

# 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

October 2019

# Agenda

<b>Overview: ACE and FDA</b>	<b>Commodity Specific Information</b>	<b>Information and Resources for All FDA Regulated Products</b>
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## **OVERVIEW: ACE AND FDA**

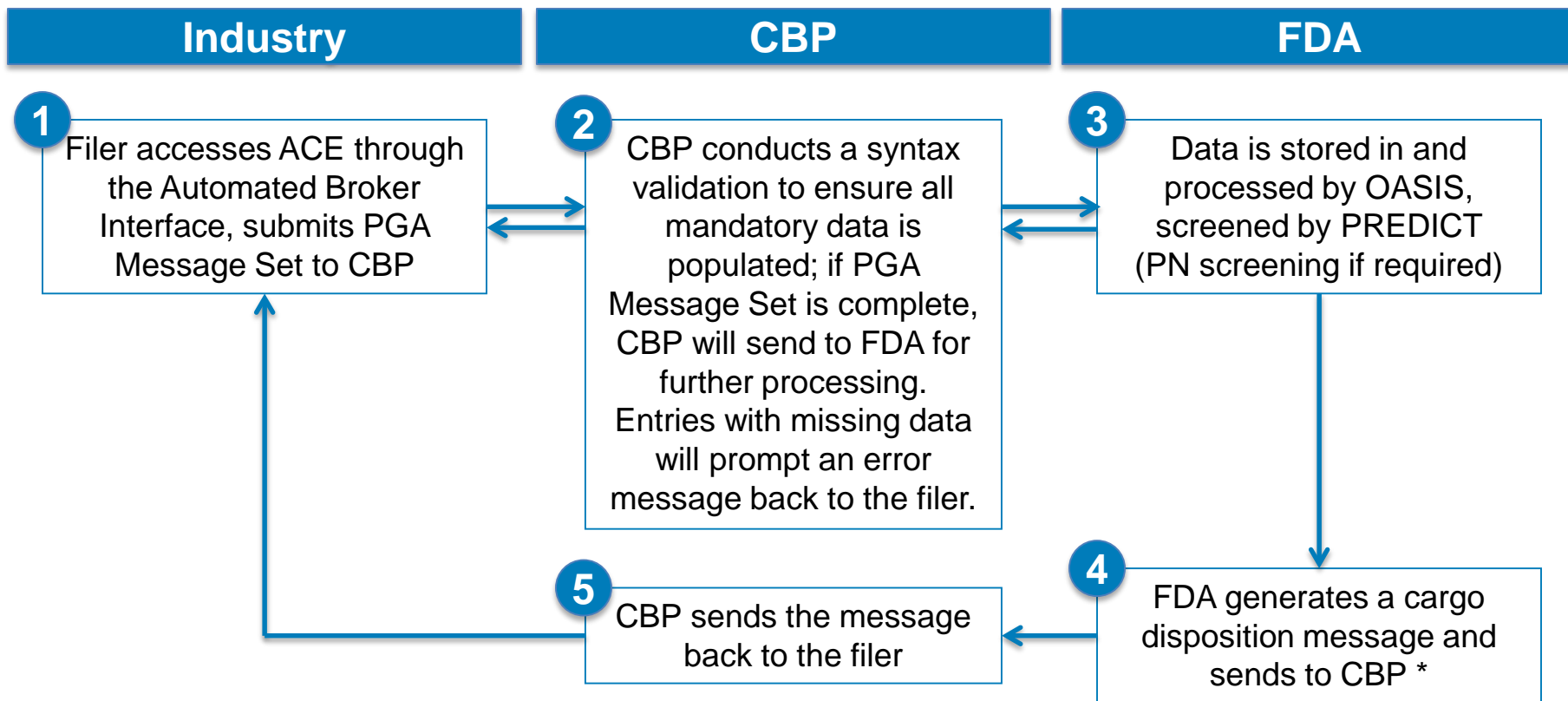
# What is ACE?

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.



**U.S Single Window  
for trade unifies  
border coordination,  
fosters government  
and industry  
collaboration, and  
yields prosperous  
and secure trade  
worldwide.**

# 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 2.5.1 released April 2018
- FDA continues to work closely with importers, brokers, and software developers to ensure understanding and compliance of the ACE process
- FDA also continues to collaborate with CBP to troubleshoot issues and make system enhancements

# 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 2018, **70%** 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 2018, approximately **2%** of (ACE) lines needed additional information to make an admissibility decision (Documents Required).



# Most Common CBP & FDA Rejects

<b>CBP Rejects</b> Jan – Sep 2019	<b>FDA Rejects</b> Jan – Sep 2019
<ul style="list-style-type: none"> <li>Missing or Invalid Affirmations of Compliance</li> </ul>	<ul style="list-style-type: none"> <li>Invalid Product Code</li> </ul>
<ul style="list-style-type: none"> <li>Missing or Invalid Entities</li> </ul>	<ul style="list-style-type: none"> <li>Cancelled Food Facility Registration</li> </ul>
<ul style="list-style-type: none"> <li>Missing or Invalid PG21 Record or Individual Qualifier Code</li> </ul>	<ul style="list-style-type: none"> <li>Invalid State/Zip Combination</li> </ul>
<ul style="list-style-type: none"> <li>Missing or Invalid Entity ID Code for FEI or DUNS</li> </ul>	<ul style="list-style-type: none"> <li>Food Facility Registration Not on File</li> </ul>
<ul style="list-style-type: none"> <li>Missing or Invalid FEI or DUNS Number</li> </ul>	<ul style="list-style-type: none"> <li>Food Facility Registration Invalidated by PGA</li> </ul>
<ul style="list-style-type: none"> <li>Only Mandatory Entities Allowed</li> </ul>	<ul style="list-style-type: none"> <li>Mismatch Between Food Facility Registration and Manufacturer</li> </ul>

# 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.

# Reminders

- **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
  - 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 •

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# ANIMAL DRUGS & DEVICES

# Submitting Animal Drug and Device Entries in ACE

- Know the Product Being Imported
- Information Needed for Submission
- Additional Resources



# Know the Product Being Imported

FD&C Act defines “drug” as “articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease” and “articles (other than food) intended to affect the structure or any function of the body of man or other animals”.

A “new animal drug” means any drug intended for use for animals other than man, including any drug intended for use in animal feed but some exclusions do apply.

Animal/Veterinary medical devices

# Know the Product Being Imported

## Examples of animal drugs

- Penicillin G Benzathine
- Butorphanol Tartrate
- Gentamicin Sulfate
- Tetracycline and Monensin

## Examples of devices for use on animals

- Immobilizer
- Scales
- X-ray systems
- Capnography and oxygen monitors

# Information Needed for Submission Program & Processing Codes

**Program Code** for animal drug and device commodities is **VME**.

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	Animal Drugs and Devices	VME	Animal Drugs	ADR
FDA	Animal Drugs and Devices	VME	Animal Devices	ADE

# 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.

# Information Needed for Submission

## Product Codes

- Product code is mandatory.

PG01: Program Code & Commodity	PG01: Processing Code & Commodity Subtype	PG02: Industry Code
VME - Animal Drug or Device*	ADR - Animal Drug	54, 56, 60, 61, 62, 63, 64, 65, 66 or 67
	ADE - Animal Device	68

\*Subject to additional rules based on FDA Program/Processing/Product codes. See PG02 in individual chapters of the Supplemental guide.

# Information Needed for Submission

## Product Descriptions, Packaging and Condition

Data Requirement	Animal Drugs and Devices
Commodity Characteristic Description	Mandatory
Quantity and Packaging* (if entered, the rules from the SG must be followed)	Optional but encouraged
PGA Line Value	Optional but highly encouraged

\* See [FDA Supplemental Guide for ACE](#) for valid units of measure for Animal Drug and Device Packaging Containers.

# Information Needed for Submission

## Intended Use Codes and Affirmations of Compliance

- Intended Use Code is mandatory for animal drugs (VME/ADR).
- Affirmation of Compliance requirements depend on the Intended Use Code.

Intended Use Codes	Import Scenario	Affirmations of Compliance
085.003	Drug subject of a new animal drug application, conditionally approved application, or Index listing	Mandatory: REG, NDC, and VAN, or VNA Optional: VFL, VFD
100.000	Importation for Personal Use	
150.013	Active Pharmaceutical Ingredient / Bulk Drug Substance to be used for Pharmacy Compounding	Mandatory: REG, NDC
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	Mandatory: REG, NDC, and VAN, or VNA

# Information Needed for Submission

## Intended Use Codes and Affirmations of Compliance

- Intended Use Code is mandatory for animal drugs (VME/ADR).
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Intended Use Codes	Import Scenario	Affirmations of Compliance
180.009	For research and development in a pharmaceutical product – clinical investigations in animals (INAD)	Mandatory: VIN
180.018	For research and development in a pharmaceutical product – for tests in-vitro or in laboratory research animals.	Optional: VIN
920.000	US Goods Returned	
970.000	Import for Export	
980.000	For Other Use: (APIs or Finished Drugs not elsewhere classified)	Mandatory: REG, NDC Optional: VAN, VNA, VFL, VFD



# Information Needed for Submission

## Entities

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

- DUNS and FEI are optional, but encouraged.

# Information Needed for Submission

## Origin and Arrival

Data Requirement	Animal Drugs and Devices
Country of Production or Country of Source	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.

# Additional Resources

- For more general information about animal drug and device products, visit <https://www.fda.gov/AnimalVeterinary/default.htm>

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# **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

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# 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](mailto: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 #16-000557, FDA ACE Entries: Common Errors  
[https://csms.cbp.gov/viewmssg.asp?Recid=21913&page=&srch\\_argv=16-000557&srctype=&btype=&sortby=&sby=](https://csms.cbp.gov/viewmssg.asp?Recid=21913&page=&srch_argv=16-000557&srctype=&btype=&sortby=&sby=)
- CSMS #16-000741, FDA ACE Reject Document Posted to FDA.gov  
[https://csms.cbp.gov/viewmssg.asp?Recid=22092&page=&srch\\_argv=16-000741&srctype=&btype=&sortby=&sby=](https://csms.cbp.gov/viewmssg.asp?Recid=22092&page=&srch_argv=16-000741&srctype=&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 <https://www.fda.gov/industry/import-systems/automated-commercial-environmentinternational-trade-data-system-aceitds>
- FDA DUNS Portal at <https://fda.dnb.com/FDAUI/login.aspx> and FDA Guide at <https://www.fda.gov/media/95828/download>
- 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](mailto: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](mailto: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	<a href="mailto:ACE_Support@fda.hhs.gov">ACE_Support@fda.hhs.gov</a> 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	<a href="mailto:FDAImportsInquiry@fda.hhs.gov">FDAImportsInquiry@fda.hhs.gov</a> 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	<a href="http://www.fda.gov/ForIndustry/ImportProgram/ucm319216.htm">http://www.fda.gov/ForIndustry/ImportProgram/ucm319216.htm</a>	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	<a href="mailto:Prior.Notice@fda.hhs.gov">Prior.Notice@fda.hhs.gov</a> 866-521-2297 <a href="http://www.fda.gov/Food/GuidanceRegulation/ImportsExports/Importing/ucm2006836.htm">http://www.fda.gov/Food/GuidanceRegulation/ImportsExports/Importing/ucm2006836.htm</a>	General questions regarding Prior Notice for food shipments

# Questions



