatory when using the S or R substitution indicator.	
Filler	71X	10-80	M	Space fills.	

Food Commodity including PN Requirement Previously Met - Data Elements and Values

In this scenario 801(a) data elements may be submitted with a PG14 record including the Prior Notice Confirmation Number. or if the Government Processing Code is CCW or if food is withdrawn from a Foreign Trade Zone (FTZ). Prior Notice Confirmation Number in PG 14 is NOT always required. Food commodities can be broken down into the following categories using the existing Government Agency data elements available in the PG01 message

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

Table 4b – Food commodity hierarchy

This chapter describes the data elements and their business rules for a 801A entry, with the Government Agency Program Code = 'FOO', which may have been subject to PN regulations. To show that the PN requirements were already satisfied, a PG14 record with the PN Conformation Number) may be included in the PG Message Set in addition to all applicable PG records described in this chapter.

The following are the potential PGA records associated with submitting Foods:

PG Record	Description
OI	The commercial description of the shipment is provided.
PG01	The shipment is regulated by the FDA program office within FDA and the intended use is provided.
PG02	The item type and Product Code detail are provided.
PG05	The scientific species name and code
PG06	Source Type(origin) other than the CBP country of origin is provided
PG07	The Trade/Brand Name
PG10	Category Code

PG Record	Description
PG14	PN Confirmation Number
PG19	The entity (manufacturer, consignee, shipper, etc.) of Record's identification information is provided.
PG20	Additional address data on the entity in PG19 is provided
PG21	The entity (manufacturer, consignee, shipper, etc.) of Record's individual point of contact, phone number and email is given.
PG23	FDA's Affirmation of Compliance Criteria is provided.
PG24	Remarks
PG25	Temperature qualifier, Lot#, Production dates, PGA Line Value and PGA Unit Value are provided
PG26	Packaging qualifier and quantity of the shipment are provided
PG27	Container Number
PG28	Can Dimensions (LACF Only)
PG29	Data pertaining to the net or gross unit of measure of the commodity
PG30	Anticipated Arrival Information
PG55	Additional roles performed by entity or individual (future use)
PG00	Data Substitution

Food Example

Food message set layout sample below:

Please refer to the external file: **FDA SG 2.4 Example PG Message Sets.xlsx** Tab: ***FOO+PNC***

Because of the flexibility of the PGA Message set, the PGA Records and Data Elements that are required may vary both from program to program and within a single program. For a more expansive set of examples of FDA PGA Message Sets, please refer to the above document.

Record Identifier OI (Record Identifier)

This is a mandatory PGA line item description input record that provides the description of the item. This record precedes the Record Identifiers for the PGA Message set.

Record Identifier OI					
Data Element	**Length/ Class**	**Position**	**Status**	**Description**	**Note**
Control Identifier	2A	1-2	M	"OI"	
Filler	8X	3-10	M	Space filled.	
Commercial Description	70X	11-80	M	The commercial description of the product. For example, NATURE'S FINEST REAL FRUIT JUICE, 12 OUNCE BOTTLES	

Record Identifier PG01 (PGA Identifier)

This is a mandatory PGA input record that provides data pertaining to the PGA Line Number, Government Agency Code, Government Agency Program Code, Globally Unique Product Identification Code, Intended Use Code, Intended Use Description, and Disclaimer. The Intended Use Code allows FDA to identify whether the imported commodity is restricted by a consumption allowance or not.

Record Identifier PG01 (PGA Identifier)					
Data Element	**Length/ Class**	**Position**	**Status**	**Description/Required Value**	**Note**
Control Identifier	2A	1-2	M	"PG"	
Record Type	2N	3-4	M	"01"	
PGA Line Number	3N	5-7	M	"001"	
Government Agency Code	3AN	8-10	M	"FDA"	
Government Agency Program Code	3X	11-13	C	"FOO"	1
Government Agency Processing Code	3AN	14-16	C	Allowed values: NSF, PRO, FEE, ADD, DSU,CCW	1
Intended Use Code	16X	42-57	O		2
Intended Use Description	22X	58-79	O		2
Disclaimer	1A	80	C	A code of A (= product is not regulated by this agency) or B (= data is not required per agency guidance) indicating there is no agency declaration requirement. Or this field is left blank for no disclaimer. No other code is accepted	

Refer to Table 4b above for commodity type and sub-type for Food

Note 1
If the Disclaimer is 'A' or 'B' then these data elements should both be populated with FDA. otherwise the Government Agency Program Code, Government Agency Processing are mandatory.

Note 2

Choose one of these intended use codes based on the product requirements.

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

Record Identifier PG02 (Product Identifier)

This mandatory PGA input record is used to indicate whether or not the information being provided relates to a product (P) or a component (C) of a product.

Record Identifier PG02 (Product Identifier)					
Data Element	**Length/ Class**	**Position**	**Status**	**Description**	**Note**
Control Identifier	2A	1-2	M	"PG"	
Record Type	2N	3-4	M	"02"	
Item Type	1A	5	M	Code identifying the following records as pertaining to P=Product. No other values accepted. Only one 'P' record is allowed for the same PGA Line # in PG01 record.	
Product Code Qualifier	4AN	6-9	M	FDP	1
Product Code Number	19X	10-28	M	Product Code Must be equal to 7 characters	

Note 1

Product Code Qualifiers and their descriptions can be found in Appendix PGA (PG02 – Product Code Qualifiers) of the ACE ABI CATAIR publication. For Food commodity, this is currently always 'FDP' for all FDA products.

Only one Product Code Number per product is allowed.

FDA Product Code Structure:

Position	1-2	3	4	5	6-7
Name	Industry Code (N)	Class Code (A)	Sub Class Code (A or '-')	Process Identification Code - PIC (A or '-')	Group Code (AN)

Legend - N: Numeric; A:Alphabetic; AN:AlphaNumeric

Record Identifier PG05 (Scientific Genus Names)

This is an optional PGA input record that provides data pertaining to Scientific Genus Names, Scientific Species, Scientific Sub Species Name, Scientific Species Code, and FWS Description Code.

Record Identifier PG05 (Scientific Genus Names)					
Data Element	**Length/ Class**	**Position**	**Status**	**Description**	**Note**
Control Identifier	2A	1-2	O	“PG”.	
Record Type	2N	3-4	O	“05”.	
Scientific Genus Name	22X	5-26	O	Scientific Genus Name of the merchandise being entered.	
Scientific Species Name	22X	27-48	O	Scientific Species Name of the merchandise being entered.	
Scientific Sub Species Name	18X	49-66	O	Scientific Sub Species Name of the merchandise being entered.	

Record Identifier PG06 (Product Origin)

This is A Mandatory PGA input record that provides data pertaining to Source Type (Origin) other than the CBP Country of Origin, in addition to Processing dates, Processing Type and Processing Description.

Record Identifier PG06 (Product Origin)					
Data Element	**Length/ Class**	**Position**	**Status**	**Description**	**Note**
Control Identifier	2A	1-2	M	"PG".	
Record Type	2N	3-4	M	"06".	
Source Type Code	3AN	5-7	M	IF Government Agency Program Code = FOO and Government Agency Processing Code = NSF THEN Source Type Code MUST BE 262 (Place of growth) ELSE Source Type Code must be 39 (Country of Production). 294 (Country of Refusal) is Allowed. There would be one PG06 with source type code of 39. If previously refused, then trade would also provide another PG06 with source type code 294.	1
Country Code	2X	8-9	M	Foods require the harvesting or production location of the product.	2

Note 1

Source Type Codes and their descriptions can be found in Appendix PGA (PG06 – Source Type Codes) of the ACE ABI CATAIR publication.

Note 2

Any of the country codes from Appendix B (ISO Country and Currency Codes) in the ACS ABI CATAIR can be entered.

Record Identifier PG07 (Product Trade Names)

This is an optional PGA input record that provides data pertaining to Trade or Brand Name.

Record Identifier PG07 (Product Trade Names)					
Data Element	**Length/ Class**	**Position**	**Status**	**Description**	**Note**
Control Identifier	2A	1-2	C	“PG”	
Record Type	2N	3-4	C	“07”	
Trade Name/Brand Name	35X	5-39	O	Market, Trade, or Brand Name that describes the food or feed product at each line level.	

Record Identifier PG10 (Product Characteristics)

For Food, this is a mandatory PGA input record that allows for importer to report the description of the product at the line level to capture the information currently collected in multiple OI records. This record can be repeated if there are more Commodity Characteristic Descriptions.

Record Identifier PG10 (Product Characteristics)					
Data Element	**Length/ Class**	**Position**	**Status**	**Description**	**Note**
Control Identifier	2A	1-2	M	“PG”.	
Record Type	2N	3-4	M	“10”.	
Commodity Characteristic Description	57X	24-80	M	Free form description, NOT product code description, of the item, either to supplement the above data elements or in place of the above. See Appendix A for the use of PG10 to capture the information currently collected in multiple OI records.	

Record Identifier PG14 (PN Confirmation Number)

For Foods with a previously submitted prior notice, the *Prior Notice Confirmation Number* information is required.

If declaring FTZ in PG30 for Entry Type 21 OR the Government Processing Code is CCW, this record is not needed.

Record Identifier PG14 (Input)					
Data Element	**Length /Class**	**Position**	**Status**	**Description**	**Note**
Control Identifier	2A	1-2	M	Must always equal PG.	
Record Type	2N	3-4	M	Must always be 14.	
Transaction Type	1N	5	C	Identifies the transaction type. 1 = single use	1
Code Type	3AN	6-8	C	Identifies Type Codes for PN Confirmation Number PN Confirmation Number = PNC	1
PNC Number	33X	9-41	C	Identifies the number that corresponds to the *PN Confirmation number*	1

Note 1

- Prior notice must be submitted before arrival and admission into a FTZ, prior notice is not required when the food is withdrawn from the FTZ, either as an export or for use within the U.S. However, if the food is withdrawn from the FTZ for consumption entry into the U.S., FDA must be notified and will make the admissibility decision about the consumption entry at that time.

Record Identifier PG19 (Entity Data)

For Foods, this is a mandatory PGA input record that provides FDA with data pertaining to Entity Role and conditionally the following data elements; Entity Identification, Entity Name, and Entity Address 1.

Record Identifier PG19 (Entity)					
Data Element	**Length/ Class**	**Position**	**Status**	**Description**	**Note**
Control Identifier	2A	1-2	M	"PG"	
Record Type	2N	3-4	M	"19"	
Entity Role Code	3AN	5-7	M	Code identifying the role of the entity being provided. For example: MF, UC	1
Entity Identification Code	3AN	8-10	C	Code identifying the Entity Identification is entered. For example: 16, 47. Mandatory, if Entity Number is entered.	2
Entity Number	15X	11-25	O	The Entity Number of the entity based on the above Entity Identification Code is entered; must conform to the descriptions in Note 2	2
Entity Name	32X	26-57	M	The name of the entity is required. See validation criteria below.	2
Entity Address 1	23X	58-80	M	The address of the entity is required. See validation criteria below.	2

Note 1
Entity Role Codes and their descriptions can be found in Appendix PGA (PG19 – Entity Role Codes) of the ACE ABI CATAIR publication. List of Entity Role codes mandatory to FDA Food Message Sets is below:

Data Element	***Code***	***Description***
Entity Role Codes§	MF	Manufacturer of goods
	DEQ	Shipper
	FD1	FDA Importer (Importer of Record)
	DP	Delivered To Party

§ Same Role Code cannot be entered more than once.

Note 2

Data Element	***Code***	***Description***	***Length/ Class***
Entity Identification Codes	16	D&B-assigned (DUNS number)	9N
	47	FDA-assigned	4-10N

FDA SELECTION CRITERIA

FDA requires Entity Name and Entity Address. Additionally, FDA prefers to use DUNS numbers for identifying the Entity; IF DUNS is not available THEN FEI.

Entity Name <>NULL AND Entity Address 1 <>NULL AND
IF Entity Identification Code =16 (DUNS) THEN Entity Number MUST BE Length = 9 and Type = N
ELSE IF Entity Identification Code =47 (FEI) THEN Entity Number MUST BE Length from 4 to 10 and Type = N

Record Identifier PG20 (Entity Address)

This is a mandatory PGA input record that provides additional data pertaining to the Entity identified in the preceding PG19 record; such as Entity Address line 2, Apartment/Suite, City, State, and Zip/Postal Code. This record is used when additional address for the entity needs to be entered.

Record Identifier PG20 (Entity Address)					
Data Element	**Length/ Class**	**Position**	**Status**	**Description**	**Note**
Control Identifier	2A	1-2	M	“PG”	
Record Type	2N	3-4	M	“20”	
Entity Address 2	32X	5-36	C	Address Line 2 for the Entity.	1
Entity Apartment Number/Suite Number	5X	37-41	C	For example, 102 A.	1
Entity City	21X	42-62	M	For example, SUGARLAND	
Entity State/Province	3AN	63-65	C	For example, TX.	2
Entity Country	2A	66-67	M	For example, US.	
Entity Zip/Postal Code	9X	68-76	C	For example, 77004.	2
Filler	4X	77-80	C	Space fill	

Note 1: If the Entity Address 1 in PG19 is longer than the allocated 23 characters then utilize these fields.

Note 2: Populated if US or Canada based entities

Record Identifier PG21 (Point of Contact)

This is a mandatory PGA input record that provides FDA with data about an Individual Point of Contact (POC) related to the Entity (the party) in the preceding PG19 record. Included in this record are the Individual Name, Telephone Number, Fax Number, and Email address. A typical example is a POC for the Filer.

At least one PG21 record is required.

Record Identifier PG21 (Point of Contact)					
Data Element	**Length/ Class**	**Position**	**Status**	**Description**	**Note**
Control Identifier	2A	1-2	M	"PG"	
Record Type	2N	3-4	M	"21"	
Individual Qualifier	3AN	5-7	M	Code identifying which entity the Point of Contact is related to. Use PK	1
Individual Name	23X	8-30	M	Name of the Individual. If the name will not fit, complete PG24 and fill out the remarks code (Individual name) and then enter the name in the remarks text field. For example, SMITH, JOHN	
Telephone Number of the Individual	15X	31-45	M	For example, (713)555-8765 in US or (+65)9052-3529 in Singapore	
Email Address or Fax Number for the Individual	35X	46-80	M	For example, T.FREDERI@OJANDMORE.COM.	

Note 1

Entity Role Codes and their descriptions can be found in Appendix PGA (PG19 – Entity Role Codes) of the ACE ABI CATAIR publication. List of Entity Role codes applicable is below:

Data Element	***Code***	***Description***
Entity Role Codes	PK	Point of Contact

Record Identifier PG23 (Affirmation of Compliance)

This is a conditional PGA input record that provides data pertaining to Food and Drug Administration Affirmation of Compliance Criteria. This record is typically only used by FDA. This record is repeatable.

Record Identifier PG23 (Affirmation of Compliance)					
Data Element	**Length/ Class**	**Position**	**Status**	**Description**	**Note**
Control Identifier	2A	1-2	C	"PG".	
Record Type	2N	3-4	C	"23".	
Affirmation of Compliance Code	5X	5-9	C	A code used to affirm compliance with FDA requirements. See Appendix PGA (Food & Drug Affirmation of Compliance Codes) of this publication for valid codes.	1, 2
Affirmation of Compliance Qualifier	30AN	10-39	C	Text describing the information required by the PGA. This could include a number or a country code, etc. Also, see Appendix PGA (Food & Drug Affirmation of Compliance Qualifier Codes) of this publication for valid codes related to certain specific Affirmation of Compliance codes.	1, 2

Note 1

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. T

The list of AoC codes **conditional** to FDA Food Message Sets is below:

Data Element	***Code***	***Description***	***Syntax***	***Business Rules***	***Note***
	FCE	Food Canning Establishment Number	7N or 10N	IF Government Agency Program Code = FOO and the product is either LACF or AF THEN FCE may be entered. See Note 1.	2
	SID	Schedule Identifier Number		IF Government Agency Program Code = FOO AND the product is either LACF or AF THEN AoC Code 'SID' may be entered. See Note 1.	2
	VOL	LACF/AF Volume		IF Government Agency Program Code = FOO AND the product is either LACF or AF THEN VOL may be entered. See Note 1.	2

The list of AoC codes **optional** to FDA Food Message Sets is below:

Data Element	***Code***	***Description***	***Syntax***	***Business Rules***	***Note***
Affirmation of Compliance Code	CCC	Chinese Ceramic Ware Factory Code	6AN	IF Government Agency Program Code = FOO THEN CCC IS ALLOWED	

Data Element	Code	Description	Syntax	Business Rules	Note
	CCN	Carrier ISO Country Code	2A	ISO Country code	
	CIN	Color Identification Number	text	IF Government Agency Program Code = FOO AND Government Agency Processing Code = ADD THEN CIN IS ALLOWED	
	ERR	Entry Review Requested	indicator only	ERR is just used as an indicator, no data will follow	
	FAP	Food Additive Petition Approval Number	6N	IF Government Agency Program Code = FOO AND Government Agency Processing Code = ADD THEN FAP IS ALLOWED	
	FCC	French Cheese Facility Certification Number	7N or 10N	IF Government Agency Program Code = FOO AND Government Agency Processing Code = PRO THEN FCC IS ALLOWED	
	AIN	Food Additive Identification Number	6N or 8N or E+7N	IF Government Agency Program Code = FOO AND Government Agency Processing Code = ADD THEN AIN IS ALLOWED	
	JIF	Juice HACCP Importer Firm	7N or 10N	IF Government Agency Program Code = FOO AND the product is HACCP THEN JIF IS ALLOWED	
	SIF	Seafood HACCP Importer Firm	7N or 10N	IF Government Agency Program Code = FOO AND the product is HACCP THEN SIF IS ALLOWED	
	IBP	Indian Black Pepper Certificate	text	IF Government Agency Program Code = FOO AND Government Agency Processing Code = NSF THEN IBP IS ALLOWED	
	IFE	Import For Export	indicator only		
	PKC	Package/Can Code		IF Government Agency Program Code = FOO THEN PKC IS ALLOWED	

Note 2:

Using the FDA Product Code in PG02, the following classifications are made where specific imported food/feed products require the submission of lot or code numbers or other identifier with prior notice. These include:

LACF and Acidified:

Industry Codes: 02-39, 41, 71, & 72
With Process Indicator Code (PIC): Acidified-**I**, Aseptic-**F**, Commercially Sterile-**E**

If the product is LACF, the can measurements (height and diameter) must be provided in PG28 unless both the FCE and SID are provided.

If Acidified Food (AF), one of the following must be provided unless FCE and SID are provided:

1. Can Measurements in PG28 (either height and diameter or height/length, width and thickness
2. Container Volume (VOL)

Record Identifier PG24 (Remarks)

This is an optional PGA input record that provides data pertaining to Remarks Codes, and Text of Remarks.

Remark Type Code should be either GEN or NAM.

If GEN, the PG24 is applicable to the preceding PG02. Only one GEN:PG24 is allowed per PG02 (this is to avoid multiple GEN:PG24 records without a guaranteed sequencing as intended by the filer). This may be expanded in future with sufficient sequencing control to receive multiple GEN:PG24 records in the same order in which the Filer entered remarks.

If NAM, the PG24 is applicable to the preceding PG21. This structure simply allows the entry of 68 characters in addition to 23 characters afforded by PG21 for the Individual Name field in PG21. When a NAM-PG24 is present, the Individual Name field in PG21 is concatenated with Remarks Text field in PG24, to the full name in the format "*Last Name, First Name Middle Name*" for a potential 91 characters. Only one NAM:PG24 is allowed per PG21.

Record Identifier PG24 (Input)					
Data Element	**Length /Class**	**Position**	**Status**	**Description**	**Note**
Control Identifier	2A	1-2	M	Must always equal PG.	
Record Type	2N	3-4	M	Must always be 24.	
Remarks Type Code	3X	5-7	O	A code indicating the type of remarks. Valid codes are listed in Appendix PGA (Remarks Type Code) of this publication. FDA uses either NAM or GEN as its valid values.	1
Remarks Text	68X	13-80	O	Free form text relevant to the shipment or the commodity.	

Note 1
If an individual's Name in the preceding PG21 is longer than 23 characters, the Remarks Type Code should be identified as NAM (Full name of the Individual) then the Remarks Text can be used to indicate the full name of that individual. Individual's Name should still follow the same format when using PG24, as following:

Last Name, First Name Middle Name

If submitting general comments then use the Remarks Type Code = GEN (General Remarks)

Record Identifier PG25 (Product Condition)

For Food, it is a mandatory PGA input record that provides data pertaining to: Temperature Qualifier, Degree Type, Actual Temperature, Lot Number, Production Date, Range of the Lot, PGA Line Value, and PGA Unit Value. This record is repeatable for multiple Lot Number Qualifiers and Lot Numbers but the line value MUST be included on each record.

Record Identifier PG25 (Product Condition)					
Data Element	**Length/ Class**	**Position**	**Status**	**Description**	**Note**
Control Identifier	2A	1-2	M	"PG".	
Record Type	2N	3-4	M	"25".	
Temperature Qualifier	1A	5	O	Temperature Category being reported for quality control or preservation purposes. A= Ambient, F=Frozen, D=Dry Ice, R=Refrigerated/Chilled, H=Fresh, U=Uncontrolled, P=Flashpoint	
Degree Type	1A	6	O	F = Fahrenheit, C = Celsius , K = Kelvin	
Negative Number	1A	7	O	If the actual temperature is in the negative numbers use an "X".	
Actual Temperature	6N	8-13	O	Required if Degree Type is entered. Reported temperature. Two decimals places are implied.	
Location of Temperature Recording	1A	14	O	Identifies recorded temperature is for A=product, B=container and C= conveyance	
Lot Number Qualifier	1AN	15	O	Code of the entity that assigned the Lot number. 1 = Manufacturer and 3 = Grower. IF Government Agency Program Code = FOO and Government Agency Processing Code = NSF THEN Lot Number Qualifier = 3 ELSE Lot Number Qualifier = 1	
Lot Number	25X	16-40	O	The lot number that the manufacturer / Grower assigned to the product.	
Production Start date of the Lot	8N	41-48	O	The date when the production for the Lot started. A numeric date in MMDDCCYY (month, day, century, year) format.	
Production End Date of the Lot	8N	49-56	O	The date when the production for the Lot ended. A numeric date in MMDDCCYY (month, day, century, year) format	
PGA Line Value	12N	57-68	M	The value associated with the PGA line number in whole dollars. It must be right-justified with preceding zeros. Must be greater than zero.	
PGA Unit Value	12N	69-80	O	The value of the lowest unit of measure reported in PG26. Two decimal places are implied. IF Government Agency Program Code = 'FOO' AND IF AoC Code = 'IFE' THEN this is MANDATORY	

Record Identifier PG26 (Product Packaging)

For Food, this is a mandatory PGA input record that provides FDA with data pertaining to Packaging Qualifier, Quantity and Unit of Measure. This record can be repeated up to six (6) times, once for each unique packaging level. The first record is used to describe the largest (outermost) container and the number of containers at this packaging level. The second record is used to describe the contents of the next smallest container. If needed, qualifiers 2-6 are used in a similar manner (largest to smallest container). The final record must describe the actual amount of the product in the smallest container.

The appearance of any 'Packaging Qualifier' number level requires all levels under it to be represented. For instance, level 3 can't be present unless levels 1 and 2 are present.

Record Identifier PG26 (Product Packaging)					
Data Element	**Length /Class**	**Position**	**Status**	**Description**	**Note**
Control Identifier	2A	1-2	M	"PG"	
Record Type	2N	3-4	M	"26"	
Packaging Qualifier	1N	5	M	Code identifying the level of packaging. For example, 4. If reporting only one level, show the total quantity for the item and report that as level 1.	1, 4
Quantity	12N	6-17	M	"Quantity of the packaging level, For example, 000000000400. Must be greater than zero.	2, 4
Unit of Measure (Packaging Level)	5X	18-22	M	Type of packaging / packaging level. For example, BX.	3, 4

Note 1
This code identifies the level of packaging for the product. Valid values are 1, 2, 3, 4, 5 and 6: Outermost (largest=1) packages to the innermost (smallest=6) packages. There can be up to 6 levels of packaging.

Note 2
There are two implied decimal points when writing the quantity in Units of Measure for the Base Unit (Last Quantity Transmitted). In this example, 4 pieces are represented as 000000000400, with the nine leading zeroes as "fill" and two decimal places following the value. The quantity for packaging containers will be in whole numbers with no decimal places. The sample shows 1 carton containing 10 boxes and each box containing 4 pieces.

Note 3
List of Unit of Measure codes applicable to FDA-Food Message Sets
For a full list of applicable Unit of Measure codes, please refer to Appendix F in this document or to the Appendix PGA (PG26 – Unit of Measure - Valid FDA Units of Measure for Packaging Containers) and Appendix PGA (PG26 – Unit of Measure -Valid FDA Units of Measure for the Base Unit (Last Quantity Transmitted)) of the CATAIR.

Valid FDA Food Units of Measure for Packaging Containers

Code	*Description*
AE	Aerosol
AM	Ampoule, Non-Protected
AP	Ampoule, Protected

AT	Atomizer
BA	Barrel (Container)
BB	Bobbin
BC	Bottlecrate, Bottlerack
BE	Bundle
BF	Balloon, Non-Protected
BG	Bag
BH	Bunch
BI	Bin
BJ	Bucket
BK	Basket
BL	Bale, Compressed
BN	Bale, Non-Compressed
BO	Bottle, Non-Protected,Cyl
BP	Balloon, Protected
BQ	Bottle, Protected, Cylnd
BR	Bar
BS	Bottle, Non-Prot Bulbous
BU	Butt
BV	Bottle, Protected Bulbous
BX	Box
BZ	Bars in Bundle/Bunch/Trus
CA	Can, Rectangular
CAG	Cage
CB	Crate, Beer
CC	Churn
CE	Creel
CF	Coffer
CH	Chest
CI	Canister
CJ	Coffin
CK	Cask
CL	Coil
CO	Carboy, Non-Protected
CON	Container
CP	Carboy, Protected
CR	Crate
CS	Case
CT	Carton
CU	Cup
CV	Cover
CX	Can, Cylindrical
CY	Cylinder

CZ	Canvas
DJ	Demijohn, Non-Protected
DP	Demijohn, Protected
DR	Drum
EN	Envelope
FC	Crate, Fruit
FD	Crate, Framed
FI	Firkin
FL	Flask
FO	Footlocker
FR	Frame
GB	Bottle, Gas
HG	Hogshead
HR	Hamper
JC	Jerrican, Rectangular
JG	Jug
JR	Jar
JT	Jutebag
JY	Jerrican, Cylindrical
KEG	Keg
KIT	Kit
MB	Bag, Multi-ply
MC	Crate, Milk
MS	Sack, Multiwall
MT	Mat
NE	Unpacked Or Unpackaged
NS	Nest
NT	Net
PA	Packet
PAL	Pallet
PC	Parcel
PH	Pitcher
PK	Package
PL	Pail
PO	Pouch
PT	Pot
PU	Tray or Tray Pack
PY	Plates in Bndl/Bnch/Truss
RG	Ring
RO	Roll
SA	Sack
SC	Crate, Shallow
SD	Spindle

SE	Sea-chest
SH	Sachet
SK	Case, Skeleton
SL	Slipsheet
SU	Suitcase
SW	Shrinkwrapped
SZ	Sheets in Bndl/Bnch/Truss
TB	Tub
TC	Tea-Chest
TD	Tube, Collapsible
TK	Tank, Rectangular
TN	Tin
TO	Tun
TR	Trunk
TS	Truss
TU	Tube
TY	Tank, Cylindrical
TZ	Tubes in Bndl/Bnch/Truss
VA	Vat
VG	Bulk Gas at 1031 MBAR
VI	Vial
VL	Bulk Liquid
VO	Bulk,Solid,Lg Particles
VP	Vacuum-packed
VQ	Bulk Liquified Gas
VR	Bulk,Solid,Granular Parti
VY	Bulk,Solid,Fine Particle
WB	Wickerbottle

Valid FDA Food Units of Measure for the Base Unit (Last Quantity Transmitted)

Code	***Description***	***Measure Type***
BBL	Barrels (42 Gallons Ea)	Volume
BOL	Boluses	Dosage
CAR	Carats	Weight
CAP	Capsules	Dosage
CFT	Cubic Feet	Volume
CG	Centigrams	Weight
CM3	Cubic Centimeters	Volume
CYD	Cubic Yards	Volume
DOZ	Dozen	Count

DPC	Dozen Pieces	Count
DPR	Dozen Pairs	Count
FOZ	Ounces, fluid	Volume
G	Grams	Weight
GAL	Gallons (US)	Volume
GR	Gross	Count
KG	Kilograms	Weight
KM3	1,000 Cubic Meters	Volume
L	Liters	Volume
LB	Pounds (avdp)	Weight
M3	Cubic Meters	Volume
MCG	Micrograms	Weight
MG	Milligrams	Weight
ML	Milliliters	Volume
NO	Number	Count
OZ	Ounces, weight (avdp)	Weight
PCS	Pieces	Count
PRS	Pairs	Count
PTL	Pints, liquid (US)	Volume
QTL	Quarts, liquid (US)	Volume
STN	Short ton (2000 LB)	Weight
T	Metric Ton	Weight
Tab	Tablets	Dosage
TON	Long Ton (2240 LB)	Weight
TOZ	Ounces, Troy or Apoth	Weight

Note 4

Quantity Data provides additional information to FDA about the product and how it is packaged. The basic format for Quantity Data is in multiple pairs of data – quantity and unit of measure, i.e., 500 cases, 12 ounces, fluid, 1000 cartons, etc. Up to 6 data pairs may be submitted, beginning with the 1st pair for the outermost packaging when Packaging Qualifier = 1. The first pair may describe the largest container and the last pair must describe the amount of product in the smallest container. For example:

Product: 1000 cases of mineral water, 24/12 ounce bottles in each case

Units 1-Quantity	1000
Units 1-Measure	CS
Units 2-Quantity	24
Units 2-Measure	BO
Units 3-Quantity	12
Units 3-Measure	FOZ

Record Identifier PG27 (Container Information)

This is an optional PGA input record that provides data pertaining to issued Container Number. The number of the shipping container is included in the Bill of Lading. Hence this record is not needed.

Record Identifier PG26 (Container Information)					
Data Element	**Length/ Class**	**Position**	**Status**	**Description**	**Note**
Control Identifier	2A	1-2	O	“PG”.	
Record Type	2N	3-4	O	“27”.	
Container Number (Equipment ID)	20AN	5-24	O	The number of the shipping container as entered in the Bill of Lading.	
Filler	7X	74-80	O	Space fill	

Record Identifier PG28 (Can Dimensions – Acidified and LACF only)

For Acidified and Low Acid Canned Food (LACF) this is a conditional PGA input record that provides data pertaining to reporting Can Dimensions for the Food and Drug.

Record Identifier PG28 (Can Dimensions – LACF only)					
Data Element	**Length/ Class**	**Position**	**Status**	**Description**	**Note**
Control Identifier	2A	1-2	C	"PG".	
Record Type	2N	3-4	C	"28".	
Can Dimensions #1	4N	5-8	C	The first dimension of the can. If the container is rectangle, the dimension is in width, height, and length order. If the can is cylindrical, the dimensions are in diameter and height order. Can 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.	1, 2
Can Dimensions #2	4N	9-12	C	The second dimension of the container. If the container is rectangle, the dimension is in width, height, and length order. If the can is cylindrical, the dimensions are in diameter and height order. The first two spaces are inches. The second two positions are in 16ths.	1, 2
Can Dimension #3	4N	13-16	C	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.	1, 2

Note 1:

IF Government Agency Program Code = FOO AND Product is Acidified or LACF
THEN PG28 - Can Dimensions ARE ALLOWED OR a PG23 – AofC Code VOL IS can be populated

If the product is LACF, the can measurements (height and diameter) must be provided in PG28 unless both the FCE and SID are provided.

If Acidified Food (AF), one of the following must be provided unless FCE and SID are provided:

1. Can Measurements in PG28 (either height and diameter or height/length, width and thickness
2. Container Volume (VOL)

Note 2:

If the container is <u>rectangular</u>, 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 144/16" width, 8" height and 6 8/16" length.

If the container is <u>cylindrical</u> 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/`6" height.

Record Identifier PG29 (Unit of Measure)

This is an optional PGA input record that provides data pertaining to the net or gross unit of measure of the commodity. This can be provided at the overall PGA Line Number and/or the Individual Unit level.

Record Identifier PG29 (Unit of Measure)					
Data Element	**Length/ Class**	**Position**	**Status**	**Description**	**Note**
Control Identifier	2A	1-2	M	“PG”.	
Record Type	2N	3-4	M	“29”.	
Unit of Measure (PGA line - net)	3AN	5-7	O	Pertaining to the overall PGA Line Number, the indication of the unit of measurement in which weight, capacity, length, area, volume or other quantity is expressed. “Unit of Measure (PGA line - net)” in this position is associated with “Commodity Net Quantity (PGA line - net)” and is required when “Commodity Net Quantity (PGA line - net)” is reported. Valid Unit of Measure codes are listed in Appendix F in this document or in Appendix C in the ACS ABI CATAIR.	
Commodity Net Quantity (PGA line - net)	12N	8-19	O	Pertaining to the overall PGA Line Number, excluding all packing and packaging. Two decimals are implied. “Commodity Net Quantity (PGA line - net)” is required when “Unit of Measure (PGA line - net)” is reported in positions 5-7 of this record.	
Unit of Measure (PGA line - gross)	3AN	20-22	O	Pertaining to the overall PGA Line Number, the indication of the unit of measurement in which weight, capacity, length, area, volume or other quantity is expressed. “Unit of Measure (PGA line - gross)” in this position is associated with “Commodity Gross Quantity (PGA line - gross)” and is required when “Commodity Gross Quantity (PGA line - gross)” is reported. Valid Unit of Measure codes are listed in Appendix F in this document or in Appendix C in the ACS ABI CATAIR.	
Commodity Gross Quantity (PGA line - gross)	12N	23-34	O	Pertaining to the overall PGA Line Number, including any packaging, but excluding weight of the carrier's equipment. Two decimals are implied. “Commodity Gross Quantity (PGA line - gross)” is required when “Unit of Measure (PGA line - gross)” is reported in positions 20-22 of this record.	

Record Identifier PG29 (Unit of Measure)					
Data Element	**Length/ Class**	**Position**	**Status**	**Description**	**Note**
Unit of Measure (Individual Unit - net)	3AN	35-37	O	Pertaining to the Individual unit (net), the indication of the unit of measurement in which weight, capacity, length, area, volume or other quantity is expressed. "Unit of Measure (Individual unit - net)" in this position is associated with "Commodity Net Quantity (Individual unit - net)" and is required when "Commodity Net Quantity (Individual unit - net)" is reported. Valid Unit of Measure codes are listed in Appendix C in the ACS ABI CATAIR.	
Commodity Net Quantity (Individual Unit - net)	12N	38-49	O	Pertaining to the Individual unit, excluding all packing and packaging. Two decimals are implied. "Commodity Net Quantity (Individual unit - net)" is required when "Unit of Measure (Individual unit - net)" is reported in positions 35-37 of this record.	
Unit of Measure (Individual Unit - gross)	3AN	50-52	O	Pertaining to the Individual unit (gross), the indication of the unit of measurement in which weight, capacity, length, area, volume or other quantity is expressed. "Unit of Measure (Individual unit - gross)" in this position is associated with "Commodity Gross Quantity (Individual unit - gross)" and is required when "Commodity Gross Quantity (Individual unit - gross)" is reported. Valid Unit of Measure codes are listed in Appendix C in the ACS ABI CATAIR.	
Commodity Gross Quantity (Individual Unit - gross)	12N	53-64	O	Pertaining to the Individual unit, including any packaging, but excluding weight of the carrier's equipment. Two decimals are implied. "Commodity Gross Quantity (Individual unit - gross)" is required when "Unit of Measure (Individual unit - gross)" is reported in positions 50-52 of this record.	

Record not supported by FDA at this time

Record Identifier PG30 (Anticipated Arrival Information)

This is a mandatory PGA input record that provides data pertaining to the date, time and location of the anticipated arrival information for all FDA products and the Foreign Trade Zone facility that the goods are being withdrawn from, if applicable.

For entry type 21 coming from a Foreign Trade Zone, a PG30 record with an "F" (Foreign Trade Zone) code and FIRMS code for the FTZ location is required to exempt the shipment from prior notice because the requirements were previously met entering the Foreign Trade Zone.

There will be at least one PG30 record with status 'A'.

Record Identifier PG30 (Inspection and Lab Information)					
Data Element	**Length/ Class**	**Position**	**Status**	**Description**	**Note**
Control Identifier	2A	1-2	M	"PG".	
Record Type	2N	3-4	M	"30".	
Status	1A	5	M	A = Anticipated arrival information. This value is mandatory. If entry type = 21, then repeat PG30 and enter F = Foreign Trade Zone.	
Anticipated Arrival date	8N	6-13	M	A numeric date in MMDDCCYY (month, day, century, year) format.	
Anticipated Arrival time	4N	14-17	M	Military time HHMM in (hour, minute) format. (Example: 1015, this represents 10:15 a.m.). For midnight, use 2400 (0000 is invalid).	
Arrival Location Code (or Foreign Trade Zone Firm Code if repeating the record for entry type 21)	4AN	18-21	C	For valid port codes, Refer to Note 1. For valid Firms Codes, Refer to ACS/ACE query.	1
Arrival Location	50X	22-71	O	Code or free form text indicating site of inspection.	
Filler	8X	72-80	M	Space fill	

Note 1:
Refer to List of Valid Port Codes:
http://www.cbp.gov/sites/default/files/documents/CBP%20Port%20Codes%20041014_1.pdf

Record Identifier PG55 (Additional Entity Roles)

This is an optional PGA input record used to provide additional roles performed by an entity or individual.

The PG55 record is not supported by FDA at this time. Multiple PG19 records should be used to input more than one Entity-Role combination. Refer to the PG19 section for details.

Record Identifier PG55 (Additional Entity Roles)					
Data Element	**Length/ Class**	**Position**	**Status**	**Description**	**Note**
Control Identifier	2A	1-2	M	“PG”.	
Record Type	2N	3-4	M	“55”.	
Entity Role Code	3AN	5-7	O	Additional role of the entity.	
Entity Role Code	3AN	8-10	O	Additional role of the entity.	
Entity Role Code	3AN	11-13	O	Additional role of the entity.	
Entity Role Code	3AN	14-16	O	Additional role of the entity.	
Entity Role Code	3AN	17-19	O	Additional role of the entity.	
Entity Role Code	3AN	20-22	O	Additional role of the entity.	
Entity Role Code	3AN	23-25	O	Additional role of the entity.	
Entity Role Code	3AN	26-28	O	Additional role of the entity.	
Entity Role Code	3AN	29-31	O	Additional role of the entity.	
Entity Role Code	3AN	32-34	O	Additional role of the entity.	
Filler	46X	35-80	M	Space fills.	

Not supported by FDA at this time

Record Identifier PG00 (Data Substitution)

This is an optional record used at the CBP entry (or entry summary) header, CBP entry (or entry summary) line and/or PGA message set levels to indicate data substitution.

Currently, the PG00 record is implemented only at the CBP entry header level. Future implementation will allow for submission at the CBP entry line and PGA Message Set level.

See the 'usage notes' in this chapter for more detailed information.

Record Identifier PG00 (Data Substitution)					
Data Element	**Length/ Class**	**Position**	**Status**	**Description**	**Note**
Control Identifier	2A	1-2	M	"PG".	
Record Type	2N	3-4	M	"00".	
Substitution Indicator	1X	5	O	Identifies either the start or end of the substitution group, or the location of where to place the substitute data within the PGA Message Set. The following codes are allowed: S=Start of the substitution group E=End of the substitution group R=Replace this record with the substitution group indicated by the Substitution Number	
Substitution Number	4AN	6-9	O	Sequential number assigned to, or referring to, a specific substitution group of data provided at the header level. This data element is mandatory when using the S or R substitution indicator.	
Filler	71X	10-80	M	Space fills.	

Medical Devices Commodity Data Elements and Values

Medical Device commodities can be broken down into the following categories using the existing Government Agency data elements available in the PG01 message

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

Table 5 – Medical Devices commodity hierarchy

* If Radiation Emitting Devices then all Medical Device data is required in addition to all applicable PG23 data elements for radiation-emitting products. See also PG23 for Radiation Emitting Products.

In submitting a Medical Device PGA Message Set to FDA, Importers are identifying themselves, the commodity, the intended use, the quantity of the commodity and valid FDA Affirmation of Compliance code values.

The following are the potential PGA records associated with submitting Medical Devices:

PG Record	Description
OI	The commercial description of the shipment
PG01	The shipment is regulated by the FDA program office within FDA and the intended use is provided.
PG02	Product Identifier; the item type and Product Code detail are provided.
PG06	Source Type(origin) other than the CBP country of origin is provided
PG07	The Trade/Brand Name, Model and Year of Manufacture are provided
PG10	Product Characteristics and other optional product information are provided
PG19	Entity Role (manufacturer, FDA importer, shipper, etc.) Entity Identification, Entity Name, and Entity Address 1 are provided.
PG20	Additional address data on the entity in PG19 is provided
PG21	Individual Name, Telephone Number, Fax Number, and Email address are provided
PG23	FDA's Affirmation of Compliance Criteria is provided.
PG24	Remarks
PG25	Temperature qualifier, Lot#, Production dates, PGA Line Value and PGA Unit Value are provided
PG26	Packaging qualifier and quantity of the shipment are provided
PG27	Data pertaining to issued Container Number is provided

PG Record	Description
PG29	Data pertaining to the net/gross unit of measure and quantity are provided
PG30	Data pertaining to date, time and location of inspection are provided
PG55	Identifies Entity from the previous PG19, PG20 and PG21 group as having additional roles.
PG00	Data substitution

Medical Devices Example

A shipment of Pediatric Tourniquet Cuff Set, is imported into the United States for domestic consumption.

Medical Device Message Set Layout for Sample

Please refer to the external file: **FDA SG 2.4 Example PG Message Sets.xlsx** Tab: ***Medical Devices***

Because of the flexibility of the PGA Message set, the PGA Records and Data Elements that are required may vary both from program to program and within a single program. For a more expansive set of examples of FDA PGA Message Sets, please refer to the above document.

Record Identifier OI (Record Identifier)

This is a mandatory PGA line item description input record that provides the description of the item. This record precedes the Record Identifiers for the PGA Message set.

Record Identifier OI (Record Identifier)					
Data Element	**Length/ Class**	**Position**	**Status**	**Description**	**Note**
Control Identifier	2A	1-2	M	“OI”	
Filler	8X	3-10	M	Space filled.	
Commercial Description	70X	11-80	M	The commercial description of the product. For example, PEDIATRIC TOURNIQUET CUFF SET.	

Record Identifier PG01 (PGA Identifier)

This is a mandatory PGA input record that provides data pertaining to the PGA Line Number, Government Agency Code, Government Agency Program Code, Globally Unique Product Identification Code, Intended Use Code, Intended Use Description, and Disclaimer. The Intended Use Code allows FDA to identify whether the imported commodity is restricted by a consumption allowance or not.

Record Identifier PG01 (PGA Identifier)					
Data Element	**Length/ Class**	**Position**	**Status**	**Description/Required Value**	**Note**
Control Identifier	2A	1-2	M	"PG"	
Record Type	2N	3-4	M	"01"	
PGA Line Number	3N	5-7	M	"001"	
Government Agency Code	3AN	8-10	M	"FDA"	
Government Agency Program Code	3X	11-13	C	"DEV"	1, 2
Government Agency Processing Code	3AN	14-16	C	Allowed values are 'RED' and 'NED'	1, 2
Intended Use Code	16X	42-57	C	Code identifying the intended use for the commodity after importation. For example, 081.001 (For Human Medical Use as a Medical Device).	2,3
Intended Use Description	22X	58-79	O	This field is used to describe the Intended Use such as 'Sample devices', 'Return shipment', etc.	2,3
Disclaimer	1A	80	C	A code of A (= product is not regulated by this agency) or B (= data is not required per agency guidance) indicating there is no agency declaration requirement. Or this field is left blank for no disclaimer. No other code is accepted	

Refer to Table 5 above for commodity type and sub-type for Medical Devices

Note 1
See Table 5 above for the commodity hierarchy for Medical Devices commodities.

Note 2
If the Disclaimer is 'A' then these data elements should both be populated with FDA. If the Disclaimer is 'B' then these data elements should both be populated with appropriate Program and Processing. Otherwise the Government Agency Program Code, Government Agency Processing Code and Intended Use Code are mandatory.

Note 3
Intended Use Codes and their descriptions can be found in Appendix R (Intended Use Codes for ACE) of the ACE ABI CATAIR publication. For Medical Devices, only one of the following Intended Use Codes may be entered:

Intended Use Code	Intended Use Definition	Relevant Medical Device Import Scenarios
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 • Import of a reprocessed device
081.002	For Human Medical Use as a Medical Device for Domestic Refurbishing	
081.003	For Human Medical Use as Medical Device–domestically manufactured device that is part of a medical device convenience kit	
081.004	For Human Medical Use as a Medical Device –foreign manufactured device that is part of a medical device convenience kit	
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).	
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	
155.010	Component for further manufacturing into a finished medical device	
155.011	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).	
170.000	For Repair of a Non-Food Product	• Repair of medical device and re-exportation
180.010	For Research and Development as a Non-Food Product - For research and development as a medical device	• Import of research or investigational use in vitro diagnostic 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 • 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	
920.001	Import of a device that is US goods returned for refund/overstock (to manufacturer)	
920.002	Import of a device that is US goods returned for sale to a third party	
940.000	Import of a Compassionate Use/Emergency Use Device	
950.001	Import of a single-use device for domestic reprocessing	
950.002	Import of a multi-use device for domestic reprocessing	
970.000	Import for Export	• Import of a medical device for further processing and re-exportation • Import of medical device or accessory for further manufacturing into an export only medical device
970.002	Import for Export	• Import of a medical device component for further manufacturing into an export only medical device

Record Identifier PG02 (Product Identifier)

This mandatory PGA input record is used to indicate if the following records relate to a product (P) or a component (C) of a product by specifying the Item Type.

For Medical Device entries, the Product Code Number is provided within this record.

Record Identifier PG02 (Product Identifier)					
Data Element	**Length/ Class**	**Position**	**Status**	**Description**	**Note**
Control Identifier	2A	1-2	M	“PG”	
Record Type	2N	3-4	M	“02”	
Item Type	1A	5	M	Code identifying the following records as pertaining to P=Product. No other values accepted. Only one ‘P’ record is allowed for the same PGA Line # in PG01 record.	
Product Code Qualifier	4AN	6-9	M	“FDP”.	1
Product Code Number	19X	10-28	M	Product Code Must be equal to 7 characters	

Note 1

Product Code Qualifiers and their descriptions can be found in Appendix PGA (PG02 – Product Code Qualifiers) of the ACE ABI CATAIR publication. For Medical Devices, this is currently always ‘FDP’ for all FDA products.

Only one Product Code Number per product is allowed.

FDA Product Code Structure:

Position	1-2	3	4	5	6-7
Name	Industry Code (N)	Class Code (A)	Sub Class Code (A or '-')	Process Identification Code - PIC (A or '-')	Product (AN)

Legend - N: Numeric; A:Alphabetic; AN:AlphaNumeric

Record Identifier PG06 (Product Origin)

This is a mandatory PGA input record that provides data pertaining to Source Type (Origin) other than the CBP Country of Origin.

Record Identifier PG06 (Product Origin)					
Data Element	**Length/ Class**	**Position**	**Status**	**Description**	**Note**
Control Identifier	2A	1-2	M	"PG".	
Record Type	2N	3-4	M	"06".	
Source Type Code	3AN	5-7	M	Mandatory valid values are 30 (Country of Source) or 39 (Country of Production). 294 (Country of Refusal) is MANDATORY if previously refused. There would be one PG06 with source type code of 30 or 39. If previously refused, then trade would also provide another PG06 with source type code 294.	1
Country Code	2X	8-9	M	Country of production or source is required for Medical Devices.	2

Note 1

Source Type Codes and their descriptions can be found in Appendix PGA (PG06 – Source Type Codes) of the ACE ABI CATAIR publication.

Note 2

Any of the country codes from Appendix B (ISO Country and Currency Codes) in the ACS ABI CATAIR can be entered.

Record Identifier PG07 (Product Trade Names)

For Medical Device, this is a mandatory PGA input record that provides FDA with data pertaining to Name.

Record Identifier PG07 (Product Trade Names)					
Data Element	**Length /Class**	**Position**	**Status**	**Description**	**Note**
Control Identifier	2A	1-2	M	“PG”	
Record Type	2N	3-4	M	“07”	
Trade Name/Brand Name	35X	5-39	M	Trade/Brand Name of the Medical Device. For example, Zimmer Reusable Tourniquet Cuff.	

Record Identifier PG10 (Product Characteristics)

This is a mandatory PGA input record that allows for reporting codes that provide additional characteristics of a product or component, not reported elsewhere in the PG Message Set. For example, this record can be used to provide the model year of a product, which can be different from the year of manufacture provided in the PG07. This record can be repeated if there are more qualifiers or categories.

Record Identifier PG10 (Product Characteristics)					
Data Element	**Length/ Class**	**Position**	**Status**	**Description**	**Note**
Control Identifier	2A	1-2	M	“PG”.	
Record Type	2N	3-4	M	”10”.	
Commodity Characteristic Description	57X	24-80	M	Free form description, NOT product code description, of the item, either to supplement the above data elements or in place of the above. See Appendix A for the use of PG10 to capture the information currently collected in multiple OI records.	

Record Identifier PG19 (Entity Data)

For Medical Devices, this is a mandatory PGA input record that provides FDA with data pertaining to Entity Role and conditionally the following data elements; Entity Identification, Entity Name, and Entity Address 1.

Record Identifier PG19 (Entity Data)					
Data Element	**Length /Class**	**Position**	**Status**	**Description**	**Note**
Control Identifier	2A	1-2	M	"PG"	
Record Type	2N	3-4	M	"19"	
Entity Role Code	3AN	5-7	M	Code identifying the role of the entity being provided. For example, MF.	1
Entity Identification Code	3AN	8-10	C	Code identifying the Entity Identification is entered. For example, 16. Mandatory, if Entity Number is entered.	2
Entity Number	15X	11-25	O	The Entity Number of the entity based on the above Entity Identification Code is entered; must conform to the descriptions in Note 2. Conditional, based on the roles and if they have been supplied at the entry and line	2
Entity Name	32X	26-57	M	The name of the entity is required. See validation criteria below.	2
Entity Address 1	23X	58-80	M	The address of the entity is required. See validation criteria below.	2

Note 1
Entity Role Codes and their descriptions can be found in Appendix PGA (PG19 – Entity Role Codes) of the ACE ABI CATAIR publication. List of Entity Role codes mandatory to FDA Device Message Sets is below:

Data Element	***Code***	***Description***
Entity Role Codes§	MF	Manufacturer of goods
	DEQ	Shipper
	FD1	FDA Importer 1 (Importer of Record)
	DII	Device Initial Importer
	DP	Delivered To Party±

§ Same Role Code cannot be entered more than once.

List of Entity Role codes also applicable to FDA Medical Device Message Sets is below:

Data Element	***Code***	***Description***
Entity Role Codes	AAR	All Applicable Roles
	APP	Applicant
	CE	Certifying Entity
	CO	Certifying Official
	CN	Consignee**
	CR	Consolidator
	CZ	Consignor
	DDF	Primary electronic business contact
	DDG	Alternate electronic business contact
	DDH	Primary government business contact
	DDI	Alternate government business contact

Data Element	Code	Description
	DEI	Means of transport operator
	DFP	Owner
	EX	Exporter
	EXE	Exporting Establishment
	FCI	FDA Clinical Investigator
	FD2	FDA Importer 2
	FD3	FDA Importer 3
	FG	Foreign Government
	GC	Goods custodian
	INC	Inspection Contact
	ITL	Independent Third Party Laboratory
	LAB	Laboratory
	LAP	LPCO Authorized Party
	LG	Location of Goods immediately after Entry Release
	LIP	LPCO Issuing Agency
	MF	Manufacturer of goods
	OV	Transport means owner
	PE	Producing Establishment
	PES	Packing Establishment
	PK	Point of Contact
	PRE	Preparer
	PRO	Processing Establishment
	RD	Retailer/Distributor
	RGO	Responsible Government Official
	SE	Seller
	SIG	Signer
	SOE	Source Establishment
	STL	Storage location
	TB	Submitter
	VW	Responsible party

Note 2
Entity Identification Codes and their descriptions can be found in Appendix PGA (PG19 – Entity Identification Codes) of the ACE ABI CATAIR publication. List of Entity Identification codes applicable to FDA Medical Device Message Sets is below:

Data Element	Code	Description	Length/ Class
Entity Identification Codes	16	D&B-assigned (DUNS number)	9N
	47	FDA-assigned	4-10N

FDA ENTITY IDENTIFICATION CODE AND ENTITY NUMBER SELECTION AND VALIDATION CRITERIA

FDA requires Entity Name and Entity Address. Additionally, FDA/CDRH prefers to use FEI numbers for identifying the Entity; IF FEI is not available THEN DUNS.

For devices the vast majority of registration numbers are FEIs

Entity Name <>NULL AND Entity Address 1 <>NULL AND
IF Entity Identification Code =47 (FEI) THEN Entity Number MUST BE Length from 4 to 10 and Type = N
ELSE IF Entity Identification Code =16 (DUNS) THEN Entity Number MUST BE Length = 9 and Type = N

Record Identifier PG20 (Entity Address)

This is a mandatory PGA input record that provides additional data pertaining to the Entity identified in the preceding PG19 record; such as Entity Address line 2, Apartment/Suite, City, State, and Zip/Postal Code. This record is used when additional address for the entity needs to be entered.

Record Identifier PG20 (Entity Address)					
Data Element	**Length/ Class**	**Position**	**Status**	**Description**	**Note**
Control Identifier	2A	1-2	M	“PG”	
Record Type	2N	3-4	M	“20”	
Entity Address 2	32X	5-36	C		1
Entity Apartment Number/Suite Number	5X	37-41	C	For example, 102 A.	1
Entity City	21X	42-62	M	For example, SAN DIEGO.	
Entity State/Province	3AN	63-65	C	For example, CA.	2
Entity Country	2A	66-67	M	For example, US.	
Entity Zip/Postal Code	9X	68-76	C	For example, 92169.	2
Filler	4X	77-80	M	Space fill	

Note 1: If the Entity Address 1 in PG19 is longer than the allocated 23 characters then utilize these fields.

Note 2: Populated if US or Canada based entities

Record Identifier PG21 (Point of Contact)

This is a mandatory PGA input record that provides FDA with data about an Individual Point of Contact (POC) related to the Entity (the party) in the **preceding** PG19 record. Included in this record are the Individual Name, Telephone Number, Fax Number, and Email address. A typical example is a POC for the Filer.

At least one PG21 record is required.

Record Identifier PG21 (Point of Contact)					
Data Element	**Length/ Class**	**Position**	**Status**	**Description**	**Note**
Control Identifier	2A	1-2	M	"PG"	
Record Type	2N	3-4	M	"21"	
Individual Qualifier	3AN	5-7	M	Code identifying which entity the Point of Contact is related to. For example, PK.	1
Individual Name	23X	8-30	M	Name of the Individual. If the name will not fit, complete PG24 and fill out the remarks code (Individual name) and then enter the name in the remarks text field. For example, JANE SIMMONS.	
Telephone Number of the Individual	15X	31-45	M	For example, (713)555-8765 in US or (+65)9052-3529 in Singapore	
Email Address or Fax Number for the Individual	35X	46-80	M	For example, JSIMMONS@ELEMENTALIMPORTERS.COM.	

Note 1

Entity Role Codes and their descriptions can be found in Appendix PGA (PG19 – Entity Role Codes) of the ACE ABI CATAIR publication. List of Entity Role codes applicable to FDA Medical Device Message Sets is below:

Data Element	***Code***	***Description***
Entity Role Codes	PK	Point of Contact

Record Identifier PG23 (Affirmation of Compliance)

For Medical Device, this is a mandatory PGA input record that provides data pertaining to Food and Drug Administration Affirmation of Compliance Criteria. This record is typically only used by FDA. This record is repeatable.

Record Identifier PG23 (Affirmation of Compliance)					
Data Element	**Length/ Class**	**Position**	**Status**	**Description**	**Note**
Control Identifier	2A	1-2	M	"PG"	
Record Type	2N	3-4	M	"23"	
Affirmation of Compliance Code	5X	5-9	M	A code used to affirm compliance with FDA requirements. .	1
Affirmation of Compliance Qualifier	30AN	10-39	C	Text describing the information required by the PGA. This could include a combination of letters and digits, specific text, etc. Follow the *Entered value of AoC Description / Business Rule* column in the table below in the Note section.	1

Note 1

The list of Affirmation of Compliance codes for FDA-Medical Devices Message Sets is below followed by the scenarios when the AofCs should be provided: : N=Numeric digits; X=Alphanumeric.

Code	***Description***	***Syntax***
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
DDM	Device Domestic Manufacturer	1 - 10N
DEV	Device Foreign Manufacturer Registration Number	1 - 10N
DFE	Device Foreign Exporter Registration Number	1 - 10N
DI	Device Identifier	6-23X
CPT	Component Identifier	Indicator only
IFE	Import For Export	Indicator only
IDE	Investigational Device Exemption Number	G+6N OR "NSR"
IRC	Device Impact Resistance Lens Certification	Indicator only
KIT	Device Imported Kit of Finished Device	Indicator only
LST	Device Listing Number	A+6N; B+6N; C+6N; D+6N; E+6N; L+6N; Q+6N; R+6N
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
IND	Biologics Investigation New Drug Application Number	4-6N
LWC	Electrode Lead Wire Or Patient Cable	Indicator Only

The table below shows which Affirmations of Compliance are Mandatory (M), Conditional (C) or Optional (O) based on the Intended Use Code/Import Scenario:

Intended Use (see PG01 for definitions)	Import Scenarios	Mandatory Affirmations	Conditional[1] Affirmations	Optional Affirmations
081.001	• Standard import of device, accessories, or components regulated as a finished device • Import of refurbished device • Import of a reprocessed device	DEV, DFE, LST	DI, IRC, LWC, PM#	
081.002*	Import of a device for domestic refurbishing	DEV, DFE, LST	DI, IRC, LWC, PM#	
081.003	domestically manufactured device that is part of a medical device convenience kit	DDM, DFE, KIT, LST	DI, IRC, LWC, PM#	
081.004	foreign manufactured device that is Part of a medical device convenience kit	KIT, DEV, DFE, LST	PM#, DI, LWC;IRC	
081.005	Device constituent part for drug-device combination product	DEV, DFE, LST	DA, IND	
140.000	Import of a device for charity	DEV, DFE, LST	DI, IRC, LWC, PM#	
155.010	Component for further manufacturing into a finished medical device	CPT		LST, PM#
155.011	Device component for use in a drug-device combination product	CPT	DA, IND	
170.000	Repair of medical device and re-exportation	DDM, IFE	DFE, DI, LST, IRC, LWC, PM#	
180.010	Import of research or investigational use in vitro diagnostic device			
180.014*	• Import of a device for non-clinical use/bench testing • Import of device sample for customer evaluation			
180.015*	Import of a medical device for clinical investigational use	IDE		
920.001	Import of a device that is US goods returned for refund/overstock (to manufacturer)	DDM, LST	DFE, DI, IRC, LWC, PM#	
920.002	Import of device that is US goods returned for sale to a third party	DFE, DDM, LST	DI, IRC, LWC, PM#	
950.001*	Import of a single-use device for domestic reprocessing	DDM, LST	DFE, DI, IRC, LWC, PM#	
950.002*	Import of a multi-use device for domestic reprocessing		DDM, DFE, DI, IRC, LST, LWC, PM#	
970.001	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	DEV, DFE, IFE, LST		
970.002	Import for Export: • Importation of a medical device component for further manufacturing into an export-only medical device	IFE, CPT, DDM, LST		
110.000* 100.000* 940.000* 081.006	• Public Exhibition/Trade Show • Device For Personal Use • Compassionate Use/Emergency device • Import under enforcement discretion provisions			

[1]: The conditional affirmations are required if applicable to the product being declared. For example, if the product requires premarket clearance (510(k)), then PM# must be provided.
*Annotates that additional information may be needed at time of entry in order for FDA to make a final admissibility decision.

Record Identifier PG24 (Remarks)

This is an optional PGA input record that provides data pertaining to Remarks Codes, and Text of Remarks.

Remark Type Code should be either GEN or NAM.

If GEN, the PG24 is applicable to the preceding PG02. Only one GEN:PG24 is allowed per PG02 (this is to avoid multiple GEN:PG24 records without a guaranteed sequencing as intended by the filer). This may be expanded in future with sufficient sequencing control to receive multiple GEN:PG24 records in the same order in which the Filer entered remarks.

If NAM, the PG24 is applicable to the preceding PG21. This structure simply allows the entry of 68 characters in addition to 23 characters afforded by PG21 for the Individual Name field in PG21. When a NAM-PG24 is present, the Individual Name field in PG21 is concatenated with Remarks Text field in PG24, to the full name in the format "*Last Name, First Name Middle Name*" for a potential 91 characters. Only one NAM:PG24 is allowed per PG21.

Record Identifier PG24 (Input)					
Data Element	**Length /Class**	**Position**	**Status**	**Description**	**Note**
Control Identifier	2A	1-2	M	Must always equal PG.	
Record Type	2N	3-4	M	Must always be 24.	
Remarks Type Code	3X	5-7	O	A code indicating the type of remarks. Valid codes are listed in Appendix PGA (Remarks Type Code) of this publication. FDA uses either NAM or GEN as its valid values.	1
Remarks Text	68X	13-80	O	Free form text relevant to the shipment or the commodity.	

Note 1
If an individual's Name in the preceding PG21 is longer than 23 characters, the Remarks Type Code should be identified as NAM (Full name of the Individual) then the Remarks Text can be used to indicate the full name of that individual. Individual's Name should still follow the same format when using PG24, as following:

Last Name, First Name Middle Name

If submitting general comments then use the Remarks Type Code = GEN (General Remarks)

Record Identifier PG25 (Product Condition)

For Medical Device, it is a mandatory PGA input record that provides data pertaining to: Temperature Qualifier, Degree Type, Actual Temperature, Lot Number, Production Date, Range of the Lot, PGA Line Value, and PGA Unit Value. This record is repeatable for multiple Lot Number Qualifiers and Lot Numbers but the line value MUST be included on each record.

Record Identifier PG25 (Product Condition)					
Data Element	**Length/ Class**	**Position**	**Status**	**Description**	**Note**
Control Identifier	2A	1-2	M	"PG"	
Record Type	2N	3-4	M	"25"	
Temperature Qualifier	1A	5	O	Temperature Category being reported for quality control or preservation purposes. A= Ambient, F=Frozen, D=Dry Ice, R=Refrigerated/Chilled, H=Fresh, U=Uncontrolled, P=Flashpoint	
Degree Type	1A	6	O	F = Fahrenheit, C = Celsius , K = Kelvin	
Negative Number	1A	7	O	If the actual temperature is in the negative numbers use an "X". This is left blank for a positive value.	
Actual Temperature	6N	8-13	O	Required if Degree Type is entered. Reported temperature. Two decimals places are implied.	
Location of Temperature Recording	1A	14	O	Identifies recorded temperature is for A=product, B=container and C= conveyance	
Lot Number Qualifier	1AN	15	O	Code of the entity that assigned the Lot number. 1 = Manufacturer	
Lot Number	25X	16-40	O	The lot number that the manufacturer assigned to the product.	
Production Start date of the Lot	8N	41-48	O	The date when the production for the Lot started. A numeric date in MMDDCCYY (month, day, century, year) format.	
Production End Date of the Lot	8N	49-56	O	The date when the production for the Lot ended. A numeric date in MMDDCCYY (month, day, century, year) format.	
PGA Line Value	12N	57-68	M	The value associated with the PGA line number in whole dollars. It must be right-justified with preceding zeros. Must be greater than zero.	
PGA Unit Value	12N	69-80	O	The value of the lowest unit of measure reported in PG26. Two decimal places are implied.	

Record Identifier PG26 (Product Packaging)

For Medical Device, this is a mandatory PGA input record that provides FDA with data pertaining to Packaging Qualifier, Quantity and Unit of Measure. This record can be repeated up to six (6) times, once for each unique packaging level. The first record is used to describe the largest (outermost) container and the number of containers at this packaging level. The second record is used to describe the contents of the next smallest container. If needed, qualifiers 2-6 are used in a similar manner (largest to smallest container). The final record must describe the actual amount of the product in the smallest container.

The appearance of any 'Packaging Qualifier' number level requires all levels under it to be represented. For instance, level 3 can't be present unless levels 1 and 2 are present.

Record Identifier PG26 (Product Packaging)					
Data Element	**Length /Class**	**Position**	**Status**	**Description**	**Note**
Control Identifier	2A	1-2	M	"PG"	
Record Type	2N	3-4	M	"26"	
Packaging Qualifier	1N	5	M	Code identifying the level of packaging. For example, 4. If reporting only one level, show the total quantity for the item and report that as level 1.	1,4
Quantity	12N	6-17	M	"Quantity of the packaging level, For example, 000000000400. Must be greater than zero.	2,4
Unit of Measure (Packaging Level)	5X	18-22	M	Type of packaging / packaging level. For example, BX. At least, 'Pieces' must be selected	3,4

Note 1
This code identifies the level of packaging for the product. Valid values are 1, 2, 3, 4, 5 and 6: Outermost (largest=1) packages to the innermost (smallest=6) packages. There can be up to 6 levels of packaging.

Note 2
There are two implied decimal points when writing the quantity in Units of Measure for the Base Unit (Last Quantity Transmitted). In this example, 4 pieces are represented as 000000000400, with the nine leading zeroes as "fill" and two decimal places following the value. The quantity for packaging containers will be in whole numbers with no decimal places. The sample shows 1 carton containing 10 boxes and each box containing 4 pieces.

Note 3
List of Unit of Measure codes applicable to FDA-Devices Message Sets
For a full list of applicable Unit of Measure codes, please refer to Appendix F in this document or to the Appendix PGA (PG26 – Unit of Measure - Valid FDA Units of Measure for Packaging Containers) and Appendix PGA (PG26 – Unit of Measure -Valid FDA Units of Measure for the Base Unit (Last Quantity Transmitted)) of the CATAIR.

Valid FDA Units of Measure for Packaging Containers

Code	***Description***
CS	Case
CT	Carton
BX	Box
PK	Package

Valid FDA Units of Measure for the Base Unit (Last Quantity Transmitted)

Code	***Description***
PCS	Pieces (Count)

Note 4

Quantity Data provides additional information to FDA about the product and how it is packaged. The basic format for Quantity Data is in multiple pairs of data – quantity and unit of measure, i.e., 200 cartons, 6 boxes, 8 pieces, etc. Up to 6 data pairs may be submitted, beginning with the 1st pair for the outermost packaging when Packaging Qualifier = 1. The first pair may describe the largest container and the last pair must describe the amount of product in the smallest container. For example:

200 Cartons of 6 boxes of PEDIATRIC TOURNIQUET CUFF SET in each carton
8 pieces per box

Units 1-Quantity	200
Units 1-Measure	CT
Units 2-Quantity	6
Units 2-Measure	BX
Units 3-Quantity	8
Units 3-Measure	PCS

For Medical Devices, the lowest unit of measure must be PCS (Pieces – Count).

Record Identifier PG27 (Container Information)

This is an optional PGA input record that provides data pertaining to issued Container Number. The number of the shipping container is included in the Bill of Lading. Hence this record is not needed.

Record Identifier PG26 (Container Information)					
Data Element	**Length/ Class**	**Position**	**Status**	**Description**	**Note**
Control Identifier	2A	1-2	M	“PG”.	
Record Type	2N	3-4	M	“27”.	
Container Number (Equipment ID)	20AN	5-24	O	The number of the shipping container as entered in the Bill of Lading.	

Record Identifier PG29 (Unit of Measure)

This is an optional PGA input record that provides data pertaining to the net or gross unit of measure of the commodity. This can be provided at the overall PGA Line Number and/or the Individual Unit level.

Record Identifier PG29 (Unit of Measure)					
Data Element	**Length/ Class**	**Position**	**Status**	**Description**	**Note**
Control Identifier	2A	1-2	M	“PG”.	
Record Type	2N	3-4	M	“29”.	
Unit of Measure (PGA line - net)	3AN	5-7	O	Pertaining to the overall PGA Line Number, the indication of the unit of measurement in which weight, capacity, length, area, volume or other quantity is expressed. “Unit of Measure (PGA line - net)” in this position is associated with “Commodity Net Quantity (PGA line - net)” and is required when “Commodity Net Quantity (PGA line - net)” is reported. Valid Unit of Measure codes are listed in Appendix F in this document or in Appendix C in the ACS ABI CATAIR.	
Commodity Net Quantity (PGA line - net)	12N	8-19	O	Pertaining to the overall PGA Line Number, excluding all packing and packaging. Two decimals are implied. “Commodity Net Quantity (PGA line - net)” is required when “Unit of Measure (PGA line - net)” is reported in positions 5-7 of this record.	
Unit of Measure (PGA line - gross)	3AN	20-22	O	Pertaining to the overall PGA Line Number, the indication of the unit of measurement in which weight, capacity, length, area, volume or other quantity is expressed. “Unit of Measure (PGA line - gross)” in this position is associated with “Commodity Gross Quantity (PGA line - gross)” and is required when “Commodity Gross Quantity (PGA line - gross)” is reported. Valid Unit of Measure codes are listed in Appendix F in this document or in Appendix C in the ACS ABI CATAIR.	
Commodity Gross Quantity (PGA line - gross)	12N	23-34	O	Pertaining to the overall PGA Line Number, including any packaging, but excluding weight of the carrier's equipment. Two decimals are implied. “Commodity Gross Quantity (PGA line - gross)” is required when “Unit of Measure (PGA line - gross)” is reported in positions 20-22 of this record.	

Record Identifier PG29 (Unit of Measure)					
Data Element	**Length/ Class**	**Position**	**Status**	**Description**	**Note**
Unit of Measure (Individual Unit - net)	3AN	35-37	O	Pertaining to the Individual unit (net), the indication of the unit of measurement in which weight, capacity, length, area, volume or other quantity is expressed. "Unit of Measure (Individual unit - net)" in this position is associated with "Commodity Net Quantity (Individual unit - net)" and is required when "Commodity Net Quantity (Individual unit - net)" is reported. Valid Unit of Measure codes are listed in Appendix F in this document or in Appendix C in the ACS ABI CATAIR.	
Commodity Net Quantity (Individual Unit - net)	12N	38-49	O	Pertaining to the Individual unit, excluding all packing and packaging. Two decimals are implied. "Commodity Net Quantity (Individual unit - net)" is required when "Unit of Measure (Individual unit - net)" is reported in positions 35-37 of this record.	
Unit of Measure (Individual Unit - gross)	3AN	50-52	O	Pertaining to the Individual unit (gross), the indication of the unit of measurement in which weight, capacity, length, area, volume or other quantity is expressed. "Unit of Measure (Individual unit - gross)" in this position is associated with "Commodity Gross Quantity (Individual unit - gross)" and is required when "Commodity Gross Quantity (Individual unit - gross)" is reported. Valid Unit of Measure codes are listed in Appendix F in this document or in Appendix C in the ACS ABI CATAIR.	
Commodity Gross Quantity (Individual Unit - gross)	12N	53-64	O	Pertaining to the Individual unit, including any packaging, but excluding weight of the carrier's equipment. Two decimals are implied. "Commodity Gross Quantity (Individual unit - gross)" is required when "Unit of Measure (Individual unit - gross)" is reported in positions 50-52 of this record.	
Filler	16X	65-80	M	Space fill	

Note 1

The HTS Units of Measure and their descriptions are in Appendix C Tariff Abbreviations table.
Each pair of Unit of Measure and Quantity of commodity is entered at Net and Gross Level and PGA Line and Individual Unit level for 4 distinct pairs of data.

All the four pairs of data are optional and for each pair, if the Quantity is entered, its corresponding Units of Measure value is required. The valid values of Units of Measure for Medical Devices are below:

HTS Units of Measure	
Code	***Description***
CC	Cubic Centimeter
CFT	Cubic Feet (Volume)
CM3	Cubic Centimeters

HTS Units of Measure	
Code	***Description***
CYD	Cubic Yards (Volume)
DOZ	Dozen
DPC	Dozen Pieces
DPR	Dozen Pairs
G	Gram
HUN	Hundreds
K	1,000
KG	1,000 Grams
KM3	1,000 Cubic Meters
LB	Pounds, (weight) avdp)
M3	Cubic Meters
NO	Number
OZ	Ounces, (weight) (avdp)
PCS	Pieces
PK	Pack
PRS	Pairs
STN	Short Ton (2000 LB) (Weight)
T	Metric Ton

Record not supported by FDA at this time

Record Identifier PG30 (Anticipated Arrival Information)

This is a mandatory PGA input record that provides data pertaining to the date, time and location of the anticipated arrival information for all FDA products. While other PGAs may use PG30 to Collect Inspection and Lab information, currently FDA will utilize this record to collect Anticipated Arrival Information at this time.

For each line a PG30 record with an "A" (Anticipated arrival information) code, date and time of arrival is Mandatory.

Record Identifier PG30 (Inspection and Lab Information)					
Data Element	**Length/ Class**	**Position**	**Status**	**Description**	**Note**
Control Identifier	2A	1-2	M	“PG”.	
Record Type	2N	3-4	M	“30”.	
Inspection/ Laboratory Testing Status	1A	5	M	A is the ONLY valid code for FDA:: A = Anticipated arrival information	
Anticipated Arrival date	8N	6-13	M	A numeric date in MMDDCCYY (month, day, century, year) format.	
Arrival time	4N	14-17	M	Military time HHMM in (hour, minute) format. (Example: 1015, this represents 10:15 a.m.). For midnight, use 2400 (0000 is invalid).	
Anticipated Arrival Location Code	4AN	18-21	O	For valid port codes, refer to Note 1.	1
Arrival Location	50X	22-71	O	Code or free form text indicating site of inspection.	
Filler	8X	72-80	M	Space fill	

Note 1:
Refer to List of Valid Port Codes:
http://www.cbp.gov/sites/default/files/documents/CBP%20Port%20Codes%20041014_1.pdf

Record Identifier PG55 (Additional Entity Roles)

This is an optional PGA input record used to provide additional roles performed by an entity or individual.

The PG55 record is not supported by FDA at this time. Multiple PG19 records should be used to input more than one Entity-Role combination. Refer to the PG19 section for details.

Record Identifier PG55 (Additional Entity Roles)					
Data Element	**Length /Class**	**Position**	**Status**	**Description**	**Note**
Control Identifier	2A	1-2	M	“PG”.	
Record Type	2N	3-4	M	“55”.	
Entity Role Code	3AN	5-7	O	Additional role of the entity.	
Entity Role Code	3AN	8-10	O	Additional role of the entity.	
Entity Role Code	3AN	11-13	O	Additional role of the entity.	
Entity Role Code	3AN	14-16	O	Additional role of the entity.	
Entity Role Code	3AN	17-19	O	Additional role of the entity.	
Entity Role Code	3AN	20-22	O	Additional role of the entity.	
Entity Role Code	3AN	23-25	O	Additional role of the entity.	
Entity Role Code	3AN	26-28	O	Additional role of the entity.	
Entity Role Code	3AN	29-31	O	Additional role of the entity.	
Entity Role Code	3AN	32-34	O	Additional role of the entity.	
Filler	8X	72-80	M	Space fill	

Not supported by FDA at this time

Record Identifier PG00 (Data Substitution)

This is an optional record used at the CBP entry (or entry summary) header, CBP entry (or entry summary) line and/or PGA message set levels to indicate data substitution.

Currently, the PG00 record is implemented only at the CBP entry header level. Future implementation will allow for submission at the CBP entry line and PGA Message Set level.

PG00 Substitution Grouping

In situations where the trade finds it would be supplying identical information more than once within the PGA Message Set, a PG00 substitution grouping can be used, instead of repeating that information multiple times. See the 'usage notes' in the ACE ABI CATAIR - Customs and Trade Automated Interface Requirements publication for more detailed information.

Record Identifier PG00 (Data Substitution)					
Data Element	**Length /Class**	**Position**	**Status**	**Description**	**Note**
Control Identifier	2A	1-2	M	"PG".	
Record Type	2N	3-4	M	"00".	
Substitution Indicator	1X	5	O	Identifies either the start or end of the substitution group, or the location of where to place the substitute data within the PGA Message Set. The following codes are allowed: S=Start of the substitution group E=End of the substitution group R=Replace this record with the substitution group indicated by the Substitution Number	
Substitution Number	4AN	6-9	O	Sequential number assigned to, or referring to, a specific substitution group of data provided at the header level. This data element is mandatory when using the S or R substitution indicator.	
Filler	71X	10-80	M	Space fills.	

Tobacco Commodity Data Elements and Values

Tobacco commodities can be broken down into the following categories using the existing Government Agency data elements available in the PG01 message

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

Table 6 – Tobacco commodity hierarchy

± Required to identify a tobacco product as “for further manufacturing (FFM)”, for “consumer use” (CSU), or for “investigational use” (INV). This information is needed to determine the marketing status of the product. Ref: Sections 905, 910, and 911 of the FD&C Act.

The following are the potential PGA records associated with submitting Tobacco Products:

PG Record	Description
OI	The commercial description of the shipment is provided.
PG01	The shipment is regulated by the FDA program office within FDA and the intended use is provided.
PG02	The item type and Product Code detail are provided.
PG06	Source Type(origin) other than the CBP country of origin is provided
PG07	The Trade/Brand Name, Model and Year of Manufacture are provided
PG10	Product Characteristics and other optional product information are provided
PG19	The entity (manufacturer, consignee, shipper, etc.) of Record’s identification information is provided.
PG20	Additional address data on the entity in PG19 is provided
PG21	The entity (manufacturer, consignee, shipper, etc.) of Record’s individual point of contact, phone number and email is given.
PG23	FDA’s Affirmation of Compliance Criteria is provided.
PG24	Remarks
PG25	Temperature qualifier, Lot#, Production dates, PGA Line Value and PGA Unit Value are provided
PG26	Packaging qualifier and quantity of the shipment are provided
PG29	Data pertaining to the net or gross unit of measure of the commodity

PG Record	Description
PG30	Inspection/Laboratory Testing
PG55	Additional roles performed by entity or individual
PG00	Data Substitution

Tobacco Example

Tobacco Message Set Layout for Sample

Please refer to the external file: **FDA SG 2.4 Example PG Message Sets.xlsx** Tab: ***Tobacco***

Because of the flexibility of the PGA Message set, the PGA Records and Data Elements that are required may vary both from program to program and within a single program. For a more expansive set of examples of FDA PGA Message Sets, please refer to the above document.

Record Identifier OI (Record Identifier)

This is a mandatory PGA line item description input record that provides the description of the item. This record precedes the Record Identifiers for the PGA Message set.

Record Identifier OI (Record Identifier)					
Data Element	**Length/ Class**	**Position**	**Status**	**Description**	**Note**
Control Identifier	2A	1-2	M	"OI"	
Filler	8X	3-10	M	Space filled.	
Commercial Description	70X	11-80	M	The commercial description of the product. For example, Tobacco leaves - unprocessed	

Record Identifier PG01 (PGA Identifier)

This is a mandatory PGA input record that provides data pertaining to the PGA Line Number, Government Agency Code, Government Agency Program Code, Globally Unique Product Identification Code, Intended Use Code, Intended Use Description, and Disclaimer. The Intended Use Code allows FDA to identify whether the imported commodity is restricted by a consumption allowance or not.

Record Identifier PG01 (PGA Identifier)					
Data Element	**Length/ Class**	**Position**	**Status**	**Description/Required Value**	**Note**
Control Identifier	2A	1-2	M	"PG"	
Record Type	2N	3-4	M	"01"	
PGA Line Number	3N	5-7	M	"001"	
Government Agency Code	3AN	8-10	M	"FDA"	
Government Agency Program Code	3X	11-13	C	"TOB"	1, 2
Government Agency Processing Code	3AN	14-16	C	Allowed values: CSU, FFM, INV	1, 2
Intended Use Code	16X	42-57	C	If Government Processing Code = INV then one of the 180 BaseCode intended use codes must be supplied. The Government Agency Processing Code and the Product Code should provide all the information the FDA need to know about the intended use.	3,4
Intended Use Description	22X	58-79	O		3,4
Disclaimer	1A	80	C	A code of A (= product is not regulated by this agency) or B (= data is not required per agency guidance) indicating there is no agency declaration requirement. Or this field is left blank for no disclaimer. No other code is accepted	2,3

Note 1

See Table 6 above for the commodity hierarchy for Tobacco commodities.

Note 2

If the Disclaimer is 'A' or 'B' then these data elements should both be populated with FDA. otherwise the Government Agency Program Code, Government Agency Processing Code are mandatory.

Note 3

If the Disclaimer is 'A' or 'B' then these data elements are optional; otherwise the Intended Use Code is conditional.

Note 4

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

** Although Section 905 of the FD&C Act only applies to domestic manufacturers, it's important for enforcement purposes to know when products are being imported for repackaging or relabeling because the repackagers / relabelers will need to register with FDA. Under Section 905, the term "manufacture, preparation, compounding, or processing" includes repackaging or otherwise changing the container, wrapper, or labeling of any tobacco product package in furtherance of the distribution of the tobacco product from the original place of manufacture to the person who makes final delivery or sale to the ultimate consumer or user. Ref: 701(b); Section 905 of the FD&C Act (21 U.S.C. §387e)

Record Identifier PG02 (Product Identifier)

This mandatory PGA input record is used to indicate whether or not the information being provided relates to a product (P) or a component (C) of a product.

Record Identifier PG02 (Product Identifier)					
Data Element	**Length/ Class**	**Position**	**Status**	**Description**	**Note**
Control Identifier	2A	1-2	M	"PG"	
Record Type	2N	3-4	M	"02"	
Item Type	1A	5	M	Code identifying the following records as pertaining to P=Product. No other values accepted. Only one 'P' record is allowed for the same PGA Line # in PG01 record.	
Product Code Qualifier	4AN	6-9	M	"FDP"	1
Product Code Number	19X	10-28	M	FDA Product Code Must be equal to 7 characters	

Note 1

Product Code Qualifiers and their descriptions can be found in Appendix PGA (PG02 – Product Code Qualifiers) of the ACE ABI CATAIR publication. For Tobacco, this is currently always 'FDP' for all FDA products.

Only one FDA Product Code Number per product is allowed.

FDA Product Code Structure:

Position	1-2	3	4	5	6-7
Name	Industry Code (N)	Class Code (A)	Sub Class Code (A or '-')	Process Identification Code - PIC (A or '-')	Product (AN)

Legend - N: Numeric; A:Alphabetic; AN:AlphaNumeric

Record Identifier PG06 (Product Origin)

This is a conditional PGA input record that provides data pertaining to Source Type (Origin) other than the CBP Country of Origin, in addition to Processing dates, Processing Type and Processing Description.

Record Identifier PG06 (Product Origin)					
Data Element	**Length/ Class**	**Position**	**Status**	**Description**	**Note**
Control Identifier	2A	1-2	M	"PG".	
Record Type	2N	3-4	M	"06".	
Source Type Code	3AN	5-7	C	For Tobacco, Source Type Code 39 (Country of Production) is required. Other Source Type Codes, 262 (Place of Growth) or HRV (Harvested) or 30 (Country of Source) may be entered, if available. There would be at least one PG06 with source type code of 39. More PG06 records may be repeated for the optional Source Type Codes, 262, HRV or 30.. Additionally, if previously refused, then trade would also provide another PG06 with source type code 294 (Country of Refusal).	1
Country Code	2X	8-9	C	Country of production or source is required for Tobacco.	2

Note 1

Source Type Codes and their descriptions can be found in Appendix PGA (PG06 – Source Type Codes) of the ACE ABI CATAIR publication.

Note 2

Any of the country codes from Appendix B (ISO Country and Currency Codes) in the ACS ABI CATAIR can be entered.

Record Identifier PG07 (Product Trade Names)

This is a conditional PGA input record that provides data pertaining to Trade or Brand Name, Model, Manufacture Year, Item Identity Number Qualifier and Item Identity Numbers.

Record Identifier PG07 (Product Trade Names)					
Data Element	**Length/ Class**	**Position**	**Status**	**Description**	**Note**
Control Identifier	2A	1-2	M	"PG"	
Record Type	2N	3-4	M	"07"	
Trade Name/Brand Name**	35X	5-39	C	If Government Agency Processing Code is INV (Investigational) or CSU (Consumer Use) then trade or brand name is mandatory. If Government Agency Processing Code is FFM (For Further Manufacturing), then trade name/brand name is optional.	

** This field is only required for products intended for consumer use and for investigational use, not for products intended for further manufacturing. Brand name is required in order to help identify if the product meets FDA's pre-market authorization requirements under Section 910 of the FD&C Act.

Record Identifier PG10 (Product Characteristics)

For Tobacco, this is a mandatory PGA input record that allows for importer to report the description of the product at the line level to capture the information currently collected in multiple OI records. This record can be repeated if there are more Commodity Characteristic Descriptions.

Record Identifier PG10 (Product Characteristics)					
Data Element	**Length/ Class**	**Position**	**Status**	**Description**	**Note**
Control Identifier	2A	1-2	M	“PG”.	
Record Type	2N	3-4	M	“10”.	
Commodity Characteristic Description	57X	24-80	M	Free form invoice description, NOT product code description. This field will capture such information as length, color, and pack count. Under 21 1140.16(b), cigarette packages are required to contain a minimum of 20 cigarettes. See Appendix A for the use of PG10 to capture the information such as length, color and pack count.	

Record Identifier PG19 (Entity Data)

For Tobacco, this is a mandatory PGA input record that provides FDA with data pertaining to Entity Role and conditionally the following data elements; Entity Identification, Entity Name, and Entity Address 1.

Record Identifier PG19 (Entity Data)					
Data Element	**Length /Class**	**Position**	**Status**	**Description**	**Note**
Control Identifier	2A	1-2	M	"PG"	
Record Type	2N	3-4	M	"19"	
Entity Role Code	3AN	5-7	M	Code identifying the role of the entity being provided. For example: MF, UC	1
Entity Identification Code	3AN	8-10	C	Code identifying the Entity Identification is entered. For example: 16, 47. Mandatory, if Entity Number is entered.	2
Entity Number	15X	11-25	O	The Entity Number of the entity based on the above Entity Identification Code is entered; must conform to the descriptions in Note 2	2
Entity Name	32X	26-57	M	The name of the entity is required. See validation criteria below.	2
Entity Address 1	23X	58-80	M	The address of the entity is required. See validation criteria below.	2

Note 1

Entity Role Codes and their descriptions can be found in Appendix PGA (PG19 – Entity Role Codes) of the ACE ABI CATAIR publication. List of Entity Role codes mandatory to FDA Tobacco Message Sets is below:

Data Element	***Code***	***Description***
Entity Role Codes§	MF	Manufacturer of goods
	DEQ	Shipper
	FD1	FDA Importer (Importer of Record)
	TB	Submitter
	DP	Delivered to Party±

§ Same Role Code cannot be entered more than once.

± Even though Title 19 141.19 (CBP) addresses - Consignee -, Title 21, Requires Prior Notice information about the - Ultimate Consignee - and Title 19 (CBP) defines - Ultimate Consignee -, FDA acknowledges that these terms cause confusion and would like to simplify and harmonize said data elements under the ACE environment.

Hence, the FDA has elected to utilize the data element --- "Deliver to Party" --- , U.S party that physically receives the good(s). The FDA's PG Message Set will, therefore, incorporate the deliver to party as issued in the ITDS Standard Data Set under the auspices of the ITDS Board of Directors. FDA's Prior Notice requirement for ultimate consignee is synonymous with deliver to party.

List of Entity Role codes **conditional** to FDA Tobacco Message Sets is below:

(If Government Agency Processing Code is INV then either ITL or LAB is mandatory.

Data Element	***Code***	***Description***
Entity Identification Codes	ITL	Independent Third Party Laboratory

	LAB	Laboratory or Clinical Site

List of Entity Role codes also applicable to FDA Tobacco Message Sets is below:

Data Element	***Code***	***Description***
	RD	Retailer/Distributor

Note 2

Entity Identification Codes and their descriptions can be found in Appendix PGA (PG19 – Entity Identification Codes) of the ACE ABI CATAIR publication. List of Entity Identification codes applicable to FDA Tobacco Message Sets is below:

Data Element	***Code***	***Description***	***Length/ Class***
Entity Identification Codes	16	D&B-assigned (DUNS number)	9N
	47	FDA-assigned	4-10N

FDA ENTITY IDENTIFICATION CODE AND ENTITY NUMBER SELECTION AND VALIDATION CRITERIA

FDA requires Entity Name and Entity Address. Additionally, an FEI number is required to import into the U.S.

Entity Name <>NULL AND Entity Address 1 <>NULL AND
IF Entity Identification Code =47 (FEI) THEN Entity Number MUST BE Length from 4 to 10 and Type = N

ELSE Entity Identification Code =16 (DUNS) THEN Entity Number MUST BE Length = 9 and Type = N

.

Record Identifier PG20 (Entity Address)

This is a mandatory PGA input record that provides additional data pertaining to the Entity identified in the preceding PG19 record; such as Entity Address line 2, Apartment/Suite, City, State, and Zip/Postal Code. This record is used when additional address for the entity needs to be entered.

Record Identifier PG20 (Entity Address)					
Data Element	**Length/ Class**	**Position**	**Status**	**Description**	**Note**
Control Identifier	2A	1-2	M	“PG”	
Record Type	2N	3-4	M	“20”	
Entity Address 2	32X	5-36	C	Address Line 2 for the Entity.	1
Entity Apartment Number/Suite Number	5X	37-41	C	For example, 102 A.	1
Entity City	21X	42-62	M	For example, SUGARLAND	
Entity State/Province	3AN	63-65	C	For example, TX.	2
Entity Country	2A	66-67	M	For example, US.	
Entity Zip/Postal Code	9X	68-76	C	For example, 77004.	2
Filler	4X	77-80	C	Space fill	

Note 1: If the Entity Address 1 in PG19 is longer than the allocated 23 characters then utilize these fields.

Note 2: Populated if US or Canada based entities

Record Identifier PG21 (Point of Contact)

This is a mandatory PGA input record that provides FDA with data about an Individual Point of Contact (POC) related to the Entity (the party) in the preceding PG19 record. Included in this record are the Individual Name, Telephone Number, Fax Number, and Email address. A typical example is a POC for the Filer.

At least one PG21 record is required.

Record Identifier PG21 (Point of Contact)					
Data Element	**Length/ Class**	**Position**	**Status**	**Description**	**Note**
Control Identifier	2A	1-2	M	"PG"	
Record Type	2N	3-4	M	"21"	
Individual Qualifier	3AN	5-7	M	Code identifying which entity the Point of Contact is related to. For example, PK	1
Individual Name	23X	8-30	M	Name of the Individual. If the name will not fit, complete PG24 and fill out the remarks code (Individual name) and then enter the name in the remarks text field. For example, THOMAS FREDERCKSEN	
Telephone Number of the Individual	15X	31-45	M	For example, (713)555-8765 in US or (+65)9052-3529 in Singapore	
Email Address or Fax Number for the Individual	35X	46-80	M	For example, T.FREDERI@OJANDMORE.COM.	

Note 1

Entity Role Codes and their descriptions can be found in Appendix PGA (PG19 – Entity Role Codes) of the ACE ABI CATAIR publication. List of Entity Role codes applicable to FDA Medical Device Message Sets is below:

Data Element	***Code***	***Description***
Entity Role Codes	PK	Point of Contact

Record Identifier PG23 (Affirmation of Compliance)

For Tobacco, this is a conditional PGA input record that provides data pertaining to Food and Drug Administration Affirmation of Compliance Criteria. This record is typically only used by FDA. This record is repeatable.

Record Identifier PG23 (Affirmation of Compliance)					
Data Element	**Length/ Class**	**Position**	**Status**	**Description**	**Note**
Control Identifier	2A	1-2	M	"PG".	
Record Type	2N	3-4	M	"23".	
Affirmation of Compliance Code	5X	5-9	C	A code used to affirm compliance with FDA requirements. See table below for valid affirmation codes.	1
Affirmation of Compliance Qualifier	30AN	10-39	C	Text describing the information required by the PGA. This could include a number or a country code, etc. Also, see Appendix PGA (Food & Drug Affirmation of Compliance Qualifier Codes) of this publication for valid codes related to certain specific Affirmation of Compliance codes.	
Filler	1X	80	M	Space fill	

Note 1

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 **conditional** to FDA Tobacco Message Sets is below:

Data Element	***Code***	***Description***	***Syntax***	***Business Rules***
Affirmation of Compliance Code	ILS	Confirmation of **Ingredient Listings Submission** to FDA: Manufacturers and importers of tobacco products to the U.S. must provide a list of ingredients to FDA. Code of "ILS" affirms Ingredients Listings was previously submitted.		If Government Agency Processing Code is "CSU", then "ILS" is mandatory.
	HPC	**Harmful or Potentially Harmful Constituents (HPHC)** Report: All manufacturers and importers of tobacco products to the U.S. must provide HPHC information to FDA. Code of "HPC" confirms HPHC information was previously submitted.		If Government Agency Processing Code is "CSU", then "HPC" is mandatory.
	CMT	**Commercially Marketed Tobacco.** Code of "CMT" **indicates that the product was** commercially marketed in the U.S. as of February 15, 2007		If Government Agency Processing Code is "CSU" and the product was commercially marketed in the U.S. as of February 15, 2007, then "CMT" is mandatory.

Data Element	Code	Description	Syntax	Business Rules
	SE or PMT or EXE	If the product was not commercially marketed in the U.S. as of February 15, 2007, then SE = Substantially Equivalent or PMT= Premarket Tobacco Application, or EXE= Exemption from Substantial Equivalence must be affirmed.		If Government Agency Processing Code is “CSU” and the product was not commercially marketed in the U.S. as of February 15, 2007 (CMT was not declared), then either SE, PMT, or EXE is mandatory.
	TST	Tobacco Submission Tracking	7X or 7X-24X	If Government Agency Processing Code is “CSU” and affirmations “SE”, “PMT”, or “EXE” were declared, then “TST” is mandatory. (i.e. “TST is mandatory if product was not commercially marketed in the U.S. as of February 15, 2007) If declaring CMT, then TST is optional.
	CCN	Carrier ISO Country Code	2A	ISO Country code
	ERR	Entry Review Requested	indicator only	ERR is just used as an indicator, no data will follow
	FTZ	FTZ Admission Number		

Record Identifier PG24 (Remarks)

This is an optional PGA input record that provides data pertaining to Remarks Codes, and Text of Remarks.

Remark Type Code should be either GEN or NAM.

If GEN, the PG24 is applicable to the preceding PG02. Only one GEN:PG24 is allowed per PG02 (this is to avoid multiple GEN:PG24 records without a guaranteed sequencing as intended by the filer). This may be expanded in future with sufficient sequencing control to receive multiple GEN:PG24 records in the same order in which the Filer entered remarks.

If NAM, the PG24 is applicable to the preceding PG21. This structure simply allows the entry of 68 characters in addition to 23 characters afforded by PG21 for the Individual Name field in PG21. When a NAM-PG24 is present, the Individual Name field in PG21 is concatenated with Remarks Text field in PG24, to the full name in the format "*Last Name, First Name Middle Name*" for a potential 91 characters. Only one NAM:PG24 is allowed per PG21.

Record Identifier PG24 (Input)					
Data Element	**Length /Class**	**Position**	**Status**	**Description**	**Note**
Control Identifier	2A	1-2	M	Must always equal PG.	
Record Type	2N	3-4	M	Must always be 24.	
Remarks Type Code	3X	5-7	O	A code indicating the type of remarks. Valid codes are listed in Appendix PGA (Remarks Type Code) of this publication. FDA uses either NAM or GEN as its valid values.	1
Remarks Text	68X	13-80	O	Free form text relevant to the shipment or the commodity.	

Note 1
If an individual's Name in the preceding PG21 is longer than 23 characters, the Remarks Type Code should be identified as NAM (Full name of the Individual) then the Remarks Text can be used to indicate the full name of that individual. Individual's Name should still follow the same format when using PG24, as following:

Last Name, First Name Middle Name

If submitting general comments then use the Remarks Type Code = GEN (General Remarks)

Record Identifier PG25 (Product Condition)

It is a mandatory PGA input record that provides data pertaining to: Temperature Qualifier, Degree Type, Actual Temperature, Lot Number, Production Date, Range of the Lot, PGA Line Value, and PGA Unit Value. This record is repeatable for multiple Lot Number Qualifiers and Lot Numbers but the line value MUST be included on each record.

Record Identifier PG25 (Product Condition)					
Data Element	**Length/ Class**	**Position**	**Status**	**Description**	**Note**
Control Identifier	2A	1-2	M	"PG".	
Record Type	2N	3-4	M	"25".	
Temperature Qualifier	1A	5	O	Temperature Category being reported for quality control or preservation purposes. A= Ambient, F=Frozen, D=Dry Ice, R=Refrigerated/Chilled, H=Fresh, U=Uncontrolled, P=Flashpoint	
Degree Type	1A	6	O	F = Fahrenheit, C = Celsius , K = Kelvin	
Negative Number	1A	7	O	If the actual temperature is in the negative numbers use an "X".	
Actual Temperature	6N	8-13	O	Required if Degree Type is entered. Reported temperature. Two decimals places are implied.	
Location of Temperature Recording	1A	14	O	Identifies recorded temperature is for A=product, B=container and C= conveyance	
Lot Number Qualifier**	1AN	15	O	Includes Lots and/or Batches IF Government Agency Program Code = TOB THEN Lot Number Qualifier = 3	
Lot Number**	25X	16-40	O	The lot number that the manufacturer assigned to the product.	
Production Start date of the Lot**	8N	41-48	O	The date when the production for the Lot started. A numeric date in MMDDCCYY (month, day, century, year) format.	
Production End Date of the Lot**	8N	49-56	O	The date when the production for the Lot ended. A numeric date in MMDDCCYY (month, day, century, year) format.	
PGA Line Value	12N	57-68	M	Line Value is needed for enforcement of User Fee Regulations. Failure to pay user fees makes a product adulterated under Section 902 of the FD&C Act in accordance with Section 919. The value associated with the PGA line number in whole dollars. It must be right-justified with preceding zeros. Must be greater than zero.	
PGA Unit Value	12N	69-80	M	The value of the lowest unit of measure reported in PG26. Two decimal places are implied.	

** Not currently required for importing tobacco products, but may be required in future CTP regulations. Ref: 21 CFR 7; 701(b)

Record Identifier PG26 (Product Packaging)

For Tobacco, this is a mandatory PGA input record that provides FDA with data pertaining to Packaging Qualifier, Quantity and Unit of Measure. This record can be repeated up to six (6) times, once for each unique packaging level. The first record is used to describe the largest (outermost) container and the number of containers at this packaging level. The second record is used to describe the contents of the next smallest container. If needed, qualifiers 2-6 are used in a similar manner (largest to smallest container). The final record must describe the actual amount of the product in the smallest container.

The appearance of any 'Packaging Qualifier' number level requires all levels under it to be represented. For instance, level 3 can't be present unless levels 1 and 2 are present.

Record Identifier PG26 (Product Packaging)					
Data Element	**Length/ Class**	**Position**	**Status**	**Description**	**Note**
Control Identifier	2A	1-2	M	"PG"	
Record Type	2N	3-4	M	"26"	
Packaging Qualifier	1N	5	M	Used to determine the quantity of tobacco products being imported, such as the number of cigarettes, cartons, cartons per pack, etc. Under 21 1140.16(b), cigarette packages are required to contain a minimum of 20 cigarettes. Code identifying the level of packaging. For example, 4. If reporting only one level, show the total quantity for the item and report that as level 1.	1, 4
Quantity	12N	6-17	M	"Quantity of the packaging level, For example, 000000000400. Must be greater than zero.	2, 4
Unit of Measure (Packaging Level)	5X	18-22	M	Type of packaging / packaging level. For example, BX.	3, 4

Note 1
This code identifies the level of packaging for the product. Valid values are 1, 2, 3, 4, 5 and 6: Outermost (largest=1) packages to the innermost (smallest=6) packages. There can be up to 6 levels of packaging.

Note 2
There are two implied decimal points when writing the quantity in Units of Measure for the Base Unit (Last Quantity Transmitted). In this example, 4 pieces are represented as 000000000400, with the nine leading zeroes as "fill" and two decimal places following the value. The quantity for packaging containers will be in whole numbers with no decimal places. The sample shows 1 carton containing 10 boxes and each box containing 4 pieces.

Note 3
List of Unit of Measure codes applicable to FDA-Tobacco Message Sets
For a full list of applicable Unit of Measure codes, please refer to Appendix F in this document or to the Appendix PGA (PG26 – Unit of Measure - Valid FDA Units of Measure for Packaging Containers) and Appendix PGA (PG26 – Unit of Measure -Valid FDA Units of Measure for the Base Unit (Last Quantity Transmitted)) of the CATAIR.

Valid FDA Units of Measure for Packaging Containers

Code	Description
CS	Case
CT	Carton
BX	Box
PK	Package

Valid FDA Units of Measure for the Base Unit (Last Quantity Transmitted)

Code	Description
DOZ	Dozen (Count)
DPC	Dozen Pieces (Count)
NO	Number (Count)
PCS	Pieces (Count)

Note 4

Quantity Data provides additional information to FDA about the product and how it is packaged. The basic format for Quantity Data is in multiple pairs of data – quantity and unit of measure, i.e., 500 cases, 12 ounces, fluid, 1000 cartons, etc. Up to 6 data pairs may be submitted, beginning with the 1st pair for the outermost packaging when Packaging Qualifier = 1. The first pair may describe the largest container and the last pair must describe the amount of product in the smallest container. For example:

For example:

Product: ***1000 cartons of cigarettes, 10 packs in each carton, 20 cigarettes in each pack***

Units 1-Quantity= 1000
Units 1-Measure =CT
Units 2-Quantity=10
Units 2-Measure=PK
*Units 3-Quantity=20 (optional)
*Units 3-Measure=PCS (optional)

*The last level of packaging is optional to describe the shipment if the product labeling already Includes the fact that each pack contains 20 individual cigarettes.

Record Identifier PG29 (Unit of Measure)

This is an optional PGA record for Government Agency Program Code = 'TOB', PGA input record that provides data pertaining to the net or gross unit of measure of the commodity. This can be provided at the overall PGA Line Number and/or the Individual Unit level.

Record Identifier PG29 (Unit of Measure)					
Data Element	**Length/ Class**	**Position**	**Status**	**Description**	**Note**
Control Identifier	2A	1-2	M	"PG".	
Record Type	2N	3-4	M	"29".	
Unit of Measure (PGA line - net)	3AN	5-7	O	Pertaining to the overall PGA Line Number, the indication of the unit of measurement in which weight, capacity, length, area, volume or other quantity is expressed. "Unit of Measure (PGA line - net)" in this position is associated with "Commodity Net Quantity (PGA line - net)" and is required when "Commodity Net Quantity (PGA line - net)" is reported. Valid Unit of Measure codes are listed in Appendix F in this document or in Appendix C in the ACS ABI CATAIR.	
Commodity Net Quantity (PGA line - net)	12N	8-19	O	Pertaining to the overall PGA Line Number, excluding all packing and packaging. Two decimals are implied. "Commodity Net Quantity (PGA line - net)" is required when "Unit of Measure (PGA line - net)" is reported in positions 5-7 of this record.	
Unit of Measure (PGA line - gross)	3AN	20-22	O	Pertaining to the overall PGA Line Number, the indication of the unit of measurement in which weight, capacity, length, area, volume or other quantity is expressed. "Unit of Measure (PGA line - gross)" in this position is associated with "Commodity Gross Quantity (PGA line - gross)" and is required when "Commodity Gross Quantity (PGA line - gross)" is reported. Valid Unit of Measure codes are listed in Appendix F in this document or in Appendix C in the ACS ABI CATAIR.	
Commodity Gross Quantity (PGA line - gross)	12N	23-34	O	Pertaining to the overall PGA Line Number, including any packaging, but excluding weight of the carrier's equipment. Two decimals are implied. "Commodity Gross Quantity (PGA line - gross)" is required when "Unit of Measure (PGA line - gross)" is reported in positions 20-22 of this record.	

Record Identifier PG29 (Unit of Measure)					
Data Element	**Length/ Class**	**Position**	**Status**	**Description**	**Note**
Unit of Measure (Individual Unit - net)	3AN	35-37	O	Pertaining to the Individual unit (net), the indication of the unit of measurement in which weight, capacity, length, area, volume or other quantity is expressed. "Unit of Measure (Individual unit - net)" in this position is associated with "Commodity Net Quantity (Individual unit - net)" and is required when "Commodity Net Quantity (Individual unit - net)" is reported. Valid Unit of Measure codes are listed in Appendix F in this document or in Appendix C in the ACS ABI CATAIR.	
Commodity Net Quantity (Individual Unit - net)	12N	38-49	O	Pertaining to the Individual unit, excluding all packing and packaging. Two decimals are implied. "Commodity Net Quantity (Individual unit - net)" is required when "Unit of Measure (Individual unit - net)" is reported in positions 35-37 of this record.	
Unit of Measure (Individual Unit - gross)	3AN	50-52	O	Pertaining to the Individual unit (gross), the indication of the unit of measurement in which weight, capacity, length, area, volume or other quantity is expressed. "Unit of Measure (Individual unit - gross)" in this position is associated with "Commodity Gross Quantity (Individual unit - gross)" and is required when "Commodity Gross Quantity (Individual unit - gross)" is reported. Valid Unit of Measure codes are listed in Appendix F in this document or in Appendix C in the ACS ABI CATAIR.	
Commodity Gross Quantity (Individual Unit - gross)	12N	53-64	O	Pertaining to the Individual unit, including any packaging, but excluding weight of the carrier's equipment. Two decimals are implied. "Commodity Gross Quantity (Individual unit - gross)" is required when "Unit of Measure (Individual unit - gross)" is reported in positions 50-52 of this record.	
Filler	16X	65-80	M	Space fill	

Record not supported by FDA at this time

Record Identifier PG30 (Anticipated Arrival Information)

This is a mandatory PGA input record that provides data pertaining to the date, time and location of the anticipated arrival information for all FDA products. While other PGAs may use PG30 to Collect Inspection and Lab information, currently FDA will utilize this record to collect Anticipated Arrival Information at this time.

For each line a PG30 record with an "A" (Anticipated arrival information) code, date and time of arrival is Mandatory.

Record Identifier PG30 (Inspection and Lab Information)					
Data Element	**Length/ Class**	**Position**	**Status**	**Description**	**Note**
Control Identifier	2A	1-2	M	“PG”.	
Record Type	2N	3-4	M	“30”.	
Inspection/ Laboratory Testing Status	1A	5	M	A is the ONLY valid code for FDA:: A = Anticipated arrival information	
Anticipated Arrival date	8N	6-13	M	A numeric date in MMDDCCYY (month, day, century, year) format.	
Anticipated Arrival time	4N	14-17	M	Military time HHMM in (hour, minute) format. (Example: 1015, this represents 10:15 a.m.). For midnight, use 2400 (0000 is invalid).	
Arrival Location Code	4AN	18-21	O	For valid port codes, refer to Note 1	1
Arrival Location	50X	22-71	O	Code or free form text indicating site of inspection.	
Filler	8X	72-80	M	Space fill	

Note 1:
Refer to List of Valid Port Codes:
http://www.cbp.gov/sites/default/files/documents/CBP%20Port%20Codes%20041014_1.pdf

Record Identifier PG55 (Additional Entity Roles)

This is an optional PGA input record used to provide additional roles performed by an entity or individual.

The PG55 record is not supported by FDA at this time. Multiple PG19 records should be used to input more than one Entity-Role combination. Refer to the PG19 section for details.

Record Identifier PG55 (Additional Entity Roles)					
Data Element	**Length/ Class**	**Position**	**Status**	**Description**	**Note**
Control Identifier	2A	1-2	M	“PG”.	
Record Type	2N	3-4	M	“55”.	
Entity Role Code	3AN	5-7	O	Additional role of the entity.	
Entity Role Code	3AN	8-10	O	Additional role of the entity.	
Entity Role Code	3AN	11-13	O	Additional role of the entity.	
Entity Role Code	3AN	14-16	O	Additional role of the entity.	
Entity Role Code	3AN	17-19	O	Additional role of the entity.	
Entity Role Code	3AN	20-22	O	Additional role of the entity.	
Entity Role Code	3AN	23-25	O	Additional role of the entity.	
Entity Role Code	3AN	26-28	O	Additional role of the entity.	
Entity Role Code	3AN	29-31	O	Additional role of the entity.	
Entity Role Code	3AN	32-34	O	Additional role of the entity.	
Filler	46X	35-80	M	Space fills.	

Not supported by FDA at this time

Record Identifier PG00 (Data Substitution)

This is an optional record used at the CBP entry (or entry summary) header, CBP entry (or entry summary) line and/or PGA message set levels to indicate data substitution.

Currently, the PG00 record is implemented only at the CBP entry header level. Future implementation will allow for submission at the CBP entry line and PGA Message Set level.

See the 'usage notes' in this chapter for more detailed information.

Record Identifier PG00 (Data Substitution)					
Data Element	**Length/ Class**	**Position**	**Status**	**Description**	**Note**
Control Identifier	2A	1-2	M	"PG".	
Record Type	2N	3-4	M	"00".	
Substitution Indicator	1X	5	O	Identifies either the start or end of the substitution group, or the location of where to place the substitute data within the PGA Message Set. The following codes are allowed: S=Start of the substitution group E=End of the substitution group R=Replace this record with the substitution group indicated by the Substitution Number	
Substitution Number	4AN	6-9	O	Sequential number assigned to, or referring to, a specific substitution group of data provided at the header level. This data element is mandatory when using the S or R substitution indicator.	
Filler	71X	10-80	M	Space fills.	

Radiation Emitting Products Commodity Data Elements and Values

Radiation Emitting Medical Product commodities can be broken down into the following categories using the existing Government Agency data elements available in the PG01 message.

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

Table 7 – Radiation Emitting Products commodity hierarchy

For informational purposes, the following table describes the Radiation Emitting Categories and whether the product requires a 2877 and whether the product is a medical device. The Radiation Emitting Product Classification website provides information on radiation emitting products.
http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPCD_RH/classification.cfm

Radiation Emitting Device Category	2877 Required	Medical Device*
Diagnostic Ultrasound Devices	N	Y
Sonic Medical Products	N	Y
Sonic Non-Medical Products	N	N
Therapeutic Ultrasonic Devices (Certified)	Y	Y
Ultrasonic Medical Devices (Miscellaneous)	N	Y
Ultrasound Non-Medical Devices	N	N
Veterinary Diagnostic Ultrasonic Products	N	N
Veterinary Therapy Ultrasonic Products	Y	N
Analytical X-Ray Systems, Non-Medical	N	N
Cabinet X-Ray Systems, Medical	Y	Y
Cabinet X-Ray Systems, Non-Medical	Y	N
Cargo Non-Intrusive Security Systems	N	N
Cathode Ray Tube (without Electronics Chassis)	N	N
Cold-Cathode Gas Discharge Tubes	Y	N
Dental Diagnostic X-Ray Equipment	Y	Y
Diagnostic Nuclear Medicine Devices	N	Y

Radiation Emitting Device Category	2877 Required	Medical Device*
Diagnostic X-Ray Equipment (Non-Certified)	N	N
High Voltage Vacuum Switches	N	N
High Voltage Vacuum Tubes	N	N
Industrial Particle Beam Systems	N	N
Industrial X-Ray Systems (Excluding Cabinet)	N	N
Medical Accelerators	N	Y
Medical Diagnostic X-Ray Equipment	Y	Y, except product codes RCA, RCB, RBZ, RCD
Non-Medical Accelerators	N	N
Personnel Security Systems	N	N
Radioisotope Therapy Devices	N	Y
Therapeutic X-Ray Systems	Y	Y
TV Receivers & Products Containing Same	Y	ONLY the following product codes are medical devices: FET, FWB, FWC, FWD, FWE, FWF, FWG, HJG, and ODA. All other product codes in this category are not medical devices.
Veterinary X-Ray Systems	N	N
X-Ray Bone Densitometers	Y	Y
X-Ray Film and Film Processing Materials	N	ONLY the following product codes are medical devices: LQA and JAC. All other product codes in this category are not medical devices.
Household ELF Products	N	N
Industrial Dielectric Heaters	N	N
Microwave Communication, Data Transmit, and Measurement Products	N	N
Microwave Diathermy Machines	N	Y
Microwave Heating and Drying Products	N	N
Microwave Hyperthermia Therapy Devices	N	Y
Microwave Identification, Safety, Security, and Surveillance Products	N	N
Microwave Medical Products	N	Y, except product code RDG
Microwave Ovens (Food Prep)	Y	N
Nuclear Magnetic Resonance Devices	N	Y

Radiation Emitting Device Category	2877 Required	Medical Device*
Other Microwave Products	N	N
Data Measurement, Transmit, Control Laser Products	Y	N
General Optical Products, Medical	N	Y, except product code RGV, RGU
General Optical Products, Non-Medical	N	N
In Vitro and Other Medical Laser Products	Y	Y, except product code RGB
Laser Light Show/Display Products	Y	N
Laser Products (Pre-Standard)	N	N
Material Processing Laser Products	Y	N
Medical Laser Products	Y	Y, except product code RGC
Mercury Vapor Lamps	Y	N
Other Demonstration Laser Products	Y	N
Other Laser Products	Y	N
Positioning Medical Laser Products	Y	Y, except product code RGC
Research, Scientific, Laboratory Laser Products	Y	N
Safety, Security, Surveillance Laser Products	Y	N
Sunlamp Products (Certified)	Y	Y
Sunlamp Products (Pre-Standard)	N	N
Surveying, Leveling, Alignment Laser Products	Y	N
Toy, Novelty, Play Laser Products	Y	N
Ultraviolet Commercial/Consumer Products	N	N
Ultraviolet Hygiene Products	N	ONLY the following product codes are medical devices: LYL, MCF, NOB. All other product codes in this category are not medical devices.
Ultraviolet Medical Products	N	Y
Ultraviolet Surveillance & Detection Products	N	N
Utility/Peripheral Laser Products	Y	ONLY the following product codes are medical devices: LMA, LMB. All other product codes in this category are not medical devices.

Table 7a – Radiation Emitting Device Categories

***If Medical Device then all Medical Device data is required, in addition to applicable PG23 message set for radiation-emitting products. See the chapter for Medical Devices.**

The following are the potential PGA records associated with submitting Radiation-Emitting Products.

PG Record	Description
OI	The commercial description of the shipment
PG01	The shipment is regulated by the FDA program office within FDA and the intended use is provided.
PG02	Product Identifier; the item type and Product Code detail are provided.
PG06	Source Type(origin) other than the CBP country of origin is provided
PG07	The Trade/Brand Name, Model and Year of Manufacture are provided
PG10	Product Characteristics and other optional product information are provided
PG19	Entity Role (manufacturer, consignee, shipper, etc.) Entity Identification, Entity Name, and Entity Address 1 are provided.
PG20	Additional address data on the entity in PG19 is provided
PG21	Individual Name, Telephone Number, Fax Number, and Email address are provided
PG23	FDA's Affirmation of Compliance Criteria is provided.
PG24	Remarks
PG25	Temperature qualifier, Lot#, Production dates, PGA Line Value and PGA Unit Value are provided
PG26	Packaging qualifier and quantity of the shipment are provided
PG27	Data pertaining to issued Container Number is provided
PG29	Data pertaining to the net/gross unit of measure and quantity are provided
PG30	Data pertaining to date, time and location of inspection are provided
PG55	Identifies Entity from the previous PG19, PG20, and PG21 group as having additional roles.
PG00	Data substitution

Radiation Emitting Products Example

Radiation Emitting Products Message Set Layout for Sample

Please refer to the external file: **FDA SG 2.4 Example PG Message Sets.xlsx** Tab: ***Radiation Emitting Products***

Because of the flexibility of the PGA Message set, the PGA Records and Data Elements that are required may vary both from program to program and within a single program. For a more expansive set of examples of FDA PGA Message Sets, please refer to the above document.

Record Identifier OI (Record Identifier)

This is a mandatory PGA line item description input record that provides the description of the item. This record precedes the Record Identifiers for the PGA Message set.

Record Identifier OI (Record Identifier)					
Data Element	**Length/ Class**	**Position**	**Status**	**Description**	**Note**
Control Identifier	2A	1-2	M	"OI"	
Filler	8X	3-10	M	Space filled.	
Commercial Description	70X	11-80	M	The commercial description of the product. For example, FDR D-EVO Suite FS by Fujifilm.	

Record Identifier PG01 (PGA Identifier)

This is a mandatory PGA input record that provides data pertaining to the PGA Line Number, Government Agency Code, Government Agency Program Code, Globally Unique Product Identification Code, Intended Use Code, Intended Use Description, and Disclaimer. The Intended Use Code allows FDA to identify whether the imported commodity is restricted by a consumption allowance or not.

Record Identifier PG01 (PGA Identifier)					
Data Element	**Length/ Class**	**Position**	**Status**	**Description/Required Value**	**Note**
Control Identifier	2A	1-2	M	"PG"	
Record Type	2N	3-4	M	"01"	
PGA Line Number	3N	5-7	M	"001"	
Government Agency Code	3AN	8-10	M	"FDA"	
Government Agency Program Code	3X	11-13	C	"RAD"	1, 2
Government Agency Processing Code	3AN	14-16	C	"REP"	1, 2
Intended Use Code	16X	42-57	C	Code identifying the intended use for the commodity after importation.	2,3
Intended Use Description	22X	58-79	O	If the Intended Use code used is 980.000, this field is used to describe the Intended Use such as 'Sample devices', 'Return shipment', etc.	2,3
Disclaimer	1A	80	C	A code of A (= product is not regulated by this agency) or B (= data is not required per agency guidance) indicating there is no agency declaration requirement. Or this field is left blank for no disclaimer. No other code is accepted	2

Note 1

See Table 7 above for the commodity hierarchy for Radiation Emitting Products commodities.

Note 2

If the Disclaimer is 'A' or 'B' then these data elements should both be populated with FDA. otherwise the Government Agency Program Code, Government Agency Processing Code and Intended Use Code are mandatory.

Note 3

Intended Use Codes and their descriptions can be found in Appendix R (Intended Use Codes for ACE) of the ACE ABI CATAIR publication. For Radiation-Emitting Products, only one of the following Intended Use Codes may be entered:

085.000	For Veterinary Medical Use as a Non-Food Product under Controlled Distribution

090.000	For Military Use as a Non- Food Product
100.000	For Personal Use as a Non- Food Product
110.000	For Public Exhibition or Display as a Non-Food Product
120.000	For Public Safety Use 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
150.000	For Commercial Processing as a Non-Food Product
155.000	For Commercial Assembly as a Non-Food Product into a medical device
170.000	For Repair of a Non-Food Product
180.000	For Research and Development as a Non-Food Product
270.000	For Industrial use as a Non-Food Product
970.001	For Immediate Re-Exportation
980.000	For Other Use

Record Identifier PG02 (Product Identifier)

This mandatory PGA input record is used to indicate whether or not the information being provided relates to a product (P) or a component (C) of a product.

For Radiation-Emitting Product entries, the Product Code Number is provided within this record.

Record Identifier PG02 (Product Identifier)					
Data Element	**Length/ Class**	**Position**	**Status**	**Description**	**Note**
Control Identifier	2A	1-2	M	“PG”	
Record Type	2N	3-4	M	“02”	
Item Type	1A	5	M	Code identifying the following records as pertaining to P=Product. Only one ‘P’ record is allowed for the same PGA Line # in PG01	
Product Code Qualifier	4AN	6-9	M	“FDP”.	1
Product Code Number	19X	10-28	M	FDA Product Code Must be equal to 7 characters	

Note 1

Product Code Qualifiers and their descriptions can be found in Appendix PGA (PG02 – Product Code Qualifiers) of the ACE ABI CATAIR publication. For Radiation-Emitting Products, this is currently always ‘FDP’ for all FDA products.

Only one FDA Product Code Number per product is allowed.

FDA Product Code Structure:

Position	1-2	3	4	5	6-7
Name	Industry Code (N)	Class Code (A)	Sub Class Code (A or '-')	Process Identification Code - PIC (A or '-')	Product (AN)

Legend - N: Numeric; A:Alphabetic; AN:AlphaNumeric

Record Identifier PG06 (Product Origin)

This is a mandatory PGA input record that provides data pertaining to Source Type (Origin) other than the CBP Country of Origin.

Record Identifier PG06 (Product Origin)					
Data Element	**Length/ Class**	**Position**	**Status**	**Description**	**Note**
Control Identifier	2A	1-2	M	Must always equal PG.	
Record Type	2N	3-4	M	Must always be 06.	
Source Type Code	3AN	5-7	M	Mandatory valid values are 30 (Country of Source) or 39 (Country of Production). 294 is MANDATORY (Country of Refusal) if previously refused There would be one PG06 with source type code of 30 or 39. If previously refused, then trade would also provide another PG06 with source type code 294.	1
Country Code	2X	8-9	M	A two-letter code that identifies the country from where the product was produced, packed or shipped. Valid International Organization for Standardization (ISO) Country and Currency Code codes are in Appendix B in the ACS ABI CATAIR.	2

Note 1

Source Type Codes and their descriptions can be found in Appendix PGA (PG06 – Source Type Codes) of the ACE ABI CATAIR publication.

Note 2

Any of the country codes from Appendix B (ISO Country and Currency Codes) in the ACS ABI CATAIR can be entered.

Record Identifier PG07 (Product Trade Names)

This is a mandatory PGA input record that provides FDA with data pertaining to Name, Model, Manufacture Year, and Item Identity Number.

Record Identifier PG06 (Product Trade Names)					
Data Element	**Length/ Class**	**Position**	**Status**	**Description**	**Note**
Control Identifier	2A	1-2	M	“PG”	
Record Type	2N	3-4	M	“07”	
Trade Name/Brand Name	35X	5-39	M	Trade/Brand Name of the Radiation-Emitting Device. For example, Sony Laser scanner RM2.	
Item Identity Number Qualifier	3AN	61-63	O	Code identifying the type of Item Identity Number being provided.	
Item Identity Number	17X	64-80	O	The Item Identity Number. This is the Model Number or the Serial Number based on the qualifier entered above.	

Record Identifier PG10 (Product Characteristics)

This is a mandatory PGA input record that allows for reporting codes that provide additional characteristics of a product or component, not reported elsewhere in the PG Message Set. For example, this record can be used to provide the model year of a product, which can be different from the year of manufacture provided in the PG07. This record can be repeated if there are more qualifiers or categories.

Record Identifier PG10 (Product Characteristics)					
Data Element	**Length/ Class**	**Position**	**Status**	**Description**	**Note**
Control Identifier	2A	1-2	M	“PG”.	
Record Type	2N	3-4	M	“10”.	
Commodity Characteristic Description	57X	24-80	M	Free form description (invoice description NOT product code description) of the item. See Appendix A for the use of PG10 to capture the information currently collected in multiple OI records.	

Record Identifier PG19 (Entity Data)

For Radiation Emitting Products, this is a mandatory PGA input record that provides FDA with data pertaining to Entity Role and conditionally the following data elements; Entity Identification, Entity Name, and Entity Address 1.

Record Identifier PG19 (Entity Data)					
Data Element	**Length/ Class**	**Position**	**Status**	**Description**	**Note**
Control Identifier	2A	1-2	M	"PG"	
Record Type	2N	3-4	M	"19"	
Entity Role Code	3AN	5-7	M	Code identifying the role of the entity being provided. For example, MF.	1
Entity Identification Code	3AN	8-10	C	Code identifying the Entity Identification is entered. For example, 16. Mandatory, if Entity Number is entered.	2
Entity Number	15X	11-25	O	The Entity Number of the entity based on the above Entity Identification Code is entered; must conform to the descriptions in Note 2	2
Entity Name	32X	26-57	M	The name of the entity is required. See validation criteria below.	2
Entity Address 1	23X	58-80	M	The address of the entity is required. See validation criteria below.	

Note 1

Entity Role Codes and their descriptions can be found in Appendix PGA (PG19 – Entity Role Codes) of the ACE ABI CATAIR publication. List of Entity Role codes applicable to FDA Radiation-Emitting Products Message Sets is below:

Data Element	***Code***	***Description***
Entity Role Codes§	MF	Manufacturer of goods
	DEQ	Shipper
	FD1	FDA Importer (Importer of Record)
	DP	Delivered To Party±

§ Same Role Code cannot be entered more than once.

± Even though Title 19 141.19 (CBP) addresses - Consignee -, Title 21, Requires Prior Notice information about the - Ultimate Consignee - and Title 19 (CBP) defines - Ultimate Consignee -, FDA acknowledges that these terms cause confusion and would like to simplify and harmonize said data elements under the ACE environment.

Hence, the FDA has elected to utilize the data element --- "Deliver to Party" --- , U.S party that physically receives the good(s). The FDA's PG Message Set will, therefore, incorporate the deliver to party as issued in the ITDS Standard Data Set under the auspices of the ITDS Board of Directors. FDA's Prior Notice requirement for ultimate consignee is synonymous with deliver to party.

List of Entity Role codes also applicable to FDA Radiation Emitting Device Message Sets is below:

Data Element	***Code***	***Description***
Entity Role Codes	AAR	All Applicable Roles

Data Element	Code	Description
	APP	Applicant
	CE	Certifying Entity
	CO	Certifying Official
	CR	Consolidator
	CN	Consignee**
	CZ	Consignor
	DDF	Primary electronic business contact
	DDG	Alternate electronic business contact
	DDH	Primary government business contact
	DDI	Alternate government business contact
	DEI	Means of transport operator
	DFP	Owner
	EX	Exporter
	EXE	Exporting Establishment
	FCI	FDA Clinical Investigator
	FD2	FDA Importer 2
	FD3	FDA Importer 3
	FG	Foreign Government
	GC	Goods custodian
	HAZ	Hazardous Material Contact
	INC	Inspection Contact
	ITL	Independent Third Party Laboratory
	LAB	Laboratory
	LAP	LPCO Authorized Party
	LG	Location of Goods immediately after Entry Release
	LIP	LPCO Issuing Agency
	MF	Manufacturer of goods
	OV	Transport means owner
	PE	Producing Establishment
	PES	Packing Establishment
	PK	Point of Contact
	PRE	Preparer
	PRO	Processing Establishment
	RD	Retailer/Distributor
	RGO	Responsible Government Official
	SE	Seller
	SIG	Signer
	SOE	Source Establishment
	STL	Storage location
	TB	Submitter
	VW	Responsible party

Note 2

Entity Identification Codes and their descriptions can be found in Appendix PGA (PG19 – Entity Identification Codes) of the ACE ABI CATAIR publication. List of Entity Identification codes applicable to FDA Medical Device Message Sets is below:

Data Element	Code	Description	Length/ Class
Entity Identification Codes	16	D&B-assigned (DUNS number); must be 9 digits	9N
	47	FDA-assigned (FEI number); must be from 4 to 10 digits	4-10N

FDA ENTITY IDENTIFICATION CODE AND ENTITY NUMBER SELECTION AND VALIDATION CRITERIA

FDA requires Entity Name and Entity Address. Additionally, FDA prefers to use DUNS numbers for identifying the Entity; IF DUNS is not available THEN FEI.

Entity Name <>NULL AND Entity Address 1 <>NULL AND
IF Entity Identification Code =16 (DUNS) THEN Entity Number MUST BE Length = 9 and Type = N
ELSE IF Entity Identification Code =47 (FEI) THEN Entity Number MUST BE Length from 4 to 10 and Type = N

Record Identifier PG20 (Entity Address)

This is a mandatory PGA input record that provides additional data pertaining to the Entity identified in the **preceding** PG19 record; such as Entity Address line 2, Apartment/Suite, City, State, and Zip/Postal Code. This record is used when additional address for the entity needs to be entered.

Record Identifier PG20 (Entity Address)					
Data Element	**Length/ Class**	**Position**	**Status**	**Description**	**Note**
Control Identifier	2A	1-2	M	“PG”	
Record Type	2N	3-4	M	“20”	
Entity Address 2	32X	5-36	C		1
Entity Apartment Number/Suite Number	5X	37-41	C	For example, 102 A.	1
Entity City	21X	42-62	M	For example, SAN DIEGO.	
Entity State/Province	3AN	63-65	C	For example, CA.	2
Entity Country	2A	66-67	M	For example, US.	
Entity Zip/Postal Code	9X	68-76	C	For example, 92169.	2
Filler	4X	77-80	M	Space fill	

Note 1: If the Entity Address 1 in PG19 is longer than the allocated 23 characters then utilize these fields.

Note 2: Populated if US or Canada based entities

Record Identifier PG21 (Point of Contact)

This is a mandatory PGA input record that provides FDA with data about an Individual Point of Contact (POC) related to the Entity (the party) in the **preceding** PG19 record. Included in this record are the Individual Name, Telephone Number, Fax Number, and Email address. A typical example is a POC for the Filer.

At least one PG21 record is required.

Record Identifier PG21 (Point of Contact)					
Data Element	**Length/ Class**	**Position**	**Status**	**Description**	**Note**
Control Identifier	2A	1-2	M	"PG"	
Record Type	2N	3-4	M	"21"	
Individual Qualifier	3AN	5-7	M	Code identifying which entity the Point of Contact is related to. For example, PK.	1
Individual Name	23X	8-30	M	Name of the Individual. If the name will not fit, complete PG24 and fill out the remarks code (Individual name) and then enter the name in the remarks text field. For example, JANE SIMMONS.	
Telephone Number of the Individual	15X	31-45	M	For example, (713)555-8765 in US or (+65)9052-3529 in Singapore	
Email Address or Fax Number for the Individual	35X	46-80	M	For example, JSIMMONS@ELEMENTALIMPORTERS.COM.	

Note 1

Entity Role Codes and their descriptions can be found in Appendix PGA (PG19 – Entity Role Codes) of the ACE ABI CATAIR publication. List of Entity Role codes applicable to FDA Medical Device Message Sets is below:

Data Element	***Code***	***Description***
Entity Role Codes	PK	Point of Contact

Record Identifier PG23 (Affirmation of Compliance)

This is a conditional PGA input record that provides data pertaining to Food and Drug Administration Affirmation of Compliance Criteria. This record is typically only used by FDA. This record is repeatable.

If Medical Device then all Medical Device data is required, in addition to relevant radiation emitting product data elements.. See also PG23 for Medical Devices.

Record Identifier PG23 (Affirmation of Compliance)					
Data Element	**Length/ Class**	**Position**	**Status**	**Description**	**Note**
Control Identifier	2A	1-2	M	"PG".	
Record Type	2N	3-4	M	"23".	
Affirmation of Compliance Code	5X	5-9	C	A code used to affirm compliance with FDA requirements. . See Appendix PGA, PG23 – Food & Drug Affirmation of Compliance, FDA Affirmation of Compliance Codes of ACE ABI CATAIR publication.	1
Affirmation of Compliance Qualifier	30AN	10-39	C	Text describing the information required by the PGA. This could include a combination of letters and digits, specific text, etc. Follow the *Entered value of AoC Description / Business Rule* column in the table below in the Note section.	1

Note 1,

List of Affirmation of Compliance codes CONDITIONAL to FDA Radiation Emitting Product Message Sets

If 2877 is required:

Affirmation	**Qualifier**	**Examples and additional information**	**Additional Affirmations Required**	**Text on 2877**
RA1	date	format MM/YYYY	-	1.Were manufactured prior to the effective date of any applicable standard. Date of Manufacture:_____
RA2	text	text is reason for exclusion. Example: DOD exemption	-	2. Are excluded by the applicability clause or definition in the standard or by FDA written guidance. Specify reason for exclusion:_____
RA3	none			3. Are personal household goods of an individual entering the U.S. or being returned to a U.S. resident (Limit: 3 of each product type)
RA4*	none			4. Are property of a party residing outside the U.S. and will be returned to the owner after repair or servicing.
RA5*	text	text is description of the end product. Example: Laser		5. Are components or subassemblies to be used in manufacturing or as replacement parts

Affirmation	Qualifier	Examples and additional information	Additional Affirmations Required	Text on 2877
		Diode		
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.- there is a quantity limit for this option-stated on the back of the 2877 (page 2)
RA7*	text	text is description of the end product		7.Are being reprocessed in accordance with P.L. 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. (ACC+7N or ANC+7N)	B1.Comply with the performance standards- 1.*Last annual report or Product/Initial Report*
RB2*	text	text is reason the product complies		B2.Comply with the performance standards-2. *Unknown manufacturer/report number. State reason:*
RC1*	none			C1.Do not comply with performance standards; are being held under a temporary import bond; will not be introduced into commerce, will be used under a radiation protection plan, and will be destroyed or exported under U.S. Customs Supervision when the mission is complete - 1*. Research , Investigations/Studies, or Training (Attach Form FDA 766)*
RC2	text	text is dates and use restriction	-	C2.Do not comply with performance standards; are being held under a temporary import bond; will not be introduced into commerce, will be used under a radiation protection plan, and will be destroyed or exported under U.S. Customs Supervision when the mission is complete - 1*. Trade Show/Demonstration; List dates and use restrictions*
RD1*	none			D1. Do not comply with performance standards; are held and will remain under bond; and will not be introduced into commerce until notification is received from FDA that products have been brought into compliance in accordance with an FDA approved petition.(See Form FDA 766) -1. *Approved Petition is attached.*
RD2*	none			D2. Do not comply with performance standards; are held and will remain under bond; and will not be introduced into commerce until notification is received from FDA that products have been brought into compliance in accordance with an FDA approved petition.(See Form FDA 766) -*2.Petition request is attached.*

Affirmation	Qualifier	Examples and additional information	Additional Affirmations Required	Text on 2877
RD3	date	date is the date form 766 will be provided, due within 60 days of submission.	-	D3. Do not comply with performance standards; are held and will remain under bond; and will not be introduced into commerce until notification is received from FDA that products have been brought into compliance in accordance with an FDA approved petition.(See Form FDA 766) - *3.Request will be submitted within 60 days.*

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

Record Identifier PG24 (Remarks)

This is an optional PGA input record that provides data pertaining to Remarks Codes, and Text of Remarks.

Remark Type Code should be either GEN or NAM.

If GEN, the PG24 is applicable to the preceding PG02. Only one GEN:PG24 is allowed per PG02 (this is to avoid multiple GEN:PG24 records without a guaranteed sequencing as intended by the filer). This may be expanded in future with sufficient sequencing control to receive multiple GEN:PG24 records in the same order in which the Filer entered remarks.

If NAM, the PG24 is applicable to the preceding PG21. This structure simply allows the entry of 68 characters in addition to 23 characters afforded by PG21 for the Individual Name field in PG21. When a NAM-PG24 is present, the Individual Name field in PG21 is concatenated with Remarks Text field in PG24, to the full name in the format "*Last Name, First Name Middle Name*" for a potential 91 characters. Only one NAM:PG24 is allowed per PG21.

Record Identifier PG24 (Input)					
Data Element	**Length /Class**	**Position**	**Status**	**Description**	**Note**
Control Identifier	2A	1-2	M	Must always equal PG.	
Record Type	2N	3-4	M	Must always be 24.	
Remarks Type Code	3X	5-7	O	A code indicating the type of remarks. Valid codes are listed in Appendix PGA (Remarks Type Code) of this publication. FDA uses either NAM or GEN as its valid values.	1
Remarks Text	68X	13-80	O	Free form text relevant to the shipment or the commodity.	

Note 1
If an individual's Name in the preceding PG21 is longer than 23 characters, the Remarks Type Code should be identified as NAM (Full name of the Individual) then the Remarks Text can be used to indicate the full name of that individual. Individual's Name should still follow the same format when using PG24, as following:

Last Name, First Name Middle Name

If submitting general comments then use the Remarks Type Code = GEN (General Remarks)

Record Identifier PG25 (Product Condition)

This is a mandatory PGA input record that provides data pertaining to: Temperature Qualifier, Degree Type, Actual Temperature, Lot Number, Production Date Range of the Lot, PGA Line Value, and PGA Unit Value. This record is repeatable for multiple Lot Number Qualifiers and Lot Numbers but the line value MUST be included on each record.

Record Identifier PG25 (Product Condition)					
Data Element	**Length/ Class**	**Position**	**Status**	**Description**	**Note**
Control Identifier	2A	1-2	M	"PG".	
Record Type	2N	3-4	M	"25".	
Temperature Qualifier	1A	5	O	Temperature Category being reported for quality control or preservation purposes. A= Ambient, F=Frozen, D=Dry Ice, R=Refrigerated/Chilled, H=Fresh, U=Uncontrolled, P=Flashpoint	
Degree Type	1A	6	O	Optional F = Fahrenheit, C = Celsius , K = Kelvin	
Negative Number	1A	7	O	Optional. If the actual temperature is in the negative numbers use an "X".	
Actual Temperature	6N	8-13	O	Optional. Required if Degree Type is entered. Reported temperature. Two decimals places are implied.	
Location of Temperature Recording	1A	14	O	Optional. Identifies recorded temperature is for A=product, B=container and C= conveyance	
Lot Number Qualifier	1AN	15	O	Code of the entity that assigned the Lot number. 1 = Manufacturer	
Lot Number	25X	16-40	O	The lot number that the manufacturer assigned to the product.	
Production Start date of the Lot	8N	41-48	O	Optional. The date when the production for the Lot started. A numeric date in MMDDCCYY (month, day, century, year) format.	
Production End Date of the Lot	8N	49-56	O	Optional. The date when the production for the Lot ended. A numeric date in MMDDCCYY (month, day, century, year) format.	
PGA Line Value	12N	57-68	M	The value associated with the PGA line number in whole dollars. It must be right-justified with preceding zeros. Must be greater than zero.	
PGA Unit Value	12N	69-80	O	The value of the lowest unit of measure reported in PG26. Two decimal places are implied. IF IFE (PG23) submitted THEN PG25 Value is MANDATORY	

Record Identifier PG26 (Product Packaging)

This is a mandatory PGA input record that provides FDA with data pertaining to Packaging Qualifier, Quantity, Unit of Measure, Package Identifier, Packaging Method, Package Material, and Packaging Filler. This record can be repeated up to six (6) times, once for each unique packaging level. The first record is used to describe the largest (outermost) container and the number of containers at this packaging level. The second record is used to describe the contents of the next smallest container. If needed, qualifiers 2-6 are used in a similar manner (largest to smallest container). The final record must describe the actual amount of the product in the smallest container.

The appearance of any 'Packaging Qualifier' number level requires all levels under it to be represented. For instance, level 3 can't be present unless levels 1 and 2 are present.

Record Identifier PG26 (Product Packaging)					
Data Element	**Length/ Class**	**Position**	**Status**	**Description**	**Note**
Control Identifier	2A	1-2	M	"PG"	
Record Type	2N	3-4	M	"26"	
Packaging Qualifier	1N	5	M	Code identifying the level of packaging. For example, 4. If reporting only one level, show the total quantity for the item and report that as level 1.	1,4
Quantity	12N	6-17	M	Quantity is MANDATORY. Quantity of the packaging level, For example, 000000000400. Must be greater than zero.	2,4
Unit of Measure (Packaging Level)	5X	18-22	M	Type of packaging / packaging level. For example, BX. At least, 'Pieces' must be selected	3,4

Note 1
This code identifies the level of packaging for the product. Valid values are 1, 2, 3, 4, 5 and 6: Outermost (largest=1) packages to the innermost (smallest=6) packages. There can be up to 6 levels of packaging.

Note 2
There are two implied decimal points when writing the quantity in Units of Measure for the Base Unit (Last Quantity Transmitted). In this example, 4 pieces are represented as 000000000400, with the nine leading zeroes as "fill" and two decimal places following the value. The quantity for packaging containers will be in whole numbers with no decimal places. The sample shows 1 carton containing 10 boxes and each box containing 4 pieces.

Note 3
List of Unit of Measure codes applicable to FDA-Radiation-Emitting Products Message Sets
For a full list of applicable Unit of Measure codes, please refer to Appendix F in this document or to the Appendix PGA (PG26 – Unit of Measure - Valid FDA Units of Measure for Packaging Containers) and Appendix PGA (PG26 – Unit of Measure -Valid FDA Units of Measure for the Base Unit (Last Quantity Transmitted)) of the CATAIR.

Valid FDA Units of Measure for Packaging **Containers**

Code	Description
CS	Case
CT	Carton
BX	Box
PK	Package

Valid FDA Units of Measure for the **Base Unit** (Last Quantity Transmitted)

Code	Description
PCS	Pieces (Count)

Note 4

Quantity Data provides additional information to FDA about the product and how it is packaged. The basic format for Quantity Data is in multiple pairs of data – quantity and unit of measure, i.e., 500 cases, 12 ounces, fluid, 1000 cartons, etc. Up to 6 data pairs may be submitted, beginning with the 1st pair for the outermost packaging when Packaging Qualifier = 1. The first pair may describe the largest container and the last pair must describe the amount of product in the smallest container. For example:

950	Microwave Ovens	24,935.00 POUNDS
	Units 1-Quantity	950
	Units 1-Measure	PCS

Record Identifier PG27 (Container Information)

This is an optionalPGA input record that provides data pertaining to issued Container Number. The number of the shipping container is included in the Bill of Lading. Hence this record is not needed.

Record Identifier PG27 (Container Information)					
Data Element	**Length/ Class**	**Position**	**Status**	**Description**	**Note**
Control Identifier	2A	1-2	M	“PG”.	
Record Type	2N	3-4	M	“27”.	
Container Number (Equipment ID)	20AN	5-24	O	The number of the shipping container as entered in the Bill of Lading.	

Record Identifier PG29 (Unit of Measure)

This is a an optional PGA input record that provides data pertaining to the net or gross unit of measure of the commodity. This can be provided at the overall PGA Line Number and/or the Individual Unit level.

Record Identifier PG29 (Unit of Measure)					
Data Element	**Length/ Class**	**Position**	**Status**	**Description**	**Note**
Control Identifier	2A	1-2	M	“PG”.	
Record Type	2N	3-4	M	“29”.	
Unit of Measure (PGA line - net)	3AN	5-7	O	Pertaining to the overall PGA Line Number, the indication of the unit of measurement in which weight, capacity, length, area, volume or other quantity is expressed. “Unit of Measure (PGA line - net)” in this position is associated with “Commodity Net Quantity (PGA line - net)” and is required when “Commodity Net Quantity (PGA line - net)” is reported. Valid Unit of Measure codes are listed in Appendix F in this document or in Appendix C in the ACS ABI CATAIR.	
Commodity Net Quantity (PGA line - net)	12N	8-19	O	Pertaining to the overall PGA Line Number, excluding all packing and packaging. Two decimals are implied. “Commodity Net Quantity (PGA line - net)” is required when “Unit of Measure (PGA line - net)” is reported in positions 5-7 of this record.	
Unit of Measure (PGA line - gross)	3AN	20-22	O	Pertaining to the overall PGA Line Number, the indication of the unit of measurement in which weight, capacity, length, area, volume or other quantity is expressed. “Unit of Measure (PGA line - gross)” in this position is associated with “Commodity Gross Quantity (PGA line - gross)” and is required when “Commodity Gross Quantity (PGA line - gross)” is reported. Valid Unit of Measure codes are listed in Appendix F in this document or in Appendix C in the ACS ABI CATAIR.	
Commodity Gross Quantity (PGA line - gross)	12N	23-34	O	Pertaining to the overall PGA Line Number, including any packaging, but excluding weight of the carrier's equipment. Two decimals are implied. “Commodity Gross Quantity (PGA line - gross)” is required when “Unit of Measure (PGA line - gross)” is reported in positions 20-22 of this record.	

Record Identifier PG29 (Unit of Measure)					
Data Element	**Length/ Class**	**Position**	**Status**	**Description**	**Note**
Unit of Measure (Individual Unit - net)	3AN	35-37	O	Pertaining to the Individual unit (net), the indication of the unit of measurement in which weight, capacity, length, area, volume or other quantity is expressed. "Unit of Measure (Individual unit - net)" in this position is associated with "Commodity Net Quantity (Individual unit - net)" and is required when "Commodity Net Quantity (Individual unit - net)" is reported. Valid Unit of Measure codes are listed in Appendix F in this document or in Appendix C in the ACS ABI CATAIR.	
Commodity Net Quantity (Individual Unit - net)	12N	38-49	O	Pertaining to the Individual unit, excluding all packing and packaging. Two decimals are implied. "Commodity Net Quantity (Individual unit - net)" is required when "Unit of Measure (Individual unit - net)" is reported in positions 35-37 of this record.	
Unit of Measure (Individual Unit - gross)	3AN	50-52	O	Pertaining to the Individual unit (gross), the indication of the unit of measurement in which weight, capacity, length, area, volume or other quantity is expressed. "Unit of Measure (Individual unit - gross)" in this position is associated with "Commodity Gross Quantity (Individual unit - gross)" and is required when "Commodity Gross Quantity (Individual unit - gross)" is reported. Valid Unit of Measure codes are listed in Appendix F in this document or in Appendix C in the ACS ABI CATAIR.	
Commodity Gross Quantity (Individual Unit - gross)	12N	53-64	O	Pertaining to the Individual unit, including any packaging, but excluding weight of the carrier's equipment. Two decimals are implied. "Commodity Gross Quantity (Individual unit - gross)" is required when "Unit of Measure (Individual unit - gross)" is reported in positions 50-52 of this record.	
Filler	16X	65-80	M	Space fill	

Not supported by FDA at this time

Record Identifier PG30 (Anticipated Arrival Information)

This is a mandatory PGA input record that provides data pertaining to the date, time and location of the anticipated arrival information for all FDA products. While other PGAs may use PG30 to Collect Inspection and Lab information, currently FDA will utilize this record to collect Anticipated Arrival Information at this time.

For each line a PG30 record with an "A" (Anticipated arrival information) code, date and time of arrival is Mandatory.

Record Identifier PG30 (Inspection and Lab Information)					
Data Element	**Length/ Class**	**Position**	**Status**	**Description**	**Note**
Control Identifier	2A	1-2	M	“PG”.	
Record Type	2N	3-4	M	“30”.	
Inspection/ Laboratory Testing Status	1A	5	M	A is the ONLY valid code for FDA:: A = Anticipated arrival information	
Anticipated Arrival date	8N	6-13	M	A numeric date in MMDDCCYY (month, day, century, year) format.	
Anticipated Arrival time	4N	14-17	M	Military time HHMM in (hour, minute) format. (Example: 1015, this represents 10:15 a.m.). For midnight, use 2400 (0000 is invalid).	
Arrival Location Code	4AN	18-21	O	For valid port codes, refer to Note 1	1
Arrival Location	50X	22-71	O	Code or free form text indicating site of inspection.	
Filler	8X	72-80	M	Space fill	

Note 1:
Refer to List of Valid Port Codes:
http://www.cbp.gov/sites/default/files/documents/CBP%20Port%20Codes%20041014_1.pdf

Record Identifier PG55 (Additional Entity Roles)

This is an optional PGA input record used to provide additional roles performed by an entity or individual.

The PG55 record is not supported by FDA at this time. Multiple PG19 records should be used to input more than one Entity-Role combination. Refer to the PG19 section for details.

Record Identifier PG55 (Additional Entity Roles)					
Data Element	**Length/ Class**	**Position**	**Status**	**Description**	**Note**
Control Identifier	2A	1-2	M	“PG”.	
Record Type	2N	3-4	M	“55”.	
Entity Role Code	3AN	5-7	O	Additional role of the entity.	
Entity Role Code	3AN	8-10	O	Additional role of the entity.	
Entity Role Code	3AN	11-13	O	Additional role of the entity.	
Entity Role Code	3AN	14-16	O	Additional role of the entity.	
Entity Role Code	3AN	17-19	O	Additional role of the entity.	
Entity Role Code	3AN	20-22	O	Additional role of the entity.	
Entity Role Code	3AN	23-25	O	Additional role of the entity.	
Entity Role Code	3AN	26-28	O	Additional role of the entity.	
Entity Role Code	3AN	29-31	O	Additional role of the entity.	
Entity Role Code	3AN	32-34	O	Additional role of the entity.	
Filler	8X	72-80	M	Space fill	

Not supported by FDA at this time

Record Identifier PG00 (Data Substitution)

This is an optional record used at the CBP entry (or entry summary) header, CBP entry (or entry summary) line and/or PGA message set levels to indicate data substitution.

Currently, the PG00 record is implemented only at the CBP entry header level. Future implementation will allow for submission at the CBP entry line and PGA Message Set level.
PG00 Substitution Grouping
In situations where the trade finds it would be supplying identical information more than once within the PGA Message Set, a PG00 substitution grouping can be used, instead of repeating that information multiple times. See the 'usage notes' in the ACE ABI CATAIR - Customs and Trade Automated Interface Requirements publication for more detailed information.

Record Identifier PG00 (Data Substitution)					
Data Element	**Length/ Class**	**Position**	**Status**	**Description**	**Note**
Control Identifier	2A	1-2	M	"PG".	
Record Type	2N	3-4	M	"00".	
Substitution Indicator	1X	5	O	Identifies either the start or end of the substitution group, or the location of where to place the substitute data within the PGA Message Set. The following codes are allowed: S=Start of the substitution group E=End of the substitution group R=Replace this record with the substitution group indicated by the Substitution Number	
Substitution Number	4AN	6-9	O	Sequential number assigned to, or referring to, a specific substitution group of data provided at the header level. This data element is mandatory when using the S or R substitution indicator.	
Filler	71X	10-80	M	Space fills.	

Animal Drugs and Devices Commodity Data Elements and Values

Animal Drugs and Devices commodities can be broken down into the following categories using the existing Government Agency data elements available in the PG01 message

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

Table 8 – Animal Drugs and Devices commodity hierarchy

The following are the potential PGA records associated with submitting **Drug**:

PG Record	Description
OI	The commercial description of the shipment
PG01	The shipment is regulated by the FDA program office within FDA and the intended use is provided.
PG02	Product Identifier; the item type and Product Code detail are provided.
PG04	Product Constituent Active Ingredient
PG06	Product Source information is provided
PG07	The Trade/Brand Name
PG10	Product/Component Reporting Code
PG19	Entity Role (manufacturer, consignee, shipper, etc.) Entity Identification, Entity Name, and Entity Address 1 are provided.
PG20	Additional Entity Identification (Address line 2, Apartment/Suite, City, State, and Zip/Postal Code).
PG21	Additional Entity Role
PG23	FDA's Affirmation of Compliance Criteria is provided.
PG24	Remarks
PG25	Temperature qualifier, Lot#, Production dates, PGA Line Value and PGA Unit Value are provided
PG26	Packaging qualifier and quantity of the shipment are provided
PG27	Container Number

PG Record	Description
PG29	Data pertaining to the net or gross unit of measure of the commodity
PG30	Product pertaining to the pertaining to the date, time and location of inspection; previous laboratory testing; inspection location; and anticipated arrival information for FDA
PG55	Additional roles performed by an entity or individual
PG00	Data Substitution

Animal Drugs and Devices Example

Animal Drugs and Devices Message Set Layout for Sample

Please refer to the external file: **FDA SG 2.4 Example PG Message Sets.xlsx** Tab: ***Animal Drugs & Devices***

Because of the flexibility of the PGA Message set, the PGA Records and Data Elements that are required may vary both from program to program and within a single program. For a more expansive set of examples of FDA PGA Message Sets, please refer to the above document.

Record Identifier OI (Record Identifier)

This is a mandatory PGA line item description input record that provides the description of the item. This record precedes the Record Identifiers for the PGA Message set.

Record Identifier OI (Record Identifier)					
Data Element	**Length/ Class**	**Position**	**Status**	**Description**	**Note**
Control Identifier	2A	1-2	M	"OI"	
Filler	8X	3-10	M	Space filled.	
Commercial Description	70X	11-80	M	The commercial description of the product. For example, Amoxicillin	

Record Identifier PG01 (PGA Identifier)

This is a mandatory PGA input record that provides data pertaining to the PGA Line Number, Government Agency Code, Government Agency Program Code, Globally Unique Product Identification Code, Intended Use Code, Intended Use Description, and Disclaimer. The Intended Use Code allows FDA to identify whether the imported commodity is restricted by a consumption allowance or not.

Record Identifier PG01 (PGA Identifier)					
Data Element	**Length/ Class**	**Position**	**Status**	**Description/Required Value**	**Note**
Control Identifier	2A	1-2	M	“PG”.	
Record Type	2N	3-4	M	“01”.	
PGA Line Number	3N	5-7	M	“001”	
Government Agency Code	3AN	8-10	M	“FDA”	
Government Agency Program Code	3X	11-13	C	“VME”	1, 2
Government Agency Processing Code	3AN	14-16	C	Codes allowed: ADR , ADE	1, 2
Intended Use Code	16X	42-57	O	See below for the list of New Intended Use Codes	3
Intended Use Description	22X	58-79	O		3
Disclaimer	1A	80	C	A code of A (= product is not regulated by this agency) or B (= data is not required per agency guidance) indicating there is no agency declaration requirement. Or this field is left blank for no disclaimer. No other code is accepted	

Note 1:
Refer to Table 8 above for commodity type and sub-type for Animal Drugs and Devices.
Also see Appendix A Commodities Matrix for valid Government Agency Program Codes and Processing Codes.

Note 2

If the Disclaimer is ‘A’ or ‘B’ then these data elements should both be populated with FDA. otherwise the Government Agency Program Code, Government Agency Processing Code are mandatory.

Note 3

180.022	For Research and Development as a Non-Food Product – Investigational use on Animals
100.000	Importation for Personal Use

Record Identifier PG02 (Product Identifier)

This mandatory PGA input record is used to indicate whether or not the information being provided relates to a product (P) or a component (C) of a product.

Record Identifier PG02 (Product Identifier)					
Data Element	**Length/ Class**	**Position**	**Status**	**Description**	**Note**
Control Identifier	2A	1 2	M	“PG”.	
Record Type	2N	3-4	M	“02”.	
Item Type	1A	5	M	Code identifying the following records as pertaining to P=Product. No other values accepted. Only one ‘P’ record is allowed for the same PGA Line # in PG01 record.	
Product Code Qualifier	4AN	6-9	M	“FDP”.	
Product Code Number	19X	10-28	M	FDA Product Code Must be equal to 7 characters	

Product Code Qualifiers and their descriptions can be found in Appendix PGA (PG02 – Product Code Qualifiers) of the ACE ABI CATAIR publication. For Animal Drugs, this is currently always ‘FDP’ for all FDA products.

Only one FDA Product Code Number per product is allowed.

FDA Product Code Structure:

Position	1-2	3	4	5	6-7
Name	Industry Code (N)	Class Code (A)	Sub Class Code (A or '-')	Process Identification Code - PIC (A or '-')	Product (AN)

Legend - N: Numeric; A:Alphabetic; AN:AlphaNumeric

Record Identifier PG04 (Product Constituent Element)

This is a mandatory PGA input record that provides data pertaining to Constituent Active Ingredient Qualifier, Name of the Constituent Element, Quantity of Constituent Element, Unit of Measure, and Percent of Constituent Element for the product identified by Product Code Number in PG02. This record can be repeated.

Using a Drug example, Appendix E shows how PG04 can be used at the Product-level for multiple Constituent Elements. The FDA will process PG05-PG06-PG07-PG08-PG10 records only at the Product-level (when they are under a PG02) at this time.

Record Identifier PG04 (Product Constituent Element)					
Data Element	**Length/ Class**	**Position**	**Status**	**Description**	**Note**
Control Identifier	2A	1-2	M	"PG"	
Record Type	2N	3-4	M	"04"	
Constituent Active Ingredient Qualifier	1A	5	M	Active ingredient = "*Y*" if yes, blank if no.	1
Name of the Constituent Element	51X	6-56	M		1
Quantity of Constituent Element	12N	57-68	M	2 decimal places are implied	1
Unit of Measure (Constituent Element)	5AN	69-73	M		1
Percent of Constituent Element	7N	74-80	M	4 decimal places are implied	1, 2

Note 1
IF Government Agency Program Code = VME AND Government Agency Processing Code = ADR
THEN Constituent Active Ingredient Qualifier and Name of the Constituent Element are Mandatory.

Either the quantity and Unit of Measurement should be entered OR the Percent Constituent Element should be entered.

Example1: Ibuprofen, 200mg tablets
Name of the Constituent Element = Ibuprofen
Quantity of Constituent Element = 200 and Unit of Measure = milligrams

Example2: Degree Expert Protection
Name of the Constituent Element = aluminum zirconimum tetrachlorohydrex
Percent of Constituent Element 18.2% (entered as 0182000)

Note 2

Examples of Percentages:

1000000	=	100%
0990000	=	99%
0090000	=	9%
0009000	=	.9%
0000900	=	.09%

0000090	=	.009%
0000009	=	.0009%

Record Identifier PG06 (Product Origin)

This is a mandatory PGA input record that provides data pertaining to Source Type (Origin) - other than the CBP Country of Origin - for the product identified by Product Code Number in PG02.

Using a Drug example, Appendix E shows how PG04 can be used at the Product-level for multiple Constituent Elements. **The FDA will process PG05-PG06-PG07-PG08-PG10 records only at the Product-level (when they are under a PG02) at this time**.

Record Identifier PG06 (Product Origin)					
Data Element	**Length/ Class**	**Position**	**Status**	**Description**	**Note**
Control Identifier	2A	1 2	M	"PG".	
Record Type	2N	3-4	M	"06".	
Source Type Code	3AN	5-7	M	Mandatory valid values are 30 (Country of Source) or 39 (Country of Production) is MANDATORY. 294 (Country of Refusal) if previously refused. There would be one PG06 with source type code of 30 or 39. If previously refused, then trade would also provide another PG06 with source type code 294.	**1**
Country Code	2X	8-9	M	Country of production or source is required for Animal Drugs	2

Note 1

Source Type Codes and their descriptions can be found in Appendix PGA (PG06 – Source Type Codes) of the ACE ABI CATAIR publication.

Note 2

Any of the country codes from Appendix B (ISO Country and Currency Codes) in the ACS ABI CATAIR can be entered.

Record Identifier PG07 (Product Trade Names)

This is a conditional PGA input record that provides FDA with data pertaining to Trade Name for the product identified by Product Code Number in PG02.

Using a Drug example, Appendix E shows how PG04 can be used at the Product-level for multiple Constituent Elements. **The FDA will process PG05-PG06-PG07-PG08-PG10 records only at the Product-level (when they are under a PG02) at this time**.

Record Identifier PG06 (Product Trade Names)					
Data Element	**Length /Class**	**Position**	**Status**	**Description**	**Note**
Control Identifier	2A	1 2	M	“PG”.	
Record Type	2N	3-4	M	“07”.	
Trade Name/Brand Name	35X	5-39	C	If Government Agency Program Code = ‘VME’ the Trade/Brand Name of the Animal Drug is MANDATORY.	

Record Identifier PG10 (Product Characteristics)

For Animal Drugs, this is a mandatory PGA input record that allows for importer to report the description of the product for the product identified by Product Code Number in PG02 at the line level to capture the information currently collected in multiple OI records. This record can be repeated if there are more Commodity Characteristic Descriptions.

Using a Drug example, Appendix E shows how PG04 can be used at the Product-level for multiple Constituent Elements **The FDA will process PG05-PG06-PG07-PG08-PG10 records only at the Product-level (when they are under a PG02) at this time.**

Record Identifier PG10 (Product Characteristics)					
Data Element	**Length/ Class**	**Position**	**Status**	**Description**	**Note**
Control Identifier	2A	1-2	M	“PG”.	
Record Type	2N	3-4	M	“10”.	
Commodity Characteristic Description	57X	24-80	M	Free form description, NOT product code description, of the item, either to supplement the above data elements or in place of the above. See Appendix A for the use of PG10 to capture the information currently collected in multiple OI records.	

Record Identifier PG19 (Entity Data)

For Animal Drugs, this is a mandatory PGA input record that provides FDA with data pertaining to Entity Role and conditionally the following data elements; Entity Identification, Entity Name, and Entity Address 1.

Record Identifier PG19 (Entity Data)					
Data Element	**Length/ Class**	**Position**	**Status**	**Description**	**Note**
Control Identifier	2A	1-2	M	"PG"	
Record Type	2N	3-4	M	"19"	
Entity Role Code	3AN	5-7	M	Code identifying the role of the entity being provided. For example, MF.	1
Entity Identification Code	3AN	8-10	C	Code identifying the Entity Identification is entered. For example, 16. Mandatory, if Entity Number is entered.	2
Entity Number	15X	11-25	O	The Entity Number of the entity based on the above Entity Identification Code is entered; must conform to the descriptions in Note 2	2
Entity Name	32X	26-57	M	The name of the entity is required. See validation criteria below.	2
Entity Address 1	23X	58-80	M	The address of the entity is required. See validation criteria below.	2

Note 1

Entity Role Codes and their descriptions can be found in Appendix PGA (PG19 – Entity Role Codes) of the ACE ABI CATAIR publication. List of Entity Role codes mandatory to FDA Drugs Message Sets is below:

Data Element	***Code***	***Description***
Entity Role Codes§	MF	Manufacturer of goods
	DEQ	Shipper
	FD1	FDA Importer (Importer of Record)
	DP	Delivered To Party±

§ Same Role Code cannot be entered more than once.

± Even though Title 19 141.19 (CBP) addresses - Consignee -, Title 21, Requires Prior Notice information about the - Ultimate Consignee - and Title 19 (CBP) defines - Ultimate Consignee -, FDA acknowledges that these terms cause confusion and would like to simplify and harmonize said data elements under the ACE environment.

Hence, the FDA has elected to utilize the data element --- "Deliver to Party" --- , U.S party that physically receives the good(s). The FDA's PG Message Set will, therefore, incorporate the deliver to party as issued in the ITDS Standard Data Set under the auspices of the ITDS Board of Directors. FDA's Prior Notice requirement for ultimate consignee is synonymous with deliver to party.

List of Entity Role codes also applicable to FDA Animal Drugs Message Sets is below:

Data Element	***Code***	***Description***
Entity Role Codes	AAR	All Applicable Roles

Data Element	Code	Description
	APP	Applicant
	CE	Certifying Entity
	CO	Certifying Official
	CR	Consolidator
	CN	Consignee*
	CZ	Consignor
	DDF	Primary electronic business contact
	DDG	Alternate electronic business contact
	DDH	Primary government business contact
	DDI	Alternate government business contact
	DEI	Means of transport operator
	DFP	Owner
	EX	Exporter
	EXE	Exporting Establishment
	FCI	FDA Clinical Investigator
	FD2	FDA Importer 2
	FD3	FDA Importer 3
	FG	Foreign Government
	GC	Goods custodian
	INC	Inspection Contact
	ITL	Independent Third Party Laboratory
	LAB	Laboratory
	LAP	LPCO Authorized Party
	LG	Location of Goods immediately after Entry Release
	LIP	LPCO Issuing Agency
	MF	Manufacturer of goods
	OV	Transport means owner
	PE	Producing Establishment
	PES	Packing Establishment
	PK	Point of Contact
	PRE	Preparer
	PRO	Processing Establishment
	RD	Retailer/Distributor
	RGO	Responsible Government Official
	SE	Seller
	SIG	Signer
	SOE	Source Establishment
	STL	Storage location
	TB	Submitter
	VW	Responsible party

Note 2

Entity Identification Codes and their descriptions can be found in Appendix PGA (PG19 – Entity Identification Codes) of the ACE ABI CATAIR publication. List of Entity Identification codes applicable to FDA Animal Drugs Message Sets is below:

Data Element	Code	Description	Length/ Class
Entity Identification Codes	16	D&B-assigned (DUNS number)	9N
	47	FDA-assigned	4-10N

FDA ENTITY IDENTIFICATION CODE AND ENTITY NUMBER SELECTION AND VALIDATION CRITERIA

FDA requires Entity Name and Entity Address. Additionally, FDA prefers to use DUNS numbers for identifying the Entity; IF DUNS is not available THEN FEI.

Entity Name <>NULL AND Entity Address 1 <>NULL AND
IF Entity Identification Code =16 (DUNS) THEN Entity Number MUST BE Length = 9 and Type = N
ELSE IF Entity Identification Code =47 (FEI) THEN Entity Number MUST BE Length from 4 to 10 and Type = N

Record Identifier PG20 (Entity Address)

This is a mandatory PGA input record that provides additional data pertaining to Entity identification such as Entity Address line 2, Apartment/Suite, City, State, and Zip/Postal Code. This record is used when additional address for the entity needs to be entered.

Record Identifier PG20 (Entity Address)					
Data Element	**Length/ Class**	**Position**	**Status**	**Description**	**Note**
Control Identifier	2A	1-2	M	“PG”	
Record Type	2N	3-4	M	“20”	
Entity Address 2	32X	5-36	C	Address Line 2 for the Entity.	1
Entity Apartment Number/Suite Number	5X	37-41	C	Apartment/Suite number of the entity.	1
Entity City	21X	42-62	M	City of the entity.	
Entity State/Province	3AN	63-65	C	State/Province of the entity.	2
Entity Country	2A	66-67	M	ISO Country Code.	
Entity Zip/Postal Code	9X	68-76	C	Zip/Postal Code of the entity.	2
Filler	4X	77-80	C	Space fills.	

Note 1: If the Entity Address 1 in PG19 is longer than the allocated 23 characters then utilize these fields.

Note 2: Populated if US or Canada based entities

Record Identifier PG21 (Point of Contact)

This is a mandatory PGA input record that provides data about an Individual and may also be related to an entity (the party) in the preceding PG19 record. Included in this record are the Individual Name, Telephone Number, Fax Number, and Email address. If multiple Individuals related to a single entity are required by an agency, this record can be repeated and should follow each entity designated in the PG19 record. This record can also be repeated in cases where multiples of these data elements need to be reported for a single Individual. (For example, for reporting two phone numbers or an email and fax number). A typical example is a POC for the Filer.

At least one PG21 record is required.

Record Identifier PG21 (Point of Contact)					
Data Element	**Length/ Class**	**Position**	**Status**	**Description**	**Note**
Control Identifier	2A	1-2	M	“PG”.	
Record Type	2N	3-4	M	“21”.	
Individual Qualifier	3AN	5-7	M	Identify the type of party or facility the Individual represents.	
Individual Name	23X	8-30	M	Name of the Individual. If the name will not fit, complete PG24 and fill out the remarks code (Individual name) and then enter the name in the remarks text field.	
Telephone Number of the Individual	15X	31-45	M	Telephone number of the Individual. For example, (713)555-8765 in US or (+65)9052-3529 in Singapore	
Email Address or Fax Number for the Individual	35X	46-80	M	Option to either submit the Fax number or Email Address of the individual.	

Record Identifier PG23 (Affirmation of Compliance)

This is a mandatory PGA input record that provides data pertaining to Food and Drug Administration Affirmation of Compliance Criteria. This record is typically only used by FDA. This record is repeatable.

Record Identifier PG23 (Affirmation of Compliance)					
Data Element	**Length/ Class**	**Position**	**Status**	**Description**	**Note**
Control Identifier	2A	1-2	M	"PG".	
Record Type	2N	3-4	M	"23".	
Affirmation of Compliance Code	5X	5-9	M	A code used to affirm compliance with FDA requirements. There must be at least one PG23 record with the AoC code of REG. See Appendix PGA PG23 – Food & Drug Affirmation of Compliance, FDA Affirmation of Compliance Codes of ACE ABI CATAIR publication.	1
Affirmation of Compliance Qualifier	30AN	10-39	M	Text describing the information required by the PGA. This could include a number or a country code, etc. Also, see Appendix PGA (Food & Drug Affirmation of Compliance Qualifier Codes) of this publication for valid codes related to certain specific Affirmation of Compliance codes.	

Note 1

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 **mandatory** to FDA Drugs Message Sets is below:

Data Element	***Code***	***Description***	***Syntax***	***Business Rules***
Affirmation of Compliance Code	REG	Drug Registration Number	9N	IF Government Agency Program Code = VME THEN REG IS MANDATORY

The list of AoC codes **conditional** to FDA Animal Drugs Message Sets is below:

Data Element	***Code***	***Description***	***Syntax***	***Business Rules***
Affirmation of Compliance Code	NDC	National Drug Code	10N	IF Government Agency Program Code = VME THEN EITHER VNA or VIN, VAN or NDC is MANDATORY
	VAN	Veterinary Abbreviated New Animal Drug Number (ANADA)	6N	IF Government Agency Program Code = VME AND PROCESSING CODE IS ADE THEN VAN is MANDATORY
	VIN	Animal Investigational New Animal Drug Number (INAD) and JNIDA	6N	IF Government Agency Program Code = VME THEN EITHER VNA, VIN, VAN or NDC is MANDATORY

Data Element	Code	Description	Syntax	Business Rules
	VNA	Animal New Animal Drug Application Number (NADA), Legally Marketed Unapproved New Animal Indexed Drugs for Minor Species (MSIF)	4N or 6N	IF Government Agency Program Code = VME THEN EITHER VNA, VIN, VAN OR NDC is MANDATORY

The list of AoC codes **optional** to FDA Animal Drugs Message Sets is below:

Data Element	Code	Description	Syntax	Business Rules
Affirmation of Compliance Code	CCN	Carrier ISO Country Code	2A	ISO Country code
	VFL	Veterinary Medicated Feed License (MFL)	6N (5NNNNN)	
	ERR	Entry Review Requested	indicator only	ERR is just used as an indicator, no data will follow
	HTS	Harmonized Tariff Number	4N	
	IFE	Import For Export	indicator only	
	UFC	Unacceptable to Foreign Country (Products other than food)	2A	ISO Country code

Record Identifier PG24 (Remarks)

This is an optional PGA input record that provides data pertaining to Remarks Codes, and Text of Remarks.

Remark Type Code should be either GEN or NAM.

If GEN, the PG24 is applicable to the preceding PG02. Only one GEN:PG24 is allowed per PG02 (this is to avoid multiple GEN:PG24 records without a guaranteed sequencing as intended by the filer). This may be expanded in future with sufficient sequencing control to receive multiple GEN:PG24 records in the same order in which the Filer entered remarks.

If NAM, the PG24 is applicable to the preceding PG21. This structure simply allows the entry of 68 characters in addition to 23 characters afforded by PG21 for the Individual Name field in PG21. When a NAM-PG24 is present, the Individual Name field in PG21 is concatenated with Remarks Text field in PG24, to the full name in the format "*Last Name, First Name Middle Name*" for a potential 91 characters. Only one NAM:PG24 is allowed per PG21.

Record Identifier PG24 (Input)					
Data Element	**Length /Class**	**Position**	**Status**	**Description**	**Note**
Control Identifier	2A	1-2	M	Must always equal PG.	
Record Type	2N	3-4	M	Must always be 24.	
Remarks Type Code	3X	5-7	O	A code indicating the type of remarks. Valid codes are listed in Appendix PGA (Remarks Type Code) of this publication. FDA uses either NAM or GEN as its valid values.	1
Remarks Text	68X	13-80	O	Free form text relevant to the shipment or the commodity.	

Note 1
If an individual's Name in the preceding PG21 is longer than 23 characters, the Remarks Type Code should be identified as NAM (Full name of the Individual) then the Remarks Text can be used to indicate the full name of that individual. Individual's Name should still follow the same format when using PG24, as following:

Last Name, First Name Middle Name

If submitting general comments then use the Remarks Type Code = GEN (General Remarks)

Record Identifier PG25 (Product Condition)

This is a mandatory PGA input record that provides data pertaining to: Temperature Qualifier, Degree Type, Actual Temperature, Lot Number, Production Date Range of the Lot, PGA Line Value, and PGA Unit Value. This record is repeatable for multiple Lot Number Qualifiers and Lot Numbers but the line value MUST be included on each record.

Record Identifier PG25 (Product Condition)					
Data Element	**Length/ Class**	**Position**	**Status**	**Description**	**Note**
Control Identifier	2A	1-2	M	"PG".	
Record Type	2N	3-4	M	"25".	
Temperature Qualifier	1A	5	O	Temperature Category being reported. for quality control or preservation purposes. A= Ambient, F=Frozen R=Refrigerated/Chilled, D=Dry Ice H=Fresh, U=Uncontrolled P=Flashpoint	
Degree Type	1A	6	O	F = Fahrenheit, C = Celsius , K = Kelvin	
Negative Number	1A	7	O	If the actual temperature is in the negative numbers use an "X".	
Actual Temperature	6N	8-13	O	Reported temperature. Two decimals places are implied.	
Location of Temperature Recording	1A	14	O	Identifies recorded temperature is for A = product B = container C = conveyance	
Lot Number Qualifier	1AN	15	O	Code of the entity that assigned the Lot number. For Animal Drugs the only valid value is: 1 = Manufacturer	
Lot Number	25X	16-40	O	The lot number that the manufacturer/ producer/grower assigned to the product.	
Production Start date of the Lot	8N	41-48	O	The date when the production for the Lot started. A numeric date in MMDDCCYY (month, day, century, year) format.	
Production End Date of the Lot	8N	49-56	O	The date when the production for the Lot ended. A numeric date in MMDDCCYY (month, day, century, year) format.	
PGA Line Value	12N	57-68	M	The value associated with the PGA line number in whole dollars. It must be right-justified with preceding zeros. Must be greater than zero.	
PGA Unit Value	12N	69-80	O	The value of the lowest unit of measure reported in PG26. Two decimal places are implied.	

Record Identifier PG26 (Product Packaging)

This is a mandatory PGA input record that provides FDA with data pertaining to Packaging Qualifier, Quantity, Unit of Measure, Package Identifier, Packaging Method, Package Material, and Packaging Filler. This record can be repeated up to six (6) times, once for each unique packaging level. The first record is used to describe the largest (outermost) container and the number of containers at this packaging level. The second record is used to describe the contents of the next smallest container. If needed, qualifiers 2-6 are used in a similar manner (largest to smallest container). The final record must describe the actual amount of the product in the smallest container.

The appearance of any 'Packaging Qualifier' number level requires all levels under it to be represented. For instance, level 3 can't be present unless levels 1 and 2 are present.

Record Identifier PG26 (Product Packaging)					
Data Element	**Length/ Class**	**Position**	**Status**	**Description**	**Note**
Control Identifier	2A	1-2	M	"PG"	
Record Type	2N	3-4	M	"26"	
Packaging Qualifier	1N	5	M	Code identifying the level of packaging. For example, 4. If reporting only one level, show the total quantity for the item and report that as level 1.	1,4
Quantity	12N	6-17	M	"Quantity of the packaging level, For example, 000000000400. Must be greater than zero.	2,4
Unit of Measure (Packaging Level)	5X	18-22	M	Type of packaging / packaging level. For example, BX.	3,4

Note 1
This code identifies the level of packaging for the product. Valid values are 1, 2, 3, 4, 5 and 6: Outermost (largest=1) packages to the innermost (smallest=6) packages. There can be up to 6 levels of packaging

Note 2
There are two implied decimal points when writing the quantity in Units of Measure for the Base Unit (Last Quantity Transmitted). In this example, 4 pieces are represented as 000000000400, with the nine leading zeroes as "fill" and two decimal places following the value. The quantity for packaging containers will be in whole numbers with no decimal places. The sample shows 1 carton containing 10 boxes and each box containing 4 pieces.

Note 3
List of Unit of Measure codes applicable to FDA-Drug Message Sets
For a full list of applicable Unit of Measure codes, please refer to Appendix F in this document or to the Appendix PGA (PG26 – Unit of Measure - Valid FDA Units of Measure for Packaging Containers) and Appendix PGA (PG26 – Unit of Measure -Valid FDA Units of Measure for the Base Unit (Last Quantity Transmitted)) of the CATAIR.

Valid FDA Units of Measure for Packaging Containers

Code	Name
BG	Bag
BI	Bin

Code	Name
BJ	Bucket
BK	Basket
AE	Aerosol
AM	Ampoule, Nonprotected
AP	Ampoule, Protected
AT	Atomizer
BA	Barrel
BC	Bottle crate, Bottle rack
BO	Bottle, Nonprotected, Cylindrical
BQ	Bottle, Protected, Cylindrical
BS	Bottle, Nonprotected, Bulbous
BV	Bottle, Protected Bulbous
BX	Box
CA	Can, Rectangular
CG	Centigrams (Weight)
CI	Canister
CON	Container
CS	Case
CT	Carton
CX	Can, Cylindrical
CY	Cylinder
DR	Drum
EN	Envelope
FD	Framed Crate
FOZ	Ounces, fluid (Volume)
G	Grams (Weight)
GAL	Gallons (US) (Volume)
KG	Kilograms (Weight)
L	Liters (Volume)
LB	Pounds (avdp) (Weight)
MB	Bag, Multi-ply
MG	Milligrams (Weight)
ML	Milliliters (Volume)
NO	Number (Count)
OZ	Ounces, weight (avdp) (Weight)
PAL	Pallet
PCS	Pieces (Count)
PK	Package
PTL	Pints, liquid (US) (Volume)
QTL	Quarts, liquid (US) (Volume)
SUP	Suppositories (Dosage)

Code	Name
TAB	Tablets (Dosage)

Note 4

Quantity Data provides additional information to FDA about the product and how it is packaged. The basic format for Quantity Data is in multiple pairs of data – quantity and unit of measure, i.e., 500 cases, 12 ounces, fluid, 1000 cartons, etc. Up to 6 data pairs may be submitted, beginning with the 1st pair for the outermost packaging when Packaging Qualifier = 1. The first pairs may describe the largest container and the last pair must describe the amount of product in the smallest container. For example:

100 Cartons, 24 Aspirin 100 tablets 325 mg

Units 1-Quantity	100
Units 1-Measure	CT
Units 2-Quantity	24
Units 2-Measure	BO
Units 3-Quantity	100
Units 3-Measure	TAB

In this case, the invoice description contains the strength of the aspirin tablets. The product quantity is listed using the "Tablets" quantity unit code.

Record Identifier PG27 (Container Information)

This is an optional PGA input record that provides data pertaining to issued Container Number. The number of the shipping container is included in the Bill of Lading. Hence this record is not needed.

Record Identifier PG27 (Container Information)					
Data Element	**Length/ Class**	**Position**	**Status**	**Description**	**Note**
Control Identifier	2A	1-2	M	“PG”	
Record Type	2N	3-4	M	“27”	
Container Number (Equipment ID)	20AN	5-24	O	The number of the shipping container as entered in the Bill of Lading.	
Filer	6X	74-80	M		

Record Identifier PG29 (Unit of Measure)

This is a an optional PGA input record that provides data pertaining to the net or gross unit of measure of the commodity. This can be provided at the overall PGA Line Number and/or the Individual Unit level.

Record Identifier PG29 (Unit of Measure)					
Data Element	**Length /Class**	**Position**	**Status**	**Description**	**Note**
Control Identifier	2A	1-2	M	“PG”.	
Record Type	2N	3-4	M	“29”.	
Unit of Measure (PGA line - net)	3AN	5-7	O	Pertaining to the overall PGA Line Number, the indication of the unit of measurement in which weight, capacity, length, area, volume or other quantity is expressed. “Unit of Measure (PGA line - net)” in this position is associated with “Commodity Net Quantity (PGA line - net)” and is required when “Commodity Net Quantity (PGA line - net)” is reported. Valid Unit of Measure codes are listed in Appendix F in this document or in Appendix C in the ACS ABI CATAIR.	
Commodity Net Quantity (PGA line - net)	12N	8-19	O	Pertaining to the overall PGA Line Number, excluding all packing and packaging. Two decimals are implied. “Commodity Net Quantity (PGA line - net)” is required when “Unit of Measure (PGA line - net)” is reported in positions 5-7 of this record.	
Unit of Measure (PGA line - gross)	3AN	20-22	O	Pertaining to the overall PGA Line Number, the indication of the unit of measurement in which weight, capacity, length, area, volume or other quantity is expressed. “Unit of Measure (PGA line - gross)” in this position is associated with “Commodity Gross Quantity (PGA line - gross)” and is required when “Commodity Gross Quantity (PGA line - gross)” is reported. Valid Unit of Measure codes are listed in Appendix F in this document or in Appendix C in the ACS ABI CATAIR.	
Commodity Gross Quantity (PGA line - gross)	12N	23-34	O	Pertaining to the overall PGA Line Number, including any packaging, but excluding weight of the carrier's equipment. Two decimals are implied. “Commodity Gross Quantity (PGA line - gross)” is required when “Unit of Measure (PGA line - gross)” is reported in positions 20-22 of this record.	

Record Identifier PG29 (Unit of Measure)					
Data Element	**Length /Class**	**Position**	**Status**	**Description**	**Note**
Unit of Measure (Individual Unit - net)	3AN	35-37	O	Pertaining to the Individual unit (net), the indication of the unit of measurement in which weight, capacity, length, area, volume or other quantity is expressed. "Unit of Measure (Individual unit - net)" in this position is associated with "Commodity Net Quantity (Individual unit - net)" and is required when "Commodity Net Quantity (Individual unit - net)" is reported. Valid Unit of Measure codes are listed in Appendix F in this document or in Appendix C in the ACS ABI CATAIR.	
Commodity Net Quantity (Individual Unit - net)	12N	38-49	O	Pertaining to the Individual unit, excluding all packing and packaging. Two decimals are implied. "Commodity Net Quantity (Individual unit - net)" is required when "Unit of Measure (Individual unit - net)" is reported in positions 35-37 of this record.	
Unit of Measure (Individual Unit - gross)	3AN	50-52	O	Pertaining to the Individual unit (gross), the indication of the unit of measurement in which weight, capacity, length, area, volume or other quantity is expressed. "Unit of Measure (Individual unit - gross)" in this position is associated with "Commodity Gross Quantity (Individual unit - gross)" and is required when "Commodity Gross Quantity (Individual unit - gross)" is reported. Valid Unit of Measure codes are listed in Appendix F in this document or in Appendix C in the ACS ABI CATAIR.	
Commodity Gross Quantity (Individual Unit - gross)	12N	53-64	O	Pertaining to the Individual unit, including any packaging, but excluding weight of the carrier's equipment. Two decimals are implied. "Commodity Gross Quantity (Individual unit - gross)" is required when "Unit of Measure (Individual unit - gross)" is reported in positions 50-52 of this record.	
Filler	16X	65-80	M	Space fill	

Not supported by FDA at this time

Record Identifier PG30 (Anticipated Arrival Information)

This is a mandatory PGA input record that provides data pertaining to the date, time and location of the anticipated arrival information for all FDA products. While other PGAs may use PG30 to Collect Inspection and Lab information, currently FDA will utilize this record to collect Anticipated Arrival Information at this time.

For each line a PG30 record with an "A" (Anticipated arrival information) code, date and time of arrival is Mandatory.

Record Identifier PG30 (Inspection and Lab Information)					
Data Element	**Length/ Class**	**Position**	**Status**	**Description**	**Note**
Control Identifier	2A	1-2	M	“PG”.	
Record Type	2N	3-4	M	“30”.	
Inspection/ Laboratory Testing Status	1A	5	M	A is the ONLY valid code for FDA:: A = Anticipated arrival information	
Anticipated Arrival date	8N	6-13	M	A numeric date in MMDDCCYY (month, day, century, year) format.	
Anticipated Arrival time	4N	14-17	M	Military time HHMM in (hour, minute) format. (Example: 1015, this represents 10:15 a.m.). For midnight, use 2400 (0000 is invalid).	
Arrival Location Code	4AN	18-21	O	For valid port codes, refer to Note 1.	1
Arrival Location	50X	22-71	O	Code or free form text indicating site of inspection.	
Filler	8X	72-80	M	Space fill	

Note 1:
Refer to List of Valid Port Codes:
http://www.cbp.gov/sites/default/files/documents/CBP%20Port%20Codes%20041014_1.pdf

Record Identifier PG55 (Additional Entity Roles)

This is an optional PGA input record used to provide additional roles performed by an entity or individual.

The PG55 record is not supported by FDA at this time. Multiple PG19 records should be used to input more than one Entity-Role combination. Refer to the PG19 section for details.

Record Identifier PG55 (Additional Entity Roles)					
Data Element	**Length /Class**	**Position**	**Status**	**Description**	**Note**
Control Identifier	2A	1-2	M	“PG”.	
Record Type	2N	3-4	M	“55”.	
Entity Role Code	3AN	5-7	O	Additional role of the entity.	
Entity Role Code	3AN	8-10	O	Additional role of the entity.	
Entity Role Code	3AN	11-13	O	Additional role of the entity.	
Entity Role Code	3AN	14-16	O	Additional role of the entity.	
Entity Role Code	3AN	17-19	O	Additional role of the entity.	
Entity Role Code	3AN	20-22	O	Additional role of the entity.	
Entity Role Code	3AN	23-25	O	Additional role of the entity.	
Entity Role Code	3AN	26-28	O	Additional role of the entity.	
Entity Role Code	3AN	29-31	O	Additional role of the entity.	
Entity Role Code	3AN	32-34	O	Additional role of the entity.	
Filler	8X	72-80	M	Space fill	

Not supported by FDA at this time

Record Identifier PG00 (Data Substitution)

This is an optional record used at the CBP entry (or entry summary) header, CBP entry (or entry summary) line and/or PGA message set levels to indicate data substitution

Record Identifier PG00 (Data Substitution)					
Data Element	**Length /Class**	**Position**	**Status**	**Description**	**Note**
Control Identifier	2A	1-2	M	“PG”.	
Record Type	2N	3-4	M	“00”.	
Substitution Indicator	1X	5	O	Identifies either the start or end of the substitution group, or the location of where to place the substitute data within the PGA Message Set. The following codes are allowed: S=Start of the substitution group E=End of the substitution group R=Replace this record with the substitution group indicated by the Substitution Number	
Substitution Number	4AN	6-9	O	Sequential number assigned to, or referring to, a specific substitution group of data provided at the header level. This data element is mandatory when using the S or R substitution indicator.	
Filler	71X	10-80	M	Space fills.	

Appendix A: Use of PG10 Record

Here is an example of how the PG10 record is used to capture the information currently collected in multiple OI records. A group of PG10...PG26 data can provide information on multiple variation of the product that was generally identified in the OI record along with specific packaging information using PG26 within the same group.

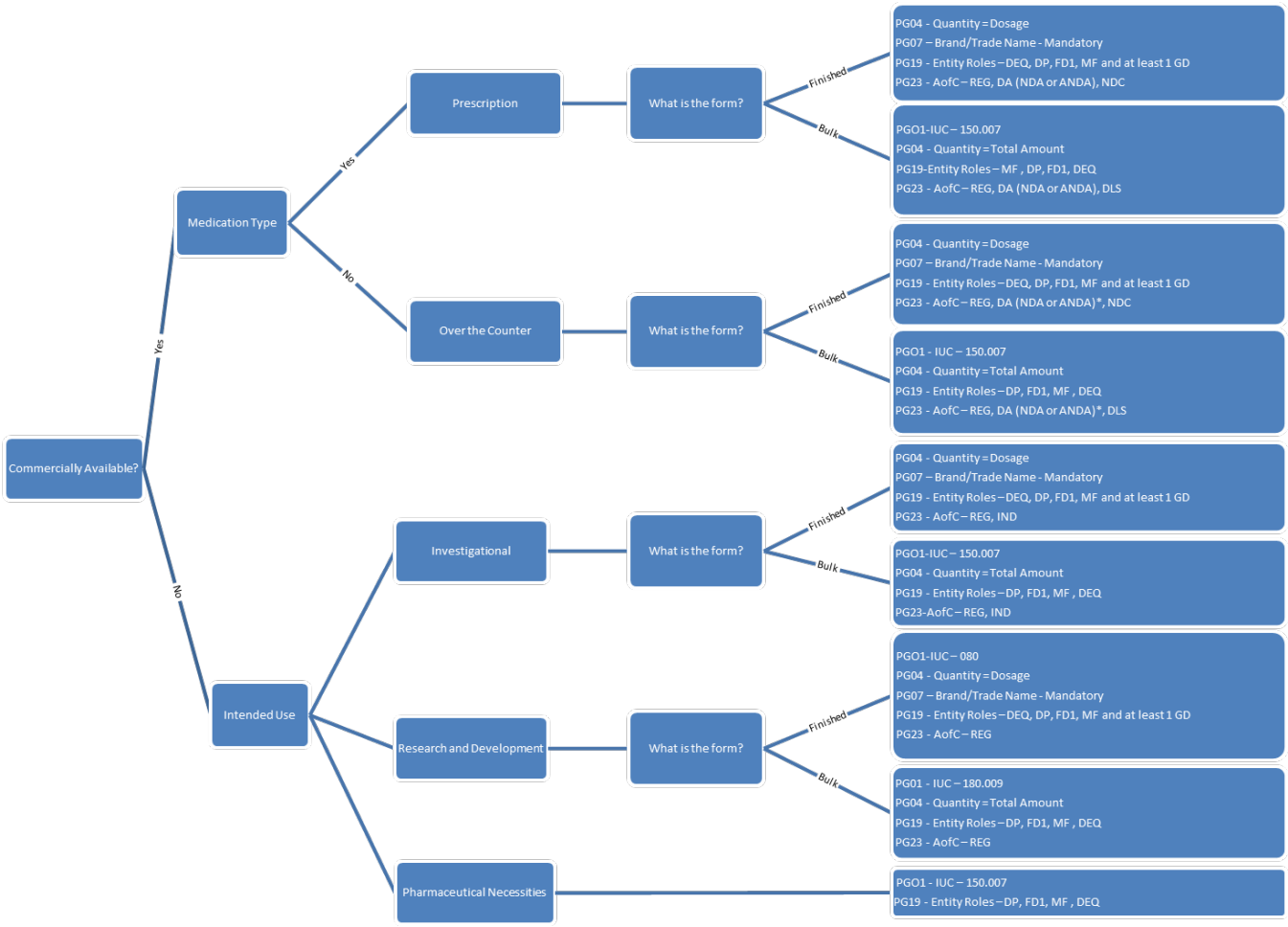
Without using PG10:

```
OI      SOFT CANDY KR CHERRY SOURS 6/8 OZ
PG01001FDAFDA
PG02PFDP 33LGT07A
...
OI      SOFT CANDY CB GUMMI BEARS 24/6 OZ PEG
PG01001FDAFDA
PG02PFDP 33LGT07A
...
OI      SOFT CANDY KR GUMMI BEARS 6/9 OZ
PG01001FDAFDA
PG02PFDP 33LGT07A
...
```

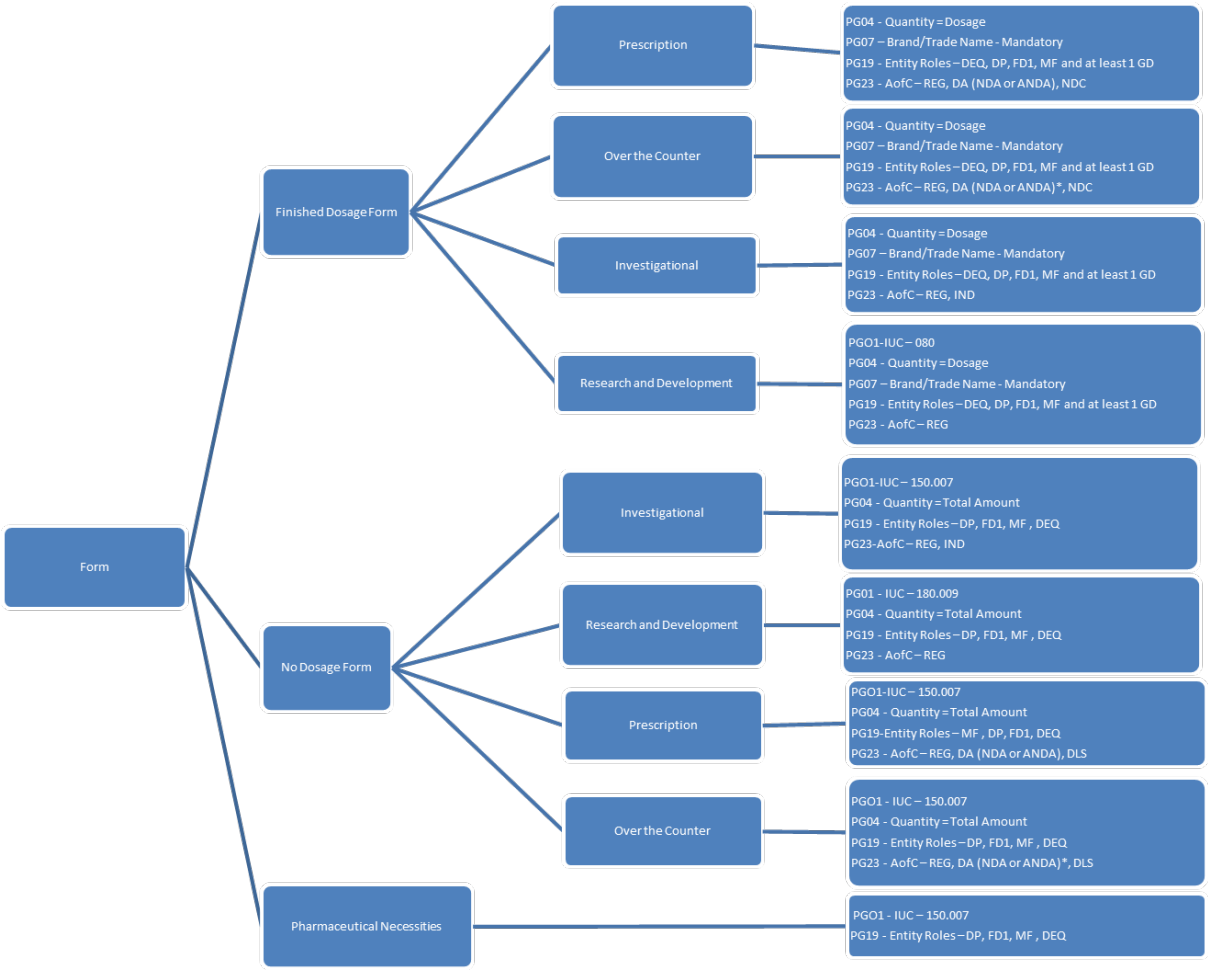
With the use of PG10:

```
OI      VARIOUS SOFT AND HARD CANDIES
PG01001FDAFDA
PG02PFDP 33LGT07A
...
PG10        SOFT CANDY KR CHERRY SOURS 6/8 OZ
...
PG01002FDAFDA
PG02PFDP 33LGT07A
...
PG10        SOFT CANDY CB GUMMI BEARS 24/6 OZ PEG
...
PG01003FDAFDA
PG02PFDP 33LGT07A
...
PG10        SOFT CANDY KR GUMMI BEARS 6/9 OZ
...
```

Appendix B: Drug Typing and Data Requirements – By Type:



Appendix C: Drug Typing and Data Requirements – By Form



Appendix D: Food Facility Registration Exemption (FME)

Code	Description
A	Facility is out of business
B	Facility is a private residence (21 CFR 1.227(b)(2))
C	Facility is a restaurant (21 CFR 1.226(d); 1.227(b)(10))
D	Facility is a retail food establishment (21 CFR 1.226(c); 1.227(b)(11))
E	Facility is a non-processing fishing vessel (21 CFR 1.226(f)
F	Facility is a non-bottled drinking water collection and distribution establishment (21 CFR 1.227(b)(2))
K	Unable to determine the registration number of the manufacturer

Appendix E: Sample use of PG04 – Product Constituent Element

Using the non-prescription Drug, ***Popular Product*** with multiple APIs[§], the example below shows how PG04 can be used at the product-level for multiple constituent elements.

OI	Analgesic/Human OTC Drug	
PG01	001	(Line#)
PG02	60LBF01	(Product Code)
PG06	39 Philippines	(Source Country Name)
PG07	Popular Product	(Brand Name)
PG10	Non/Rx Combination Ingredient - Modified Release Hard Gelatin Capsules	
PG04	API1	(Constituent Element #1)
PG04	API2	(Constituent Element #2)
PG04	API3	(Constituent Element #3)
PG19		

[§] API = Active Pharmaceutical Ingredient

The above example shows how the records PG05-PG06-PG07-PG08-PG10 are used at the **Product level**.

The FDA will accept PG05-PG06-PG07-PG08-PG10 records only at the Product-level (when they are under a PG02) at this time.

Avoid including PG05-PG06-PG07-PG08-PG10 under a PG04. PG05-PG06-PG07-PG08-PG10 records follow immediately the PG02 ; before any PG04 records.

Appendix F: Unit of Measurement Codes; See Base Units below

AE	Aerosol
AM	Ampoule, Non-Protected
AP	Ampoule, Protected
AT	Atomizer
BA	Barrel (Container)
BB	Bobbin
BC	Bottlecrate, Bottlerack
BD	Board
BE	Bundle
BF	Balloon, Non-Protected
BG	Bag
BH	Bunch
BI	Bin
BJ	Bucket
BK	Basket
BL	Bale, Compressed
BN	Bale, Non-Compressed
BO	Bottle, Non-Protected,Cyl
BP	Balloon, Protected
BQ	Bottle, Protected, Cylindrical
BR	Bar
BS	Bottle, Non-Protected Bulbous
BT	Bolt
BU	Butt
BV	Bottle, Protected Bulbous
BX	Box
BY	Board in Bndl/Bnch/Truss
BZ	Bars in Bundle/Bunch/Trus
CA	Can, Rectangular
CAG	Cage
CAR	Carats Weight
CC	Churn
CE	Creel
CF	Coffer
CG	Centigrams Weight
CH	Chest
CI	Canister
CJ	Coffin
CK	Cask
CL	Coil
CO	Carboy, Non-Protected

CON	Container
CP	Carboy, Protected
CR	Crate
CS	Case
CT	Carton
CU	Cup
CV	Cover
CX	Can, Cylindrical
CY	Cylinder
CZ	Canvas
DJ	Demijohn, Non-Protected
DP	Demijohn, Protected
DR	Drum
EN	Envelope
FC	Crate, Fruit
FD	Crate, Framed
FI	Firkin
FL	Flask
FO	Footlocker
FOZ	Fluid Ounces (Volume)
FP	Filmpack
FR	Frame
G	Grams Weight
GAL	Gallons (US) Volume
GB	Bottle, Gas
GI	Girders
GZ	Girders in Bndl/Bnch/Trus
HG	Hogshead
HR	Hamper
IN	Ingot
IZ	Ingots in Bundle/Bnch/Trs
JC	Jerrican, Rectangular
JG	Jug
JR	Jar
JT	Jutebag
JY	Jerrican, Cylindrical
KEG	Keg
KG	Kilograms Weight
L	Liters Volume
LB	Pounds (avdp) Weight
LG	Log
LZ	Logs In Bundle/Bunch/Trus

M3	Cubic Meters Volume
MB	Bag, Multi-ply
MC	Crate, Milk
MG	Milligrams Weight
MCG	Micrograms Weight
ML	Milliliters Volume
MS	Sack, Muitiwall
MT	Mat
MX	Matchbox
NE	Unpacked Or Unpackaged
NS	Nest
NT	Net
OZ	Ounces, weight (avdp) Weight
PA	Packet
PAL	Pallet
PC	Parcel
PCS	Pieces (Count)
PG	Plate
PH	Pitcher
PI	Pipe
PK	Package
PL	Pail
PN	Plank
PO	Pouch
PT	Pot
PTL	Pints, liquid (US) Volume
PU	Tray or Tray Pack
PY	Plates in Bndl/Bnch/Truss
PZ	Planks or Pipes, Bnd/Bnch
QTL	Quarts, liquid (US) Volume
RG	Ring
RL	Reel
RO	Roll
RT	Rednet
RZ	Rods in Bundle/Buch/Truus
SA	Sack
SC	Crate, Shallow
SD	Spindle
SE	Sea-chest
SH	Sachet
SK	Case, Skeleton
SL	Slipsheet

SM	Sheetmetal
ST	Sheet
STN	Short ton (2000 LB) Weight
SU	Suitcase
SUP	Suppositories (Dosage)
SW	Shrinkwrapped
SY	Syringe
SZ	Sheets in Bndl/Bnch/Truss
T	Metric Ton Weight
TAB	Tablets (Dosage)
TB	Tub
TC	Tea-Chest
TD	Tube, Collapsible
TK	Tank, Rectangular
TN	Tin
TO	Tun
TON	Long Ton (2240 LB) Weight
TOZ	Ounces, Troy or Apoth Weight
TR	Trunk
TS	Truss
TU	Tube
TY	Tank, Cylindrical
TZ	Tubes in Bndl/Bnch/Truss
VA	Vat
VG	Bulk Gas at 1031 MBAR
VI	Vial
VL	Bulk Liquid
VO	Bulk,Solid,Lg Particles
VP	Vacuum-packed
VQ	Bulk Liquified Gas
VR	Bulk,Solid,Granular Parti
VY	Bulk,Solid,Fine Particle
WB	Wickerbottle