FDA’s Transition to the Automated Commercial Environment (ACE)

Office of Enforcement and Import Operations
Food and Drug Administration
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What is ACE/ITDS?

The Automated Commercial Environment/ International Trade Data System is a single access point in which industry can electronically submit information for all government agencies involved in international trade.

How Does ACE Change Current Business Processes?

- All entry information for all government agencies is submitted in ACE; messages from each agency are sent back to the filer
- FDA will require complete data sets at the time of transmission of the entry
- Complete and correct information will reduce the need for document requests, and improve processing times

FDA ACE Process

Industry	CBP	FDA

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

3 Data is stored in & processed by OASIS, screened by PREDICT

4 FDA generates a cargo disposition message and sends to CBP*

5 CBP sends the message back to the filer

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

When is ACE mandatory?

CSMS 16-000093: Updated ACE Transition Guidance

"FDA filings will continue to be allowed in ACS to provide more time for industry to transition to ACE. Further information will be provided on the mandatory filing in ACE for FDA data"

CBP and FDA are highly encouraging ACE filings and will prioritize resources to support ACE entries beginning February 28, 2016.

Current Status

- FDA began processing ACE entries in August 2015; open to all ports and all product types.
- 80K entries processed to date.
- Facilitating onboarding of first-time ACE filers each day.

How to Start Filing in ACE

- Get to know FDA's Requirements for importing in ACE (FDA Supplemental Guide)
- Contact your software developer & work with him/her to understand changes to your software
- Keep your ABI Representative informed
- To start filing in ACE for FDA, contact: ACE_Support@fda.hhs.gov

Tips for Importing Drug Products

Expedite FDA's Processing by Providing:

- Correct Product Code and Intended Use Code
- Active Ingredient Name and Dosage
- Brand Name
- Name, Address (and DUNS# if known) for:
    - MF, Shipper, Importer, Delivered To Party, and API Producer
- Affirmations of Compliance: (required based on Intended Use)
    - REG (Drug Registration)
    - DLS (Drug Listing)
    - DA (Drug Application Number)
    - IND (Investigational New drug)

Tips for Importing Medical Devices

Expedite FDA's Processing by Providing:

- Correct Product Code, Intended Use, Brand Name
- Name, Address and FEI for:
    - MF, Shipper, Importer, Delivered To Party, and Device Initial Importer (DII is no longer an AofC)
- Affirmations of Compliance: (required based on Intended Use)
    - DEV (Device Registration)
    - DFE (Device Foreign Exporter Registration)
    - LST (Device Listing Number)
    - PM# (Premarket Number - formerly PMA/PMN – if applicable)

Verify information in CDRH Registration & Listing Database and obtain FEI#:
http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfRL/rl.cfm

Tips for Importing Food Products with Prior Notice

Expedite FDA's Processing by Providing:

- Correct Product Code
- Country of Production/Growth AND Country of Shipment
- Name, Address (and DUNS# if known) for:
    - MF/Grower/Consolidator, Shipper, Importer, Ultimate Consignee, PN Submitter, PN Transmitter, Owner
- Affirmations of Compliance: (required based on product/Mode Of Transportation)
    - PFR or FME (Food Facility Registration or Exemption with Reason Code)
    - VFT (Voyage, Flight, Trip Number)
    - VES (Vessel Name)
- Container Number

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- Container Number
- Lot Number (if applicable)

New Prior Notice Functionality

- Ability to file the Secure Holding Facility under trade entity “Location of Goods”
- Ability to file registration number for any trade entity to facilitate review and release of the shipment
- Ability to file contact information for each trade entity to facilitate review and release of the shipment
- Ability to file prior notice utilizing carrier name and license plate information for informal shipments
- Ability to file prior notice utilizing a Express Courier tracking number for informal shipments

Tips for Importing FDA-Regulated Products in ACE

FDA Division of Compliance Systems 2016

Diagram depicts mandatory data elements by commodity-type. For certain products, additional data elements may apply. Refer to FDA's Supplemental Guide for further specificity For more information email: ACE_Support@fda.hhs.gov

Drugs:

Intended Use Code*

Active Ingredient Name(s) & Dosage

Brand Name

Name & Address of API Producer(s), Sponsor (if applicable)

Affirmations of Compliance*

Medical Devices & Radiation-Emitting Products:

Intended Use Code

Brand Name (if available)

Name and Address of Device Initial Importer (medical devices only)

Affirmations of Compliance*

Required Data Elements for all FDA Products:

Commodity & Subtype

Product Code

Country of Production or Source

Invoice Description

Names & Addresses of Manufacturer, Shipper, Importer, Delivered To Party

Entry Point of Contact

Quantity , Packaging , Line Value

Arrival Date & Time

Biologics:

Intended Use Code

Brand or Proper Name (except for cells and tissues)

Affirmations of Compliance*

Animal Drugs & Devices:

Active Ingredient Name(s) & Dosage (drugs only)

Brand Name

Affirmations of Compliance*

Food Products requiring Prior Notice:

Country of Shipment; Place of Growth (if applicable)

Names and Addresses of PN Transmitter, Submitter, Owner, Ultimate Consignee;(in lieu of DP) Grower or Consolidator if Applicable

Contact Information for Transmitter & Submitter

Container Number

Affirmations of Compliance*

Port of Arrival

Tobacco:

Intended Use Code

Submitter

Affirmations of Compliance*

**DUNS or FEI numbers are not mandatory but are highly encouraged and may expedite processing.

*Affirmations of Compliance are mandatory in some instances but are not required for all scenarios. Cosmetics and food contact surfaces do not require any additional data elements other than those listed in the center of the diagram.

Start filing in ACE today

- If you are not yet filing in ACE for FDA, contact ACE_Support@fda.hhs.gov to get started.

- If you are already filing, increase and diversify your ACE entries.

- Deadline for full implementation is December 2016.

References

FDA Supplemental Guide: http://www.cbp.gov/ document/guidance/fda-supplemental-guide- release-16 (Full list of data elements required for admissibility)

FDA DUNS Portal: www.fdadunslookup.com (Query or request DUNS numbers for free)

FDA encourages you to start filing in ACE and continues to support you throughout this transition. We remain mindful of the overall goal of this project: to facilitate trade and reduce supply chain barriers to commerce while continuing to protect national security and public health.