FedEx Express

U.S. FDA

Additional Information Requirements

Effective: 9th February 2017

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1. Summary

On 29th December 2016 The U.S Food Drug Administration implemented its Final Rule with regard to ACE (Automated Commercial Environment) submissions; ACE being the U.S, single-window' clearance application. Additional information requirements have been made mandatory and entry cannot be made without all data elements being in place.

This document sets to highlight information provided within FDA Guidance* in relation to Medical Devices, Biologics and Drugs (Human Use).

*http://www.fda.gov/downloads/forindustry/importprogram/entryprocess/importsystems/ucm533750.pdf

2. New Requirements

2.1 What additional mandatory information is required?

1. The FDA Product Code

2. The Intended Use Code

2.2 Are these items mandatory for all FDA product types?

The FDA Product Code is mandatory, the Intended Use Code is mandatory only for specific FDA product categories:

It is important that all customers in the above sectors are fully aware of the new requirements.

* as per reviewing the FDA on line website

FDA Product Categories	Mandatory Codes		Other Mandatory FDA data based on intended use
	FDA Product Code?	Intended Use Code?	Check the pages listed below to determine other FDA Data based on intended use in the FDA Supplemental Guidance www.fda.gov/downloads/forindustry/importprogram/entryprocess/importsystems/ucm533750.pdf
Medical Devices	Yes	Yes	Pages 235 – 236*
Radiation Emitting Devices	Yes	Yes	Pages 288 - 291* (for use with 2877 form)
Biologics	Yes	Yes	Pages 39 – 41*
Drugs	Yes	Yes	Pages 98 – 99*
Animal Drugs	Yes	Yes	Page 321*
Food	Yes	No	Does Not Apply
Cosmetics	Yes	No	Does Not Apply
Animal Devices	Yes	No	Does Not Apply
Tobacco	Yes	No	Does Not Apply

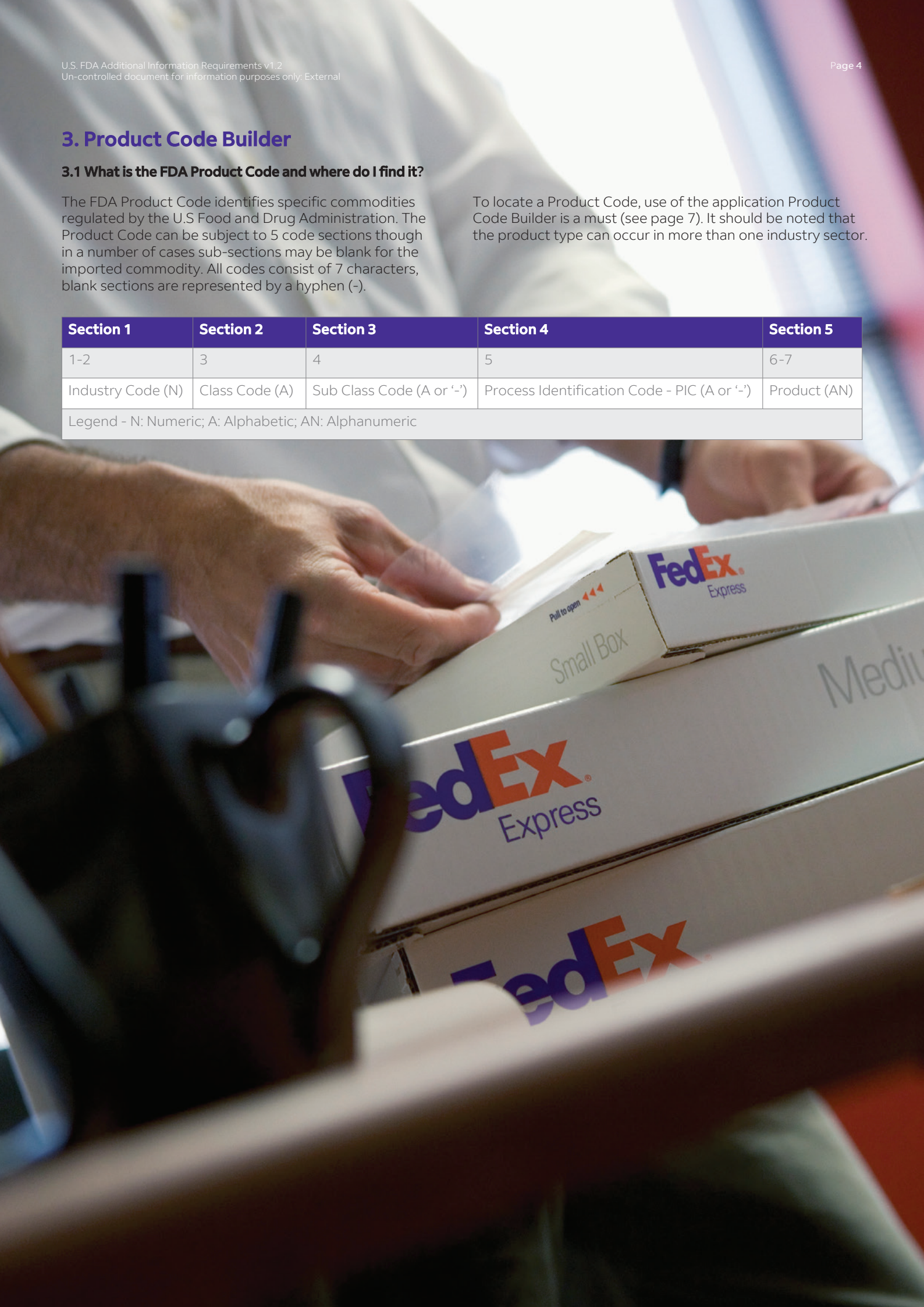
3. Product Code Builder

3.1 What is the FDA Product Code and where do I find it?

The FDA Product Code identifies specific commodities regulated by the U.S Food and Drug Administration. The Product Code can be subject to 5 code sections though in a number of cases sub-sections may be blank for the imported commodity. All codes consist of 7 characters, blank sections are represented by a hyphen (-).

To locate a Product Code, use of the application Product Code Builder is a must (see page 7). It should be noted that the product type can occur in more than one industry sector.

Section 1	Section 2	Section 3	Section 4	Section 5
1-2	3	4	5	6-7
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				



Medical Devices	Code
Anaesthesiology	73
Antibiotics	56
Bio & Licensed In-vivo & In-vitro Diagnostic	57
Cardiovascular	74
Dental	76
Ear, Nose and Throat	77
Gastroenterological & Urological	78
General and Plastic Surgery	79
General Hospital and Personal Use	80
Haematology	81
Immunology	82
Microbiology	83
Neurological	84
Obstetrical & Gynaecological	85
Ophthalmic	86
Orthopaedic	87
Pathology	88
Physical Medicine	89
Radiological	90
Toxicology	91
Type A Medicated Articles	67

Drugs	Code
Antibiotics	56
Colour Additives	50
Human Drugs	60
Human Drugs	61
Human Drugs	62
Human Drugs	63
Human Drugs	64
Human Drugs	65
Human Drugs	66
Multiple Drug Warehouses	59
Pharmaceutical Necessities & Centre for Drug / Bio	55
Physical Medicine	89
Vitamins / Minerals / Dietary Supplements	54

Other	Code
Ionising Non-Medical Devices and Components	94
Light -Emitting Non-Device Products	95
Radio Frequency Emitting Products	96
Sound Emitting Products	97
Tobacco Products	98

Veterinary / Animal Drugs	Code
Animal Devices and Diagnostic Products	68
Antibiotics	56
Animal Drug/Medicated Feeds / Medical Devices	99
Animal Drugs	60
Animal Drugs	61
Animal Drugs	62
Animal Drugs	63
Animal Drugs	64
Animal Drugs	65
Animal Drugs	66
Medicated Animal Feeds	69
Multiple Drug Warehouses	59

Biologics	Code
Chemistry	75
Antibiotics	56
Bio & Licenced In-vivo & In-vitro Diagnostic	57
Egg / Egg Products	15
Haematology	81
Immunology	82
Microbiology	83
Molecular Genetics	92
Pathology	88
Pharmaceutical Necessities & Centre for Drug / Bio	55
Toxicology	91

Cosmetics	Code
Colour Additives	50
Cosmetics	53

3.2 Industry Codes (illustrative list):

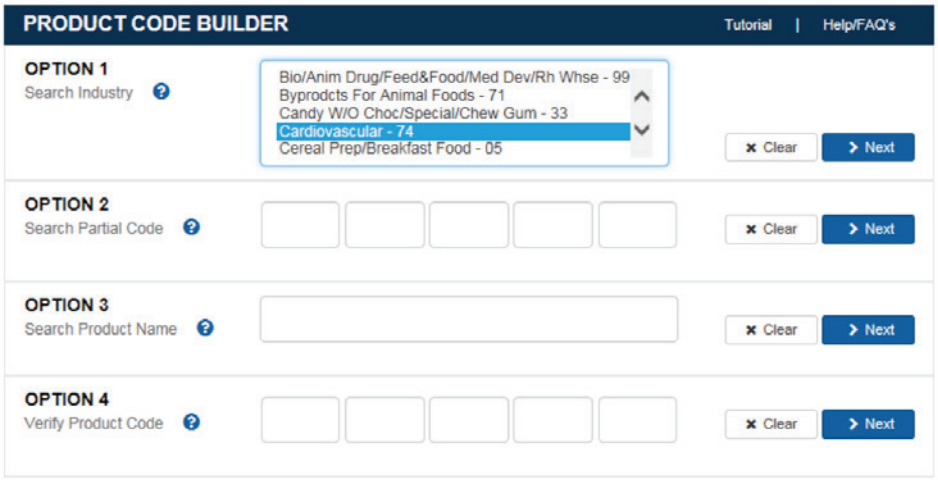
Food	Code
Alcoholic Beverages	32
Animal Food (non- medicated)	68
Baby Food Products	40
Bakery Products / Dough / Mix / Icing	03
Beverage Bases / Concentrates and Nectar	30
By-products for Animal Foods	71
Candy without Chocolate / Special / Chewing Gum	33
Cereal Preparations / Breakfast Food	05
Cheese/Cheese Product	12
Chocolate / Cocoa Products	34
Coffee / Tea	31
Colour Additives	50
Dietary Convenience Food / Meal Replacement	41
Dressing / Condiment	27
Edible Insects and Insect Derived Foods	42
Egg/Egg products (note: Prohibited from Europe)	15
Filled Milk /Limited Milk Products	14
Fishery / Seafood Products	16
Food Additives (Human Use)	45
Food Additives (Human Use)	46
Food Service / Conveyance	51
Food Sweeteners (Nutritive)	36
Fruit / Fruit Product	20
Fruit / Fruit Product	21
Fruit / Fruit Product	22
Gelatine / Rennet / Pudding Mix / Pie Filling	35
Ice Cream Products	13
Macaroni / Noodle products	04
Meat, Meat products and Poultry	17
Milk / Butter / Dried Milk Products	09
Miscellaneous Food Related Items (includes game, cook and tableware and coffee/ tea makers and the like)	52
Multi Food Dinner / Gravy / Sauce / Special	37
Multiple Food Warehouses	47
Nuts / Edible Seed	23
Pet / Lab Animal Food	72
Prepared Salad Products	39
Snack Food Item	07

Food	Code
Soft Drink / Water	29
Soup	38
Spices, Flavours and Salts	28
Vegetable Oils	26
Vegetable Protein Food	18
Vegetable / Vegetable Products	24
Vegetable / Vegetable Products	25
Vitamins / Minerals / Dietary Supplements	54
Whole Grain / Milled Grain Products /Starch	02

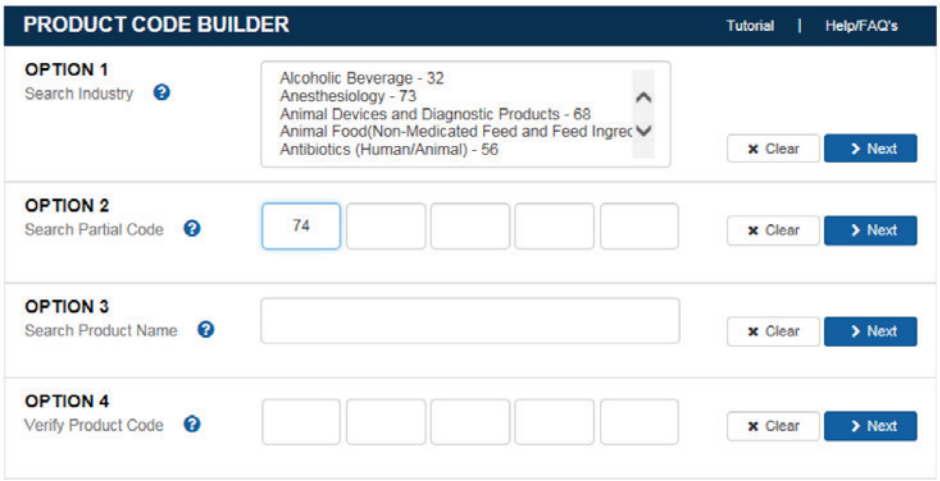
3.3 How is the Product Code Builder used?

The primary FDA category must be chosen first. This can be achieved by either searching the drop down menu 'Option 1' or by inserting the category number 'Option 2'.

Option 1

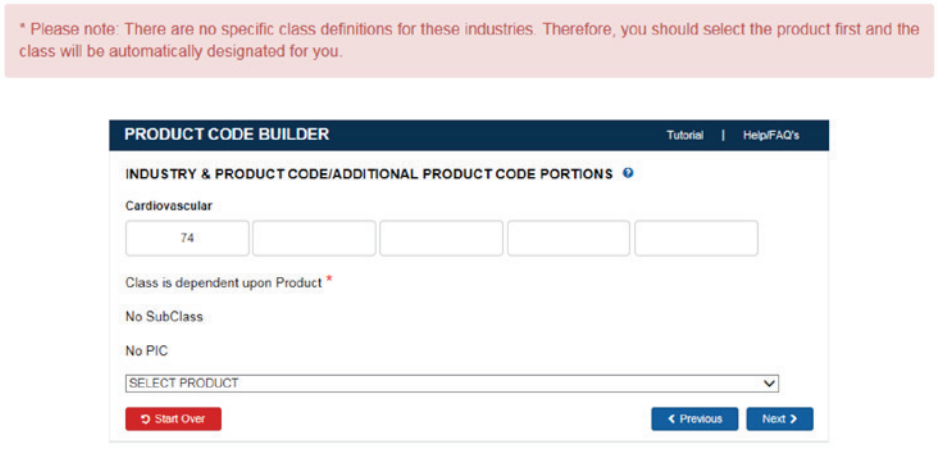


Option 2

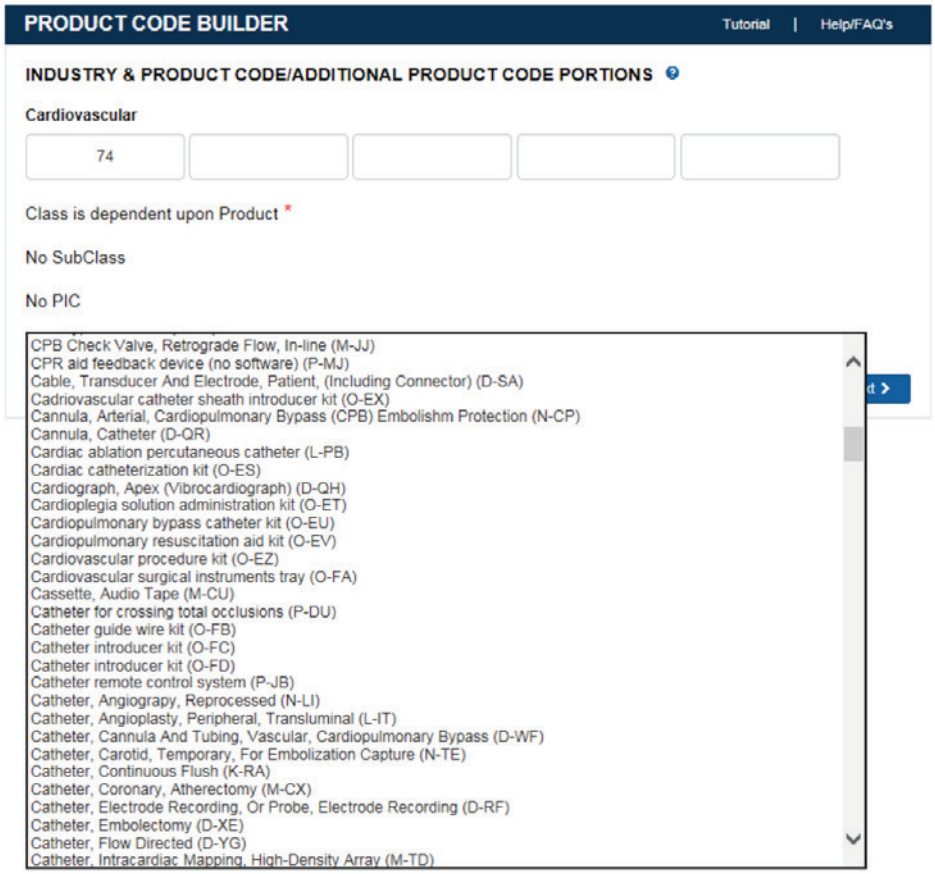


Select: > Next

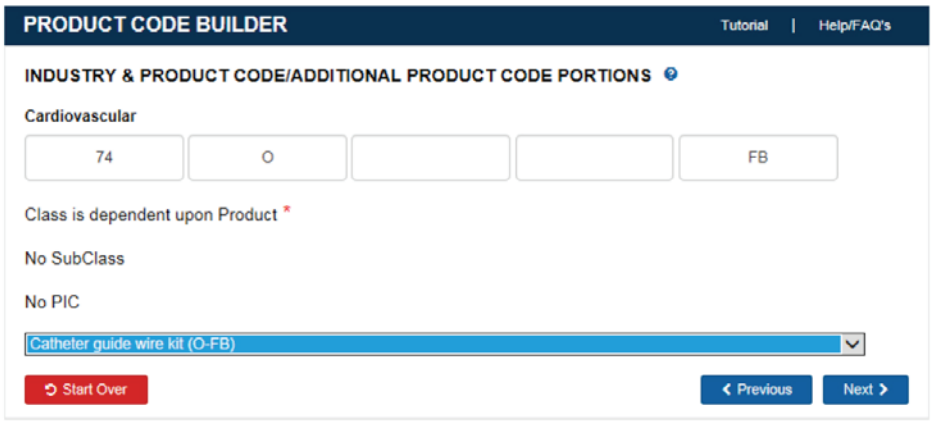
If there is no Sub-Class, the application inform the user. The user then progresses to the next available choice, which here is 'Select Product'.



As with other searches within this application the product choice is selected from a dropdown list



Codes at the end of each description populate fields in the Product Code Builder



Continue: Next > to finish

The FDA Product code in this example is 74 0 - - FB for a catheter guide wire kit for cardiovascular use.

An additional example of the Product Code Builder can be found in Appendix B

4. Medical Devices

4.1 What information is required for Medical Devices?

Certain sets of information are required to enable the U.S. FDA entry to be completed in ACE. The minimum information is to include:

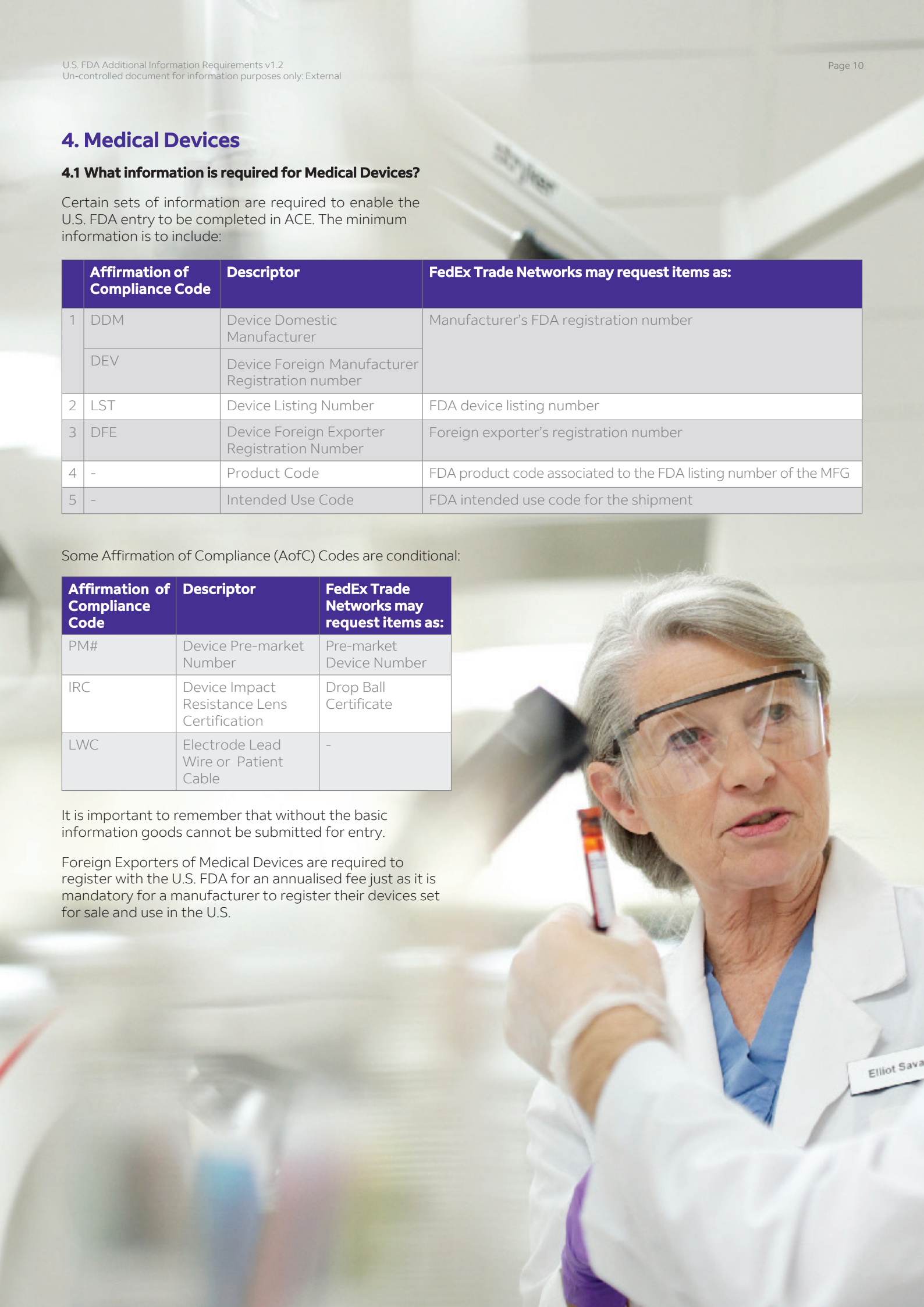
	Affirmation of Compliance Code	Descriptor	FedEx Trade Networks may request items as:
1	DDM	Device Domestic Manufacturer	Manufacturer's FDA registration number
	DEV	Device Foreign Manufacturer Registration number	
2	LST	Device Listing Number	FDA device listing number
3	DFE	Device Foreign Exporter Registration Number	Foreign exporter's registration number
4	-	Product Code	FDA product code associated to the FDA listing number of the MFG
5	-	Intended Use Code	FDA intended use code for the shipment

Some Affirmation of Compliance (AofC) Codes are conditional:

Affirmation of Compliance Code	Descriptor	FedEx Trade Networks may request items as:
PM#	Device Pre-market Number	Pre-market Device Number
IRC	Device Impact Resistance Lens Certification	Drop Ball Certificate
LWC	Electrode Lead Wire or Patient Cable	-

It is important to remember that without the basic information goods cannot be submitted for entry.

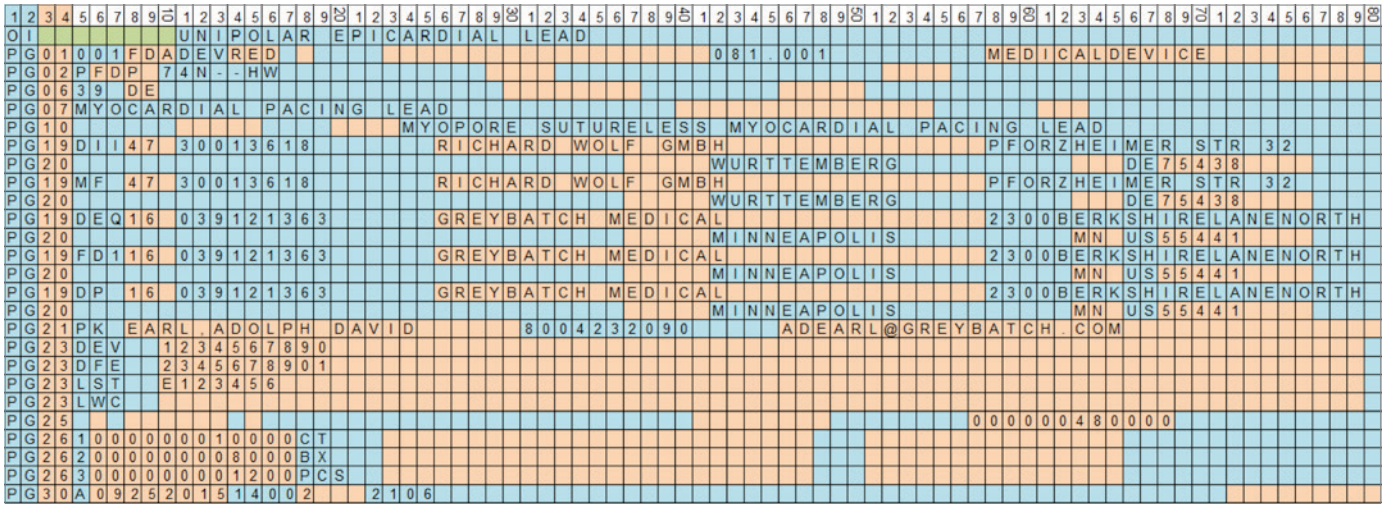
Foreign Exporters of Medical Devices are required to register with the U.S. FDA for an annualised fee just as it is mandatory for a manufacturer to register their devices set for sale and use in the U.S.



4.2 Why am I being asked for so much information?

The information is requested due to the above items being mandatory fields for completion in FDA ACE import entry submissions.

4.3 Example FDA Medical Devices Entry:



4.4 What are the medical device intended use codes?

Intended Use codes for Medical Devices are listed in pages 233 & 234 of the FDA Supplemental Guide for the Automated Commercial Environment and International Trade Data System (ACE/ITDS) version 2.5 dated 30th November 2016 and reproduced here:

The table above 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 or UNK	• Standard import of device, accessories, or components regulated as a finished device • Import of refurbished device • Import of a reprocessed device	DEV, DFE, LST	IRC, LWC, PM#	DI
081.002*	Import of a device for domestic refurbishing	DEV, DFE, LST	IRC, LWC, PM#	DI
081.003	Domestically manufactured device that is part of a medical device convenience kit	DDM, DFE, KIT, LST		DI
081.004	Foreign manufactured device that is part of a medical device convenience kit	DDM, DFE, KIT, LST	PM#, LWC;IRC	DI
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	IRC, LWC, PM#	DI
081.007	Component for further manufacturing into a finished medical device	CPT		LST, PM#
081.008	Component for further manufacturing into a finished medical device	CPT	DA, IND	
170.000	Repair of medical device and re-exportation	IFE	DFE, LST, IRC, LWC, PM#, DDM	DI
180.010	Import of research or investigational use in vitro diagnostic device			

Intended Use (see PG01 for definitions)	Import Scenarios	Mandatory Affirmations	Conditional(1) Affirmations	Optional Affirmations
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, IRC, LWC, PM#	DI
920.002	Import of device that is US goods returned for sale to a third party	DFE, DDM, LST	IRC, LWC, PM#	DI
950.001*	Import of a single-use device for domestic reprocessing	DDM ,LST	DFE, IRC, LWC, PM#	DI
950.002*	Import of a multi-use device for domestic reprocessing		DDM, DFE, IRC, LST, LWC, PM#	DI
970.000	Import for Export: • Import of a medical device for further processing and re-exportation • Importation of a medical device or accessory for further manufacturing into an export-only medical device	DEV, DFE, IFE, LST		
970.001	Import for Export: • Importation of a medical device component for further manufacturing into an export-only medical device	IFE, CPT, DDM, LST		
100.000*	Device For Personal Use			
110.000*	Public Exhibition/Trade Show			
940.000*	Compassionate Use/Emergency device			
081.006	Import under enforcement discretion provisions per final guidance			

(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.

5. Biologics

Biological items may require additional supporting documents as well as Intended Use Codes and FDA Product Codes. Typical documents are:

- End Use statement
- U.S. Department of Agriculture (USDA) exemption statement (depending on the source of the biologic item)
- TSCA (Toxic Substances Controls Act) positive or negative declaration (limited use in this industry)

Recommended description will include the biological source (animal, plant, human, synthetic) and its quantity and how the item is packaged in addition to what the item does or is to be used for (even though an Intended Use Code is to be submitted).

The manufacturer's name and address are required. These details can be replaced by a MID code at item level using the same construction techniques as with textile or wood products.

5.1 How is an MID code constructed?

- Use the country two letter ISO code (For Canada specific Province codes apply). www.iso.org/iso/country_codes/iso_3166_code_lists.html
- Take the first three letters of the manufacturer's first name and the first three letters of the second name if applicable.
- Select the largest digits, up to four, from the address line.
- Take the first three letters of the manufacturer's city name

5.2 What do the Affirmation of Compliance Codes listed in the Biologics Intended Use table mean?

Affirmation of Compliance Codes used in the above table is outlined below:

AofC Code	Descriptor
DA	Biologics New Drug Application Number or Abbreviated New Drug Application Number (NDA or ANDA)
HRN	Biologics Human Cells, Tissues/ Cellular and Tissue-Based Product Establishment Registration Number (HCT/P Registration Numbers)
IND	Biologics Investigation New Drug Application Number
HCT	Human Cells & Tissue
BLN	Biologics License Number
STN	Import of a device for charity
CPT	Component Identifier
IFE	Import For Export
REG	Drug Registration Number
DLS	Drug Listing Number

5.3 What are the Biologics Intended Use Codes?

Details are shown below reproduced from pages 39 - 41 of the FDA Supplemental Guide for the Automated Commercial Environment and International Trade Data System (ACE/ITDS version 2.5 dated 30th November 2016.

Government Agency Processing codes for BIOt	CBER Regulated Products Import Scenario	Intended Use Code	CBP Intended Use Name	Mandatory AofC	Optional AofC
ALG, BBA, BDP, CGT, PVE, VAC, or XEN	Biological or chemical for research and development into a pharmaceutical product – Investigational New Drugs (IND); clinical trials or other human/animal	180.009	Biological or chemical for research and development into a pharmaceutical product	IND	REG
ALG, BDP, BLD, BLO, CGT, VAC, or XEN	CBER-regulated Final product; ready for use. Importation of a licensed biological product. The Biologics License number (BLN) is the U.S. License Number. The Submission Tracking Number (STN) is associated with the manufacturer and a specific product and the first six digits represent the original submission tracking number.	080.000	For Human Medical Use as a Non-Food Product under Controlled Distribution	BLN or STN or Both	REG, DLS
BBA, PVE	CBER-regulated Final product; ready for use. Importation of drug regulated by CBER	080.000	For Human Medical Use as a Non-Food Product under Controlled Distribution	DA, REG, (DA includes NDA and ANDAs only)	DLS
HCT	Human Cells, tissues, and cellular and tissue based products (HCT/Ps) for implant, transplant, infusion, or transfer into a human recipient. The HCT affirmation should be used to indicate the HCT/Ps being importer or offered for import are in compliance with all applicable requirements of 21 CFR 1271	082.000	For Immediate use by authorized medical officials in the medical treatment of humans	HCT (No Qualifier Needed for HCT)	
HCT	Human Cells, tissues, and cellular and tissue based products (HCT/Ps) for implant, transplant, infusion, or transfer into a human recipient. The HRN Affirmation should be used for Importation of human cells, tissues and cellular and tissue-based product where the establishment is registered with the FDA.	082.000	For Immediate use by authorized medical officials in the medical treatment of humans	HRN	HCT
ALG, BDP, BLD, BLO, CGT, VAC, or XEN	CBER Product Sample for testing or lot release	180.016	For processing samples submitted to CBER for lot release testing.	BLN or STN or both	REG, DLS
ALG, BLO, BLD, BDP, VAC, XEN, or CGT.	Bulk drug substance for processing into a pharmaceutical product	150.008	For commercial processing as a non-food product; for processing into a pharmaceutical product	DA	IND, REG DLS

Government Agency Processing codes for BIOt	CBER Regulated Products Import Scenario	Intended Use Code	CBP Intended Use Name	Mandatory AofC	Optional AofC
ALG, BLO, BLD, BDP, VAC, XEN, or CGT.	CBER product For further manufacture of a licensed biological product under a short supply agreement (21 CFR 601.22)*	155.000	For processing into a pharmaceutical product	BLN or STN or both	REG, DLS
ALG, BBA, BDP, BLD, BLO, CGT, PVE, VAC, or XEN	Importation for Personal Use	100.000	For private non-commercial use under the FDA personal importation policy (PIP)		
ALG, BDP, BLD, BLO, CGT, VAC, or XEN	Bulk biological drug substance for processing into a pharmaceutical product	150.007	For commercial processing as a non- food product; for processing into a pharmaceutical product	BLN or STN or both	IND, REG DLS
BBA or PVE	Bulk Drug Substance or CBER product for processing into a pharmaceutical product	150.007	For commercial processing as a non-food product; for processing into a pharmaceutical product	DA	IND, REG DLS
ALG, BBA, BDP, BLD, BLO, CGT, PVE, VAC, or XEN	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.		BLN, STN, DA, IND
ALG, BBA, BDP, BLD, BLO, CGT, PVE, VAC, or XEN	Import of biological drug or device for trade show	110.000*	For Public Exhibition or Display as a Non-Food Product		BLN, STN, DA, IND
ALG, BBA, BDP, BLD, BLO, CGT, HCT, PVE, VAC, or XEN	For reconditioning or repair of a Non-Food. Product	170.000*	For repair of a Non-Food Product		BLN, STN, DA, IND, HCT, HRN,
ALG, BBA, BDP, BLD, BLO, CGT, PVE, VAC, or XEN	Importation of non-compliant articles (including blood, blood components; source plasma and source leukocytes) under the import for export provisions 801(d)(3), & 801(d)(4) of the FD&C Act.	970.000*	Import for Export	IFE (No qualifier required)	
BLO, ALG, BBA, BDP, BLD, CGT, HCT, PVE, VAC, or XEN	Import of biologic for non- clinical research use only, bench testing, etc. These entries could be disclaimed if the HTS code allows it.	180.000	For Research and Development as a Non-Food Product		
ALG, BLO, CGT, HCT, VAC, XEN, BDP, BLD, BBA, PVE	Importation of a drug (including a biological product) or device for compassionate use/emergency use	940.000*	Compassionate Use/ Emergency Use Device		BLN, STN, DA, IND, HCT, HRN,
ALG, BLO, CGT, HCT, BAC, XEN, BDP, BLD, BBA, PVE	Import of US Goods Returned	920.000	For return to the United States (US Goods Returned).		

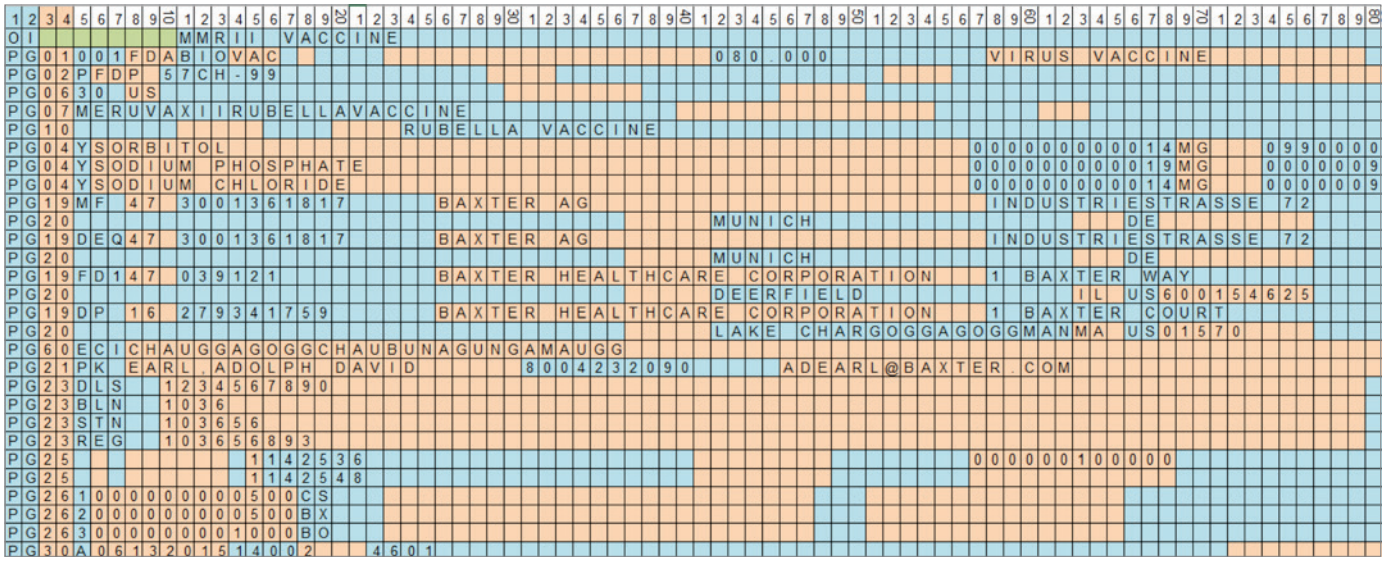
*Annotates that additional information may be needed at time of entry in order for FDA to make a final admissibility decision.

Note: The government agency processing code BRD, the corresponding Intended Use Code, and Affirmation of Compliance Codes (PM# and IDE) have been removed from the Biologics Commodity Data Elements and Values section. These devices will be handled using the Medical Device Commodity Data Elements and Values in the ACE/ITDS environment.

5.4 What are the Government Agency Codes for Biologics?

Program Code & Commodity	Processing Code & Commodity Sub Type	Industry Code (Product code first 2 characters)
BIO	ALG - Allergens	57
	BLO - Blood & Blood Products	
	HCT - Human Cells & Tissue	
	VAC - Vaccines	
	XEN - Xenotransplants	
	BDP - Blood Derivatives	
	BBA - Blood Bag with anti-coagulant	
	BLD - Licensed Devices	
	PVE - Plasma Volume Expanders	

5.5 Example FDA Biologics entry



5.6 Does an exception exist to supplying an FDA Product Code?

Yes, items of human origin such as blood, serum, saliva and cells that are non-infectious and for laboratory bench testing only have the ability to be disclaimed from FDA entry.

The Intended Use Code for in-vitro research and development of a non-food product is 180.000.

6. Drugs (Human Use)

When importing drugs to the United States a series of rules determines what information is required for entry. The stage at which the drug is at when placed on the market provides the basis for these rules and as outlined within mandatory Affirmation of Compliance codes.

6.1 What are the Affirmation of Compliance Codes used for drugs?

The following AofC codes are mandatory or optional based on rules shown. Where required details must be declared within the shipping paperwork, preferably within the Commercial Invoice.

Mandatory / Optional Codes:

Code	Description	Business Rules
DA	New Drug Application Number or Abbreviated New Drug Application Number or Therapeutic Biologic Application Number	IF Government Agency Program Code = DRU AND Government Agency Processing Code = 'PRE' AND Intended Use Code = 080.012, or 150.007, **then DA is mandatory** IF Government Agency Program Code = DRU AND Government Agency Processing Code = 'OTC' AND Intended Use Code = 130.000, or 150.007, 150.017, 155.009, or 920.000, **then DA is optional** IF Government Agency Program Code = DRU AND Government Agency Processing Code = ' 'PRE',AND Intended Use Code = 150.017, 155.009, or 920.000, **then DA is optional** The DA AofC includes all the previous AofC codes, NDA, ANDA and BLA.
REG	Drug Registration Number	IF Government Agency Program Code = DRU and IF Government Agency Processing Code is 'PRE' AND Intended Use Code = 080.012, or 980.000, **then REG is mandatory** IF Government Agency Program Code = DRU and IF Government Agency Processing Code is 'OTC' AND Intended Use Code = 130.000, **then REG is mandatory** IF Government Agency Program Code = DRU and IF Government Agency Processing Code is 'PRE' or 'OTC' AND Intended Use Code = 150.007, 150.013, 150.017, or 155.009, **then REG is mandatory** IF Government Agency Program Code = DRU AND Intended Use Code = 920.000, **then REG is optional**
DLS	Drug Listing Number	IF Government Agency Program Code = DRU and IF Government Agency Processing Code is 'PRE', AND Intended Use Code = 080.012, or 980.000, **then DLS is mandatory unless affirmation "PLR" is declared.** IF Government Agency Program Code = DRU and IF Government Agency Processing Code is 'OTC' AND Intended Use Code = 130.000, **then DLS is mandatory** IF Government Agency Program Code = 'DRU' and IF Government Agency Processing Code is 'PRE', or 'OTC' AND Intended Use Code = 150.007, 150.013, 150.017, or 155.009, **then DLS is mandatory** IF Government Agency Program Code = DRU AND Intended Use Code = 920.000, **then DLS is optional** The DLS AofC includes both the previous NDC and DLS AofC codes.
IND	Investigational New Drug Number	IF Government Agency Program Code = DRU and IF Government Agency Processing Code is 'INV' AND Intended Use Code = 180.009, **then IND is mandatory**

Exceptions:

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, Inactive Pharmaceutical Ingredients and Excipients; or RND: Research and Development
- Import for Export entries and Personal Importations do not require AofCs. For Government Program Code = DRU AND Intended Use Code =
  - 100.000: Importation for Personal Use; OR
  - 970.000: Import For Export

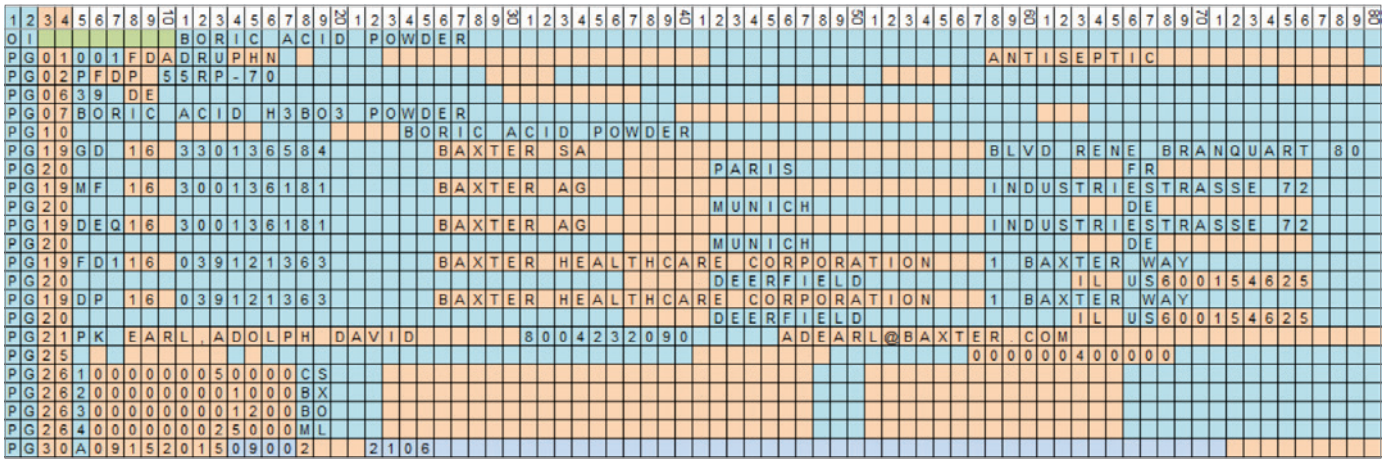
6.2 What other Affirmation of Compliance Codes are Optional for Drugs messages?

AofC Code	Descriptor
LST	Device Listing Number
PM#	Device Premarket Number
IDE	Investigational Device Exemption Number

6.3 What are the intended use codes related to Drug imports?

Intended Use Code	Import Scenarios	Mandatory AofC Codes	Conditional AofC Codes	Optional AofC Codes
080.012	Prescription health or medical product for human use that is the subject of an approved new drug application, abbreviated new drug application, or biologics license application	REG, DLS, DA		PLR
100.000	Importation for Personal Use			
130.000	For Consumer Use as a Non-Food Product – Over the Counter (OTC)	REG, DLS		DA
150.007	Active Pharmaceutical Ingredient / Bulk Drug Substance for processing into a pharmaceutical product	REG, DLS	DA	
150.013	Active Pharmaceutical Ingredient / Bulk Drug Substance to be used for Pharmacy Compounding	REG, DLS		
150.017	Importation of a drug component (API) for use in a medical product regulated under a device (CDRH) application type (e.g., for use in a PMA/510(k) drug-device combination product)	REG, DLS		DA, LST, PM#, IDE
155.009	Importation of a drug constituent part (drug product) for use in a medical product regulated under a device (CDRH) application type (e.g., for use in a PMA/510(k) drug-device combination product)	REG, DLS		DA, LST, PM#, IDE
180.009	Chemical for research and development of a pharmaceutical product – subject of an Investigational New Drug application (IND), including Placebos	IND		
180.017	Chemical for research and development of a pharmaceutical product – laboratory testing only , no human/animal use			
180.018	Chemical for research and development; investigational use in animals			
180.026	Finished drug or API intended for use in an in vivo bioequivalence or bioavailability study in humans that qualifies under 21 CFR 320.31 for an exemption from the Part 312 requirements; or finished drug intended for use in clinical investigation in humans that qualifies for an exemption from Part 312 requirements.			
920.000	US Goods Returned			REG, DLS, DA, IND
970.000	Import for Export			
980.000	For Other Use: (APIs or Finished Drugs not elsewhere classified)	REG, DLS		

6.4 Example FDA Drugs Entry



7. Other FDA Regulated Products

Although this document has focused predominantly on Medical Devices, Biologics and Drugs, it is worth noting that other impacted commodities do exist.

FDA Product Categories	MANDATORY Codes		Notes
	FDA Product Code?	Intended Use Code?	
Radiation Emitting Devices	Yes	Yes	Form FDA 2877 also required AofC Codes Pages 288 - 291 of FDA Supplemental Guidance v2.5
Animal Drugs	Yes	Yes	Intended Use Codes Page 321 of FDA Supplemental Guidance v2.5 AofC codes required. Manufacturer or MID Code required
Food	Yes	No	FDA Product Code is supplied as part of the Prior Notice submission process. Both Web entry and Prior Notice parts are to be supplied with the Shipping/Commercial invoice. Food will include Food contact surfaces, mugs, plates, cutlery, drinking glasses, coffee makers etc. No Prior Notice is required but Manufacturer / MID code and FDA product Code need to be included in shipping paperwork.
Cosmetics	Yes	No	Mandatory stating of the FDA Product Code is new and affects manufacturers, vendors and shippers associated with the fashion industry. Manufacturer or MID code information is required.
Animal Devices	Yes	No	Mandatory stating of the FDA Product Code is new AofC codes required Manufacturer or MID code required
Tobacco	Yes	No	Mandatory stating of the FDA Product Code is new

Appendix A – Source Materials

U.S. FDA Guides and Documents

FDA Supplemental Guidance v2.5:

www.fda.gov/downloads/forindustry/importprogram/entryprocess/importsystems/ucm533750.pdf

FDA Affirmation of Compliance Codes
www.fda.gov/downloads/ForIndustry/ImportProgram/EntryProcess/ImportSystems/UCM487261.pdf

FDA Affirmation of Compliance Codes – Quick Reference
www.fda.gov/downloads/ForIndustry/ImportProgram/EntryProcess/ImportSystems/UCM498013.pdf

FDA Registration and Listing
www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/RegistrationandListing/default.htm

FDA Establishment Registration and Listing Search Tool
www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfRL/rl.cfm

FDA Medical Device Searches: Pre-Market Approvals
www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMA/pma.cfm

Pre-Market Notification (510K
www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmn.cfm

Intended Use Codes: Full list with definitions (Appendix R):
www.cbp.gov/sites/default/files/assets/documents/2016-Dec/Appendix%20R%20-December%202016.pdf

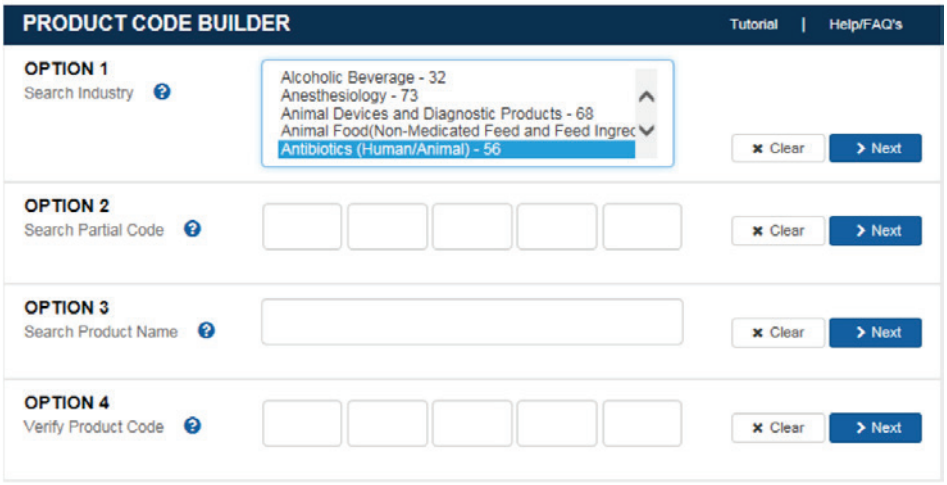
FedEx Regulatory Publications

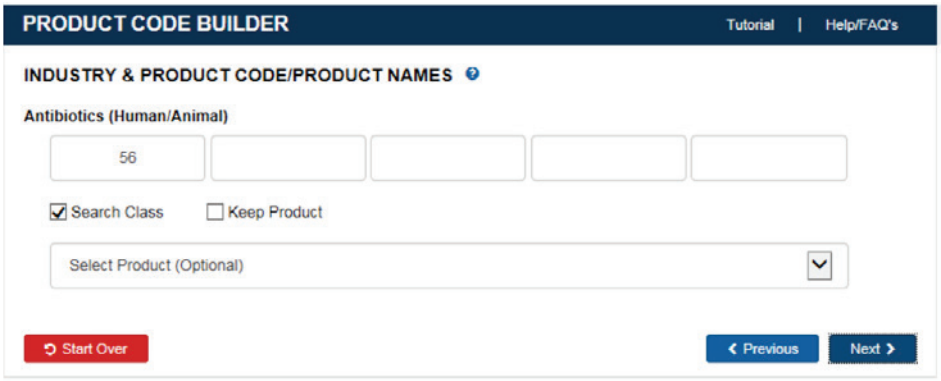
External:

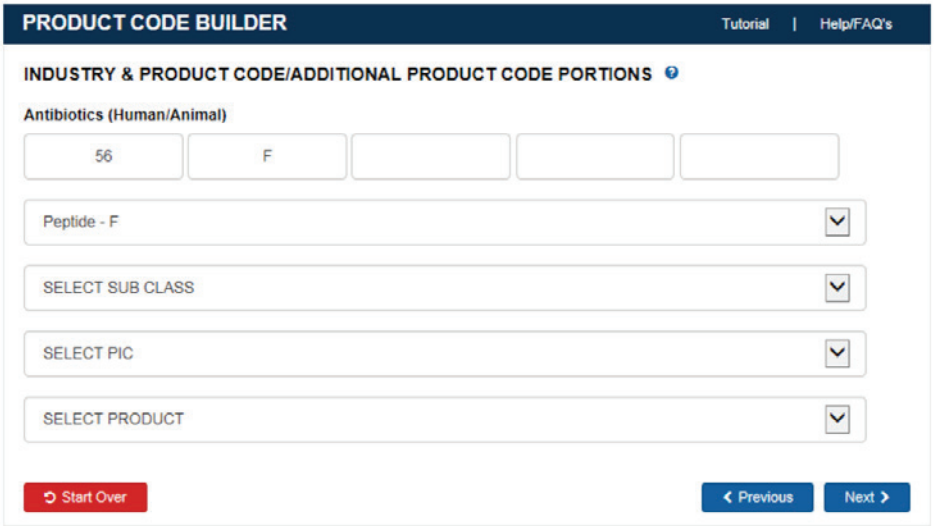
Small Business Centre
smallbusiness.fedex.com/international/regulatory-alerts.html

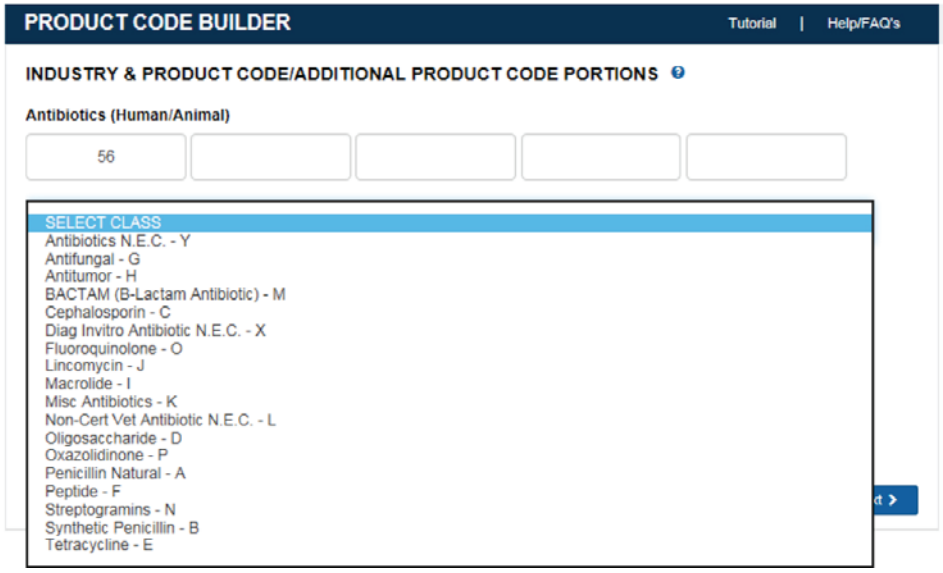
Appendix B – Additional FDA Product Code Builder Example

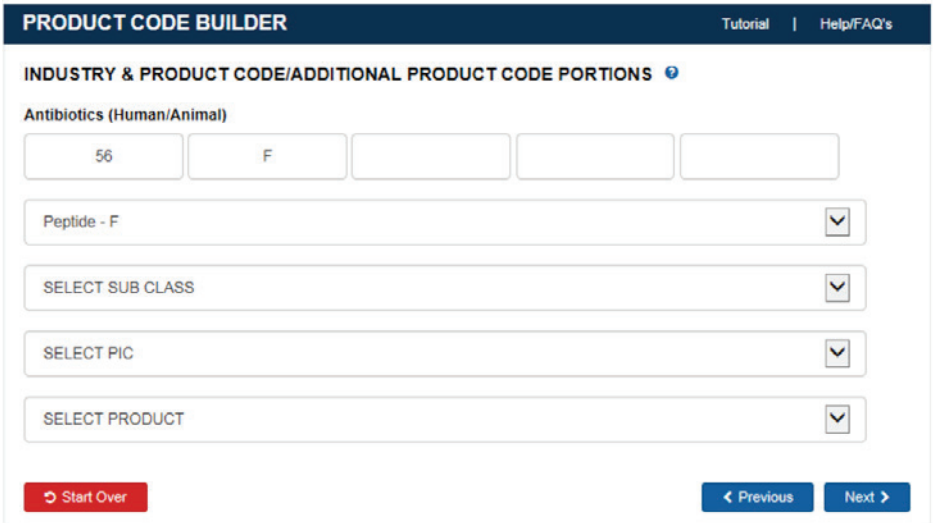
Antibiotics – Completing Subclasses

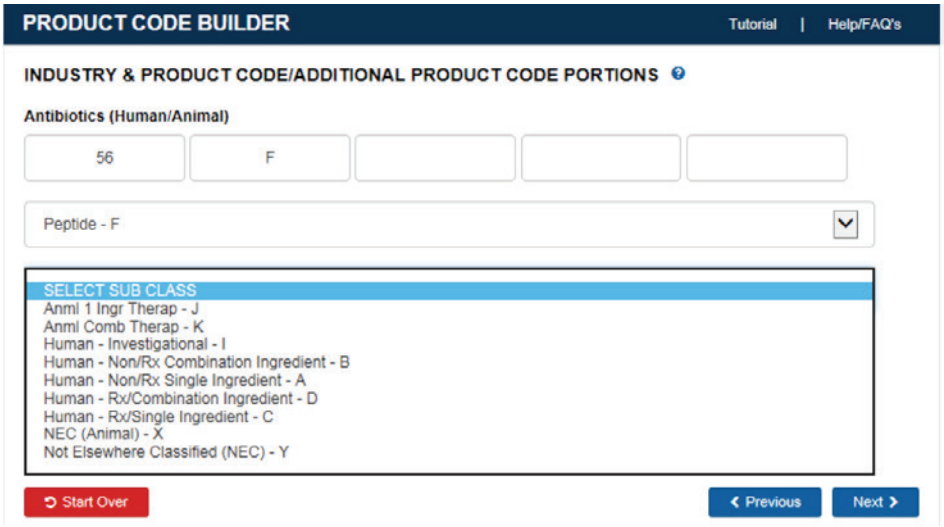


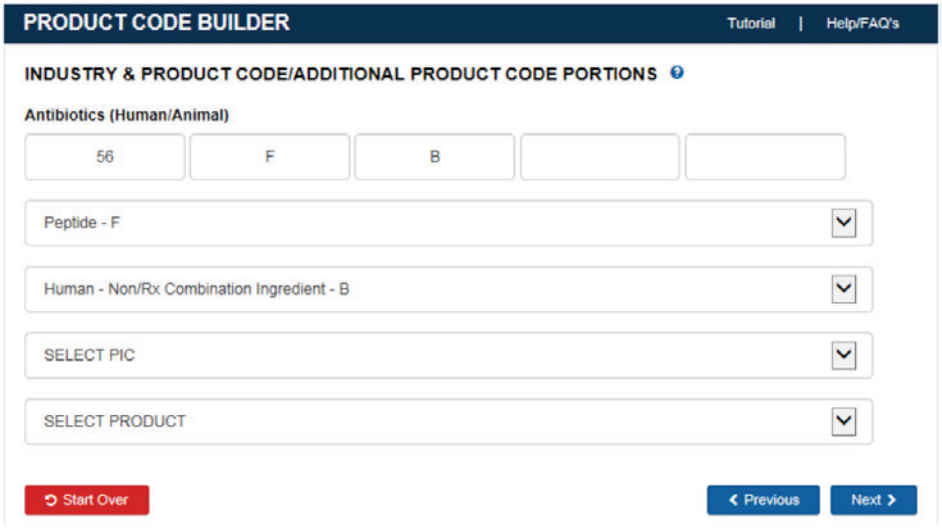


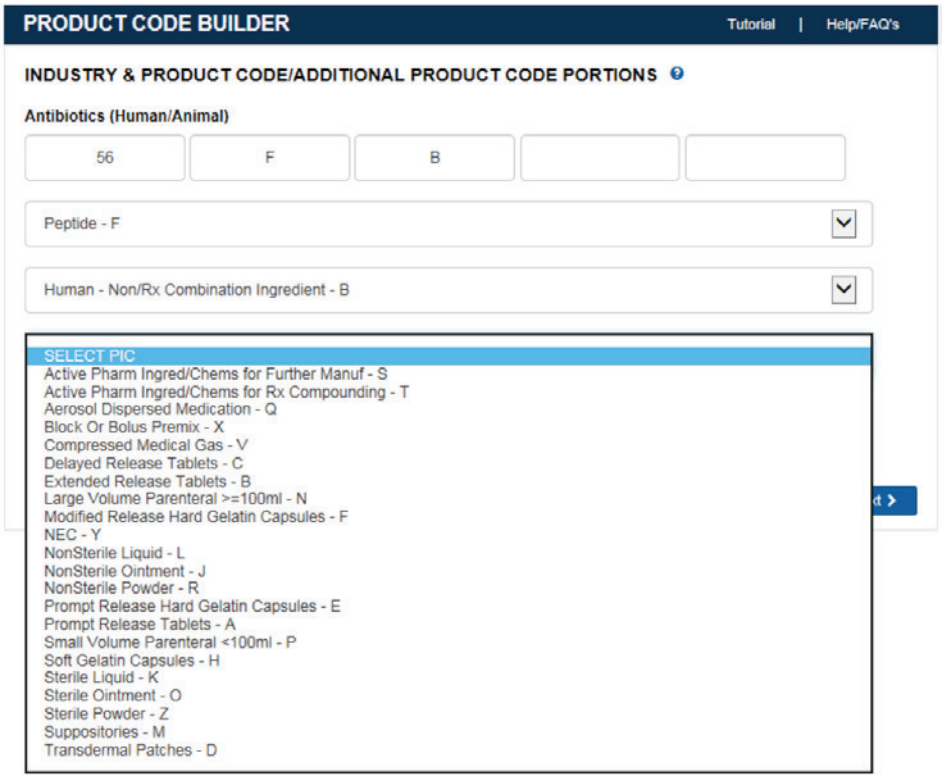


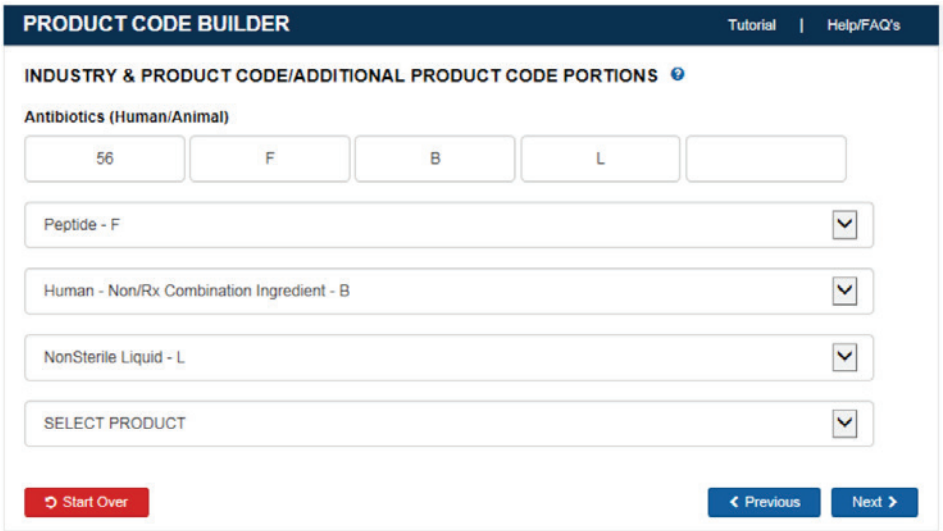

PRODUCT CODE BUILDER
Tutorial | Help/FAQ's
INDUSTRY & PRODUCT CODE/ADDITIONAL PRODUCT CODE PORTIONS
Antibiotics (Human/Animal)
56
SELECT CLASS
Antibiotics N.E.C. - Y
Antifungal - G
Antitumor - H
BACTAM (B-Lactam Antibiotic) - M
Cephalosporin - C
Diag Invitro Antibiotic N.E.C. - X
Fluoroquinolone - O
Lincomycin - J
Macrolide - I
Misc Antibiotics - K
Non-Cert Vet Antibiotic N.E.C. - L
Oligosaccharide - D
Oxazolidinone - P
Penicillin Natural - A
Peptide - F
Streptogramins - N
Synthetic Penicillin - B
Tetracycline - E

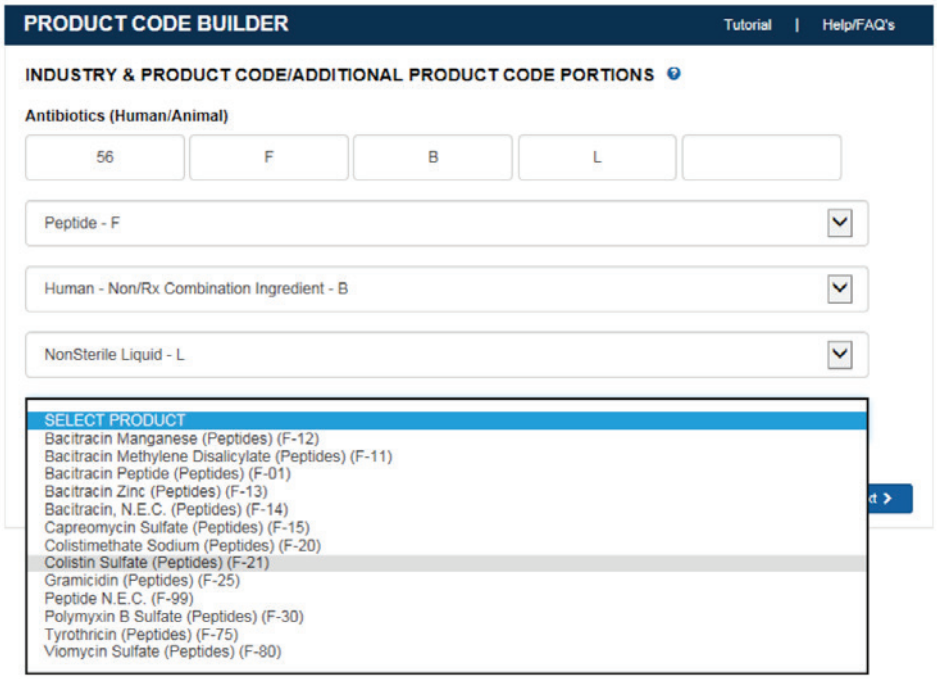

PRODUCT CODE BUILDER
Tutorial | Help/FAQ's
INDUSTRY & PRODUCT CODE/ADDITIONAL PRODUCT CODE PORTIONS
Antibiotics (Human/Animal)
56
F
Peptide - F
SELECT SUB CLASS
SELECT PIC
SELECT PRODUCT
Start Over
Previous
Next

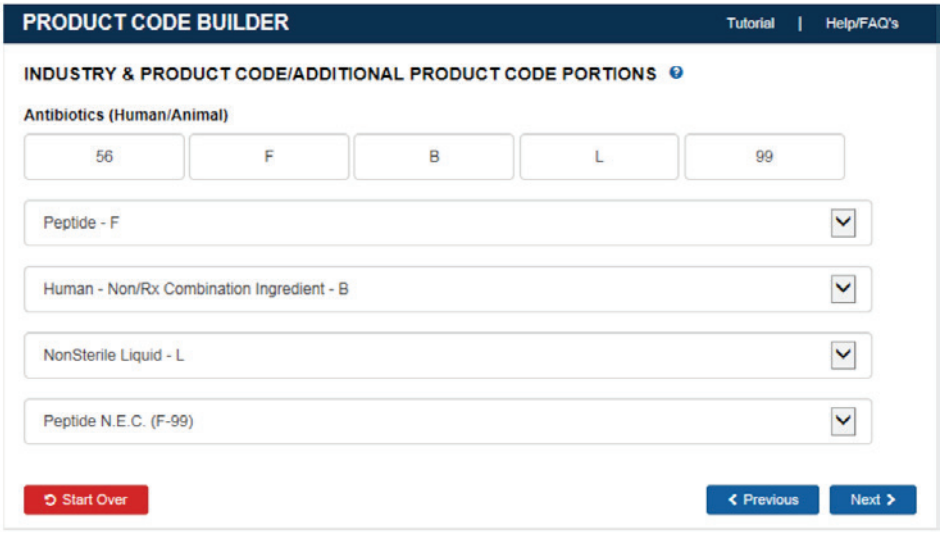

PRODUCT CODE BUILDER
Tutorial | Help/FAQ's
INDUSTRY & PRODUCT CODE/ADDITIONAL PRODUCT CODE PORTIONS
Antibiotics (Human/Animal)
56
F
Peptide - F
SELECT SUB CLASS
Anml 1 Ingr Therap - J
Anml Comb Therap - K
Human - Investigational - I
Human - Non/Rx Combination Ingredient - B
Human - Non/Rx Single Ingredient - A
Human - Rx/Combination Ingredient - D
Human - Rx/Single Ingredient - C
NEC (Animal) - X
Not Elsewhere Classified (NEC) - Y
Start Over
Previous
Next


PRODUCT CODE BUILDER
Tutorial | Help/FAQ's
INDUSTRY & PRODUCT CODE/ADDITIONAL PRODUCT CODE PORTIONS
Antibiotics (Human/Animal)
56
F
B
Peptide - F
Human - Non/Rx Combination Ingredient - B
SELECT PIC
SELECT PRODUCT
Start Over
Previous
Next


PRODUCT CODE BUILDER
Tutorial | Help/FAQ's
INDUSTRY & PRODUCT CODE/ADDITIONAL PRODUCT CODE PORTIONS
Antibiotics (Human/Animal)
56
F
B
Peptide - F
Human - Non/Rx Combination Ingredient - B
SELECT PIC
Active Pharm Ingred/Chems for Further Manuf - S
Active Pharm Ingred/Chems for Rx Compounding - T
Aerosol Dispersed Medication - Q
Block Or Bolus Premix - X
Compressed Medical Gas - V
Delayed Release Tablets - C
Extended Release Tablets - B
Large Volume Parenteral >=100ml - N
Modified Release Hard Gelatin Capsules - F
NEC - Y
NonSterile Liquid - L
NonSterile Ointment - J
NonSterile Powder - R
Prompt Release Hard Gelatin Capsules - E
Prompt Release Tablets - A
Small Volume Parenteral <100ml - P
Soft Gelatin Capsules - H
Sterile Liquid - K
Sterile Ointment - O
Sterile Powder - Z
Suppositories - M
Transdermal Patches - D


PRODUCT CODE BUILDER
Tutorial | Help/FAQ's
INDUSTRY & PRODUCT CODE/ADDITIONAL PRODUCT CODE PORTIONS
Antibiotics (Human/Animal)
56
F
B
L
Peptide - F
Human - Non/Rx Combination Ingredient - B
NonSterile Liquid - L
SELECT PRODUCT
Start Over
Previous
Next


PRODUCT CODE BUILDER
Tutorial | Help/FAQ's
INDUSTRY & PRODUCT CODE/ADDITIONAL PRODUCT CODE PORTIONS
Antibiotics (Human/Animal)
56
F
B
L
Peptide - F
Human - Non/Rx Combination Ingredient - B
NonSterile Liquid - L
SELECT PRODUCT
Bacitracin Manganese (Peptides) (F-12)
Bacitracin Methylene Disalicylate (Peptides) (F-11)
Bacitracin Peptide (Peptides) (F-01)
Bacitracin Zinc (Peptides) (F-13)
Bacitracin, N.E.C. (Peptides) (F-14)
Capreomycin Sulfate (Peptides) (F-15)
Colistimethate Sodium (Peptides) (F-20)
Colistin Sulfate (Peptides) (F-21)
Gramicidin (Peptides) (F-25)
Peptide N.E.C. (F-99)
Polymyxin B Sulfate (Peptides) (F-30)
Tyrothricin (Peptides) (F-75)
Viomycin Sulfate (Peptides) (F-80)


PRODUCT CODE BUILDER
Tutorial | Help/FAQ's
INDUSTRY & PRODUCT CODE/ADDITIONAL PRODUCT CODE PORTIONS
Antibiotics (Human/Animal)
56
F
B
L
99
Peptide - F
Human - Non/Rx Combination Ingredient - B
NonSterile Liquid - L
Peptide N.E.C. (F-99)
Start Over
Previous
Next


PRODUCT CODE BUILDER
Tutorial | Help/FAQ's
FINAL RESULTS
Industry
Product
Code
Antibiotics (Human/Animal)
Peptide / Human - Non/Rx Combination Ingredient / NonSterile Liquid / Peptide N.E.C.
56 F B L 99
Start Over
Previous
Print

Appendix C –
FDA Commodities, Commodity Sub-Types & Corresponding Industry Codes

Program Code & Commodity	Processing Code & Commodity Sub Type	Industry Code (Product code first 2 characters)
BIO	ALG - Allergens	57
	BLO - Blood & Blood Products	
	CGT - Cell and Gene Therapy	
	HCT - Human Cells & Tissue	
	VAC - Vaccines	
	XEN - Xenotransplants	
	BDP - Blood Derivatives	
	BBA - Blood Bag with anti-coagulant	
	BLD - Licensed Devices	
	PVE - Plasma Volume Expanders	
COS - Cosmetic	Not applicable	50 or 53
DRU – Drug*	PRE - Prescription	50, 54, 55, 56, 60, 61, 62, 63, 64, 65, or 66
	OTC - Over the Counter	
	RND - Research & Development	
	INV - Investigational	
	PHN - Pharmaceutical Necessities	55, various codes could apply
VME - Animal Drug or Device*	ADR - Animal Drug	54, 56, 60, 61, 62, 63, 64, 65, 66 or 67
	ADE - Animal Device	68
FOO – Food*	NSF - Natural State Food	01-46, 48, 49, 50, 52, 54, 69, 70, 71 or 72
	PRO - Processed Food	
	FEE - Animal Feed	
	DSU - Dietary Supplement	
	ADD - Additives and Colours	
	CCW - Ceramic ware or Food Contact Substance	52
DEV - Medical Device	NED - Non-Radiation Emitting Device	73-92
	RED - Radiation-Emitting Device	
RAD - Radiation-Emitting Products	REP - Non-Medical Radiation-Emitting Product	94-97
Tobacco	CSU - Consumer Use	98
	FFM - For further manufacturing	
	INV - Investigational	

*Subject to additional rules based on FDA Program/Processing/Product codes

FedEx Express