

Tips for Importing FDA-Regulated Products in ACE

Diagram depicts mandatory data elements by commodity type. For certain products, additional data elements may apply. Refer to FDA's Supplemental Guide for further instruction. For more information, call 1-877-345-1101 or email ACE_Support@fda.hhs.gov.



Required Data Elements for all FDA Products:

Commodity & Subtype

Product Code

Country of Production or Source

Product Description

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

Contact Information

Estimated Arrival Date & Time

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); if Applicable: Grower or Consolidator; FSV

Container Number

Quantity, Packaging

Affirmations of Compliance*

Anticipated Port of Arrival

Drugs:

Intended Use Code*

Affirmations of Compliance*

Medical Devices & Radiation-Emitting Products:

Intended Use Code

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

Affirmations of Compliance*

Biologics:

Intended Use Code

Brand or Proper Name
(except for cells and tissues)

Affirmations of Compliance*

Animal Drugs & Devices:

Intended Use Code
(Animal Drugs only)

Affirmations of Compliance*

Tobacco:

Brand Name
(for consumer-use products only)

*Indicates data elements are mandatory in some instances but not required for all scenarios. Cosmetics and Food Contact Items do not require any additional data elements other than what is listed in the center of the diagram. See FDA Supplemental Guide for conditions

The following data elements are optional, but may expedite processing if transmitted:
Quantity and Value, Filer Contact Information (PK), DUNS or FEI. Please note DUNS is required for FSV.