# 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

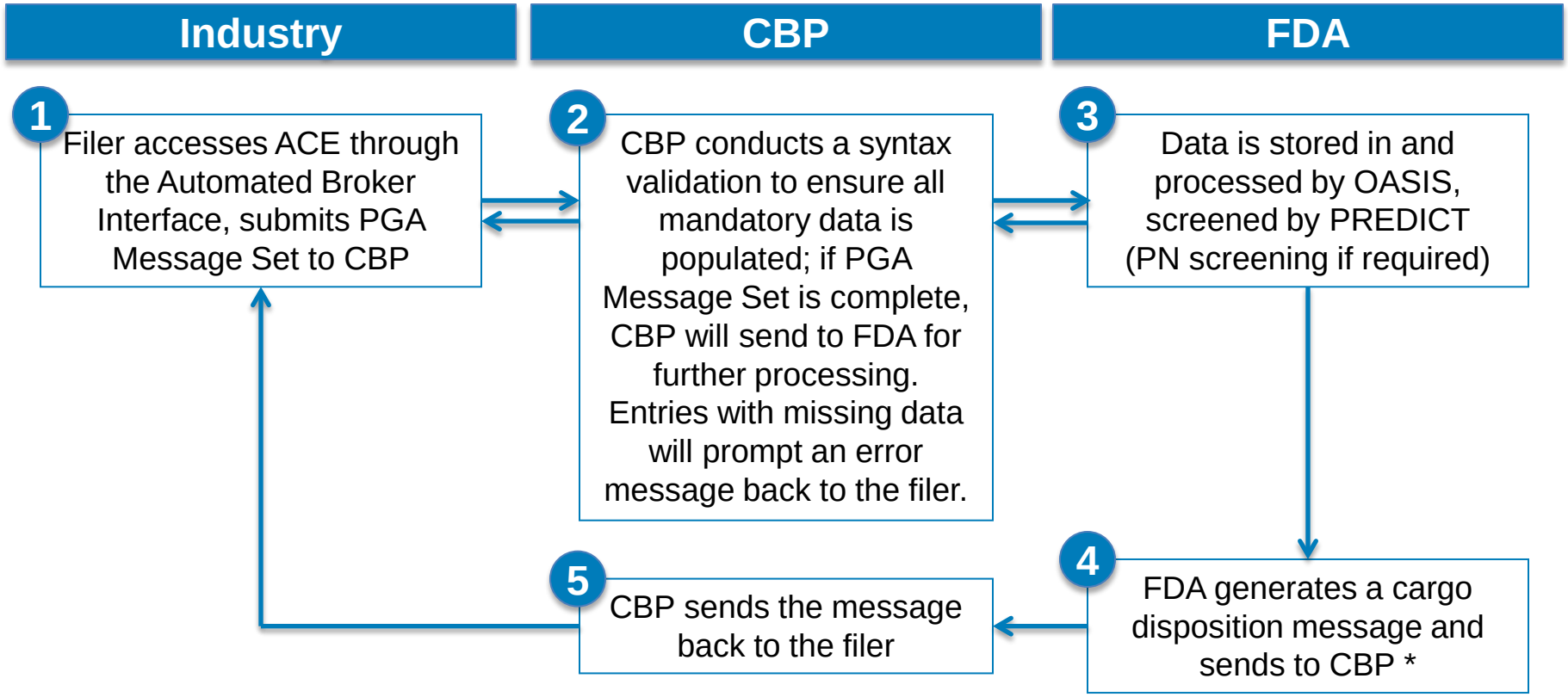
| Overview: ACE and FDA | Commodity Specific Information | Information and Resources for All FDA Regulated Products |
|---|---|---|
| • What is ACE?<br>• How ACE Works for FDA<br>• FDA Current Status<br>• Most Common CBP and FDA Rejections<br>• Common Data Errors<br>• FDA Flags<br>• FDA ACE Final Rule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

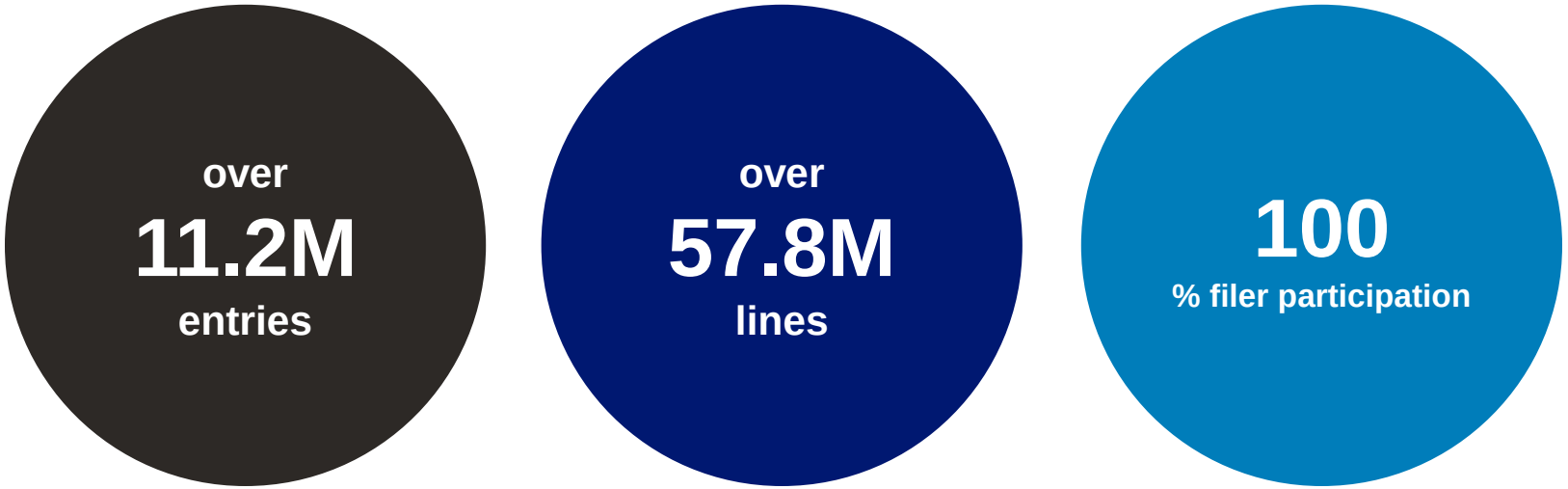



* Data that is electronically validated may be automatically "May Proceeded"

# 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 •

Making ACE Work for You:  Importing FDA Regulated Products

# BIOLOGICS

# Submitting Biologic Entries in ACE

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

# Know the Product Being Imported

A Biologic Product is defined in Section 351 of the Public Health Service Act as, “a virus, therapeutic serum, toxin, antitoxin, vaccine, blood, blood component or derivative, allergenic product, protein (except any chemically synthesized polypeptide), or analogous product, or arsphenamine or derivative of arsphenamine (or any other trivalent organic arsenic compound), applicable to the prevention, treatment, or cure of a disease or condition of human beings.”

Human cells, tissues, or cellular or tissue-based products (HCT/Ps) are defined in Section 361 of the PHS Act as “Human cells, tissues, or cellular or tissue-based products (HCT/Ps) means articles containing or consisting of human cells or tissues that are intended for implantation, transplantation, infusion, or transfer into a human recipient.”

# Know the Product Being Imported

## Examples of biologic products

- Blood and blood products for transfusion and/or manufacturing into other products
- Allergenic extracts, which are used for both diagnosis and treatment (for example, allergy shots)
- Vaccines
- Gene therapies
- Cellular therapies
- Tests to screen potential blood donors for infectious agents such as HIV
- HCT/Ps - for example, bone, ligaments, skin, dura mater, heart valve, cornea, hematopoietic stem/progenitor cells derived from peripheral and cord blood, and semen or other reproductive tissue.

BIO

FDA

# Information Needed for Submission

## Program & Processing Codes

**Program Code** for biologic commodities is **BIO**.

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 | Biologics | BIO | Allergens | ALG |
| FDA | Biologics | BIO | Vaccines | VAC |
| FDA | Biologics | BIO | Human Cells & Tissue | HCT |
| FDA | Biologics | BIO | Xenotransplant | XEN |
| FDA | Biologics | BIO | Cell & Gene Therapy | CGT |
| FDA | Biologics | BIO | Blood and Blood Products | BLO |
| FDA | Biologics | BIO | Licensed Devices | BLD |
| FDA | Biologics | BIO | Blood Derivatives | BDP |
| FDA | Biologics | BIO | Blood Bag with Anti-coagulant | BBA |
| FDA | Biologics | BIO | Plasma Volume Expanders | PVE |

# 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.

BIO

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# Information Needed for Submission

## Product Codes

- Product code is mandatory.

| PG01: Program Code & Commodity | PG01: Processing Code & Commodity Subtype | |
|---|---|---|
| BIO - Biologic | ALG - Allergens | |
| | 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 | |

BIO

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# Information Needed for Submission

## Product Descriptions, Packaging and Condition

| Data Requirement | Biologics |
|---|---|
| Commodity Characteristic Description | Mandatory |
| Trade Name/Brand Name | Mandatory *only* if one of the following government agency processing codes applies:<br>ALG, BDP, BLD, BLO, CGT, VAC, XEN, BBA or PVE |
| Quantity and Packaging* | Optional but encouraged<br>(if entered, the rules from the SG must be followed) |
| PGA Line Value | Optional but highly encouraged |

# Information Needed for Submission

## Intended Use Codes and Affirmations of Compliance

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

| Intended Use Codes | Import Scenario | Affirmations of Compliance |
|---|---|---|
| 180.009 | Biological or chemical for research and development into a pharmaceutical product – Investigational New Drugs (IND); clinical trials or other human/animal use | Mandatory: IND<br>Conditional: REG |
| 080.000 | CBER-regulated Final product; ready for use.<br>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. | Mandatory: BLN or STN or both<br>Conditional: REG, DLS |
| 080.000 | CBER-regulated Final product; ready for use.<br>Importation of drug regulated by CBER. | Mandatory: DA, REG, (DA includes NDA and ANDAs only)<br>Conditional: DLS |
| 082.000 | Human Cells, tissues, and cellular and tissue based products (HCT/Ps) for implant, transplant, infusion, or transfer into a human recipient.<br>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. | Mandatory: HCT (No Qualifier Needed for HCT) |

# Information Needed for Submission

## Intended Use Codes and Affirmations of Compliance

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| Intended Use Codes | Import Scenario | Affirmations of Compliance |
|---|---|---|
| 082.000 | 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. | Mandatory: HRN<br>Conditional: HCT |
| 180.016 | CBER Product sample for testing or lot release | Mandatory: BLN or STN or both<br>Conditional: REG, DLS |
| 155.000 | CBER product For further manufacture of a licensed biological product under a short supply agreement (21 CFR 601.22)* | Mandatory: BLN or STN or both<br>Conditional: REG, DLS |
| 100.000 | Importation for personal use | |
| 150.007 | Bulk biological drug substance for processing into a pharmaceutical product | Mandatory: BLN or STN or both<br>Conditional: IND, REG, DLS |
| 150.007 | Bulk drug substance for processing into a pharmaceutical product | Mandatory: DA<br>Conditional: IND, REG, DLS |
| 140.000* | Standard import of a biological drug or device for non-commercial distribution in government and non-government support program. | Conditional: BLN, STN, DA, IND |

# Information Needed for Submission

## Intended Use Codes and Affirmations of Compliance

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

| Intended Use Codes | Import Scenario | Affirmations of Compliance |
|---|---|---|
| 110.000* | Import of a biological drug or device for trade show | Conditional: BLN, STN, DA, IND |
| 170.000* | For reconditioning or repair of a non-food product | Conditional: BLN, STN, DA, IND, HCT, HRN |
| 970.000* | 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. | Mandatory: IFE<br>(No qualifier required) |
| 180.000 | Import of a biologic for non-clinical research use only, bench testing, etc. These entries could be disclaimed if the HTS code allows it. | |
| 940.000* | Importation of a drug (including a biological product) or device for compassionate use/emergency use | Conditional: BLN, STN, DA, IND, HCT, HRN |
| 920.000 | Import of US Goods Returned | |

- Optional product affirmation of compliance data:
  - Entry Review Requested (ERR)

# 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 |
| Delivered to Party (DP) | Mandatory | Mandatory | |
| Filer's/Broker's Point of Contact (PK) | 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 | Biologics |
|---|---|
| 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.

# Common Reasons for Biologic Entry Processing Delays

Entry review processing delays occur when the requirements for submission are not understood.

- FDA PREDICT lookup failures: 5.27% have insufficient Affirmation of Compliance Code transmitted for biologic products.

# Additional Resources

- For more information about vaccines, blood & biologics, visit http://www.fda.gov/BiologicsBloodVaccines/default.htm

- For more information about human cells & tissues, visit http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/EstablishmentRegistration/TissueEstablishmentRegistration/FindaTissueEstablishment/default.htm

- CBER approved and cleared devices can be found under the CDRH registration and listing system, visit http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfRL/rl.cfm

- Drug products regulated by CBER – Establishments Current Registration Site, visit http://www.accessdata.fda.gov/scripts/cder/drls/default.cfm

# 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<br>Toll Free: 877-345-1101<br>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<br>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<br>866-521-2297<br>http://www.fda.gov/Food/GuidanceRegulation/ImportsExports/Importing/ucm2006836.htm | General questions regarding Prior Notice for food shipments |

# Questions


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