U.S. FOOD & DRUG ADMINISTRATION

Review of FDA Supplemental Guide 2.5 (Requirements for Importing in ACE)

January 31, 2017

Status Update

- Since ACE went live in August 2015, FDA has successfully processed approximately 6.7M entries (34M lines).

- The purpose of today's webinar is to review changes which will be deployed on February 9 between 6-7 a.m., answer questions, and provide further clarity on requirements.

Overview of Changes

- Importer of Record contact information is required for all FDA lines (changing from optional to mandatory) (does not apply to PN data sets).

- When contact information is mandatory, PG19 and PG21 entity codes must match.

- FDA highly suggests additional transmission of Filer Contact Information: “PK.” Filer Contact Information - “PK” - can only be sent once per FDA line.

Requirements for Biologics

- Product Code must start with Industry Code “57”

- Code for Biologics Regulated Devices “BRD” will no longer be accepted. Affirmations of Compliance “IDE” and “PM#” have also been removed. These products fall under program code “DEV”
    - Corresponding Intended Use Codes have also been updated

Requirements for Biologics

- Clarification on Intended Use Code 082.000: If this code is used, either “HCT” or “HRN” is mandatory

Processing Code		Scenario	Intended Use Code		Mandatory AofC	Optional AofC
7	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)	
8	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

Requirements for Cosmetics

- Product Code must start with Industry Code “50” or “53”
- Intended Use is **NOT** required.
- If it has a Drug Listing Number or National Drug Code, it is **NOT** a cosmetic.

Requirements for Human Drugs

- Product Code Restrictions based on Industry Code:

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

- Brand Name is optional, but encouraged.

Requirements for Human Drugs

- Updated Intended Use Codes:

Code	Intended Use Description
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
100.000	Importation for Personal Use
130.000	For Consumer Use as a Non- Food Product – Over the Counter (OTC)
150.007	Active Pharmaceutical Ingredient / Bulk Drug Substance for processing into a pharmaceutical product
150.013	Active Pharmaceutical Ingredient / Bulk Drug Substance to be used for Pharmacy Compounding
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)
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)
180.009	Chemical for research and development of a pharmaceutical product – subject of an Investigational New Drug application (IND), including Placebos
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 of a pharmaceutical product – 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
970.000	Import for Export
980.000	For Other Use: (APIs or Finished Drugs not elsewhere classified)

Requirements for Human Drugs

- Because Intended Use Codes were updated, corresponding logic for Affirmations of Compliance requirements was also updated.

Requirements for Food

- Product Code restrictions based on Industry Code:

FOO – Food*	NSF - Natural State Food	01-46, 48, 49, 50, 52, 54, 69, 70, 71 or 72
	PRO - Processed Food	
	FEE - Animal Feed	
	DSU - Dietary Supplement	
	ADD - Additives and Colors	
	CCW - Ceramicware or Food Contact Substance	52

- Prior Notice requirements remain unchanged.

- **Note: Intended Use is not required for Food. If the food is for research or personal use, select the appropriate code, otherwise leave this field blank.**

Requirements for Tobacco

- Product Code must start with Industry Code “98”
- Brand name is only required for Consumer Use products
- Affirmations of Compliance are optional

Requirements for Medical Devices

- Product Code must start with Industry Codes 73-92

- If “UNK” is provided for Intended Use, DEV, DFE, and LST are required. CDRH encourages transmitting the correct intended use code for the import scenario.

Requirements for Radiation-Emitting Products

- Product Code must start with Industry Codes 94-97

Requirements for Animal Drugs

- Product Code must start with Industry Codes 54, 56, or 60-67

- Intended Use Codes are required for animal drugs:

085.003	Drug subject of a new animal drug application, conditionally approved application, or Index listing
100.000	Importation for Personal Use
150.013	Active Pharmaceutical Ingredient / Bulk Drug Substance to be used for Pharmacy Compounding
150.020	Active Pharmaceutical Ingredient / Bulk Drug Substance used to be further manufactured into a finished drug subject of a new animal drug application, conditionally approved application, or Index listing
180.009	For research and development in a pharmaceutical product – clinical investigations in animals (INAD)
180.018	For research and development in a pharmaceutical product – for tests in-vitro or in laboratory research animals.
920.000	US Goods Returned
970.000	Import for Export
980.000	For Other Use: (APIs or Finished Drugs not elsewhere classified)

Requirements for Animal Drugs

- Because Intended Use Codes were updated, corresponding logic for Affirmations of Compliance requirements was also updated.

Requirements for Animal Devices

- Product Code must start with Industry Code “68”
- Intended Use Codes and Affirmations of Compliance are not required for Animal Devices at this time.

For Software Vendors:
Sample of PG19 and PG21 Record for PN Lines

PG19MF
PG20

PG19DEQ
PG20

PG19FD1
PG20

PG19UC
PG20

PG19PNS
PG20
PG21PNS

PG19PNT
PG20
PG21PNT

PG19DFP
PG20

PG19 and PG21 for PN entities must match

For Software Vendors:
Sample of PG19 and PG21 Record for Non-PN Lines

PG19MF
PG20

PG19DEQ
PG20

PG19FD1
PG20
PG21FD1

PG19 and PG21 for FD1 entity must match;

PG19DP
PG20
PG21PK

PK could be added to any PG21 or sent as a PG19/21/21 set

PG19PK
PG20
PG21PK

Frequently Asked Questions

Q: Does FDA want DUNS or FEI numbers?

A: Either DUNS or FEI numbers can be submitted.

For medical devices and biologics, FEIs are encouraged because FEIs are often the registration numbers for those products.

For drugs and other products, DUNS is encouraged. Drug registration numbers are DUNS numbers.

Frequently Asked Questions

Q: For the Importer of Record Contact information, can we list a general email and phone number or does it have to be a specific person?

A: Importer of Record may be a person or a corporation. A general email for the company is fine, but it should be an email that is regularly monitored.

Frequently Asked Questions

Q: Are there exceptions for the Device Foreign Exporter when a foreign-manufactured device is sent to the U.S. for recycling or reprocessing?

A: Devices coming in for reprocessing do not require a DFE. (Reference Intended Use Codes 950.0001 and 950.002).

Frequently Asked Questions

Q: Is the Device Foreign Exporter required for U.S. Goods Returned?

A: When U.S. Goods are returned for refund/overstock to manufacturer, DFE is not required. If the original manufacturer is not a U.S. firm, this is not U.S. Goods Returned, and the Device Foreign Exporter would be required to register.

Frequently Asked Questions

Q: When transmitting the Manufacturer address, should we provide the corporate headquarters information or the physical location who produces the product?

A: The manufacturer is the site-specific location where the product is manufactured, produced, or grown. CBP and FDA consider this to be the site where the product last went a “substantial transformation” (resulting in an increase in value).

Frequently Asked Questions

Q: How should packaging be transmitted?

A: Each level of packaging should be transmitted, largest to smallest. Each commodity has specific units of measure and base units. Only one base unit is allowed. Examples:

Medical Device:

(200 cartons, 6 boxes in each carton, 8 pieces in each box)

200 CT
6 BX
8 PCS (base unit)

Food:

(1000 cases, 24 bottles in each case, 16 ounces in each bottle)

1000 CS
24 BO
16 OZ (base unit)

Frequently Asked Questions

Q: Is “UNK” still allowed?

A: “UNK” (unknown) is allowed for an Intended Use Code for all commodities. It is not allowed for any other data element. FDA discourages filers from using “UNK” and may request documentation if “UNK” is submitted. FDA encourages filers to talk with their importers to determine the intended use and contact FDA if you need assistance or have a question.

Resources

To obtain/query a DUNS number, visit:

www.fdadunslookup.com

To query a FEI number for a medical device, visit:

http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfRL/rl.cfm

Resources

For questions about ACE entries, data requirements, or help with rejects, contact FDA 24/7 ACE Help Desk:

ACE_Support@fda.hhs.gov ; 1-877-345-1101

For questions about if a product is subject to FDA, can be disclaimed, or questions related to HTS Codes, contact:

FDAImportsInquiry@fda.hhs.gov

Questions?

Thank You.