Making ACE Work for You: Importing FDA Regulated Products

Office of Enforcement and Import Operations and
Office of Information Systems Management

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US Food and Drug Administration

August 2017

Agenda

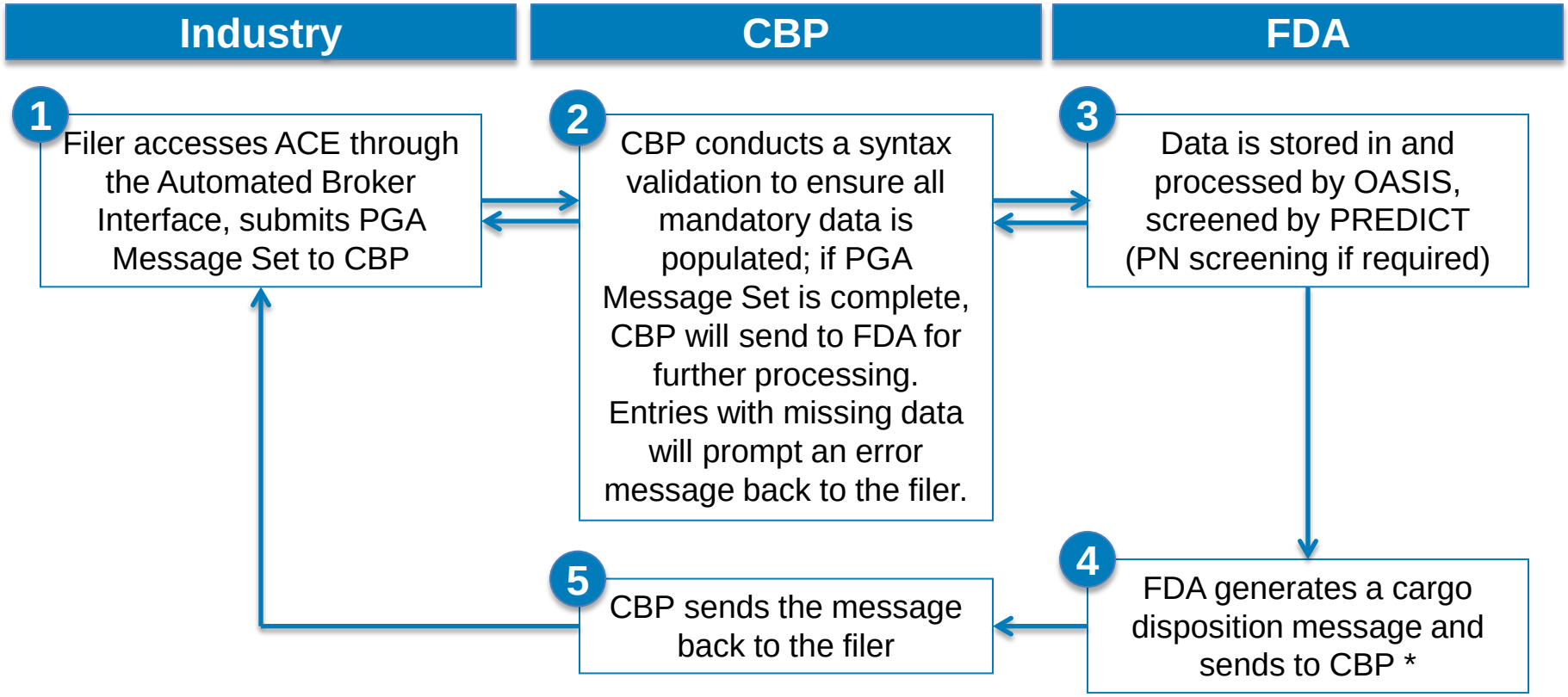
Overview: ACE and FDA	Commodity Specific Information	Information and Resources for All FDA Regulated Products
• What is ACE? • How ACE Works for FDA • FDA Current Status • Most Common CBP and FDA Rejections • Common Data Errors • FDA Flags • FDA ACE Final Rule Changes	• Know the Product Being Imported • Information Needed for Submission • Common Reasons for Commodity Specific Entry Processing Delays • Commodity Specific Resources	• Avoiding Delays with FDA • Use the Supplemental Guide • Summary • Frequently Asked Questions • Resources • FDA Points of Contact for Imports

OVERVIEW: ACE AND FDA

What is ACE?

The Automated Commercial Environment is a centralized system for all transactions related to imports and exports. Filers electronically submit all information related to an inbound shipment and the government processes the transaction systematically and sends status updates.

How ACE & PREDICT Work for FDA

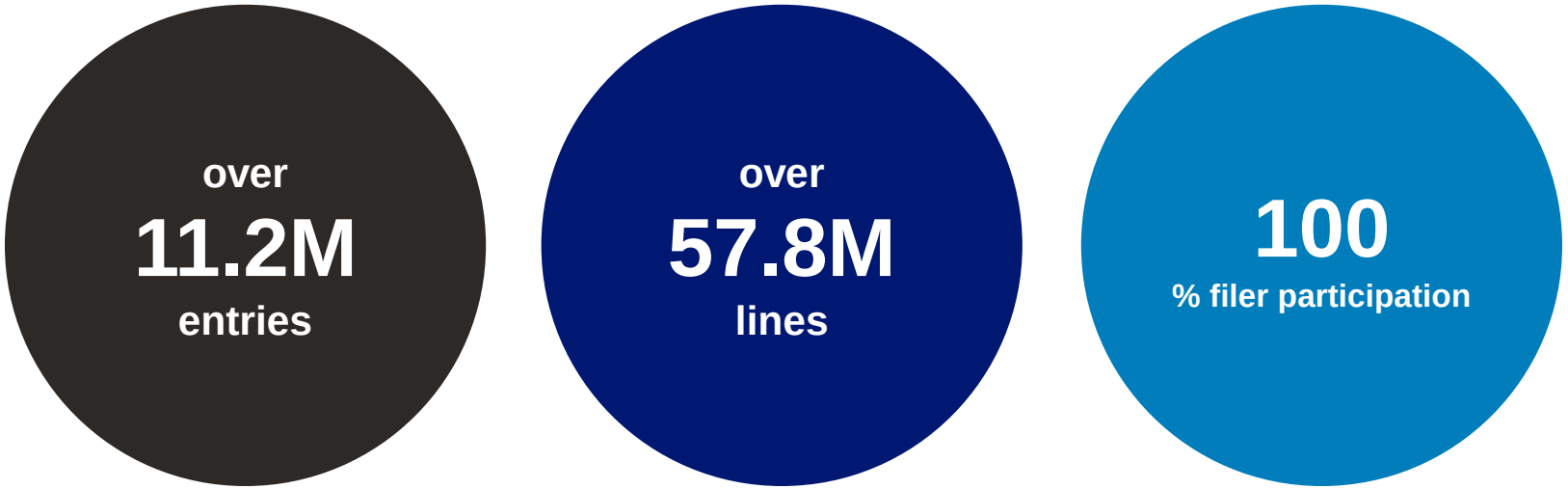


* Data that is electronically validated may be automatically "May Proceeded"

FDA Current Status

- ACE became mandatory in June 2016
- Final Rule issued in November 2016
- FDA Supplemental Guide version 2.5 released February 2017
- FDA continues to work closely with importers, brokers, and software developers to ensure understanding and compliance of the “new” ACE process
- FDA also continues to collaborate with CBP to troubleshoot issues and make system enhancements

Data as of July 7, 2017



FDA Current Status

- Automated May Proceeds have increased in ACE, and the percentage of lines requiring manual review have decreased.
  - In 2014, only **26%** of (ACS) lines were Automated May Proceeds.
  - In 2016, (after full implementation of ACE and updates to FDA processing tools including line level release functionality), **62%** of lines were Automated May Proceeds.

FDA Current Status

- In ACE, FDA requests less documents.
  - In 2014, approximately **3%** of (ACS) lines needed additional information to make an admissibility decision (Documents Required).
  - In 2016, approximately **2%** of (ACE) lines needed additional information to make an admissibility decision (Documents Required).
- There were approximately **28,374 fewer** lines needing additional information to make an admissibility decision (Documents Required) in 2016 than in 2014.

Most Common CBP & FDA Rejects

CBP Rejects	FDA Rejects
• Missing or Invalid Affirmations of Compliance	• Invalid Food Facility Registration Number – 27%
• Missing or Invalid Entities	• Cancelled Food Facility Registration Number - 21%
• Missing or Invalid Unit of Measure	• Invalid Product Code – 15%
• Product Code Conflicts with Program	• Foreign UC/DP must be U.S. based
• Missing or Invalid Source Type (Country Type)	
• Submitting UC instead of DP and vice versa	

Common Data Errors

Areas for Improvement

- Must know the Intended Use Code of the product prior to transmitting entry data (foods do not require an IUC)
- Know required Entities and Affirmation of Compliance (AoC) Codes for commodity type
- Other than the few repeatable AoC codes listed in the SG, do not submit the same AoC code more than once per line
- Submit correct entity addresses and DUNS or FEI number

Common Data Errors

Consumer Use is different than Personal Use

- Base Code 130 For Consumer Use as a Non-Food Product
- Base Code 100 For Personal Use as a Non-Food Product
- Base Code 210 For Personal Use as Human Food

FD Flags

- **FD1** – Indicates that the article may be subject to FDA jurisdiction, including FDA review under 801(a) of the FD&C Act. For products not subject to FDA jurisdiction, a filer can "Disclaim" product from FDA notification requirements.

- **FD2** – Indicates that the article is under FDA jurisdiction and review of entry information by FDA under section 801(a) will take place. However, the article is not "food" for which prior notice information is required.

- **FD3** – Indicates that the article may be subject to prior notice under section 801(m) of the FD&C Act and 21 CFR Part1, subpart I. , e.g., the article has both food and non-food uses.

- **FD4** – Indicates that the article is "food" for which prior notice is required under section 801(m) of the FD&C Act and 21 CFR Part1, subpart I.

Final Rule

The Final Rule for submission of information to the Automated Commercial Environment (ACE) was published in the Federal Register on November 29, 2016.

Final Rule Changes

- **Optional** – Line Value
- **Optional** – Quantity and Unit of Measure
  - Except for Radiation Emitting Products subject to a Form FDA 2877, Declaration for Imported Electronic Products Subject to Radiation Control Standards and Prior Notice datasets
- **Mandatory** – Importer of Record contact information is required for all non-food lines

• Although data elements may be optional, transmitting them may expedite processing •

MEDICAL DEVICES

Submitting Medical Device Entries in ACE

- Know the Product Being Imported
- Information Needed for Submission
- Common Reasons for Medical Device Entry Processing Delays
- Additional Resources

Know the Product Being Imported

If a product is labeled, promoted or used in a manner that meets the following definition in section 201(h) of the Federal Food Drug & Cosmetic (FD&C) Act it will be regulated by the Food and Drug Administration (FDA) as a medical device and is subject to premarketing and post marketing regulatory controls.

DEV

Know the Product Being Imported

- ***Component*** means any raw material, substance, piece, part, software, firmware, labeling, or assembly which is intended to be included as part of the finished, packaged, and labeled device. (21 CFR 820.3(c))

- ***Finished device*** means any device or accessory to any device that is suitable for use or capable of functioning, whether or not it is packaged, labeled, or sterilized. (21 CFR 820.3 (l))

Know the Product Being Imported

Examples of medical devices

- Tongue depressors and bedpans
- Myocardial and Epicardial leads
- Surgical lasers
- In vitro diagnostic test kits
- Reagents
- Diagnostic ultrasound products
- X-ray machines

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Information Needed for Submission

Program & Processing Codes

Program Code for medical device commodities is **DEV**.

The **Processing Code** will be determined by the commodity sub-type:

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

Information Needed for Submission

Product Code Overview

Structure of the FDA Product Code					
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					

- FDA Product Code errors are among the most common reasons for FDA Entry Rejections.
- Use a valid FDA Product Code per the FDA Product Code Builder.

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Information Needed for Submission

Product Codes

- Product code is mandatory.

PG01: Program Code & Commodity	PG01: Processing Code & Commodity Subtype	PG02: Industry Code
DEV - Medical Device	NED - Non-Radiation Emitting Device	73-92
	RED - Radiation-Emitting Device	

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Information Needed for Submission

Product Descriptions, Packaging and Condition

- Data requirements depend on whether the product is:
  - Radiation Emitting Device
  - Non-Radiation Emitting Device

Data Requirement	Radiation Emitting Devices	Non-radiation Emitting Devices
Commodity Characteristic Description	Mandatory	Mandatory
Quantity and Packaging* (if entered, the rules from the SG must be followed)	Mandatory if the product requires a 2877	Optional but encouraged
PGA Line Value	Optional but highly encouraged	Optional but highly encouraged

See the FDA Supplemental Guide for ACE v2.5 for valid units of measure for medical device packaging containers.

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Information Needed for Submission

Intended Use Codes and Affirmations of Compliance

- Intended Use Code is mandatory for medical devices.
- Affirmation of Compliance requirements depend on the Intended Use Code.

Intended Use Codes	Import Scenario	Affirmations of Compliance
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	Mandatory: DEV, DFE, LST Conditional: IRC, LWC, PM# Optional: DI
081.002*	Import of a device for domestic refurbishing	Mandatory: DEV, DFE, LST Conditional: IRC, LWC, PM# Optional: DI
081.003	Domestically manufactured device that is part of a medical device convenience kit	Mandatory: DDM, DFE, KIT, LST Conditional: IRC, LWC, PM# Optional: DI
081.004	Foreign manufactured device that is Part of a medical device convenience kit	Mandatory: KIT, DEV, DFE, LST Conditional: PM#, LWC; IRC Optional: DI

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

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Information Needed for Submission

Intended Use Codes and Affirmations of Compliance

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Intended Use Codes	Import Scenario	Affirmations of Compliance
081.005	Device constituent part for drug-device combination product	Mandatory: DEV, DFE, LST Conditional: DA, IND
140.000	Import of a device for charity	Mandatory: DEV, DFE, LST Conditional: IRC, LWC, PM# Optional: DI
081.007	Component for further manufacturing into a finished medical device	Mandatory: CPT Optional: LST, PM#
081.008	Device component for use in a drug-device combination product	Mandatory: CPT Conditional: DA, IND
170.000	Repair of medical device and re-exportation	Mandatory: IFE Conditional: DFE, LST, IRC, LWC, PM#, DDM Optional: DI

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Information Needed for Submission

Intended Use Codes and Affirmations of Compliance

- Intended Use Code is mandatory for medical devices.
- Affirmation of Compliance requirements depend on the Intended Use Code.

Intended Use Codes	Import Scenario	Affirmations of Compliance
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	Mandatory: IDE
920.001	Import of a device that is US goods returned for refund/overstock (to manufacturer)	Mandatory: DDM, LST Conditional: DFE, IRC, LWC, PM# Optional: DI
920.002	Import of device that is US goods returned for sale to a third party	Mandatory: DFE, DDM, LST Conditional: IRC, LWC, PM# Optional: DI

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Information Needed for Submission

Intended Use Codes and Affirmations of Compliance

- Intended Use Code is mandatory for medical devices.
- Affirmation of Compliance requirements depend on the Intended Use Code.

Intended Use Codes	Import Scenario	Affirmations of Compliance
950.001*	Import of a single-use device for domestic reprocessing	Mandatory: DDM, LST Conditional: DFE, IRC, LWC, PM# Optional: DI
950.002*	Import of a multi-use device for domestic reprocessing	Conditional: DDM, DFE, IRC, LST, LWC, PM# Optional: 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	Mandatory: DEV, DFE, IFE, LST

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

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Information Needed for Submission

Intended Use Codes and Affirmations of Compliance

- Intended Use Code is mandatory for medical devices.
- Affirmation of Compliance requirements depend on the Intended Use Code.

Intended Use Codes	Import Scenario	Affirmations of Compliance
970.001	Import for Export: • Importation of a medical device component for further manufacturing into an export-only medical device	Mandatory: IFE, CPT, DDM, LST
100.000*	Device For Personal Use	
110.000*	Public Exhibition/Trade Show	
940.000*	Compassionate Use/Emergency device	

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

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Information Needed for Submission

Entities

Entity Role (Code)	Entity Name	Entity Address	Individual Name, Tel# and eMail
Manufacturer (**MF**)	Mandatory	Mandatory	
Shipper (**DEQ**)	Mandatory	Mandatory	
FDA Importer (**FD1**)	Mandatory	Mandatory	Mandatory
Device Initial Importer (**DII**)	Mandatory	Mandatory	
Delivered to Party (**DP**)	Mandatory	Mandatory	
Filer's/Broker's Point of Contact (**PK**)	Optional but encouraged	Optional but encouraged	Optional but encouraged

- FEI number is preferred and DUNS number is encouraged when FEI number is unknown.

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Information Needed for Submission

Origin and Arrival

Data Requirement	Medical Devices
Country of Production for a finished product or Country of Source for a component	Mandatory
Country of Refusal	Mandatory if refused by other country(-ies)

Anticipated Arrival Date	Mandatory
Anticipated Arrival Time	Mandatory
Anticipated Port of Entry	Optional

Summary

- Know the product being imported and associated requirements
- Understand the data elements
- Provided correct and accurate information
- Give Entry Filers the information they need
- Obtain all necessary information from the Importer

NOTE: FDA will not be able to process an entry without this information. You can help expedite FDA's review of your imported product(s) by initially providing accurate and complete information and by responding quickly to requests from FDA for additional documents or information.

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Common Reasons for Medical Device Entry Processing Delays

- Required Affirmation of Compliance (A of C) Codes incomplete or incorrect (LST, DEV, DFE, etc.)
- Firm Name does not match A of C
- Device Initial Importer Entity
- Product Code Incorrect
- Country Code U.S.
- Transmitting “UNK”

Additional Resources

- For more information about medical devices, visit http://www.fda.gov/medicaldevices/deviceregulationandguidance/overview/classifyyourdevice/ucm051512.htm
- For examples of accessories to medical devices, visit https://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM429672.pdf
- Device Advise, visit https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/default.htm
- CDRH Learn, visit https://www.fda.gov/Training/CDRHLearn/default.htm
- Device Registration Database, visit https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfRL/rl.cfm
- Premarket Approval Database , visit https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMA/pma.cfm
- Product Classification Database, visit https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPCD/classification.cfm
- Who Must Register and List, visit https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/RegistrationandListing/ucm053165.htm

INFORMATION AND RESOURCES FOR ALL FDA REGULATED PRODUCTS

Avoiding Delays with FDA

- Delays occur when:
  - Inaccurate information such as incorrect product code are submitted
  - Intended Use Code qualifier “UNK” (Unknown)

- To expedite FDA review:
  - All information provided should be complete and accurate
  - Provide **conditional data elements** if applicable to the product being declared
  - Provide **optional data elements** such as:
    - FEI and/or DUNS
    - Quantity and Unit of Measure

Use the FDA Supplemental Guide

- Review each of the PG records until all required information is understood and has been provided by the importer
- Each section identifies:
  - mandatory, optional, and conditional data elements
  - codes and code descriptions
  - length/class (syntax) for data element types
- Follow any instructions provided by your software vendor to ensure all data elements are entered for transmission.

Summary

- Know the product being imported and associated requirements
- Understand the data elements
- Provided correct and accurate information
- Give Entry Filers the information they need
- Obtain all necessary information from the Importer

Frequently Asked Question

Q: If I transmit an FDA entry, does ACE allow me to correct the data if I realize I made a mistake?

A: When CBP receives an entry, it will automatically send the entry to FDA to process in real time if the entry is within five days of arrival. Unless CBP or FDA rejected the entry, no corrections can be made. If CBP or FDA did reject your entry, work with your ABI representative to send a correction.

Frequently Asked Question

Q: When does FDA receive the entry data from CBP? I have had an "FDA Review Message" for several days.

A: Once the entry is accepted by CBP, CBP sends out a generic message that says "DATA UNDER PGA REVIEW." This is not a confirmation that the data was sent to FDA. CBP will only send the entry to FDA, if the transmitted arrival date is within five days. If it is more than five days out, CBP will wait until it is within that timeframe to send it to FDA.

If it is within five days of arrival and you have not received any FDA response **within your usual turnaround time**, contact FDA's ACE Help Desk at ACE_Support@fda.hhs.gov and your CBP Client Representative.

Frequently Asked Question

Q: Does FDA prefer DUNS or FEI numbers for entity identification codes (PG19)?

A: FEI and DUNS are optional, but encouraged.

Note: As of 5/30/2017, the DUNS will be required for the FSVP importer for each line entry of food, unless they are subject to exemption and/or modified requirements. For additional information, visit https://www.fda.gov/Food/NewsEvents/ConstituentUpdates/ucm549668.htm.

Frequently Asked Questions

Q: Is the Drug Registration number an FEI number?

A: The Drug Registration Number (REG) is the 9-digit DUNS number the firm has on file with FDA Center for Drugs, Evaluation, and Research (CDER) Drug Registration (eDRLS). Only those DUNS numbers on file with eDRLS are Drug Registration Numbers (REG).

These can be found at on the **Drug Firm Registration Lookup** webpage**:**
http://www.accessdata.fda.gov/scripts/cder/drls/default.cfm

Frequently Asked Question

Q: Why can't I see the status of my entry in ITACS? Why does it say "FDA entry status information is not available pending receipt of conveyance arrival notification" when the shipment has arrived?

A: CBP is not consistently sending arrival notifications to FDA upon arrival of a shipment. Without receipt of that notification, ITACS will display the above message. This does not affect the ability to submit documents, submit availability information, or FDA's ability to review the entry.

Reference: CSMS #16-001003

Frequently Asked Question

Q: What are the lessons learned for how ACE changed filing for FDA?

A: Communicate early and often about FDA requirements. (Importer, Broker, and Software Vendor).

Delays and rejects occur when inaccurate information is provided, such as invalid product code or an unknown intended use code.

Use FDA as a resource. Attend webinars or request a training session. We are here to help.

Frequently Asked Questions

Q: Is “UNK” (Unknown) still allowed as an Intended Use Code?

A: UNK is still allowed as an Intended Use Code when the IUC is mandatory. If “UNK” is declared, CBP will not reject the entry if Affirmations of Compliance are not provided.

FDA highly encourages the transmission of complete data, including the correct Intended Use Code and Affirmations of Compliance. Refer to the FDA Supplemental Guide for a full list of requirements based on the import scenario.

UNK should only be used if information is not able to be obtained. Utilizing this code may lead to manual reviews and delayed processing by FDA.

Resources

- CSMS #16-000897, Multiple FDA Lines are Allowed on One Tariff Line https://apps.cbp.gov/csms/viewmssg.asp?Recid=22246&page=&srch_argv=&srchtype=&btype=&sortby=&sby

- CSMS #16-000557, FDA ACE Entries: Common Errors https://apps.cbp.gov/csms/viewmssg.asp?Recid=21913&page=&srch_argv=16-000557&srchtype=all&btype=&sortby=&sby

- CSMS #16-000741, FDA ACE Reject Document Posted to FDA.gov https://apps.cbp.gov/csms/viewmssg.asp?Recid=22092&page=&srch_argv=&srchtype=&btype=&sortby=&sby

Resources Available Online

- FDA ACE Affirmations of Compliance and Affirmations of Compliance Quick Reference at http://www.fda.gov/forindustry/importprogram/entryprocess/entrysubmissionprocess/ucm461234.htm

- FDA ACE/ITDS Webpage (including FDA Supplemental Guide) at http://www.fda.gov/ForIndustry/ImportProgram/ucm456276.htm

- FDA ACE/ITDS DUNS Portal at https://fdadunslookup.com and FDA Guide at https://www.fda.gov/downloads/ForIndustry/UCM483657.pdf

- Product Code Builder Tool and Tutorial at https://www.accessdata.fda.gov/scripts/ora/pcb/index.cfm

- For more information about FDA's Import Program, visit http://www.fda.gov/forindustry/importprogram/default.htm

- For information about ACE Quantity Data Instructions, visit https://www.fda.gov/downloads/ForIndustry/ImportProgram/EntryProcess/ImportSystems/UCM487256.pdf

Resources

Contact the **FDA Imports Inquiry Team** for questions regarding FDA import operations and policy, product coding, FD flags associated with HTS codes, entry declaration requirements for determining admissibility, if a product is regulated by FDA and other general import questions.

FDAImportsInquiry@fda.hhs.gov

301-796-0356

Resources

Contact **FDA ACE Support Center** for technical questions related to the FDA Supplemental Guide, required data elements, ACE entries, rejects, and errors.

ACE_Support@fda.hhs.gov
877-345-1101 (domestic toll-free)
571-620-7320 (local or international)

CSMS #17-000162: The ACE Support Center operates from 6 a.m. to 10 p.m. EST seven days per week.

Always keep your CBP Client Representative on all ACE-related email traffic

FDA Points of Contact for Imports

FDA Unit	Contact Information	Areas of Focus
ACE Support Center	ACE_Support@fda.hhs.gov Toll Free: 877-345-1101 Local/International: 571-620-7320	Technical issues related to the FDA supplemental guide, required data elements, and general ACE submission questions, including entry submissions rejected by FDA.
FDA Imports Inquiry	FDAImportsInquiry@fda.hhs.gov 301-796-0356	General questions regarding FDA import operations and policy, including product classification (program, processing, product and HTS codes) and declaration
Local FDA Office	http://www.fda.gov/ForIndustry/ImportProgram/ucm319216.htm	First-line support for product coding and entry-specific questions, including working through the FDA entry admissibility process, once the entry is successfully transmitted to FDA and accepted
Division of Food Defense Targeting	Prior.Notice@fda.hhs.gov 866-521-2297 http://www.fda.gov/Food/GuidanceRegulation/ImportsExports/Importing/ucm2006836.htm	General questions regarding Prior Notice for food shipments

Questions


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