Making ACE Work for You: Importing FDA Regulated Products

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

US Food and Drug Administration
August 2017
## Agenda

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Making ACE Work for You: Importing FDA Regulated Products

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

Industry:
1. Filer accesses ACE through the Automated Broker Interface, submits PGA Message Set to CBP.

CBP:
2. CBP conducts a syntax validation to ensure all mandatory data is populated; if PGA Message Set is complete, CBP will send to FDA for further processing. Entries with missing data will prompt an error message back to the filer.
5. CBP sends the message back to the filer.

FDA:
3. Data is stored in and processed by OASIS, screened by PREDICT (PN screening if required).
4. FDA generates a cargo disposition message and sends to CBP.

* 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

- over 11.2M entries
- over 57.8M lines
- 100 % filer participation
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

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

DRUGS
Submitting Drug Entries in ACE

• Know the Product Being Imported

• Information Needed for Submission

• Common Reasons for Drug Entry Processing Delays

• Additional Resources
Know the Product Being Imported

“Drug” is defined in the Food, Drug, and Cosmetic Act 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" [FD&C Act, sec. 201(g)(1)].

This includes:

• Articles that are not active ingredients, but are labeled with a claim to “diagnose, cure, mitigate, treat, or prevent disease”
Know the Product Being Imported

Examples of drug products

• Active pharmaceutical ingredients (API)
  – boric acid powder used to manufacture antiseptic

• Over-The-Counter (OTC)
  – acetaminophen pain killer (analgesic)

• Prescription Drugs (RX)
  – Dexamisole (anti-depressant)

• Pharmaceutical Necessities
  – inactive ingredients, excipients, intermediates

• For Research Use Only
  – not to be used with humans and may be used in animals

• Investigational Use Only
  – will be used with humans or animals
Information Needed for Submission
Program & Processing Codes

Program Code for drug commodities is **DRU**.

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

<table>
<thead>
<tr>
<th>PG01 - Government Agency Code</th>
<th>Commodity Type</th>
<th>PG01 - Government Agency Program Code</th>
<th>Commodity Sub-Type</th>
<th>PG01 - Government Agency Processing Code</th>
</tr>
</thead>
<tbody>
<tr>
<td>FDA</td>
<td>Drugs</td>
<td>DRU</td>
<td>Prescription</td>
<td>PRE</td>
</tr>
<tr>
<td>FDA</td>
<td>Drugs</td>
<td>DRU</td>
<td>Over the Counter</td>
<td>OTC</td>
</tr>
<tr>
<td>FDA</td>
<td>Drugs</td>
<td>DRU</td>
<td>Pharmaceutical Necessities, Containers, Inactive Pharmaceutical Ingredients and Excipients</td>
<td>PHN</td>
</tr>
<tr>
<td>FDA</td>
<td>Drugs</td>
<td>DRU</td>
<td>Research and Development</td>
<td>RND</td>
</tr>
<tr>
<td>FDA</td>
<td>Drugs</td>
<td>DRU</td>
<td>Investigational</td>
<td>INV</td>
</tr>
</tbody>
</table>
Information Needed for Submission
Product Code Overview

<table>
<thead>
<tr>
<th>Position</th>
<th>1-2</th>
<th>3</th>
<th>4</th>
<th>5</th>
<th>6-7</th>
</tr>
</thead>
<tbody>
<tr>
<td>Name</td>
<td>Name Industry Code (N)</td>
<td>Class Code (A)</td>
<td>Sub Class Code (A or “-”)</td>
<td>Process Identification Code – PIC (A or “-”)</td>
<td>Product (AN)</td>
</tr>
</tbody>
</table>

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.

<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>DRU – Drug*</td>
<td>PRE - Prescription</td>
<td>54, 56, 60, 61, 62, 63, 64, 65, or 66</td>
</tr>
<tr>
<td></td>
<td>OTC - Over the Counter</td>
<td></td>
</tr>
<tr>
<td></td>
<td>RND - Research &amp; Development</td>
<td></td>
</tr>
<tr>
<td></td>
<td>INV - Investigational</td>
<td></td>
</tr>
<tr>
<td></td>
<td>PHN - Pharmaceutical Necessities</td>
<td>55, various codes could apply</td>
</tr>
</tbody>
</table>

*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

<table>
<thead>
<tr>
<th>Data Requirement</th>
<th>Drugs</th>
</tr>
</thead>
<tbody>
<tr>
<td>Commodity Characteristic Description</td>
<td>Mandatory</td>
</tr>
<tr>
<td>Quantity and Packaging*</td>
<td>Optional but encouraged</td>
</tr>
<tr>
<td></td>
<td>(if entered, the rules from the SG must be followed)</td>
</tr>
<tr>
<td>PGA Line Value</td>
<td>Optional but highly encouraged</td>
</tr>
</tbody>
</table>

* See Appendix D of the [FDA Supplemental Guide for ACE v2.5](https://www.fda.gov) for valid units of measure for Drugs Packaging Containers.
Information Needed for Submission
Intended Use Codes (IUC) and Affirmations of Compliance (AoC)

- IUC is mandatory for drugs. Only IUCs listed in the chart can be used for drugs.
- AoC requirements depend on the IUC.

<table>
<thead>
<tr>
<th>Intended Use Codes</th>
<th>Import Scenario</th>
<th>Affirmations of Compliance</th>
</tr>
</thead>
<tbody>
<tr>
<td>080.012</td>
<td>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</td>
<td>Mandatory: REG, DLS, DA Optional: PLR</td>
</tr>
<tr>
<td>100.000</td>
<td>Importation for Personal Use</td>
<td></td>
</tr>
<tr>
<td>130.000</td>
<td>For Consumer Use as a Non-Food Product – Over the Counter (OTC)</td>
<td>Mandatory: REG, DLS Optional: DA</td>
</tr>
<tr>
<td>150.007</td>
<td>Active Pharmaceutical Ingredient / Bulk Drug Substance for processing into a pharmaceutical product</td>
<td>Mandatory: REG, DLS Conditional: DA</td>
</tr>
<tr>
<td>150.013</td>
<td>Active Pharmaceutical Ingredient / Bulk Drug Substance to be used for Pharmacy Compounding</td>
<td>Mandatory: REG, DLS</td>
</tr>
<tr>
<td>150.017</td>
<td>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)</td>
<td>Mandatory: REG, DLS Optional: DA, LST, PM#, IDE</td>
</tr>
</tbody>
</table>
Information Needed for Submission

Intended Use Codes (IUC) and Affirmations of Compliance (AoC)

- IUC is mandatory for drugs. Only IUCs listed in the chart can be used for drugs.
- AoC requirements depend on the IUC.

<table>
<thead>
<tr>
<th>Intended Use Codes</th>
<th>Import Scenario</th>
<th>Affirmations of Compliance</th>
</tr>
</thead>
<tbody>
<tr>
<td>155.009</td>
<td>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).</td>
<td>Mandatory: REG, DLS Optional: DA, LST, PM#, IDE</td>
</tr>
<tr>
<td>180.009</td>
<td>Chemical for research and development of a pharmaceutical product – subject of an Investigational New Drug application (IND), including Placebos</td>
<td>Mandatory: IND</td>
</tr>
<tr>
<td>180.017</td>
<td>Chemical for research and development of a pharmaceutical product – laboratory testing only, no human/animal use</td>
<td></td>
</tr>
<tr>
<td>180.018</td>
<td>Chemical for research and development; investigational use in animals</td>
<td></td>
</tr>
</tbody>
</table>
Information Needed for Submission
Intended Use Codes (IUC) and Affirmations of Compliance (AoC)

- IUC is mandatory for drugs. Only IUCs listed in the chart can be used for drugs.
- AoC requirements depend on the IUC.

<table>
<thead>
<tr>
<th>Intended Use Codes</th>
<th>Import Scenario</th>
<th>Affirmations of Compliance</th>
</tr>
</thead>
<tbody>
<tr>
<td>180.026</td>
<td>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.</td>
<td></td>
</tr>
<tr>
<td>920.000</td>
<td>US Goods Returned</td>
<td>Optional: REG, DLS, DA, IND</td>
</tr>
<tr>
<td>970.000</td>
<td>Import for Export</td>
<td></td>
</tr>
<tr>
<td>980.000</td>
<td>For Other Use: (APIs or Finished Drugs not elsewhere classified)</td>
<td>Mandatory: REG, DLS</td>
</tr>
</tbody>
</table>
Information Needed for Submission

Entities

<table>
<thead>
<tr>
<th>Entity Role (Code)</th>
<th>Entity Name</th>
<th>Entity Address</th>
<th>Individual Name, Tel# and eMail</th>
</tr>
</thead>
<tbody>
<tr>
<td>Manufacturer (MF)</td>
<td>Mandatory</td>
<td>Mandatory</td>
<td></td>
</tr>
<tr>
<td>Shipper (DEQ)</td>
<td>Mandatory</td>
<td>Mandatory</td>
<td></td>
</tr>
<tr>
<td>FDA Importer (FD1)</td>
<td>Mandatory</td>
<td>Mandatory</td>
<td>Mandatory</td>
</tr>
<tr>
<td>Delivered to Party (DP)</td>
<td>Mandatory</td>
<td>Mandatory</td>
<td></td>
</tr>
<tr>
<td>Filer’s/Broker’s Point of Contact (PK)</td>
<td>Optional but encouraged</td>
<td>Optional but encouraged</td>
<td>Optional but encouraged</td>
</tr>
<tr>
<td>Sponsor (New) – if different than MF or FD1 (SPO)</td>
<td>Optional</td>
<td>Optional</td>
<td></td>
</tr>
<tr>
<td>Producer (Producer of API) (GD)</td>
<td>Optional</td>
<td>Optional</td>
<td></td>
</tr>
</tbody>
</table>

• DUNS and FEI are optional, but encouraged.
# Information Needed for Submission

## Origin and Arrival

<table>
<thead>
<tr>
<th>Data Requirement</th>
<th>Drugs</th>
</tr>
</thead>
<tbody>
<tr>
<td>Country of Production or Country of Source</td>
<td>Mandatory</td>
</tr>
<tr>
<td>Country of Refusal</td>
<td>Mandatory if refused by other country(-ies)</td>
</tr>
<tr>
<td>Anticipated Arrival Date</td>
<td>Mandatory</td>
</tr>
<tr>
<td>Anticipated Arrival Time</td>
<td>Mandatory</td>
</tr>
<tr>
<td>Anticipated Port of Entry</td>
<td>Optional</td>
</tr>
</tbody>
</table>
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 Drug Entry Processing Delays

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

- FDA PREDICT lookup failures: 8.03% of Affirmation of Compliance Codes are incorrectly transmitted for drug products.
Additional Resources

- Drug Approvals and Databases: http://www.fda.gov/Drugs/InformationOnDrugs/default.htm
- DUNS Number Lookup: http://www.dnb.com/duns-number/lookup.html
- NDC Number Lookup: http://www.fda.gov/Drugs/InformationOnDrugs/ucm142438.htm
Additional Resources continued

- **Investigational New Drugs (IND):**

- **Investigational Use Only Labeling:**

- **OTC (Nonprescription) Drugs:**

- **OTC Drug Labeling:**

- **New Drug Applications (NDA):**

- **Abbreviated New Drug Applications (ANDA):**

- **Prescription Drug Labeling:**
Making ACE Work for You: Importing FDA Regulated Products

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

• CSMS #16-000557, FDA ACE Entries: Common Errors

• CSMS #16-000741, FDA ACE Reject Document Posted to FDA.gov
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
- For more information about FDA’s Import Program, visit http://www.fda.gov/forindustry/importprogram/default.htm
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.

[FDAlmportsInquiry@fda.hhs.gov](mailto:FDAlmportsInquiry@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

<table>
<thead>
<tr>
<th>FDA Unit</th>
<th>Contact Information</th>
<th>Areas of Focus</th>
</tr>
</thead>
<tbody>
<tr>
<td>ACE Support Center</td>
<td><a href="mailto:ACE_Support@fda.hhs.gov">ACE_Support@fda.hhs.gov</a> Toll Free: 877-345-1101 Local/International: 571-620-7320</td>
<td>Technical issues related to the FDA supplemental guide, required data elements, and general ACE submission questions, including entry submissions rejected by FDA.</td>
</tr>
<tr>
<td>FDA Imports Inquiry</td>
<td><a href="mailto:FDAImportsInquiry@fda.hhs.gov">FDAImportsInquiry@fda.hhs.gov</a> 301-796-0356</td>
<td>General questions regarding FDA import operations and policy, including product classification (program, processing, product and HTS codes) and declaration</td>
</tr>
<tr>
<td>Local FDA Office</td>
<td><a href="http://www.fda.gov/ForIndustry/ImportProgram/ucm319216.htm">http://www.fda.gov/ForIndustry/ImportProgram/ucm319216.htm</a></td>
<td>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</td>
</tr>
<tr>
<td>Division of Food Defense Targeting</td>
<td><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></td>
<td>General questions regarding Prior Notice for food shipments</td>
</tr>
</tbody>
</table>
Questions